Accreditation is the independent evaluation of Conformity Assessment Bodies (CABs) against recognized conformity assessment standards to ascertain their integrity, impartiality, objectivity and competence to carry out specific conformity assessment activities.

Motor Inspection in Kenya

In the recent past, motor vehicle inspection has often been associated with national police law enforcement crackdowns on public service vehicles during road safety campaigns.

However with the coming into force of the National Transport Safety Authority (NTSA) Act of 2012, that perception has taken a new dimension. According to the act, all road vehicles from July 1st 2012 will be required to undergo mandatory inspections at least once a year in line with national standards to be listed under regulations. This new development has brought into focus the country’s capacity and competence to carry out such inspections in large numbers.

The NTSA recently decided, as a matter of policy, to subcontract the motor vehicle inspection function under its mandate to private motor garages and inspection centers under a regulatory framework. This announcement generated plenty of excitement in the auto and insurance industries due to the business potential.

The motor garages who until now were conducting only accident repairs and routine car...
service will now be in a position to get government contracts to inspect and charge for mandatory vehicle checks. The insurance companies are not only excited on the prospects of getting into car inspections, but also are set to benefit from lower risks from defective vehicles leading to lower premiums and eventually a greater uptake of motor insurance services.

According to road safety statistics from the NTSA, of the close to 3,000 lives lost on the road annually, 12 per cent are attributed to faulty motor vehicles. This figure has spurred NTSA on to ensure all road vehicles are inspected to prevent further loss of lives. Statistics from the motor vehicle registration office at KRA indicate that there are close to 2 million vehicles on the road and monthly import figures stand at almost 6,000 vehicles.

This presents a great opportunity for garages and inspection centers to market their services not only in Kenya, but also in the greater East African Community by mutual recognition of inspection certificates through accreditation. The umbrella association of motor garages, the Kenya Motor Repairers Association (KEMRA) recently hosted a standards dissemination seminar on road vehicles standards in conjunction with the Kenya Bureau of Standards (KEBS) on the 21st of August 2014 at Hilton hotel. The theme of the seminar was ensuring road safety through the use of standards. The focus was on creating awareness on the three main standards crucial for any garage or inspection center to demonstrate its ability to conduct inspections. They are:

- KNWA 2460, Kenya Standard, Motor vehicle garages for repair and services – Code of practice.

These standards were formulated by the KEBS TC 122 on Road Vehicles. KENAS is ably represented in the Technical Committee (TC) to sparerheed matters touching on accreditation. During the standards dissemination seminar, on official assignment, I made a presentation on the benefits of accreditation and also gave a brief introduction on the inspection accreditation standard ISO/IEC 17020:2012 - Conformity assessment - Requirements for the operation of various types of bodies performing inspection.

The core message from KENAS to the forum was that accreditation presents the best possible solution to the enforcement of all the 3 KEBS standards on motor vehicle inspection. Feedback from the standards dissemination seminar gave a positive indication by the motor garages on their willingness to embrace accreditation. Already a few garages who have ISO 9001:2008 certification have shown willingness to apply for accreditation. The future of accreditation in motor vehicle inspection is bright. The Government of Kenya through the NTSA must be applauded for making the bold step to privatise this crucial mandate under regulation. To this end, KENAS is engaging the NTSA constantly to ensure that accreditation be included as a mandatory requirement in the upcoming NTSA regulations that will govern the enforcement and monitoring of motor vehicle inspection services.

Article by Tiony Calvin, Case Officer, Inspection & Verification, KENAS
KENAS NEWS

CRESAC PERSONNEL ON ATTACHMENT TO KENAS
KENAS hosted two CRESAC (Centre Regional d’Évaluation en Sante et d’Accreditation des Établissement Sanitaires en Afrique) personnel on their study visit to learn the establishment of KENAS as an accreditation body. The two personnel were taken through ISO 15189 and the SLMTA process (Strengthening Laboratory Management Towards Accreditation).

INDUSTRIAL SECRETARY (MoIED) VISITS KENAS
The newly appointed, Industrial Secretary, Mr. Julius Korir (centre) of Ministry of Industrialization and Enterprise Development held a familiarization meeting with KENAS management as planned by the Ministry. This meeting was a courtesy visit planned to create cohesion and understanding of all Parastatals and departments under the Ministry so that the Ministry can enhance its performance.

INTERLABORATORY COMPARISON (ILC) CONSULTATIVE FORUM by CALIBRATION LABS
The ILC consultative forum was held on 23rd October at KENAS headquarters. Proficiency Testing /Inter-Laboratory comparison) is an important way of meeting requirements of ISO/IEC 17025 in quality assurance of laboratory results. It’s mandated by accreditation bodies such as KENAS that labs participate in proficiency testing programs for all types of analyses undertaken in that lab, when suitable programs exist. The timeframe for this activity for calibration laboratories accredited by KENAS was September 2014. This forum was held to discuss in ways of enhancing that this activity was effectively held and understood by its stakeholders.

