African, Caribbean and Pacific Group of States

"Strengthening the capacity of RBS conformity assessment services towards Accreditation"

"ACP-EU TBT PROGRAMME"

(REG/FED/022-667)

Project code: EuropeAid 132552/D/SER/Multi

NEEDS ASSESSMENT

National Quality Testing Laboratories

11 to 15 August 2014

TBT Programme implemented by AESA • Avenue de Tervuren 32, box 31 • 1040 Brussels • Belgium
Tel: +32-2 739 00 00 • Fax: +32-2 739 00 09 • e-mail: contact@acp-eu-tbt.org • www.acp-eu-tbt.org

Table of Contents

1. INTRODUCTION

Rwanda Bureau of Standards (RBS) was visited from 11 to 15 August 2014 to perform a gap analysis to determine their readiness for accreditation based on the requirements of ISO/IEC 17025:2005 (General Requirements for the Competence of Testing and Calibration Laboratories).

The Rwanda Bureau of Standards is a public standardisation institution established by an Act of Parliament (no 03/2002) of 19-01-2002 as revised under Law N°43/2006 of 05/10/2006. RBS consist of five different Divisions of which the National Quality Testing Laboratories (NQTL) are in the process of implementing a Quality Management System based on ISO/IEC 17025:2005. The NQTL is divided into three laboratory units: Chemistry Laboratories, Material Testing and Biotechnology. Each unit has different sections under which different laboratories are found. Each Laboratory is managed by a Lead Officer who is responsible for the technical operation of the laboratory.

The Quality Management System has been documented in a Quality Manual with supporting documentation and records. NTQL has applied for a pre-assessment from the South African National Accreditation System (SANAS) and the Quality Manual has been reviewed for compliance as part of the process. The laboratory requested that the focus of the evaluation and gap analysis to be on the scope of methods that was submitted to SANAS for the pre-assessment.

2. OBJECTIVE OF THE NEEDS ASSESSMENT

The main objective of the assessment was to determine if the NQTL have documented and implemented a Quality Management System based on the requirements of ISO/IEC 17025:2005 to enable them to apply for accreditation and to support them with the process. The implementation of requirements of the Accreditation Body (SANAS), from which they applied for pre-assessment, was also evaluated.

Accreditation is the formal recognition of competence, by an authoritative third party. It is about obtaining third party recognition for your organisation's competence in producing consistent and reliable results/measurements for a defined set of methods/activities that is detailed in a schedule of accreditation.

The primary function of NQTL is to provide testing in the areas of chemistry, food, microbiology, material engineering and textiles. Samples are tested for internal and external customers. The Quality System has been implemented in the chemistry, food and microbiology laboratories at this point in time.

The Quality Management System was evaluated for implementation as per documented Quality Manual and procedures (Management Requirements and Technical Requirements). The following laboratories of the NQTL division were evaluated to determine the level of compliance with ISO/IEC 17025:2005 as well as SANAS requirements:

1. Inorganic Chemistry Laboratory: 5 methods
2. Organic Chemistry Laboratory: 1 method
3. Food Laboratory: 4 methods
4. Microbiology Laboratory: 7 methods

3. KEY FINDINGS

3.1 SANAS Document Review of Quality Manual

In general the document review that was done by SANAS on the Quality Manual indicated that the Manual is in compliance with the requirements of ISO/IEC 17025:2005, however the following feedback was given by the Assessor:

3.1.1 **Clause 4.2.2 (e):** "The laboratory management's commitment to comply with the International Standard and to continually improve the effectiveness of the system". The clause was only partially addressed as the procedure for continually improvement was not documented.

3.1.2 **Clause 4.5.3:** "The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used". The clause was not addressed in the Quality Manual.

3.1.3 **Clause 4.14.1:** "Internal audits shall be carried out by trained and qualified personnel". The clause was partially addressed as the evaluation and competence criteria for internal auditors were not documented.

3.1.4 **Clause 5.2.1:** "Laboratory management shall ensure the competence of all who evaluate results". Clause partially addressed as evaluation, criteria and approval of Technical Signatories were not documented.

