

SADCAS Achieves Signatory Status in ILAC

SADCAS is proud to announce the achievement of signatory status to the International Laboratory Accreditation Cooperation Mutual recognition Arrangement (ILAC MRA) for **Testing (ISO/IEC 17025)** and **Calibration (ISO/IEC 17025)**.

The decision was made by the ILAC Arrangement Council at its meeting held on 4 November 2015 in Milan, Italy. The MOU was signed at a gala dinner held on Thursday, 5 November 2015 in Milan, Italy. With this achievement SADCAS has therefore been admitted as Full Member of ILAC. In paying tribute to all those who contributed towards this achievement Mrs Maureen Mutasa the SADCAS Chief Executive Officer quoted from an African saying, "When we stand tall it is because we stand on the shoulders of those that have gone before us, and those that surround us", she added.

SADCAS originally joined ILAC as an Affiliate Member in 2008. SADCAS membership was then upgraded to Associate Member in 2011 having accredited enough testing laboratories and calibration to meet the competence requirements for consideration as a Full member. In June 2014 SADCAS underwent a pre peer evaluation of its Testing and Calibration Laboratories Accreditation Programs to determine its readiness for peer evaluation which was subsequently undertaken in May 2015 and culminating in the achievement.

With this achievement the accreditation certificates issued by SADCAS for the testing and calibration accreditation programmes are now internationally recognized thus enhance the acceptance of products across national borders and remove the need for retesting of products traded internationally. In line with its value proposition SADCAS is truly delivering confidence, assuring technical competence and guaranteeing quality.

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From left to right Mr Pete Unger, Chairman ILAC; Mrs Maureen Mutasa, SADCAS CEO; Mr Steve Sidney SADCAS Board Chairman and Mr Filippo Trifiletti General Director of Accredia, Italy



Proudly displaying the duly signed ILAC MRA Certificate with SANAS Officials



Proudly displaying the duly signed ILAC MRA Certificate with AFRAC members

SADCAS Value Proposition

- ✓ Delivering confidence
- ✓ Assuring competency
- ✓ Guaranteeing quality

SADCAS Accepted as a Member of the AFRAC Mutual Recognition Arrangement

SADCAS is proud to announce its admission as **Arrangement Member** of the African Accreditation Cooperation (AFRAC) in the scope **Testing** and **Calibration**. The admission is in acknowledgement of SADCAS having fulfilled the requirements of AFRAC Mutual Recognition Arrangement (MRA), and committing itself to comply with the requirements and obligation of the AFRAC MRA Members.

The decision was made on 8 October 2015 by the AFRAC MRA Council followed by the signing ceremony held on Friday, 9 October 2015 during the gala dinner held to mark the end of the 2015 AFRAC annual meetings including the General Assembly meeting. SADCAS joins SANAS (South Africa), EGAC (Egypt) and TUNAC (Tunisia) the other Arrangement members of AFRAC.

This achievement comes after SADCAS went through the rigorous peer evaluation of its Testing and Calibration Laboratories Accreditation Programs starting with the pre peer evaluation undertaken in June 2014 then the peer evaluation in May 2015. The peer evaluation was undertaken under the applicable AFRAC procedures following which SADCAS was deemed to comply with the requirement for admission as a signatory to the AFRAC MRA.



From left to right: Mr Boughalmi Moez, Chairman AFRAC MRA Council; Mr Ron Josias Chairman AFRAC; Mrs Maureen Mutasa, SADCAS CEO; and Ms Jeanne Ranorovelo SADCAS Technical Manager

Proudly displaying the duly signed MRA Certificate

SADCAS is now working towards signatory status of the other accreditation programs on offer prioritizing the Medical Laboratories Accreditation Program and the Inspection Bodies Accreditation Program.

Sekgoma Memorial Hospital Certificate Handover Ceremony

Sekgoma Memorial Hospital Laboratory is the 10th medical laboratory to be accredited by SADCAS and the 4th medical laboratory in Botswana to be accredited by SADCAS. Sekgoma Memorial Hospital Laboratory has been accredited in the scopes: Virology; Haematology; Serology; Blood Bank; Chemistry; and Microbiology in accordance with ISO 15189: 2007. Through this accreditation, Sekgoma Memorial Hospital Laboratory based along Serowe/Palapye Main Road in Dinokwane Ward, Serowe has been granted the unique accreditation number: MED 010 indicating that Sekgoma Memorial Hospital Laboratory is now a SADCAS accredited medical laboratory. The Sekgoma Memorial Hospital Laboratory certificate which was issued on 19 May 2015 is valid for 5 years until 18 May 2015.

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Sekgoma Memorial Hospital Cafeteria venue of the accreditation certificate handover ceremony

The accreditation certificate handover ceremony was held on 25 August 2015 at the Hospital Cafeteria in Serowe, Botswana and started off with a prayer and followed by introductions by Dr N Kombe, Head of Serowe Health District Management Team. The Hospital Superintendent Dr G N Simwanza gave the welcoming remarks and congratulated the Laboratory staff for the landmark achievement and for a job well done. In the key note address Mr David Matema, the Chief Medical Scientific Officer gave a brief background to the establishment of medical laboratories in Botswana of which 40 now exist in the public sector. He said that accreditation of laboratories and hospital is in the forefront of the Ministry's strategy to improve the competence and quality of health care delivery system in Botswana and that they plan to have 19 public medical laboratories accredited by 2019 of which 9 including Sekgoma Memorial Hospital Laboratory have been accredited so far.



From Left to right: Dr Simwanza, Mr Matema and Mrs Mutasa



Kgalemang JSS School Band

In her remarks Ms K Ntshambiwa, the Laboratory Manager outlined the journey towards accreditation which started in earnest in 2009 with the training of staff and the development of the quality manual followed by implementation of the system which she said was "tough and bumpy". An application for accreditation was submitted to SADCAS in November 2012 followed by an initial assessment which was undertaken in November 2014 after achieving a 4 star rating under the SLIPTA process. She then thanked all those who had assisted in the process, the laboratory staff, hospital staff and suppliers. She also thanked the Ministry of Health for the support, CDC Botswana for the equipment support, Botswana Bureau of Standards for the technical support and Nyangabgwe Hospital Laboratory for the mentorship.

In the certificate handover remarks Maureen P Mutasa, the SADCAS CEO noted the tremendous importance of medical laboratories in any health care delivery system. The main purpose of a medical laboratory is to provide diagnosis and management system for the physician to use in the care of patients. "The competence and efficient operation of a medical laboratory as well as timeous delivery of medical laboratory services to the physician is therefore critical in any health care delivery system. Accreditation which is the process of independently evaluating competency is the strategy for medical laboratories to achieve this" she said. She noted that a number of countries in the region, including Botswana have embraced accreditation as a strategy for the competence of medical laboratories and this has spurred interest in

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the SADCAS Medical Laboratories Accreditation Programme with 26% of the applications under process being medical laboratories. Mrs Mutasa encouraged Sekgoma Memorial Hospital Laboratory to maintain its accreditation throughout the validity period of the accreditation certificate during which SADCAS would undertake surveillance assessments annually to ensure continued compliance. She also reminded Sekgoma Memorial Hospital Laboratory of the need to transition to the 2012 version of ISO 15189 within the stipulated timelines failing which the accreditation will be suspended. She also encouraged the Laboratory to extend its scope of accreditation to other scopes of operation under the SADCAS Medical laboratories Accreditation Programme.



Mrs Maureen P Mutasa handing over the certificate to Dr Simwanza with Ms Ntshambiwa looking on



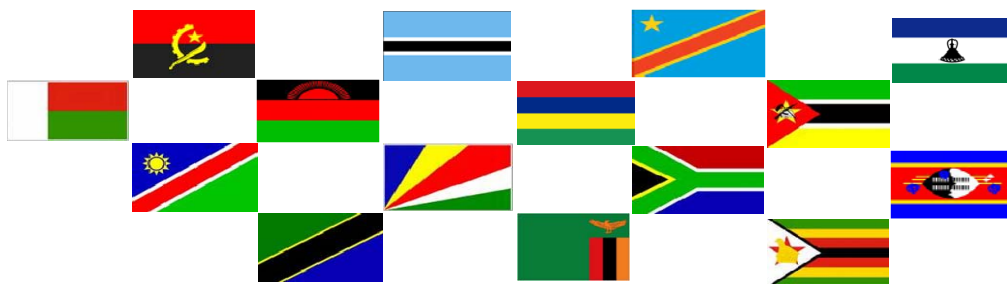
Tour of the laboratory



The ceremony was attended by over 50 people including the Serowe District Councilor Mr Raditanka. Entertainment was provided by Kgalemang JSS School band. The vote of thanks was given by Ms K Ngwako the Hospital Matron. After the ceremony a tour of the Laboratories was also undertaken.



A Multi-economy Accreditation Body!!



SADCAS Accredits Princess Marina Hospital Laboratory

SADCAS accredited another medical laboratory in Botswana. Princess Marina Hospital Laboratory is the 5th medical laboratory in Botswana and the 11th to be accredited under the SADCAS Medical Laboratories Accreditation Program. Princess Marina Hospital Laboratory has been accredited in the scopes: Haematology; Serology; Blood Bank; Chemistry; and Microbiology in accordance with ISO 15189: 2012. Through this accreditation, Princess Marina Hospital Laboratory based at Plot 1836 Hospital Way in Gaborone has been granted the unique accreditation number: MED 011 indicating that the Princess Marina Hospital Laboratory is now a SADCAS accredited medical laboratory. The accreditation certificate which was issued on 25 June 2015 is valid for 5 years until 24 June 2015.

The accreditation certificate handover ceremony was held on 28 August 2015 at The Paddock, in Gaborone, Botswana and started off with a prayer and followed by introductions by the Laboratory Manager, Ms Shirley Johane. Welcome remarks were given by Dr Kelebogile Motumise who congratulated the Laboratory staff for the achievement which he said was a token of excellence. In his remarks Mr Lawrence Masvingise, the Laboratory Quality Officer outlined the journey towards accreditation a process which he compared to the cutting of a rough diamond. An application for accreditation was submitted to SADCAS in December 2013 culminating in accreditation in June 2015. In his remarks Mr David Matema, the Chief Medical Scientific Officer marvelled at the progress made in implementing the Ministry's goal of having 19 medical laboratories accredited by 2019 with 8 public medical laboratories already accredited which he said was contributing to enhanced health care delivery in Botswana.



Dr Motumise receiving certificate from SADCAS CEO



Mrs Mutasa congratulating Ms Johane with Dr Motumise and Mr Lawrence Masvingise looking on

In the certificate handover remarks Maureen P Mutasa, the SADCAS CEO noted that the use of accreditation is expanding both in terms of greater reliance by regulators and business. In many economies now accreditation is being embraced by governments as a mandatory activity in many regulated areas such as health care because of the benefits accreditation brings to help governments meet their responsibilities and safeguard the public. "The focus on delivering excellence within the health care sector is underpinned by accreditation", she said. Accreditation supports and delivers the aim of consistent high quality care with reliable outcomes that patients can trust and provides a piece of mind that the service will meet expectations. Mrs Mutasa encouraged Princess Marina Hospital Laboratory to maintain its accreditation throughout the validity period of the accreditation certificate during which SADCAS would undertake surveillance assessments annually to ensure continued compliance. She also encouraged the Laboratory to extend its scope of accreditation to other scopes of operation under the SADCAS Medical laboratories Accreditation Programme.