KENAS PARTICIPATES IN TREE PLANTING
In partnership with the Nairobi Greenline team, KENAS participated in a tree planting activity at the Nairobi National Park in July. Prior to this activity, the Environment Sustainability Committee of the Performance Contract at KENAS gave an awareness talk on environment conservation to all staff.
KENAS News

CREATING AWARENESS OF ACCREDITATION SERVICES

NAIROBI INTERNATIONAL TRADE FAIR

For the fourth year running, KENAS has participated in the annual Nairobi International Trade Fair which brings government institutions, corporates, non-governmental organisations, farmers, entrepreneurs and youth and women groups to showcase to the general public their services and products as they share knowledge on new innovations and technology. KENAS was housed by the Ministry of Industrialization & Enterprise Development (MOIED) together with other parastatals under this Ministry. We received more than 150 recorded guests at this stand. This was a good avenue for sharing information about accreditation.

ISO/IEC 17025 IMPLEMENTATION TRAINING

(Pictured below).

As part of our awareness programs targeted to our clients and potential markets we can work with to enhance accreditation, KENAS offers training on how to implement the accreditation standards. This was one of the implementation training for ISO/IEC 17025 held at Ole Sereni Hotel in September 2014. Some of the participants were from ILRI, Nyeri Water Company, KEPHIS etc.

BURUNDI DELEGATION VISIT

(Pictured above)

KENAS hosted a Burundi delegation team that was on a building study tour to know more about Standards and Quality Assurance, accreditation and trade capacity building platforms in Kenya. The delegation comprised of representatives from the Burundi Ministry of Trade and Industry Posts and Tourism, the Trade Capacity Building Burundi Steering committee, Burundi Bureau of Standards and Quality Control, and a representative from Directorate of Plant Protection.
TWIGA CHEMICALS INDUSTRIES ACCREDITATION CEREMONY

Senior officials in government and partners of Twiga Chemicals on a tour of the Twiga factory. Twiga Chemicals held their accreditation ceremony at the Twiga Chemicals Headquarters in Industrial Area. Twiga Chemicals are accredited to ISO/IEC 17025:2005 to the scope of Chemistry testing. The Chief Guest was Min. of Industrialization PS, Dr. W. Songa. Other dignitaries present were the outgoing Chairperson of Kenya Association of Manufacturers, Poly-carp Igathe & KENAS CEO, Sammy Milgo.

QUALITY CONTROL/ METHOD VALIDATION AND UNLOCKING ISO 15189 COURSE

Case Officer in Health & Safety, Robert Njuguna attended this course from 5th – 17th October in South Africa. This program was sponsored by CDC through AFENET.

UNGA LTD ACCREDITED TO ISO/IEC 17025

Unga Group Managing Director, Nick Hutchinson (right) receives the accreditation certificate from KENAS CEO Sammy Milgo (left). Unga Ltd was accredited to ISO/IEC 17025:2005 to the scope of proximate analysis of ash, oil, fiber, moisture, protein and calcium on maize and wheat products, feed stuffs and other cereals.

NQRL IMPLEMENTATION TRAINING ON ISO/IEC 17025

The National Quality Reference Laboratory underwent implementation training in preparation of accreditation in the near future. Leading the training was the Assistant Director, Testing and Calibration, Felista Nyakoe.
NEW BROCHURE PUBLISHED BY ILAC/IAF
A new brochure titled “Accreditation: Delivering confidence in the provision of Energy” has been published and is available here. This brochure promotes the role accreditation plays in providing confidence in the provision of energy.

ILAC LAUNCHES NEW WEBSITE
Visit the newly launched ILAC (International Laboratory Accreditation Cooperation) website. http://ilac.org/. The website includes several new features that improve the availability of information, such as:

a) a dedicated search for the signatories to the ILAC MRA;
b) consolidation of the information on the signatories to the ILAC MRA to one page;
c) a specific area for regulators and users of the ILAC MRA;
d) link to the directories of accredited proficiency testing providers and reference material producers where available in addition to the current links to accredited laboratories and inspection bodies.

AFRAC NEWSLETTER FIRST EDITION LAUNCHED:

IAF-ILAC JOINT ANNUAL MEETINGS, VANCOUVER, CANADA
The above mentioned joint meetings took place in Vancouver, Canada from 8th—17th October 2014. The meeting was attended by over 300 delegates from various countries of the world. Among the delegates were CEO’s and Technical Officers from various Accreditation Bodies worldwide. The CEO KENAS, Sammy Milgo, who is also the AFRAC TC Chairperson, wore two hats as he represented KENAS and AFRAC in the meetings.