3.2 Implementation of the Documented Quality Management System (QMS)

Assessment/evaluation was made on the implementation of the QMS as documented in the Manual and supporting documented procedures. The following general findings/observations were made as per ISO /IEC 17025:2005 Clauses:

3.2.1 Management Requirements

- **Clause 4.1** – **Organisation:** Deputies have not been appointed for key managerial personnel. No evidence could be provided that communication takes place regarding the effectiveness of the QMS.
- **Clause 4.2** – **Management System:** Supporting procedures (Tier 3) still need to be compiled in some laboratories. Although the system was communicated to the personnel, no evidence was available that it was understood. The laboratory did not document and implement SANAS requirements. No evidence was available that personnel were aware and trained on SANAS documentation and requirements.
- **Clause 4.3 – Document Control:** Not always followed, uncontrolled forms were in use in some laboratories, external documents not always controlled and review not done as per procedure (time frames not kept). Work books containing technical records were not always controlled.
- **Clause 4.6 – Purchasing Service and Supplies:** Verification records of new supplies were not available and some chemicals in use have expired with no evidence that they were still fit for use or comply with quality criteria.
- **Clause 4.7 – Service to the Customer:** It was not clear when action from customer feedback should be taken as no specific criteria were documented.

- **Clause 4.9 – Control of Non-conforming Testing:** Register was only available for ad hoc and not non-conformances identified during internal audits.
- **Clause 4.11 – Corrective Action:** Time line for completion was not documented in procedure and there were a number of corrective action requests that were outstanding for more than 2 months with no indication of any progress. Root-cause analysis was not always carried out as required with sufficient detail. No evidence/records were available that follow-up evaluations were done to monitor effective implementation of corrective actions.
- **Clause 4.13 – Control of Records:** Technical records were not always readily available and all observations and raw data were not recorded/documented e.g. preparation of standards. The quality of these records was not as required, as mistakes were not crossed out and signed, but scratched out. Some records were not legible.
- **Clause 4.14 – Internal Audits:** Although internal audits were conducted, no evidence was available that any of the methods were witnessed and vertical audits were not done on all methods. Internal Auditors have not been evaluated and approved. Procedure and criteria for deeming Auditors competent were not documented. Audit schedule did not cover all areas of the Quality Management System. Most of the non-conformance forms (NQTL/F-24) were not completed with all the required information. Some of the non-conformances were classified as minor where it should be major.

3.2.2 Technical Requirements

- **Clause 5.2 – Personnel:** Training and competence records for most of the staff were not available as per documented procedure. Evaluation and appointment of Technical Signatories have not been done.
- **Clause 5.3 – Accommodation and environmental conditions:** Records of environmental conditions were not available in some of the laboratories.
- **Clause 5.4 – Test methods and method validation:** Although some data was available, all requirements have not been met and data still need to be generated and reports to be compiled and approved. Uncertainty of measurement also needs to be calculated.
- **Clause 5.5 – Equipment:** Calibration and maintenance records were not completed for some equipment. Correction factors from calibration certificates were not taken into account during measurements. Technical records were not always traceable to the equipment used.
- **Clause 5.6 – Measurement traceability:** Certified reference materials were not available for some chemical determinants. Preparation of standards was not recorded and therefore traceability to batch numbers and expiry dates were not available.
- **Clause 5.9 – Assuring the quality of test results:** Quality control procedures have not been implemented as per procedure for some chemical methods. Control charts have not been established for food and chemical methods. Proficiency test results were not available for some of the methods on the scope to be accredited. Proficiency results were not evaluated and trend analysis was not done. 5 year Proficiency Testing Scheme (PTS) Plan was not available.

3.3 Laboratory Specific Findings

The following observations were made in each of the laboratories that were evaluated:

3.3.1 Inorganic and Organic Chemistry Laboratory

- Supporting documents still to be done, e.g. reference material.
- List of environmental conditions and requirements to be drawn up for Inorganic Chemistry and monitoring and recording to be done.
- Up dated training and competence records were not available for all staff. Although procedure available, implementation was not evident. Authorization for staff to use equipment as per procedure was also not available.
- pH method procedure still needs to be finalised. pH buffers expired 2010 and calibration not recorded.
- Standards in use for AAS have expired in 2011, preparation not recorded.
- Maintenance records for equipment were not up to date.
- Verification of pipettes between calibrations was not done, no procedure, frequency and tolerances were available.
- PTS results (2012) for Copper and Magnesium were not available. Lead failed – no evidence of corrective action. No results for any determinants were available for 2013.
- Quality control chart not available. Quality control sample not different from calibration standards. Procedure available but not fully implemented.
- Raw data book not controlled and no evidence that data checked for correctness.
- Results not traceable to equipment used.