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Princess Marina Hospital Laboratory staff proudly display their Certificates Appreciation

The ceremony was attended by over 55 people. Certificates of appreciation were presented to the Laboratory staff in recognition of their achievement. The vote of thanks was given by Ms Tswelelo Kahiya the Hospital Matron after which dinner was served followed by a party to celebrate the achievement.

More Facilities Accredited

Scientific Services City of Windhoek, Namibia: 2015-08-06—SADCAS is proud to announce the accreditation of Scientific Services City of Windhoek in Namibia in the scope of Microbiological Analysis in accordance with ISO/IEC 17025. Scientific Services City of Windhoek accreditation covers heterotrophic plate count; enumeration of total coliforms, enumeration of enterococci, enumeration of *P. aeruginosa* and enumeration of *E.coli*. Through this accreditation, Scientific Services City of Windhoek has granted the unique accreditation number **TEST-1 0007** indicating that Scientific Services City of Windhoek is a SADCAS accredited laboratory.

Medicines Control Authority Zimbabwe: 2015-08-06—SADCAS is proud to announce the accreditation of Medicines Control Authority of Zimbabwe in Harare, Zimbabwe in the scope of Chemical Analysis and Physical Testing in accordance with ISO/IEC 17025.

Medicines Control Authority of Zimbabwe accreditation covers quantitative and qualitative analysis of pharmaceutical formulations by High Performance Liquid Chromatography (HPLC UV-VIS detection): identification, assay, dissolution, decomposition of products and related substances and by UV-VIS Spectrophotometry: identification, assay and dissolution in pharmaceutical raw materials and finished products. Medicines Control Authority of Zimbabwe accreditation also covers determination of width, length and thickness, freedom from holes test and package seal integrity test for male rubber latex condoms. Through this accreditation, Medicines Control Authority of Zimbabwe has granted the unique accreditation number **TEST-5 0016** for Chemical Analysis and **TEST-11 0002** for Physical Testing indicating that Medicines Control Authority of Zimbabwe is a SADCAS accredited laboratory.

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Tanzania Bureau of Standards (Fuel Testing): 2015-10-14—SADCAS is proud to announce the accreditation of Tanzania Bureau of Standards in Dar es Salaam, Tanzania in the scope of Chemical Analysis in accordance with ISO/IEC 17025. Tanzania Bureau of Standards accreditation covers determination of density in gasoil, gasoline and Jet A 1, determination of flash point and density in gasoil and heavy fuel oil, determination of research octane number in gasoline. Through this accreditation, Tanzania Bureau of Standards has granted the unique accreditation number **TEST-5 0017** indicating that Tanzania Bureau of Standards is a SADCAS accredited laboratory.

Bdellium Enterprises t/a Gammatec Inspection Services, Zimbabwe: 2015-10-06—SADCAS is proud to announce the accreditation of Bdellium Enterprises t/a Gammatec Inspection Services in Harare, Zimbabwe in the scope of Inspection in-service in accordance with ISO/IEC 17020.

Bdellium Enterprises t/a Gammatec Inspection Services accreditation covers Type A (third party) Inspection Authority for modifications, repairs and statutory examinations and tests – pressure vessels. Through this accreditation, Bdellium Enterprises t/a Gammatec Inspection Services has granted the unique accreditation number **INSP-5 004** indicating that Bdellium Enterprises t/a Gammatec Inspection Services is a SADCAS accredited laboratory.

Kilimanjaro Christian Medical Centre: 2015-09-15—SADCAS is proud to announce the accreditation of Kilimanjaro Christian Medical Centre in Moshi, Tanzania in the scope of Clinical Chemistry and Molecular Biology in accordance with ISO 15189:2012.

Kilimanjaro Christian Medical Centre accreditation covers alanine aminotransferase, aspartate aminotransferase, HDL-cholesterol, total cholesterol, creatinine, potassium, sodium, triglyceride, urea and glucose in serum, HIV DNA in DBS and HIV Viral Load in Plasma. Through this accreditation, Kilimanjaro Christian Medical Centre has granted the unique accreditation number **MED 013** indicating that Kilimanjaro Christian Medical Centre is a SADCAS accredited laboratory.

Advisory Committee for Inspection Bodies in Zimbabwe Holds its 5th Meeting

The Advisory committee for Inspection in Zimbabwe held its 5th meeting at the Standards Association of Zimbabwe's Headquarters on 17 September 2015. The meeting which was attended by 17 members was chaired by Mr Ngoni Chirinda who was appointed chairman at the 4th meeting held in 2014. The purpose of the meeting was to provide update on developments in SADCAS especially developments in the Inspection Bodies Accreditation Program, to update members on the revisions of SADCAS AP 12: Part 2: Accreditation of inspection bodies operating in the regulatory/voluntary area, to discuss draft 1, Issue 1 of SADCAS TR 13: Criteria for the accreditation of inspection bodies performing inspection of metallic tanks in Zimbabwe and to consider other scopes for extension for the program.

A minute of silence was observed at the beginning of the meeting in remembrance of Mr Rogers Dhlwayo, Director Occupational Health and Safety who represented National Social Security Authority (NSSA) on the Committee who passed on in June 2015. Mr Dhlwayo was instrumental in pushing for the use of accreditation as an assurance for the competence of inspection bodies operating under the factories and Works Act which culminated in the Memorandum of Understanding between SADCAS and NSSA the delegated authority for occupational health and safety issues in Zimbabwe.

The draft SADCAS TR 13 was developed based on a draft prepared by a Working Group (WG) established for that purpose in 2013. The Working Group draft was considered at the 4th meeting of the Advisory Committee held on 29 October 2014 following which and taking into account the comments raised was revisited and WG draft 2 was prepared. The document was reviewed by the delegated regulatory authority in Zimbabwe, the National Social Security Authority (NSSA) who proposed some changes to the document which thereafter was forwarded to SADCAS on 29 April 2015. SADCAS considered the draft document and presented it in the SADCAS format. S ADCAS TR 13, draft 1, Issue 1 was circulated to all the Advisory Committee members on 4 August 2015 for comment by 18 August 2015. Comments received were then considered during the 5th Advisory Committee meeting held on 17 September 2015. The draft was

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discussed clause by clause and a number of changes were made to focus the document on metallic tanks. Issue 1 of SADCAS TR 13: Criteria for the accreditation of inspection bodies performing inspection of metallic tanks" has since been published and uploaded on the SADCAS website.

Regarding scope extension to cover lifting equipment, the Chief Inspector of Factories Mr Mutswatiwa advised that there was no progress on the regulations for lifting equipment. Members then discussed the possibilities of extending the accreditation program scope to cover lifting equipment as a voluntary activity and for which the composition of the Advisory Committee would have to be extended to include the interested parties. A proposal was made to also consider extending the scopes to cover non - metallic tanks and verification activities which the meeting agreed to consider developing the necessary technical requirements documents in future meetings. On other topics for discussion in future meeting the Committee agreed to discuss the fine line between NDT activities and inspection activities a matter which is also under discussion at international level.

The Document Working Group which was established to review international documents was reminded to submit comments on ILAC document on Guidance on measurements performed as part of an inspection process whose deadline for comment was set at 7 October 2015 to allow SADCAS enough time to collate comments and submit them to ILAC by 14 October 2015 which was subsequently done and the comments were reviewed by Working Group 4 of the ILAC Inspection Committee (IC). Another draft will be prepared incorporating agreed changes after which the draft document will be circulated to ILAC Accreditation Committee then comments received will be reviewed by the ILAC IC Working Group 4 before recommending it to the ILAC IC to go for 60 day comment by all ILAC members.

SADCAS TR 13 has since been finalized and published by SADCAS and is available on the website www.sadcas.org

SADCAS Signs MOU with NAMLS

The SADC Accreditation Service (SADCAS) has signed a Memorandum of Understanding with the Namibia Association of Medical Laboratory Sciences (NAMLS). The objective of the MOU is to advance professional laboratory medicine practice in Namibia through accreditation.

NAMLS is the national association for Namibia's medical laboratory professionals whose mission is to serve as the voice of all medical laboratory professionals and is committed to the advancement of the medical laboratory practice through advocating the value and the role of the profession in ensuring effective health care. NAMLS vision is to improve health care in Namibia through promoting the strengthening of medical laboratory practice. On the other hand SADCAS is a multi economy accreditation body established to meet the accreditation needs of 13 SADC Member States including Namibia. SADCAS offers accreditation programmes including the medical laboratories accreditation program in accordance with ISO 15189. SADCAS also offers training in accreditation related activities including training for medical laboratories.

Realizing the common goal of advancing professional laboratory medicine practice through accreditation, SADCAS and NAMLS have agreed to cooperate by:

- Training of medical laboratory professionals;
- Sharing technical information on areas of mutual interest and developing suitable linkages to facilitate easier access to information from the 2 organizations;
- Advocating for the critical needs of laboratory medicine and the need for policy makers to embrace accreditation as a strategy for quality laboratory service delivery; and
- Cooperating in other activities or projects that are of mutual interest and in support of the implementation of the MoU.

The MoU negotiations started in February 2015 when SADCAS received a proposal from NAMLS. SADCAS responded to the proposal in March 2015 outlining possible areas of cooperation taking into account the need for SADCAS to abide by principle of impartiality and to ensure that there is no conflict of interest in the activities under cooperation. Upon agreement of the possible areas of cooperation a draft MOU was prepared and subject of negotiations for a good 5 months.

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In July 2015 NAMLS formally advised of their approval of the draft MoU which was subsequently approved by the SADCAS Board of Directors at its meeting held on 2 September 2015.



Dr Hikuam NAMLS President and Mrs Maureen P Mutasa SADCAS CEO during the signing of the MOU

Speaking during the signing ceremony both Parties committed to abide with the undertakings in the MOU for successful realization of its objectives. "Let us therefore safeguard our integrity and reputation by making this MoU a success not just a paper exercise" Mrs Mutasa said in her remarks.

The MOU between SADCAS and the NAMLS was signed on 26 September 2015 in Windhoek during a seminar organized by NAMLS. The seminar was attended by over 50 NAMLS members under the theme "Striving towards quality of Medical laboratory Services". Various papers were presented including a paper on "SADCAS Experiences from the Medical laboratories Accreditation Programme" by Mrs Mutasa, a paper entitled "Point of Care Testing: The past, present and the future" which was presented by Ms K Kuun a representative of Scientific Group, South Africa suppliers of medical equipment. Other papers were presented throughout the day of the seminar.

7th Annual Report Published.

The seventh SADCAS annual report for the year ended 31 March 2015 has been published. This annual report gives an insight in to the activities and achievements that SADCAS made during the financial year. As noted in the SADCAS Chairman's Statement by Mr Steven Bruce Sidney, **'Great strides have been made towards international recognition of its accreditation certificates, with SADCAS successfully undergoing a joint pre-peer evaluation by the International Laboratory Accreditation Cooperation (ILAC) and the African Accreditation Cooperation (AFRAC) in June 2014, and a full peer evaluation in May 2015.'** To view the annual report please visit the SADCAS website on www.sadcas.org/annual_repot.php



SADCAS Reaches Out to More CABs in Zimbabwe

As part of SADCAS promotional and marketing plans for 2015/16 and as a follow up on actions arising from the 22nd review meeting of SADCAS/SANAS Twinning Partnership Arrangement held on 16 September 2015, the SADCAS CEO and Technical Manager visited 3 testing laboratories in Zimbabwe namely Tobacco Research Board, Central Veterinary Laboratory and Antech Laboratory. All the laboratories visited by SADCAS are still accredited by SANAS hence the purpose of the visit was to convince the facilities to changeover to SADCAS noting the great strides made by SADCAS towards international recognition of its Testing /Calibration laboratories Accreditation Programmes.