The meetings were supported by PTB, the National Metrology Institute of Germany considering that AFRAC is one of the key Pan African Quality Infrastructure Institution recognized by the African Union.

The meetings were kept abreast on new developments in the field of accreditation emanating from participating accrediting bodies, regional cooperation bodies and stakeholders. AFRAC’s position with regard to various documents reviewed and especially in technical matters of accreditation were well articulated.

The meeting also pursued the issue of KENAS pre-evaluation with the Lead Evaluator, Mr. Geoffrey Hallam with the aim of ensuring conclusion of the exercise as KENAS prepares for full membership to ILAC.
SPECIAL ISSUE ON SLMTA PUBLISHED ONLINE AT
The Health & Safety team at KENAS has published in the African journal for Laboratory Medicine a special issue on SLMTA (Strengthening Laboratory Management Towards Accreditation). The paper attached is available online at www.ajlmonline.org. The paper alongside others published in this special issue will be presented and distributed in the upcoming ASLM International conference in Cape Town in 30th Nov to 4th Dec 2014. We thank all of you for your support as we put KENAS on the global map. Click here for the document.

AFRAC HOLDS ITS 5TH ANNUAL GENERAL ASSEMBLY
The fifth annual General Assembly for the African Accreditation Cooperation (AFRAC) was held in Addis Ababa, Ethiopia from 20th–24th September 2014. KENAS was represented by two senior officials: CEO, Sammy Milgo and Deputy Director, Technical Services, Susan Munyiri-Ochieng.

During this General Assembly, it was reported that there are 7 full memberships to AFRAC: MAURITAS, SANAS, EGAC, SADCAS, KENAS, ENAO, TUNAC.

AFRAC has admitted four new stakeholder members as well:
A) FHI 360–stakeholder member
B) ASLM–Stakeholder members
C) Laboratoire de Securite Alimentaire et d’Hygiene de l’Environment (LSAHE)
D) Systeme Ouest Africain d/Accreditation (SOAC) - Associate member.

The meeting prioritized during its discussions on the testing labs, calibration labs, Quality Management Systems (QMS), EMS and Inspection. Mid-term meetings on the above have been scheduled for February 2015.

The 6th General Assembly and annual meetings have been scheduled for September 2015 in Tunis, Tunisia.
The following Conformity Assessments Bodies have been accredited by KENAS:

1. **GMP Services Limited:**
   Accreditation is based on the following test parameters on flour, tea and water: total plate count, total coliform count, total dissolved solids, Escherichia coli, copper, zinc, iron, chloride, pH, total suspended solids and total hardness.

2. **KEMRI Production Department**
   Accredited to the scope of HIV, PT

3. **Bungoma county Referral Hospital Laboratory**
   Accredited to the scope of: routine chemistry, hematology, immunology and parasitology.

4. **KEMRI DSLP Laboratory**
   Accredited to the scope of: Molecular biology, virus isolation and detection, bacteriology isolation and detection, antimitotic sensitivity, serology.

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**LEARNING EXCHANGE PROGRAM**

Two officers representing KENAS attended a ten day learning exchange program in Germany on Quality Management and Accreditation within the German healthcare system. The two officers were Doris Mueni and Evelyne Kabongo. The objective of this initiative (sponsored by GIZ) was to provide an opportunity for leading Kenyan Institutions in quality improvement. In addition, these institutions would be acquainted with health service providers and certifiers who are offering different quality improvement systems with a view to improve Kenya Quality Model for health. This is anticipated to contribute to improving the quality of health in Kenya and act as an incentive toward engagement of health providers involved in quality improvement.

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**ISO/TECHNICAL COMMITTEE 212 MEETING**

This meeting was held in Toronto, Canada from the 14th to 17th October 2014. The Assistant Director, Health and safety KENAS Doris Mueni, represented KENAS this year. The standards under review, discussion and development include ISO 22870, ISO 15190 and ISO 15195 which are critical for accreditation in the medical laboratory sector. This program was sponsored by CDC through APHL.

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**MEDICAL LABORATORY INTERNAL AUDIT COURSE**

KENAS held an internal audit course for ISO 15189:2012 on 17th to 19th September at Panari hotel. Participants were from both the private and public medical laboratories from Nairobi region.
Accreditation is emerging as a preferred framework for building quality medical laboratory systems. Despite the low numbers of laboratories accredited to date, accreditation has the potential to improve the quality of health care for patients through the reduction of testing errors and attendant decreases in inappropriate treatment.

Use of accredited medical laboratories in breast cancer diagnosis
Medical laboratories are the key partners in patient safety and laboratory results influence 70% of medical diagnoses. The quality of laboratory service is the major factor which directly affects the quality of health care. The clinical laboratory, as a whole, has to provide the best patient care that promotes excellence. Accreditation of medical labs in accordance with ISO 15189 standards is the only means to assure credibility of such labs. Through accreditation, the lab demonstrates that it produces valid results as per requirements of the ISO 15189 standard. The credibility of an accredited medical laboratory adds benefits to the patients, pathologists and the doctors. It also contributes immensely towards improvement of overall health care system.

