Hello,

This is the first issue that the editorial team has dedicated to a relevant and comprehensive overview of Proficiency Testing (PT) and Inter-Laboratory Comparison (ILC) with the intent of interpreting the requirements set out in ISO/IEC 17025 for labs.

We have also published a report after an assessment of public medical laboratories was done between August 2011 and August 2012 which gives more than practical evidence that medical laboratories ought to embrace External Quality Assurance (EQA) for quality service delivery.

We have also outlined the complete list of all Conformity Assessment Bodies which we have accredited so far (Page 7). Our journey to demystify Accreditation has started thus, your feedback will be appreciated to enable us improve on future issues of this newsletter.

On behalf of the entire KENAS family, we wish you a Merry Christmas and a Happy New Year.

The Editor
The implementation of accepted quality assurance practices to measurements is recognized as a prerequisite to producing data with known metrological qualities. Regardless of the target sample type, quality assurance and quality control are the cornerstones to analytical data validation. In addition to daily internal performance verifications via reference materials, a good quality assurance plan should include regular external performance evaluations for an independent assessment of analytical proficiency.

Inter-laboratory studies demonstrate that participating to Inter-Laboratory Comparisons (ILCs) and Proficiency Tests (PTs) leads to improved quality of analytical results. The results from ILCs or PTs are of crucial interest for laboratories as these provide clear information of its measurement capabilities. It would be pointed out that the participation is either voluntary or forced by external requirements (e.g. legal, accreditation, control bodies). Inter-laboratory Comparison (ILC) exercises and Proficiency Test (PT) schemes involve comparison of participant’s results with an assigned value.

What is Proficiency Testing?
Proficiency testing is an activity conducted to confirm the competence of labs to perform specific test/calibration by an inter-laboratory comparison using the same sample or artifacts. In the assessment for the accreditation of laboratories, the results of proficiency testing play an important role to support and complement assessment process on the technical aspects.

Why is Proficiency Testing Necessary?
Participation in proficiency testing schemes is a useful tool for testing laboratories to achieve different objectives, such as assessing personnel skills, analysing the differences between testing methods, assigning values to reference materials and, of course, demonstrating the consistency of the data produced through said tests.

ISO/IEC standard 17025 establishes a requirement, whereby laboratories can only be accredited if they take part in proficiency testing schemes, provided there are suitable programmes available for the labs to participate in.

The necessity of the proficiency testing is prescribed as:

- The laboratory shall have quality control procedures for monitoring the validity of test and calibrations undertaken.... b) participation in inter-laboratory comparison or proficiency testing programs; ... (ISO/IEC 17025 5.9)
- The accreditation body shall ensure that its accredited laboratories participate in proficiency testing or other comparison programmes, where available and appropriate, and that corrective actions are carried out when necessary. (ISO/IEC 17011 7.15.3)

Schemes of Proficiency Testing
The technique of the proficiency testing is changed according to the property of the test or calibration item, a test or calibration method to be used, and the number of the participating laboratories, etc. Typical cases are illustrated as follows:
Proficiency Testing and Inter-laboratory Comparisons

continued...

1. Testing field: Inter-laboratory testing schemes

Sub-samples randomly selected from a material source are simultaneously distributed to the participating laboratories. After completing the testing, respective results are returned to the coordination body and compared with an assigned value to give an indication of the performance of the individual laboratory and a group as a whole group.

The diagram across shows an example of Inter-laboratory testing scheme (the arrows show the distribution of the sample).

2. Calibration Field: Measurement comparison schemes

The item or artifact to be measured or calibrated is circulated successively from one participating laboratory to the next. This is often called as Round-robin test. The diagram across shows cases of measurement comparison schemes (the arrows show the circulation of the item).

3. (Reference) Standards of Proficiency Testing


This collage of pictures illustrates the many forms of Proficiency Testing available.
This article was written following a review of performance of five laboratories after initial assessment by Kenya Accreditation Service (KENAS).

Improvement of quality of testing services in medical laboratories is a high priority in many countries and a prerequisite for accreditation. This has called for many public laboratories in the developing countries to be placed under the WHO-AFRO laboratory accreditation process known as "Strengthening Laboratory Management Towards Accreditation [SLMTA]." External assessment of these laboratories by an established accreditation body is paramount as a tool for measuring progress made over a specified period of time, identifying areas that need corrective actions and highlighting opportunities for improvement.