The SADCAS CEO, Technical Manager and a representative of NAFFP – Zimbabwe office Ms Gamuchirayi Mutetwa met with 3 representatives of the **Tobacco Research Board Laboratory** Mr T Chagonda, Ms F Mutenda and Ms C Musunda Garwe at its premises located in Hatfield, Harare, Zimbabwe on 17 September 2015. In support of its services the Tobacco Research Board has 2 main laboratory services divisions namely: Analytical Chemical Services and Molecular Biology Services divisions which offer a wide range of chemical, microbiological and molecular biology tests such as GMO testing, DNA profiling, viral diagnostic testing. Tests are undertaken on water (domestic, borehole, irrigation), effluent water, food, plant material especially tobacco etc. Services are provided not only for internal purposes but also to external clients such as the food industry, agricultural sector including farmers, manufacturing and tobacco merchants, local authorities and academic research institutions. The Laboratories are accredited by SANAS in the scopes Chemical and Molecular Biology. The Laboratory Manager welcomed the SADCAS delegation and gave a brief background of the Tobacco Research Board Laboratories, the services it offers, the sectors served, the laboratory organization and the accreditation status of the laboratories. The SADCAS Chief Executive Officer then gave a brief overview of SADCAS and the achievements made so far in particular the great strides made in working towards signatory status in international accreditation arrangements with SADCAS having successfully undergone a pre peer evaluation in June 2014 and full peer evaluation in May 2015. With this development and noting that Tobacco Research Board Laboratories had been accredited by SANAS with accreditation set to be reconfirmed subject to clearance of findings, the SADCAS Chief Executive Officer then outlined the changeover process which has been agreed with SANAS and encouraged the TRB laboratories to changeover to SADCAS as they fall within the boundaries of SADCAS mandate.

On 18 September 2015 the SADCAS CEO, Technical Manager and a representative of NAFFP – Zimbabwe office Ms G Mutetwa met with 2 representatives of the **Central Veterinary Laboratory** (Zimbabwe) Dr PV Makaya, Deputy Director and Ms Mahlangu the Acting Quality Manager at its premises located in Harare, Zimbabwe.



From left to right: Ms Jeanne Ranorovelo, Ms Manhlangu, Dr Makaya and Mrs Maureen P Mutasa pose for a photo after the meeting



Technologist at work

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In order to guarantee the quality of diagnostics and research outputs the Veterinary Laboratory Diagnostic and Research Branch adopted and implements a management system based on ISO/IEC 17025 which is used by all the 9 diagnostic sections under the Central veterinary Laboratory. However, only the CVL's Virology and bacteriology sections are accredited by SANAS. The accreditation which is in the scopes Bacteriology and Serology expires in November 2015 and was reassessed by SANAS in August 2015 for the scopes Bacteriology, Serology and Protozoology with the latter being a scope extension. The Deputy Director indicated CVL's intention to changeover to SADCAS as soon as their accreditation has been confirmed by SANAS. Here again the SADCAS CEO explained the changeover process. The meeting was also an opportunity for SADCAS to be appraised of the 1st meeting of the SADC Veterinary Laboratory Subcommittee held from 16 to 18 September 2015. Dr Makaya is the Chairman of the SADC Subcommittee. The CVL Zimbabwe plays a leadership role in veterinary issues at regional level and has served as a benchmark on accreditation issues for the other veterinary laboratories in the region.

On 21 September 2015 the SADCAS CEO and Ms G Mutetwa met with Mr Luwobo the Laboratory Manager for **Antech Laboratories** an accredited laboratory which services mainly the mining sector in Zimbabwe. The Laboratory is based in Kwekwe, Zimbabwe. This meeting was a follow up to the visit made to the Laboratory premises by the SADCAS CEO in September. Antech Laboratory offers geological, metallurgical and environmental tests mainly to the mining sector in and around Kwekwe and services some of the mining giants Anglo Platinum, Metallon Gold, Zimplats, and Duration Gold etc. The laboratory employs 49 staff and has been in operation for over 22 years. The purpose of the visit was to follow up on the previous visit and establish if they had made a decision on changeover. Mr Luwobo then advised SADCAS delegation of their intention to changeover from SANAS to SADCAS accreditation at the next surveillance assessment.

SADCAS Moves to New Offices

On 26 and 27 November 2015, SADCAS relocated to new spacious offices about 200m from the current location. SADCAS offices are now housed at **Plot 50669 Unit 2A, Tholo Office Park, Fairgrounds, Gaborone, Botswana**

SADCAS postal address, telephone and fax numbers remain the same. SADCAS' primary email address is also still the same: info@sadcas.org.

SADCAS opened its doors in April 2008 and since that time, has grown both in business as well as staff compliment. Located in the business hub of Gaborone, SADCAS new offices are easily accessible, bright and more spacious and will no doubt strengthen SADCAS' identity as an independent accreditation authority. We therefore look forward to having our customers, suppliers and other business partners to our new home.

NOTICE!!

Christmas and New Year Holidays!!

SADCAS office will be closed from Monday, 21
December 2015 and re-opens on
Monday, 11 January 2016

Sixth AFRAC General Assembly in Tunis, Tunisia

The African Accreditation Cooperation (AFRAC) held its 6th General Assembly meeting on 9 October 2015 at the Carthage Thalasso Resort in Tunis, Tunisia. The meeting was hosted by the Tunisian Accreditation Council (TUNAC). A number of training workshops and meetings were held before and during the week as follows:

- ❑ Training of AFRAC Peer evaluators from 1 to 3 October 2015;
- ❑ Workshop on MRA decision making; Workshop on Accreditation: Building global trust; and Evaluators' Working Group meeting held on 5 October 2015;
- ❑ Marketing and Communications Working Group meeting, Calibration, Testing and Inspections Technical Committee Working Groups and MRA Documents Working Group meeting held on 6 October 2015;
- ❑ Technical Committee and MRA Committee an MRA Council meetings held on 7 October 2015;
- ❑ Workshops for new accreditation bodies and Standards in Transition ISO/IEC 17021-1 held on 8 October 2015 and
- ❑ AFRAC Executive Committee meetings held on 6 and 8 October 2015; and
- ❑ AFRAC General Assembly (GA) held on 9 October 2015.

The 6th AFRAC General Assembly meeting was officially opened by the Honourable Zakaria Hamad the Tunisian Minister of Industry, Energy and Mines at a ceremony held on Monday 5 October 2015 and attended by over 40 delegates from African countries mainly from accreditation bodies, regional trading blocs, international development partners such as Physikalisch - Technische Bundesanstalt (PTB) Germany, accreditation cooperation partners such as the Arab Accreditation Cooperation (ARAC).



From left to right: Mr Anour Zouari, TUNAC General Director; Mrs Roxanne Robinson, ILAC Representative, Honorable Zakaria Hamad Minister of Industry, Energy and Mines; Mr Ron Josias, AFRAC Chair; and Mr Mahmoud Eltayeb, ARAC Chair.

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The General Director of TUNAC Mr Anour Zouari welcomed delegates to the 6th AFRAC Annual meetings and thanked the AFRAC for the opportunity afforded to TUNAC to host this special event in Tunisia. In his remarks Mr Ron Josias the Chairman of AFRAC noted that over the last decade Africa has been home to 6 of the fastest growing economies in the world hence it was incumbent on all of us to play our part in supporting the building of robust and sustainable economies. He outlined the milestones attained since the establishment and launch of AFRAC in 2010 and the benefits of the cooperation to the continent such as supporting the development of accreditation bodies and serving as the voice for Africa in accreditation matters in international accreditation fora. He advised delegates that AFRAC had submitted an application to join the ILAC Mutual recognition and the IAF Multilateral Arrangement and hoped that signatory status will be achieved in the next 2 years. He then thanked Tunisia for hosting the 6th AFRAC General Assembly meeting and also thanked PTB Germany for the support provided to AFRAC thus far. In her remarks delivered on behalf of the ILAC Chairman, Mrs Roxanne Robinson wished AFRAC fruitful deliberations and thanked AFRAC for the opportunity to visit Tunisia. The ARAC Chairman Mr Mahmoud Eltayeb informed delegates about ARAC and the close cooperation with AFRAC and noted the remarkable progress that AFRAC had made since its establishment. In his speech Honourable Zakaria Hamad welcomed all delegates to Tunisia and noted the importance of accreditation in economic integration and called upon African countries to develop their national quality infrastructures. He prided in TUNAC's achievements and participation in regional and international accreditation activities. He called upon African leaders to come up with a regional strategy to better channel financial support towards accreditation activities. "Tunisia is ready to cooperate in order to achieve this objective" he said.



Delegates at the 6th AFRCA General Assembly Opening Ceremony

A number of training and awareness workshops were held in conjunction with the 6th AFRAC GA starting with the AFRAC peer evaluator course which was held from 1 to 3 October 2015 and attended by 15 participants from EGAC, KENAS, MAURITAS, TUNAC, SANAS and SADCAS as well as an observer from ECOWAS. The course was very ably facilitated Mrs Robinson and Mr Eltayeb both of whom are seasoned evaluators with the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and AFRAC respectively. In a presentation on the MRA decision making process, Mr Moez Boughalmi outlined the terms of reference (TORs) of the MRA Committee and Council and defined the timelines of the MRA Committee and Council and the decision process. This was followed by a workshop on "Accreditation: Building Global Trust" which was held on 5 October 2015. On 8 October 2015 an orientation for new members of AFRAC was held and hosted by the AFRAC Chairman and Vice Chairman followed by a workshop for new and emerging

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Accreditation bodies. On the same day a workshop was held to update members on the revisions of ISO/IEC 17021: 2011 now published as ISO/IEC 17021-1: 2015. The workshop was ably facilitated by Mr Michael Talam the Assistant Director Certification, KENAS.

The Technical Committee Working Groups, MRA Committee Documents Working Group and Marketing and Communications Working Group met on 6 October 2015 followed by the Technical Committee and MRA Committee and MRA Council meetings on 7 October 2015.

The Technical Committee meeting was chaired by Mr Sammy Milgo from KENAS and attended by 9 participants from TUNAC, SANAS, KENAS, SADCAS, ENAO, EGAC, ARAC, BOBS and one observer Mr Prags Govender the SANAS Board Chairman. The meeting reviewed the terms of reference of the Technical Committee and progress made on the 2014/15 work plan and developed the 2016 work plan. A Task Force comprised of Ms J Ranorovelo, Mr Pilot Masunga and Mr Hani was set up to analyze the responses received, advise on actions to be taken and provide summary of the feedback by mid-December 2015. The feedback received on the AFRAC Toolkit was analyzed following which changes were made on the toolkit which will now be finalized and posted on the AFRAC website. Regarding Proficiency Testing (PT), it was noted that a list of PT service providers is available on the AFRAC website and members were encouraged to have links to the AFRAC website. The meeting also agreed on a definition for AFRAC National Accreditation Focal Points which upon approval will be applied accordingly in AFRAC documents. Reports from the Inspection WG, Testing and Calibration WG and Certification WG were



Participants at the MRA Decision Making Workshop pose for photo with the Trainers Mrs Robinson and Mr Eltayeb

respectively presented during the meeting and the terms of reference of each WG were discussed, activities undertaken and actions to be undertaken were noted and fed into the ensuing development of the 2016 Technical Committee work plan whose main activities are: awareness and promotion of accreditation; promotion of the use of the accreditation toolkit; coming up with an AFRAC position on accreditation of sampling as a standalone activity for presentation at the next ILAC meeting; and evaluation of conformity assessment bodies' participation in PT/ILC. The meeting reviewed and approved the guidelines for the accreditation of NMIs. On the revision of ISO/IEC 17011, a Working Group comprised of representatives from TUNAC, SANAS & ENAO reviewed comments from AFRAC members, consolidated and submitted them on behalf of AFRAC. Members were also updated on the revisions of ISO/IEC 17025. The proposed document for the expansion of AFRAC MRA scopes was also reviewed by the Technical Committee.