3.3.2 Food Laboratory

- Supporting documents in progress and need to be completed.
- Temperature records for furnace and ovens during use were not available.
- Quality control charts not implemented as per procedure.
- Balance was not verified in range of use. 30 g mass piece used, but 5 g sample was weighed.
- Acceptance for duplicate sample <5% but the criteria was not documented in the method.
- Preparation of reagents not recorded. Expiry dates after preparation not available in procedure.
- Chemical containers not always labelled with received and opened dates.
- Expired chemicals (Methyl red, 2009) were in use.
- Results were not traceable to equipment used.

- Calibration of oven used for Fat analysis was done at 130°C, but used at 103°C.
- New desiccator temperature monitoring system still to be calibrated.
- Cleaning schedule not updated since 2012.
- Equipment user book was not controlled.

3.3.3 Microbiology

- No records were available of room temperature.
- Environmental monitoring (swabs) not always done as per schedule i.e. every 2 weeks.
- Air monitoring done but no frequency documented.
- Reference culture list available, but not controlled document.
- Thermometer used to monitor culture fridge not clearly identified, only container labelled.
- Thermometers were not used in the vertical position, but were horizontal in incubators and fridge.
- Correction factors for thermometers were not taken into account during monitoring.
- Autoclave temperature were recorded as 133°C, although the temperature criteria was documented as 121°C ± 1°C and no action were taken.
- Results for PTS were not available for all methods.
- Training and competence records for all staff were not up to date and as per procedure.
- Pipette verification was not done as per schedule and tolerances were not available. Previous data were not traceable to the balance that was used.
- Membrane filter batch numbers were not available and not verification before use.
- Tolerance for 100 ml water sample was not available.
- Balance was not verified in operation range i.e. checked with 1 g and 50 g mass pieces, but 18.3 g was weighed.
- Maintenance for distiller not recorded for June and July 2014.
- Media preparation records were done in book that was not controlled and labelled "Sample receival".
- Supplement were recorded during media preparation, but only name and not batch number.
- pH of media determined, but the data not traceable to the equipment and batch number of buffers used.
- 10 ml graduated pipette was used to measure 1 ml volumes during analysis of samples. Pipette was only calibrated at 10 ml. Volumes not accurate as per procedure that was followed. 1 ml pipette to be used for measuring 1 ml of sample.
- Only positive procedural control used, negative to be included.

- Mould positive culture still to be introduced during quality control.

3.4 Shortcoming

The following observations and findings should be dealt with to ensure the RBS National Quality Testing Laboratories readiness for accreditation:

3.4.1 In general most of the available procedures were found to be documented comprehensive and all necessary details were available but need to be implemented by the laboratories.

3.4.2 The personnel were found to be sufficiently qualified and competent, although data and records not available. Technical Signatories need to be evaluated and appointed by Management. The lack of understanding accreditation requirements could be the reason for outstanding supporting documents and technical records. Lack of awareness of the Accreditation body's requirements was also evident.

3.4.3 Recent proficiency test results were not available for most of the methods and this could have a major impact on progress towards accreditation. Participation and recent results that were acceptable is a requirement for accreditation and a method will only be recommended should it be in place. Therefore, the accreditation body requires a 5 year PTS plan that should be followed at all times.

3.4.4 Expired standards and chemicals in use will also not be acceptable and all standards were not traceable to NIST (National Institute of Standards and Technology). These standards are in general more expensive but are a requirement for calibration of equipment.

3.4.5 Internal audits based on the requirements of ISO 17025:2005 as well as the accreditation body needs to be implemented. Auditors should be trained and declared competent for specific areas.

3.4.6 Quality control procedure should be fully implemented as per procedure and additional laboratory specific procedures should be compiled.

3.4.7 Validation and uncertainty of measurement should be completed and reports approved by technically competent person.

4. RECOMMENDATIONS

As can be seen from the findings, the laboratories still need to implement a number of requirements and supporting documents need to be compiled and/or completed. It is recommended that a work plan be drafted to determine the process to be followed. There are certain aspects that need to be in place before progressing to the next phase. All supporting documents should be compiled as first step, as well as forms or books should be in place to ensure recording of all technical observations during testing. Personnel training and competence records, calibration and verification of equipment should be in place before methods are validated and uncertainty of measurement determined.

Annex 1: People Consulted

The following people were consulted during the evaluation and needs assessment of the National Quality Testing Laboratories (NQTL):

Quality Management System: Sibomana Theresia Paul

Chemistry Laboratory: Wiclef Kagisha, Ally Clair Harerimana

Food Laboratory: Isaie Ntakiyimana, Emmanuel Rudacogora, Nkezabera Egidia

Microbiology: Nkuranga Innocent, Mbabazi Alphonse, Mugeni Francoise