The report was presented on 25th October 2012 to over 155 participants of the medical laboratory fraternity during the Human Quality Assessment Services Annual Scientific Conference at the Kenya Institute of Education. It was reported that the five public laboratories went through initial assessment. The initial assessment conducted in August 2011 was the midterm assessment for the SLMTA program while the subsequent assessment was SLMTA end-term assessment conducted a year later. Each of these labs received eight weeks of embedded mentorship six months after the initial assessment delivered at an interval of two weeks. The assessments were conducted using WHO-AFRO checklist by independent assessors from KENAS. Quality improvement based on the 12 Quality System Essentials specified in the WHO-AFRO checklist was measured at the initial assessment and later at the end term assessment. This retrospective data analysis of assessment reports from the five laboratories in Kenya assessed by KENAS was between August 2011 and August 2012.

The diagram illustrates the SLAM-TA program. It was established as a form of health systems support to the recognition of step-wise fulfillment of ISO 15189.

KENAS as the national accreditation body has been involved in providing objective assessment of labs in SLAMTA program and guiding them towards full accreditation.

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The following were the findings:

- During the initial assessment, four of the five laboratories scored Zero SLIPTA star rating while one laboratory scored 3 Stars.

- After one year, addressing nonconformities identified from the initial assessment, two laboratories improved from zero to three stars, one laboratory improved from three to four stars while the remaining two laboratories improved from zero to one star.

- The average percentage improvement was 25% with the best improved lab having improved by 46%. Although there was no statistically significant difference (p=1.439) in the average scores between the initial (120.8) and the end term (182.8) assessments, there was notable improvement particularly in the two labs that improved from zero to three stars. Laboratory that performed poorly did not address nonconformities identified from the initial assessment. See the diagram below showing the percentage improvement for each laboratory.

Some of the limitations that were noted in this research were:

A) The sample size was too small (5 labs)
B) Other initiatives that could have impacted on quality improvement such as mentorship were not measured
C) The use of different versions of WHO-AFRO checklist
D) Lack of baseline data

In conclusion, the research showed that external assessment provides an objective measure of a laboratory performance leading to significant improvement where the laboratories are committed to addressing the identified nonconformities. Assessment reports should serve as basis for developing corrective action plan and preferably be used as a tool for a mentorship program.

KENAS WEBSITE UNDER CONSTRUCTION

The KENAS website www.kenyaaccreditation.org is currently under review in an effort to realize one of the organisations objectives in improving service delivery and communication to all our stakeholders whilst staying current with technology. This exercise should be complete by the end of December 2012. Thereafter, we shall be in use of our newly acquired domain www.kenas.go.ke. When this transition does happen, we shall inform you for that change. Meanwhile, we seek your patience as we undertake this upgrade and seek to remain relevant, informative and interactive.

The current website will still be available until the changeover. More updates on the website progress will be availed on your e-mails, our Facebook and LinkedIn pages soon.
Acreditation Certificates issued...

On 14th November, KENAS issued certificates to three conformity assessment bodies that were recently accredited. Polucon Ltd; HUQAS Ltd and Elisters 2000 Ltd were well represented at the meeting by the MD of each company and KENAS staff members. The fourth company SGS Ltd though also accredited postponed their certificate issuance meeting to 20th November.

From the picture above, representing Elisters 2000 Ltd was Mr. Benson Muiru (seated right); Mr. Dominic Mureithi (seated left) represented the Polucon Services Ltd team whilst Mr. Paul Wambura (seated center) Chairperson of HUQAS Ltd was the representative of the team. The KENAS Technical Services team welcomed the new clients through a networking session thereafter.

KENAS PRESENTS on CONFORMITY ASSESSMENT AND QUALITY INFRASTRUCTURE at IAEA PROJECT

KENAS participated in the final coordination meeting of the International Atomic Energy Agency (IAEA) project for the Africa region RAF/0/027 for consumer safety and trade development through competent nuclear testing and metrology. It was the third African conference on quality management in nuclear and research laboratories in Algiers, Algeria from 4th to 8th November 2012.

Stanslaus Masinza, Case Officer, Inspection & Verification pillar presented a paper titled “Conformity Assessment and Quality Infrastructure: The road towards Kenya’s quest for global competitiveness”. This paper was co-authored by Assistant Director, Inspection & Verification, Abraham Wekesa and Deputy Director, Technical Services, Susan Ochieng.