The Marketing and Communications Working Group meeting was chaired by Mrs Susan Munyiri from KENAS and attended by 9 participants from TUNAC, Ghana, ENAO, KENAS, SADCAS, SANAS and Mr Mike McNerney, the E Learning Project Consultant. The meeting reviewed progress on the draft corporate identity manual and identification of promotional materials for which it was agreed that a designer be engaged and for which a funding proposal has been developed and is to be submitted to donors once approved by the EXCO; agreed that editing of AFRAC Newsletter be on a rotational basis with each assigned editor providing 2 Newsletters in January and July per year; identified the need to develop 2 brochures on AFRAC and the AFRAC MRA drafts of which will be circulated for comment by 30 November 2015; discussed about the AFRAC tagline for which "Confidence and Trust was the most popular and will be presented for approval by the GA; reviewed the list of Frequently Asked Questions which will now be presented to the EXCO for approval before uploading on the AFRAC website; reviewed proposals for future WAD Themes and agreed on various themes on the construction sector, environment, consumer pharmaceutical sector etc. which will now be submitted to ILAC/IAF for consideration; and reviewed the draft questionnaire for identification and engagement of regulators/drivers which will be presented to the EXCO for approval. The meeting was also appraised of the proposed AFRAC E-learning

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project which will comprise of 6 modules covering requirements of ISO/IEC 17011, the establishment of an accreditation body, training of NAFFPs, peer evaluator training and support to conformity assessment bodies and accreditation contacts.

The MRA Committee meeting which was Chaired by Mr Boulghami was attended by 8 members and the Secretariat. In reviewing its TORs the MRA Committee noted the need to separate the TORs of the MRA Committee from those of the MRA Council with the latter being responsible for decision making. It was also agreed that the MRA Committee TORs include the review of final PE reports to ensure that a thorough evaluation was undertaken, findings well classified, all findings cleared, queries from members thoroughly explained, all relevant documents available and to prepare a summary of the MRA Committee's recommendations to the MRA Council. In effecting these changes the MRA Committee Documents Working Group was requested to revise M001 to reflect the revised role in reviewing PE final reports, separate TORs of MRA Committee from Council, adapt the template taking into account other templates used. The meeting then reviewed progress in implementation of the 2015 work plan and noted that 3 peer evaluations for SADCAS, SANAS and ENAO had been undertaken during the period of review. The meeting also scheduled the peer evaluations to be undertaken and for incorporation into the 2016 work plan i.e. peer evaluation of KENAS, pre peer evaluation of MAURITAS, Scope extensions to medical and inspection in the case of SADCAS and inspection for ENAO. Based on the recommendations of the Evaluator Working Group, Mr Chankar Bheekhun was qualified as a peer evaluator for Testing whilst Mr Moslem Barrak was qualified as a Team Leader. The MRA Committee also agreed to the registration and inclusion of the 15 trainee evaluators in the AFRAC database of trainee peer evaluators. On standards under transition and in effort to monitor transitions, the MRA Committee reminded all AFRAC signatories and full members to ensure that transition timelines are met and to submit reports to the Secretariat before each MRA Committee. In reviewing the training workshops held the MRA Committee agreed to have practical cases to consider in future training on decision making. Regarding the evaluation of AFRAC as a region, an internal audit will be undertaken in April 2016 followed by the evaluation of the region around mid-June 2016 and for which an application had already been submitted to ILAC and IAF. On extension of the MRA scope to Food Safety Management Systems (FSMS), the meeting agreed that a needs survey be undertaken by end of January 2016 to serve as the basis for decision on extension and for which guidelines would have to be developed by the Technical Committee in support of the scope. The Committee also reviewed a number of MRA documents and resolved that M001 and P002-02 be submitted for approval by the General Assembly, F 022 be approved by the EXCO whilst a number of documents (M002-02, M003-01, P011-02, F019, F009, F026 and F 014) were held back subject to changes suggested by the MRA Documents Working Group being incorporated.

The newly constituted MRA Council held its inaugural meeting immediately after the MRA Committee meeting and approved that SADCAS be admitted as Arrangement Member of the African Accreditation Cooperation (AFRAC) in the scope Testing and Calibration. The admission is in acknowledgement of SADCAS having fulfilled the requirements of AFRAC Mutual Recognition Arrangement (MRA), and committing itself to comply with the requirements and obligation of the AFRAC MRA Members.

The Committee meetings were followed by the 6th AFRAC GA Meeting during which a total of 32 resolutions were adopted. In his report to the General Assembly the AFRAC Chairman, Mr Ron Josias reviewed the progress made since the 5th annual general meeting held in Ethiopia. He informed delegates that 2017 had been declared the year for quality in Africa and that Pan African Quality Infrastructure (PAQI) had been tasked by the AU to lead the programs. He commended members for commemorating World Accreditation Day and noted that awareness on accreditation was increasing. The Chairman noted that accreditation issues were becoming more and more important in trade and cited the invitation extended to ILAC to talk about accreditation and its contribution to trade at the WTO TBT meetings in November 2015. He noted that a lot of progress had been made in progressing the AFRAC agenda with more peer evaluators having been trained, qualified and registered and more peer evaluations being undertaken during the period of review. He thanked PTB Germany for sponsoring the participation of AFRAC representatives at the mid - term ILAC/IAF meeting held in April 2015 and also for sponsoring the mid - term AFRAC meetings held in South Africa in July 2015. He also advised the GA about the E learning project which had been commissioned and was underway with consultations meetings being held in conjunction with the AFRAC meetings.

The GA received the reports of the MRA Committee and Technical Committee and approved their respective 2016 work plans as presented by the respective committees Chairmen. The GA also approved the financial statements for the year

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ending 31 December 2014 and the 2016 budget as presented. The proposed tagline "Confidence and Trust" was approved and will be incorporated in AFRAC promotional material as appropriate. Standards Organisation of Nigeria (SON) Nigeria (SON) and the Medical Laboratory Science Council of Nigeria were admitted as Stakeholder members of AFRAC. Various reports were presented to the General Assembly by PTB Germany, ARAC, IAAC, APLAC, ILAC, IAF, PAC, SADCA, PAQI and ACP EU TBT Group. The GA elected Mrs Maureen P Mutasa, the Chief Executive Officer of SADCAS as the AFRAC vice Chair and re - elected Mr Moez Boughalmi (TUNAC) as Chairman of the MRA Committee and Mr Sammy Milgo the Managing Director of KENAS as the Chairman of the Technical Committee for terms of office in accordance with the AFRAC Bylaws. The GA thanked TUNAC for hosting the 6th General Assembly of AFRAC, for the excellent arrangements and hospitality. The newly admitted members of AFRAC and SADCAS who was admitted as an Arrangement member all signed their respective MOU as commitment to abide with AFRAC by laws and the various members' obligations at a gala dinner held to mark the end of the GA meeting.



Delegates pose for photos during tea/coffee break

AFRAC Workshop on Standards in Transition ISO/IEC 17021-1

On 8 October 2015 AFRAC held half day workshop to update members on the revisions of ISO/IEC 17021: 2011 now published as ISO/IEC 17021-1: 2015. The workshop was ably facilitated by Mr Michael Talam the Assistant Director Certification, KENAS who gave the history of the standard, outlined the revision process of ISO/IEC 17021: 2011 culminating in the publication of ISO/IEC 17021-1 in September 2015.

In going through each clause of the new standard, Mr Talam highlighted the key changes which had been made most of which are under Clauses 3, 4.8, 5.2, 5.3, 7, 8 and 9 of the new standard. In Clause 3 nonconformity, major nonconformity, minor nonconformity, technical expert, certification scheme, audit time and duration of management system certification audits were defined. In sub - clause 4.8 a new principle on risk based approach was added. In sub - clause 5.2, the responsibility for managing impartiality has been shifted from the impartiality committee to the conformity assessment body and a requirement for a process to identify, analyze, evaluate, treat, monitor and document the risks has been added. In clause 5.3 the need for the impartiality committee to review income analysis has been removed. In shifting the responsibility of impartiality to the conformity assessment body, clause 6 has been strengthened by requiring certification activities to be structured so as to ensure impartiality and emphasis has been made on the control of sites, agencies and franchises and outlines requirements for conformity assessment body to establish appropriate level and method of controlling activities. Under Clause 7 on competence of personnel, skills has been added to general considerations, competence will need to be demonstrated prior to performing activities and each auditor shall be monitored taking into consideration each type of management system to which the auditor is deemed competent.

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Most of the changes have been made in Clause 9 of the standard on process requirements where the need to develop audit programme which shall cover the complete management system requirements is explicitly required with differentiation being made between the audit programme for initial certification cycle and subsequent certification cycles. Clarification has also been made that surveillances need to be undertaken once in a calendar year except in recertification years. Specific requirements for the auditing of shifts have been added. New requirements regarding auditing of systems against multiple system standards have also been added together with the need for technical experts in the audit team which shall have the totality of the competencies identified for the audit. The role of the technical experts is elaborated on. The new standard also introduces electronic means of auditing and virtual audits. Types of decisions have been clarified by adding decisions for granting certification, expanding or reducing the scope of certification, suspending or restoring certification, withdrawing certification or renewing certification. The standard further requires the recording of certification decisions and the information taken into consideration in making the decision. The workshop resulted in very good interactions as the accreditation body members in attendance wanted to understand the interpretations of some of the changes made and how to apply them during assessments of management system(s) conformity assessment bodies.



Delegates at the ISO/IEC 17021-1 Workshop

ISO/IEC 17021-1: 2015 Training

SADCAS now offers training on the updated version of ISO/IEC 17021-1: Conformity assessment- Requirements for bodies providing audit and certification of management systems ISO 17021-1 was published on 15 June 2015 and replaces and cancels ISO/IEC 17021: 2011 which has been technically revised.

Participants will gain a general understanding of the requirements of ISO/IEC 17021-1:2015 and its relationship with other accreditation requirements such as ISO/IEC Technical Specification (TS) 17021-3: Competence requirements for auditing and certification of quality management systems and IAF documents.

The training course is intended for management systems certification bodies' staff and SADCAS assessors.

For more information contact:

Linda Dirorimwe on +267 3132909/10 or
Email on ldirorimwe@sadcas.org; info@sadcas.org

Invitation to Register as SADCAS Assessors

The Southern African Development Community Accreditation Service (SADCAS) invites qualified assessors to be registered as SADCAS assessors for its testing/calibration/medical laboratories, and certification (management systems/product)/ inspection bodies' accreditation programmes. SADCAS' strategy over the next few years is to grow its pool of assessors so as to cover the anticipated scopes of accreditation, and the geographical and language diversity in the SADC region of which 13 Member States are serviced by SADCAS.