Benefits of Medical Labs Accreditation with KENAS
- Enhances the competence & performance capabilities of the Medical labs
- Builds the confidence of the customers in the services provided by the Medical Labs
- Creates an environment of healthy competition and enhances the overall socio-economic development of the Nation
- Provides competitiveness to health care unit to benchmark with the best

Who can be accredited?
Medical Labs that examine the materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of diseases covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigations like: Molecular biology lab, Microbiology lab, Immunological lab, Virology lab, Pathology/histopathology lab/ forensic lab, Clinical chemistry lab and hematology lab, etc.
What is breast cancer?

Breast cancer is an uncontrolled growth of breast cells. Sometimes, a malignant tumor made up of a group of cancer cells that can grow into (invade) surrounding tissues or spread (metastasize) to distant areas of the body. The disease occurs almost entirely in women, but men can get it, too.

Cancer occurs as a result of mutations, or abnormal changes, in the genes responsible for regulating the growth of cells and keeping them healthy. The genes are in each cell’s nucleus, which acts as the “control room” of each cell. Normally, the cells in our bodies replace themselves through an orderly process of cell growth: healthy new cells take over as old ones die out. But over time, mutations can “turn on” certain genes and “turn off” others in a cell. That changed cell gains the ability to keep dividing without control or order, producing more cells just like it and forming a tumor.

Benign tumors are not considered cancerous: their cells are close to normal in appearance, they grow slowly, and they do not invade nearby tissues or spread to other parts of the body. Malignant tumors are cancerous. Left unchecked, malignant cells eventually can spread beyond the original tumor to other parts of the body.

Diagnosis of cancerous cells

Doctors use many tests to diagnose cancer and find out if the cancer has spread or metastasized to other parts of the body beyond the breast and the lymph nodes under the arm. Some tests may also help the doctor decide which treatments may be the most effective. For most types of cancer, a biopsy is the only way to make a definitive diagnosis of cancer. A biopsy is the removal of a small amount of tissue for examination under a microscope.

The following tests may be used to diagnose breast cancer or for follow-up testing after the cancer has been diagnosed.

Not every person will need all of these tests.

I. Imaging tests

- **Diagnostic mammography**
  Diagnostic mammography is similar to screening mammography except that more pictures of the breast are taken, and it is often used when a woman is experiencing signs, such as nipple discharge or a new lump. Diagnostic mammography may also be used if something suspicious is found on a screening mammogram.
Ultrasound
An ultrasound uses high-frequency sound waves to create an image of the breast tissue. An ultrasound can distinguish between a solid mass, which may be cancer, and a fluid-filled cyst, which is usually not cancer. Ultrasounds are not used for screening.

MRI
An MRI uses magnetic fields, not x-rays, to produce detailed images of the body. An MRI can also be used to measure the tumor’s size. A special dye called a contrast medium is given into the patient’s vein before the scan to help create a clear picture of the possible cancer. A breast MRI may be used after a woman has been diagnosed with cancer to check the other breast for cancer or to find out how much the disease has grown throughout the breast. It may also be used for screening, particularly along with mammography for some women with a high risk of developing breast cancer.

II. Molecular testing of the tumor
The standard tests to further evaluate an invasive breast cancer include estrogen receptor (ER), progesterone receptor (PR), HER2, and Ki67 tests. ER is often measured for DCIS as well. These tests are used to determine the appropriate treatment plan to lower the chance that the cancer will return.

III. Blood tests
The doctor may also need to do several types of blood tests to learn more about the cancer:

- **Complete blood count.** A complete blood count (CBC) is used to measure the number of different types of cells, such as red blood cells and white blood cells, in a sample of a person’s blood. It is done to make sure that your bone marrow is functioning normally.
- **Serum chemistry.** These tests are often done to look at minerals in your blood, such as potassium and calcium, called electrolytes and specialized proteins called enzymes that can be abnormal if cancer has spread. However, many noncancerous conditions can cause changes in these tests, and they are not specific to cancer.
- **Blood tumor marker tests.** Serum tumor markers are proteins found in a person’s blood that can be associated with cancer. High levels of a serum tumor marker may be due to cancer or a noncancerous condition.

*It is therefore important to note, as a patient or physician, the importance of using a medical or pathology laboratory that offers quality medical laboratory services. This means that a patient receives the right results in a timely manner to ensure prompt treatment, hence reducing the risk of the disease progressing or reducing chances of untimely death due to cancer. All this can be achieve by ensuring that laboratories that diagnose cancer are accredited to ISO 15189:2012.*