TRAINING:

UNCERTAINTY of MEASUREMENTS

Health and Safety Pillar organized for a training on Uncertainty of Measurement in Medical Laboratories which was held at KENAS from 12th to 14th November 2012. The attendees were from various medical labs in Kenya among them being CDC Kisumu and Ampath Laboratories. The Deputy Director, Technical Services, Susan Munyiri issues a certificate to one of the attendees.
INTERNATIONAL ACCREDITATION NEWS

KENAS ATTENDS THE ILAC/IAF ANNUAL MEETING AT RIO, BRAZIL

Three KENAS officials attended the MCC Committee as part of the annual IAF/ILAC Meetings which happened from 17th to 26th October 2012. The Chairperson of the KENAS Board, Prof. Marion Mutugi, the CEO KENAS, Sammy Milgo and Deputy Director, Technical Services, Susan Munyiri participates in the committee meetings.

The discussions revolved on best practices that ILAC and IAF could take up to improve on communication and sharing of information on accreditation and impacting its members as well to take up the same as well as part of continuous improvement which establishes quality service in the long run.

IEC-ILAC–IAF MoU RE-SIGNED

As a result of the confidence established between the IEC Conformity Assessment Systems and Members of International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF), the parties have agreed to expand the existing tripartite Memorandum of Understanding to cover initial assessments, surveillance and reassessments carried out in their respective systems.

INTERNATIONAL AGREEMENT ON INSPECTION

Thirty-nine members of ILAC (International organisation for accreditation of laboratories) signed a Mutual Recognition Agreement with International Accreditation Forum (IAF) on 25th October 2012 that gives international recognition for inspection carried out by accreditation bodies. The ILAC MRA for inspection is based on the recognition of the mutual recognition arrangements for inspection that have been established and evaluated in the three recognised regional cooperation bodies of ILAC, namely:

- APLAC (www.aplac.org),
- EA (www.european-accreditation.org) and

The accreditation bodies that are signatories to the ILAC MRA for inspection, use the international standard ISO/IEC 17020 Conformity assessment – Requirements for the operation of various types of bodies performing inspection to accredit the inspection bodies. This ensures a uniform approach to assessing inspection body competence all over the world.

For more information go to: -
https://www.ilac.org/ilac_mra_includes_inspection.html

A sprinkle of stardust
to wish you luck
A star alight
to shower with love
May the joy of christmas
touch you anew
May all the hope
be blessed on you...

Merry Christmas

From KENAS Family
We issue our complete list of accredited CABs below.

**MEDICAL LABORATORIES:**
1. Ampath Reference Laboratories. Accreditation scope is medical testing of chemistry, haematology, serology, flow cytometry and molecular biology.

**INSPECTION BODIES:**
1. Avante Garde Engineers and Consultants in India. Accreditation scope is pre and post inspection of plant and machinery.
2. SGS Kenya Ltd. Accreditation scope is inspection of quality and quality of goods, imported and local oil, gas, chemical, and agricultural produce.

**PROFICIENCY TEST PROVIDERS:**
1. Human Quality Assessment Services (HUQAS). Re-accreditation scope is microbiology, haematology, and medical chemistry, point of care, coagulation, transfusion of medicine, clinical microscopy, diagnostic immunology, comprehensive serology, serology, nucleic acid testing, andrology, bacteriology, mycobacteriology, mycology, parasitology, virology.

**TESTING AND CALIBRATION LABORATORIES:**
1. Kenya Agricultural Research Institute (KARI). Accreditation scope is soil testing.
2. Kenya Industrial Research Development Institute (KIRDI). Accreditation scope is water and waste water testing
3. Good Manufacturing Practice (GMP) Services Ltd. Accreditation scope is water testing.
4. Nyeri Water and Sewerage Company Ltd. Accreditation scope is water testing and meter calibration.
5. Instrumentation Ltd. Accreditation scope is pressure, revolution, temperature and calibration.
6. Sonic Quality Inspection. Accreditation scope is pressure, volume, force, industrial measurement and temperature.
7. Quality Assurance Systems Ltd. Accreditation scope is pressure, mass, volume, force, industrial measurement and temperature.
8. Estec Ltd. Accreditation scope is mass.
9. Azania Physical Laboratory. Accreditation Scope is force, pressure, temperature and mass.
10. AgriQ-Quest Laboratory. Accreditation Scope is testing for copper and zinc in water, testing for coliforms and salmonella in food.
11. Elisters 2000 Ltd. Accreditation scope is mass, temperature and pressure.
12. Polucon Services Kenya Ltd in Mombasa. Its scope of accreditation is microbiological and chemical testing in water food, animal feeds, tea, salt, grains and cereals, agricultural food products and vegetable fats and oils.

**Note:** Kenya Industrial Research Institute (KIRDI) accredited for the scope of water and waste water testing are under voluntary suspension with effect from October 2012 until further notice.