Assessors are experts from the public and private sectors as well as from technical institutions/ associations who have been trained, qualified and registered as assessors by an accreditation body.

SADCAS will review and evaluate all applications to ensure that the assessors have the prerequisite qualifications, technical knowledge and experience required by SADCAS.

Applications shall be addressed to:

Ms Jeanne F Ranorovelo

Technical Manager

P Bag 00320

Gaborone, Botswana

Email: jfranorovelo@sadcas.org; info@sadcas.org

Highlights of the 2015 IAF-ILAC Meetings

The 2015 joint annual meetings of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) were held at the Marriott Hotel in Milan, Italy from 28 October to 6 November 2015. Over 350 delegates attended the meetings with the following economies from the Africa region attending the meetings: AFRAC and ARAC represented by some members of the regional cooperations' executive members; 15 the SADC countries represented by SADCA; Egypt; and accreditation bodies ENAO (Ethiopia); KENAS (Kenya); SADCAS (13 SADC Member States); SANAS (South Africa); and TUNAC (Tunisia). The meetings started with a series of IAF working groups meetings followed by ILAC and IAF committee meetings which were held in parallel. The ILAC and IAF General Assemblies and the joint ILAC/IAF General Assembly were held during the last 3 days of the meeting from 4 to 6 November.

The 2015 ILAC/IAF annual meetings were hosted by ACCREDIA, the Italian Accreditation Body and were held in conjunction with the EXPO 2015 which was being held under the theme 'Feeding the Planet, Energy for Life'. This provided delegates with a major international window for raising recognition of the international network of accreditation bodies and promotion of accreditation worldwide. ACCREDIA is the designated national accreditation body of Italy and accredits certification/verification/

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Membership and Secretariat issues – Four accreditation bodies including SEMAC (Morocco) were admitted to the IAF Memorandum of Understanding (MoU) since the 2014 General Assembly held in Vancouver, Canada. This brought the total membership of the IAF to 74 accreditation body members, 18 Associate members, 6 regional group members and 2 observer members.

On the other hand, ILAC upgraded membership status of a number of accreditation bodies' members including SADCAS which was upgraded to full member. Two members were admitted into the Associate category, 1 affiliate being the Medical Laboratory Sciences Council of Nigeria (MLCSN), 3 stakeholder members all of which are laboratory associations including ASCOLAB the Laboratory Association for the Democratic republic of Congo. At the same time membership was terminated for 3 members due to non - payment of fees, 2 of which were in the Affiliate category including Libyan National Centre for Standardization and Metrology (LNCMSM) and one in the Stakeholder category.



IAF Technical Committee Meeting in session

ILAC GA in session

New IAF Multilateral Arrangement (MLA) and ILAC Mutual Recognition Arrangement Signatories - Since the 2014 annual meetings the IAF welcomed 2 new members in the main scope Product Certification ISO/IEC 17065 (2) and Management system certification ISO/IEC 17021 in the sub - scopes Level 5 ISO 9001 and 14001 (1). Extensions were granted to 3 regional Multilateral Arrangements sub - scopes Level 4 ISO/TS 22003 and ISO/IEC 27006 (1 to PAC), Product Level 4 Global GAP – General regulations (3 to PAC, IAAC and EA), Product Level 5 Global GAP IFA Control Points and Compliance Criteria (3 to PAC, IAAC and EA), Level 5 ISO 22000 (1 to PAC). The IAF also granted extensions to 15 new IAF MLA signatories for the main scopes of ISO/IEC 17065 Sub-scope Global GAP Level 4 (2) and ISO/IEC 17021 Sub - scope Level 5 ISO 9001 (1) and ISO 14001 (1), Level 4 ISO/TS 22003 (11) and Level 5 ISO 22000 (1 region), Level 4 ISO/IEC 27006 (1) and Level 5 ISO/IEC 27001 (1 region).

The ILAC General Assembly welcomed 4 new signatories to the ILAC Arrangements, 2 of which are for calibration, 4 for testing (ISO/IEC 17025) including SADCAS for both calibration and testing. Five (5) accreditation bodies extended their scopes to testing - ISO 15189 (2), calibration –ISO/IEC 17025 (2) and one to Inspection (ISO/IEC 17020). At the same time the ILAC Arrangement council suspended the signatory status of Kyrgyz Accreditation Centre for testing (ISO/IEC 17025). Representatives of the signatory accreditation bodies signed their respective MLAs/MRAs at a ceremony held during the signing ceremony and gala dinner on 5 November 2015.

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Transition periods - The IAF General Assembly acting on the recommendation of the Technical Committee endorsed the following:

- ❑ **ISO/IEC 27006: 2015:** Information technology – Security techniques requirements for bodies providing audit and certification of information security management systems will be 2 from the date of publication of the standard i.e. 30 September 2017.
- ❑ **Revision of ISO 13485: 2003:** Medical devices – Quality management systems – Requirements for regulatory purposes will be 3 years from date of publication of the revised standard.

ILAC Inspection Committee (IC) - Various reports were presented by the regions on accreditation of inspection activities with the IAAC looking into ways of harmonizing assessments to ISO/IEC 17020: 2012 which exercise is being done amongst assessors and peer evaluators. The EA is looking at ISO/IEC 17020, ISO/IEC 17065 and ISO/IEC 17025 with a view to determine which standard is best for type approvals and there are ongoing discussions on NDT, testing in inspection and sampling as a standalone activity. Currently the EA is accrediting to 30 scopes and some work is underway to harmonize the scopes. The meeting also reviewed ongoing revisions of ISO/IEC 17011 and ISO/IEC 17025 and how the revisions will affect the work of the Committee. A review of CD ISO/IEC 17011 noted the inclusion of remote assessments and the need to now qualify assessors by area of inspection activity rather than by key accreditation standard in this case ISO/IEC 17020. The Inspection Committee concluded that the current revisions to ISO/IEC 17011 adequately covered inspection activities. Work progressed on the draft document for inspection scopes with Working Group reviewing the 51 comments received from members. Further improvements will be made on definitions, clarification of terms used for multi - site inspections, inclusion of examples of scopes to highlight components that should be included in the scopes and inclusion of more inspection bodies' examples. Discussions on the status of the document vis a vis the ongoing revisions of ISO/IEC 17011 and 17025 agreed that the document be published as a Guidance document for now. Another draft will now be produced for comment by WG members before ballot. Regarding the Guidance on measurements performed as part of an inspection process Working Group 4 reviewed the 13 pages of comments received. A lot of comments arose due to the confusion of the intention of the document which is to give guidance on how to address cases where measurements are performed as part of inspection rather than on the choice of standard. Having reviewed the comments and noting that the draft had not yet been circulated to the ILAC Accreditation Committee (AIC) it was agreed that another draft will be prepared incorporating agreed changes after which the draft document be circulated to the AIC then comments received will be reviewed by the Working Group before recommending it to the ILAC IC to go for 60 day comment by all ILAC members. A presentation was also made to the ILAC IC by IHAF an international initiative from the United Arab Emirates designed to ensure credibility of halaal certified products, processes etc. which the meeting noted was a principle issue that has to be discussed at higher levels in IAF and ILAC. A question paper on IB monopolies in governmental inspection bodies undertaking inspection of other Government legal entities was discussed and the meeting noted that the matter touches on impartiality/independence. Discussions on whether there is a need for a guidance concluded that a statement could be added in the ILAC MCC publicity document on Use of accreditation by regulators instead of coming up with a different document for which the ILAC MCC will be consulted after drafting the proposed text additions.

ILAC Laboratory Committee (LC) allows stakeholders i.e. laboratory associations to have an input into ILAC activities. The ILAC LC members have no voting rights in ILAC. The LC finalized its terms of reference and membership subscription fee and presentations were made to the meeting by the ILAC Chair and ILAC Committee Chairs. The LC members also presented reports to the meeting. The meeting was also an opportunity to update members on the ongoing revisions of ISO/IEC 17025. Accreditation bodies' harmonization issues were considered such as frequency of surveillances assessments which vary from 12 months to 18 months. A decision was taken by the ILAC LC to progress case studies but will not request for funding from ILAC. Three laboratory associations from India and DRC (ASCOLAB) were admitted as new members of the ILAC LC.

ILAC Accreditation Committee has a total of 13 WGs which have liaison roles in major international bodies for input into AIC work. On the ongoing revisions of ISO/IEC 17025 the Committee discussed whether the revision should be explicitly applicable to organizations that perform sampling without subsequent testing or calibration. The results of a survey undertaken show that quite a number would like a separate standard. On Clause 7.5 Reporting of Results specifically calibration certificates the meeting discussed whether or not to include uncertainty of measurements outlined in P!\$

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which is in compliance with the VIM whilst the meeting agreed on the proposed wording in 7.5.6 for reporting on results From External Provider. It was agreed that the wording in 6.5.4 required some tidying up whilst a rearrangement of Clause 7 would be required. The meeting noted the ongoing revisions of ISO/IEC Guide 34 with a lot of discussions on the approach to categorization of reference materials. A draft international standard (DIS) was circulated in October with a deadline of December 2015. Terms of reference for the review of G 18 were adopted and it was agreed to cover scopes for both testing (including medical) and calibration. The Committee noted the need to note the ongoing work in the ILAC IC on scoping. A workshop will be organized in during the 2016 mid - term meetings on how to prepare scopes. The Committee noted the growing interest in the medical area for which a number of standards prepared by ISO TC 212 are applicable such as ISO/TS 20658 specimen procurement new document regarding pre examination stage. ISO PD TS 22367 risk management, ISO 22870 on point of care testing (POCT), ISO 15190 Bio risk management which is up for review (this standard is not used for accreditation but is used by medical laboratories in addressing safety issues), ISO 15195 Medical Reference Laboratories and ISO 17511 traceability for medical accreditations. On accreditation of medical imaging 9 accreditation bodies provide accreditation services to medical imaging with some accrediting to ISO 15189 and others to ISO/IEC 17020 and for which a proposal was made to develop a guidance document. The meeting also noted that ISO TC 212 has finished drafting a document for measurement uncertainty in medical laboratories. In conclusion on this matter the meeting noted that more work is required on the revision of ILAC G 26 needs after which it will go for ILAC ballot. The meeting also noted that a number of documents are being revised such as the VIM and GUM, ILAC G 18 and ILAC G 11 and G 3 which maybe combined. The CIPM MRA is being reviewed. SS representing ILAC on the JCJG, reports on progress available on website. The AIC will look at its structure with a view effectively its activities.

Arrangement Management Committee - The ILAC MRA Annual report was published in June 2015 and is available on the ILAC website. The revised ILAC P4 and P5 will be send out for comments. Evaluation schedule with nominations from regions is under preparation. A number of peer evaluations including a pre peer evaluation of MAURITAS and Peer evaluation of KENAS are being scheduled with teams being set up jointly by ILAC/IAF/AFRAC. The Committee also considered the reports on transition to ISO 15189: 2012 and agreed to undertake another survey around mid - March 2016 to assess transition. Members were reminded that the implementation of R7 Rules for the use of the ILAC Mark will be the accreditation body's responsibility and that a template on reporting will be circulated for full members to complete and sign.

ILAC Marketing and Communications Committee and the IAF Communications and Marketing Committee – Members were encouraged to adopt/adapt the materials produced by the ILAC MCC and IAF CMC and use them for promotional purposes. In particular members' attention was drawn to the Guide for engaging with Governments and regulators, Handbook on the global accreditation system and Guide for use of social media for accreditation bodies. A set of general theme based brochures are aimed at conformity assessment bodies. ILAC has recently published a brochure on Reference Materials Producers aimed at end users and clients. The ILAC MCC is working with UNIDO to update UNIDO guide for developing countries. Members were encouraged to get a link to the Directories of signatories. ILAC News and



Members of the ILAC MCC and IAF CMC pose for a photo after the meeting

ARC Meeting in session

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IAF News were published during the period under review. Both the ILAC and IAF are now using social media platforms such as Twitter and YouTube and have witnessed a greater reach to stakeholders through these media. The theme for 2016 World Accreditation day is **Accreditation: Supporting public policy**. For the commemorations a video on the theme has already been produced and also the public sector case studies are up on ILAC for which a link has been provided on the SWADCAS website. The platform which contains 37 research papers show cases relevant public sector cases and is a tool for promoting accreditation to regulators and the public sector. Members were encouraged to submit more cases.

IAF/ILAC Joint Development Support Committee (JDSC) - The JDSC meeting was attended by over 70 delegates. JDSC is important in implementation and achievement of SD#5 of the ILAC Strategic Plan. At the Milan meeting a presentation was made by the Gulf Accreditation Council a multi economy accreditation body established to meet the accreditation needs of 7 Gulf States with explanations on why they decided to go for a multi economy set up and how the system works. Various other presentations were made by cooperating partners such as UNIDO highlighting the project in which they are assisting the Iraq Accreditation Body, PTB Germany and ISO CASCO during which members were updated on the ongoing revisions of standards associated with accreditation. For the first time the IFCC and WHO attended the meetings and informed the meeting about developments of relevance to accreditation in the medical area. Results of the ILAC survey on accreditation in the medical area were presented and discussed. This was followed by a discussion fora on all the health presentations.

A Series JWG - Revisions of ILAC/IAF A2: Evaluation of single accreditation body have been completed and the document will now be cleaned up then circulated to members again after which it will go for comment by the larger group in January 2016. The changes in A2 take into account the need to address inconsistencies amongst accreditation bodies in line with one of the strategic direction of the ILAC and IAF Strategic Plans. Revisions of ILAC AI have also been completed and the document will be tidied up by the JWG before circulation to ILAC/IAF in January 2016. The template for reporting on peer evaluations for single accreditation bodies which is aimed at harmonizing practices in all the regions and to reduce redundancy was discussed. There is still some work to be done on the template before sending it out for comment in 2016. Now that a template for reporting is being developed ILAC/IAF A3 will have to be modified. Reporting template for evaluation of regions needs to be revised to ensure that it is aligned to the 2015 versions of ILAC/IAF A1 and A2.

MRA Joint Management Committee (JMC) - The meeting was advised that the final report of the recent evaluation of the EA region will be circulated for evaluation and comment by the elected (Joint Task Force Group (JTFG)). The IAAC region's re-evaluation was scheduled to be undertaken in September 2017. A JTFG was nominated to review the SANAS re-evaluation report whilst the EGAC re-evaluation has been set to be undertaken in 2017. Applications had been received from 2 new regions namely: ARAC and AFRAC and the JMC is now working on scheduling the evaluation. Efforts are also underway to establish teams for the KENAS and MAURITAS evaluations to be carried out in 2016.

ILAC/IAF Joint General Assemblies - The Joint ILAC/IAF General Assemblies was held on 5 November 2015 during which 5 resolutions were passed. Various reports were presented by international organizations ISO CASCO, OIML, ITU and UNIDO during which members were updated on developments in their respective organizations. A report was also presented on ILAC and IAF's representation at the WTO TBT meeting during which a number of presenters made reference to ILAC and IAF in their respective presentations. Reports of the joint IAF/ILAC Committees such as the JDSC, the MLA/MRA Joint Management Committee (JMC), and Joint WG on Maintenance of A Series were also presented at the ILAC/IAF Joint General Assemblies and in addition reports from regional accreditation co-operations APLAC, EA, IAAC, PAC, AFRAC, ARAC and SADCA were also presented. During the Joint General Assembly an update report was presented on further harmonization of activities within the IAF, ILAC and the Regions by the convener of the Task Force (TF) which was established in 2010 following the vote on merger and comprises members from the regions. At the Milan meeting 2 Task Forces were established to deal with the 2 identified key issues namely global recognition and consistency with TF 1 dealing with division of responsibilities between IAF/ILAC. Mahmoud a member of the TF and TF 2 dealing with Long term governance of ILAC/IAF of which Mr Ron Josias Chairman of AFRAC is a member. The Task Forces will report on progress at the mid - term meetings. Other issues discussed at the Joint Gas were counterfeit certificates, code of conduct for governing behavior during meetings. Once finalized the document on hosting meetings will be given to event management companies to identify possible venues for future meetings.

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Election of Directors IAF - Mr Xiao Jianhua (CNAS, China) was elected Chairman of IAF whilst Mr Emanuele Riva (ACCREDIA, Italy) was elected Vice Chairman of the IAF. Ms Sheronda Jeffries (QuEST Forum, USA) was elected as Director representing Users and Industry Association Members and automatically becomes the Chair of the User Advisory Committee (UAC). Mr Geir Samuelsen (NA, Norway) was elected as Director representing High Income Economy Accreditation Body members and automatically becomes the Co - Chair of the Accreditation Body Information Exchange Group (ABIEG). Mr Vu Xuan Thuy (BOA, Bangladesh) will complete his first term as Director representing Low and Medium Income Accreditation Body Member at the 2016 General Assembly. Mr Ekanit Romyanon (NSC, Thailand) was re-elected as IAF Technical Committee Chairman, Mr Norman Brunner (AA) was elected as IAF MLA Chairman and Mr J Murthy (UKAS) was re - elected as IAF Communications and Marketing Committee Chairman whilst Ms Andrea Barroso Melo Monteiro de Queiroz (CGCRE, Brazil) was elected as the Development Support Committee Chair. Regarding membership of the Financial Oversight Committee the General Assembly agreed that Mr Marcos Aureio Lima de Oliveira completes his second term as Chairman at the end of 2016 and Mr Eric Janssens will complete is term as FOC Association Member at the end of 2016. The IAF also expressed its appreciation to all the outgoing Board members, Chairs and FOC members.

Elections of Directors ILAC – No elections were at the ILAC General Assembly as the Directors are still serving their terms of office. However Ms Kwei Fern Chang (SAC Singapore) and Mr Paul Stenner (UKAS, United Kingdom) were appointed as members of the Financial Audit Committee. The rest of the Executive maintained their positions as they are still serving on their respective terms of office.

The 2015 ILAC/IAF meetings were once again a good opportunity for networking, sharing experiences and keeping up to date with accreditation developments worldwide. The meetings provided an invaluable opportunity to enhance collaborations and strengthen the credibility of accreditations worldwide. Many thanks to ILAC for sponsoring SADCAS Chief Executive Officer's attendance to these very important meetings. The 2015 ILAC/IAF Annual meetings will be held in New Delhi, India.



Angola Appoints New NAFP

The Government of Angola has appointed Mrs Indira Coelho as the National Accreditation Focal Point (NAFP) for Angola. The appointment was made by the Ministry responsible for Trade / Industry in their letter of October 2015. Speaking to SADCAS on the appointment, Mrs Coelho said that It is such a great opportunity to join the SADCAS team as a NAFP. "Accreditation is increasingly becoming appreciated and understood across all sectors of an economy, and the conducted research has confirmed that accreditation has a positive economic value for countries' she said.

During her term, Mrs Coelho intends to promote accreditation in Angola as a valuable tool for the government to create better regulation, good governance, fair markets and public confidence. Angola being one of the 13 SADC Member States serviced by SADCAS will take advantage of SADCAS capabilities and reduce the serious deficiencies of the conformity assessment infrastructures, by promoting accreditation so as to raise awareness of the benefits and importance of accreditation and promote an understanding of the accreditation standards requirements.

"I truly believe that SADCAS is playing a key role in strengthening the quality infrastructure for trade enhancement, competitiveness and consumer protection in Angola" she said. She however noted that language has been a barrier for Angola conformity assessment bodies to get accreditation through SADCAS and therefore urged SADCAS to seek a way of eliminating this barrier.

First Assessor Conclave held in Zimbabwe

SADCAS held its first assessor conclave in Harare, Zimbabwe on 18 September 2015 and was attended by assessors based in Zimbabwe. The credibility of SADCAS accreditation services hinges on the competence of assessors who undertake assessments on behalf of SADCAS. Continuous communication between SADCAS and the pool of assessors is key in ensuring consistency, integrity and continuous improvement of SADCAS services as SADCAS strive to consolidate and streamline service delivery of SADCAS services to the target population. SADCAS is now in its 7th year of operation as a multi economy accreditation body and has gathered enough assessment experiences to meet and share concerns and also to hear from assessors how SADCAS can continuously enhance service delivery. The purpose of this first round of conclaves is to update assessors on developments in SADCAS, discuss general assessor issues as well as continuous professional development requirements and to identify issues for discussion at future conclaves.

The assessor conclave started off with welcome remarks by the SADCAS Chief Executive Officer, Mrs Maureen P Mutasa who also outlined the programme of the conclave. This was followed by introductions with each assessor briefly indicating their expertise and experience in assessments. In an update on developments in SADCAS, Mrs Mutasa informed the assessors on progress in the 5 result areas agreed upon for the 2015/16 financial year and in particular the outcome of the joint AFRAC/ILAC peer evaluation of the testing and calibration laboratories accreditation programmes during which assessors were witnessed undertaking assessments on behalf of SADCAS. She also informed the meeting about progress in the development of the pool of assessors with more assessors being trained, mentored, qualified and registered.

The SADCAS Technical Manager Ms Jeanne Ranorovelo then introduced a number of assessor issues including assessor commitment, accreditation process timelines, assessor claims, assessor records and behaviour. Discussions were held on these various issues with more time being spent on accreditation timelines and the need for assessor to abide with the timelines set for their respective roles in the process. The conclave was an opportunity to hear at first hand the preventive measures that should be taken to avoid delays in the accreditation process. On assessor records the assessors meeting agreed that assessors shall submit updated CVs by the end of February each year rather than to wait for requests from SADCAS. On behaviour, assessors were reminded of the need to be impartial, objective and to behave in a friendly and unprejudiced manner and to allow for open discussions during assessments. Assessors were also reminded of the need for team work. Noting that information for assessors was incorporated in a number of SADCAS QMS documents, the meeting recommended that SADCAS comes up with a handbook, to serve as one stop shop for information on assessor issues such as roles of the assessors throughout the accreditation process, assessment procedures and techniques as well as assessor ethics. A Task Force comprising of one assessor each from the various accreditation programs on offer and the SADCAS Technical Manager was set up to draft the handbook a draft of which will be circulated to all assessors for input and comment before publication. The assessor handbook is scheduled to be published by May 2016.



Assessor conclave n session

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Regarding ongoing training of assessors the meeting was advised that SADCAS plans for ongoing training on revised key accreditation standards, workshops on accreditation related matters and assessor conclaves. Training needs are identified through monitoring the performance of assessors as well as from feedback on team performance which is reviewed by the Accreditation Approvals Committee. Assessor training plans are drawn up by the Technical Manager who is responsible for the management of assessors. Assessors are however responsible for ongoing CPD in their areas of expertise and are required to submit records of attendance to SADCAS. The conclave identified the need for training of assessors on method validation and measurement uncertainty for uniform assessments of these requirements.



Mrs Mutasa and Ms Ranorovelo pause for a photo with the assessors

For discussions during the second round of assessor conclaves, the meeting identified the following topics: witnessing of certification audits, PT/ILC requirements and measurement traceability issues. It was also suggested that breakout sessions be organized based on topics of discussion and taking into account the accreditation programmes.

Due to the geographical and language diversity assessor conclaves will be held in the various countries where assessors are based. SADCAS plans to have 2 other assessor conclaves during the 2015/16 financial year.

Third ISO/IEC 17020 Conducted for Zambia Bureau of Standards Staff

SADCAS conducted a third ISO/IEC 17020:2012—Requirements and Internal Auditing course for Zambia Bureau of Standards staff. The training was held from 9 to 13 November 2015 Golden Peacock Hotel—Lusaka, Zambia. A total of 15 inspectors attended the course.

The course went on in accordance with the scheduled training programme without any adjustments with Mr Francis Mwela— ZABS Inspections Manager giving the opening remarks. He reminded participants to take the training seriously noting the need for ZABS to have appropriately qualified personnel, facilities , technical expertise and management system in order to conduct inspections professionally.

In his introductory remarks the Trainer defined the ISO/IEC 17020 as a standard used for conformity assessment that specifies the general criteria for the competence of impartial inspection bodies irrespective of the sector involved. A comprehensive elaboration on each of the 8 clauses of the standard were made by the Trainer and examples on how other organization have met the requirements were given. Participants were made to understand the importance of competence evaluation of personnel, facilities, traceability of measurements, environment conditions and inspection methods procedures as vital tools toward accreditation. Participants were also appraised on why procedures need to be documented by all staff performing specific tasks and why procedures should be available at all relevant locations of their work.



Training in Session

Judging from the feedback given by participants, the course was well organized and met the participants' expectations.

SADCAS offers accreditation programmes for:

- Calibration laboratories in accordance with ISO/IEC 17025;
- Testing laboratories in accordance with ISO/IEC 17025;
- Medical laboratories in accordance with ISO 15189;
- Management systems certification bodies in accordance with ISO/IEC 17021;
- Product certification bodies in accordance with ISO/IEC 17065; Personnel certification bodies in accordance with ISO/IEC 17024; and
- Inspection bodies in accordance with ISO/IEC 17020.

Status of Transition to ISO 15189:2012 within the Region

The Southern African Development Community Cooperation in Accreditation (SADCA) is a Regional Cooperation whose objective is to coordinate accreditation activities in the region and facilitate the national, regional and international recognition and acceptance of SADC accreditation infrastructure and providing Member States with accreditation as a tool for facilitating trade and the protection of health and safety of the public and the environment in both the voluntary and regulatory areas. SADCA comprises of 3 accreditation body members namely: the Mauritius Accreditation Service (MAURITAS); Southern African Development Community Accreditation Service (SADCAS); and the South African National Accreditation System (SANAS) with SADCAS being a multi economy accreditation body servicing 13 out of the 15 SADC Member States whilst MAURITAS and SANAS service Mauritius and South Africa respectively.

In all the accreditation bodies in the region offer medical laboratories accreditation program in accordance with ISO 15189. Up to date only SANAS is signatory to the ILAC Mutual Recognition Arrangement (MRA) in the scope of Testing (ISO 15189) whilst both SADCAS and MAURITAS are working towards signatory status for their respective said programs. Table 1 summarizes the activities of the 3 accreditation bodies' with respect to the Scope Testing (ISO 15189).

As at 9 October 2015 a total of 286 facilities in the region had been accredited by MAURITAS, SADCAS and SANAS in accordance with ISO 15189 with SANAS having the highest number of accreditations at 268 followed by SADCAS at 13 and MAURITAS at 5. Refer to Figure 1. A total of 146 facilities (51%) were accredited to the 2012 version of ISO 15189 whilst 140 (49%) are still accredited to the 2007 version of the standard. Refer to Figures 2 and 3.

Figure 1—Accreditation in Accordance with ISO 15189 (2007 and 2012)

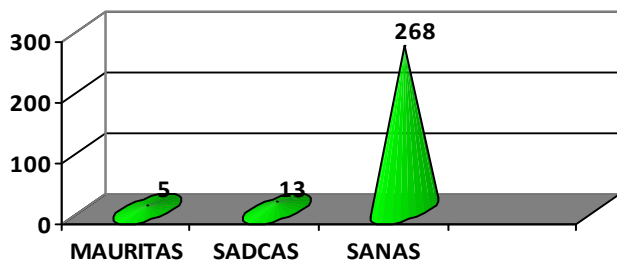
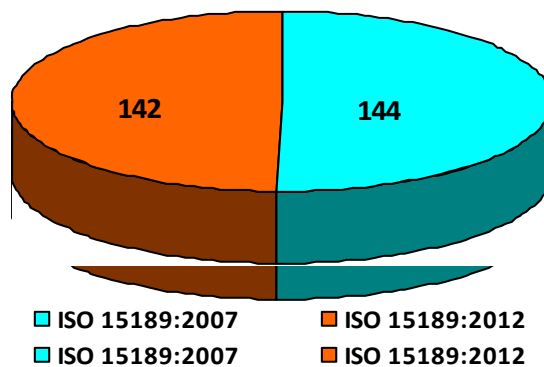


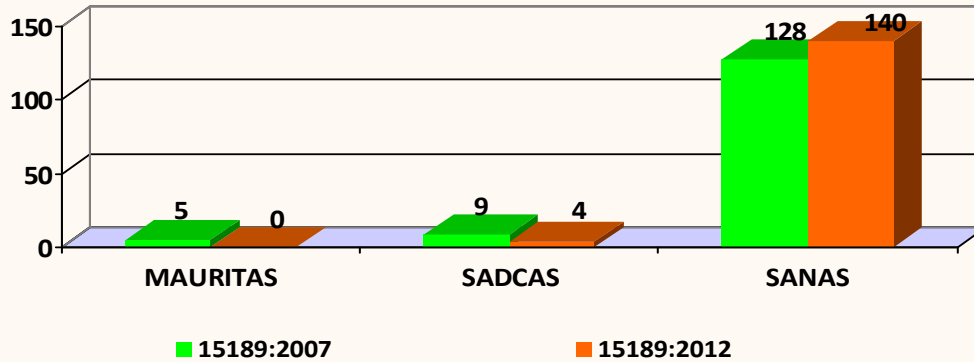
Figure 2—Accreditation by Version of Standard



The International Laboratory Accreditation Cooperation (ILAC) of which all the 3 accreditation body members of SADCA are members, passed a resolution for the transition from ISO 15189:2007 to ISO 15189:2012. The **ILAC GA Resolution GA 16.21** says that **“By 1st March 2016 all references to ISO 15189 in accreditation certificates shall refer to the latest edition of ISO 15189, whereas at the end of the transition period, accreditation of a laboratory to ISO 15189:2007 will not be recognized under the ILAC Arrangement. Compliance will be determined during normal surveillance or reassessment activities or as a separate activity.”**

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Figure 3 - Accreditations in Accordance with ISO 15189 by Accreditation Body



MAURITAS, SADCAS and SANAS each have policies in place to meet the transition deadline as stated above by ILAC. Therefore all the facilities in the region that are still accredited to the 2007 version of the standard are undergoing transition to the 2012 version with 11 (8%) at accreditation certificate finalization, 27 (19%) at accreditation decision stage, 42 (30%) at corrective action stage and 60 (43%) still to be assessed to the 2012 version of the standard. Refer to Figures 4 and 5.

Figure 4 - Status of Transition to ISO 15189: 2012

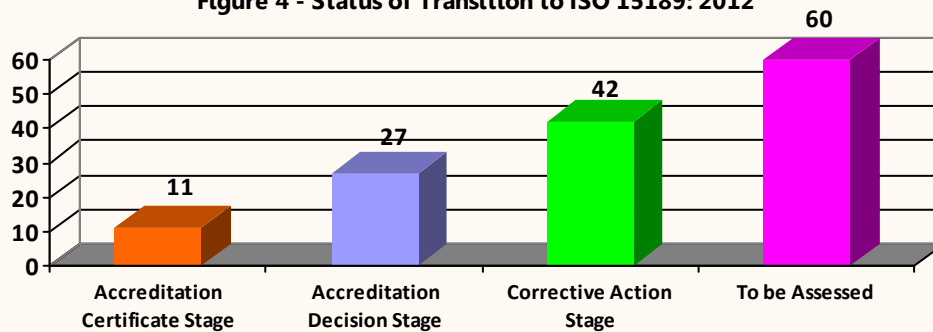
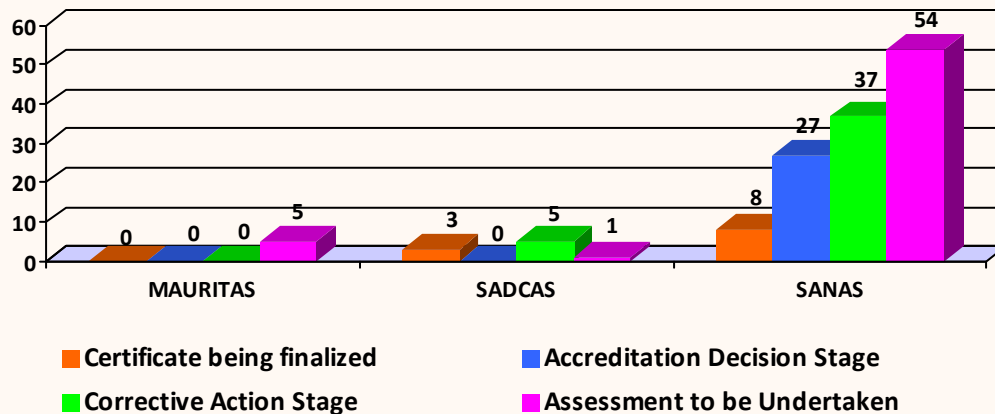


Figure 5 - Status of Transition to ISO 15189:2012 by Accreditation Body



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Generally transition to ISO 15189: 2012 is going on well with outstanding cases due to undergo transition assessments by:

- ❑ 30 November 2015 in the case of the one facility accredited by SADCAS;
- ❑ 31 December 2015 in the case of the 5 facilities accredited by MAURITAS; and
- ❑ 30 January 2016 in the case of the 55 facilities accredited by SANAS.

As signatory to the ILAC MRA in the case of SANAS and working towards signatory status in the case of MAURITAS and SADCAS, all accreditation body members of SADCA are committed to abide by the **ILAC Resolution GA 16.21**.

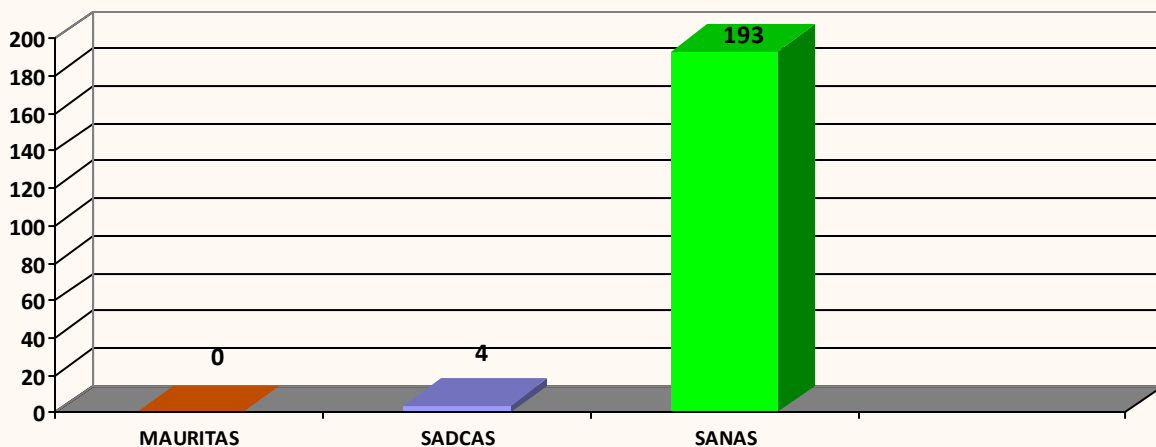
This article is part of the report submitted by SADCA to the ILAC Arrangement Council meeting held on 4 November 2015 in Milan, Italy.

Inspection Bodies Accreditation Programmes in the Regional

The Southern African Development Community Cooperation in Accreditation (SADCA) is a Regional Cooperation whose objective is to coordinate accreditation activities in the region and facilitate the national, regional and international recognition and acceptance of SADC accreditation infrastructure and providing Member States with accreditation as a tool for facilitating trade and the protection of health and safety of the public and the environment in both the voluntary and regulatory areas. SADCA comprises of 3 accreditation body members namely the Mauritius Accreditation Service (MAURITAS), Southern African Development Community Accreditation Service (SADCAS) and the South African National Accreditation System (SANAS) with SADCAS being a multi economy accreditation body servicing 13 out of the 15 SADC Member States whilst MAURITAS and SANAS service Mauritius and South Africa respectively.

Up to date only SANAS is signatory to the ILAC Mutual recognition Arrangement (MRA) for inspection whilst both SADCAS and MAURITAS are working towards signatory status for the scope inspection. A total of 197 inspection bodies operating in the region are accredited by SADCAS and SANAS with SANAS having the highest number of accreditations at 193 followed by SADCAS at 4. Refer to Figure 1.

Figure 1 - Accreditation of Inspection Bodies in the SADC Region

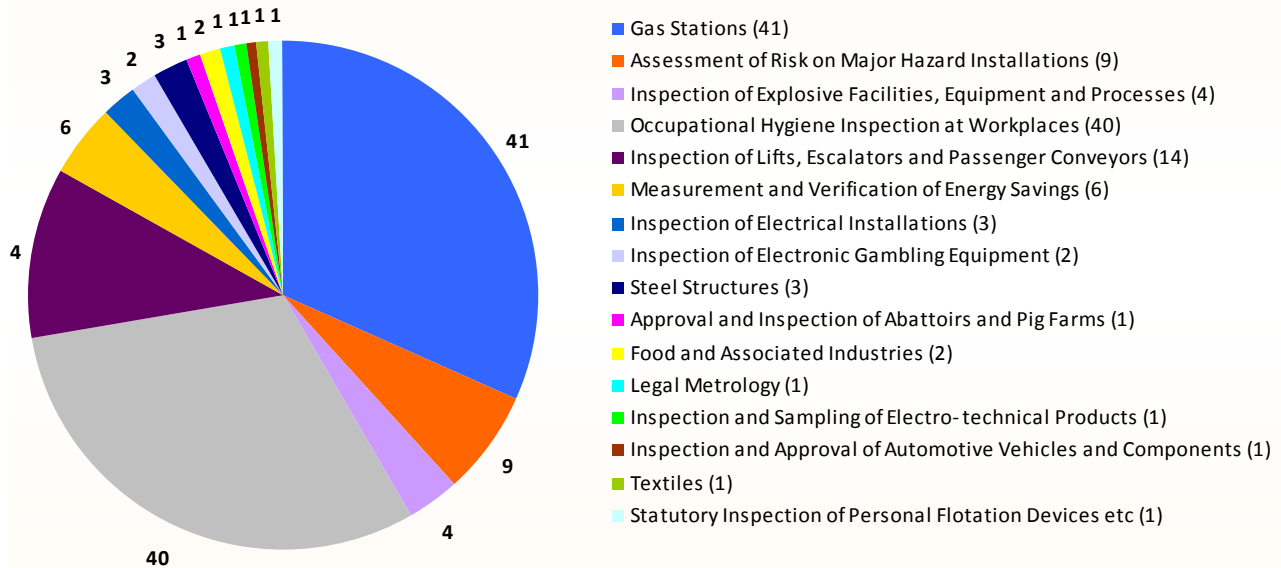


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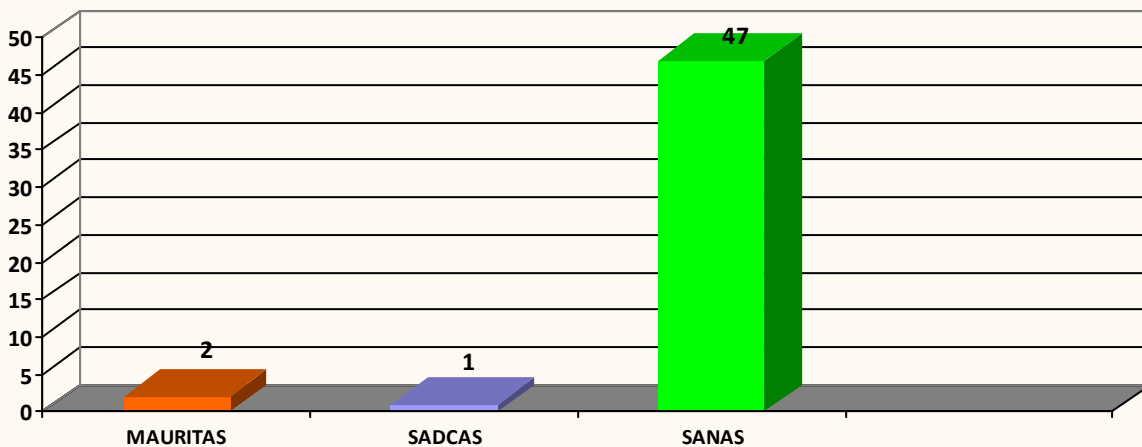
The most common scopes of inspection bodies' accreditation are: Inspection of Pressure Equipment; Gas Stations; Occupational Hygiene Inspection at Workplaces; Inspection of Diagnostic X Ray Imaging Systems; Lifts, Escalators and Passenger Conveyors; Assessment of Risk on Major Hazard Installations; Measurement and Verification of Energy Savings; Inspection of Explosive Facilities, Equipment and Processes; and Steel Structures. Refer to Figure 2.

Figure 2 – Scopes of Accreditation



All the accredited inspection bodies are accredited to ISO/IEC 17020: 2012. A total of 50 applications are under process by the 3 accreditation bodies with SANAS having the highest number of applications under process. Refer to Figure 3.

Figure 3 - Applications under Process



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SADCAS and SANAS have both entered into Memorandum of Understanding with the respective regulators and are operating in the regulatory domain. The MOUs buttress the relation between the respective accreditation body and the regulator and detail how accreditation body services are utilized in the regulatory domain. Advisory committees have been set up to advise the accreditation bodies on technical matters to do with inspection bodies.

SANAS has quite a wide scope of accreditation of inspection bodies and is looking at extending the scope further. SADCAS is working at extending the scope of accreditation and with expert input from the Advisory Committee has already finalized criteria for accreditation of inspection bodies that inspect metallic storage tanks. Criteria will also in future be developed for inspection bodies that undertake inspection of lifts, escalators and passenger conveyors. MAURITAS on the other hand has 2 applications under process in the scope textiles and cargo inspection.

This article is part of the report submitted by SADCA to the ILAC Inspection Committee meeting held on 31 October 2015 in Milan, Italy.

SADCAS Recruits New Staff

SADCAS is proud to announce the appointment of 2 additional staff Mrs Pinkie Malebe and Mrs Tsitsi R Mazibuko.

Mrs Pinkie Malebe joins SADCAS as a Lead Assessor for the Testing Laboratory Accreditation Program. Ms Malebe brings to SADCAS vast experience as a Laboratory Scientist, a Botswana Qualifications Authority (BQA) accredited Quality Management Systems Trainer and a Consultant on Quality Management Systems for ISO/IEC 17025 and ISO 15189 for Conformity Assessment Bodies. A Microbiologist by profession, she has worked for the Botswana Bureau of Standards for 9 years as a Principal Scientist where she was responsible for product conformance testing, training, laboratory management systems consultancies and coordinator of the SADC MET Proficiency Testing for microbiological analysis of potable water in SADC and East African Community (EAC) water testing laboratories. Mrs Malebe started her career as a Medical Laboratory Scientific Officer with the National Health Laboratories, Ministry of Health in Botswana and joined the National Drug Quality Control Laboratory in the Ministry of Health as a Pharmaceutical Analyst. At SADCAS she will be responsible for the Testing Laboratory Accreditation Program, planning and conducting assessments as well as monitoring assessors and mentoring trainee assessors. Mrs Malebe is currently pursuing part-time Masters in Business Administration. She is married to Eric and has 3 daughters.

Mrs Tsitsi R. Mazibuko joined as an Accreditation Administrator responsible for ensuring that all administration activities needed to effect the assessment processes are undertaken timeously. Having worked for diverse organisations, Ms Mazibuko brings with her extensive experience of 10 years in business administration. She took up position in SADCAS in September 2015. Prior to joining SADCAS, Mrs Mazibuko was a Senior Personal Assistant at Civil Aviation Authority Botswana. She has a Diploma in Secretarial Studies and Advanced Diploma in CIPS. She is married and has 2 children.

SADCAS welcomes both Mrs Malebe and Mrs Mazibuko to Team SADCAS and look forward to their contributions in growing SADCAS in line with its strategy.



Mrs Pinkie Malebe

Mrs Tsitsi Maibilip

Update on ISO/IEC 17011 Revision

The International Standard which accreditation bodies have to comply with for international recognition ISO/IEC 17011: 2004: Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies is being revised. The revision is being undertaken by Working Group 42 of the ISO Policy Committee on Conformity assessment (ISO CASCO WG 42).

The WG has already now held 3 meetings in November 2014, February 2015 and May 2015. After consideration of the Working Draft (WD) a Committee Draft was published on 8 August 2015 with a deadline of 8 October 2015 and passed with a 92% positive vote. 1700 comments were received and will be reviewed at the next meeting of the WG scheduled to be held from 8 to 11 December 2015. From the collated comments Definition virtual and remote assessments caused some concerns, and assessment techniques and assessment activity need clarification. Although impartiality requirements have been significantly enhanced there are suggestions for improvement. Process requirements terminology issues, requirements for onsite assessments, reinstatement of key activities, scopes of accreditation, types of accreditation decision especially maintaining and renewing accreditation are other issues that have been commented on in CD 1.

Meanwhile a Task group of the WG has been collating the comments. In view of the number of comments submitted and nature of the comments it is envisaged that a CD 2 will have to be developed and circulated for comment before publication of the Draft International Standard. The CD 2 will hopefully be published in January 2016 and a meeting held in April 2016 to review the comments on CD2. Thereafter the Draft International standard (DIS) is scheduled to be issued around June 2016 with a deadline of November 2016 after which the Final Draft International Standard will be published.

Upcoming Training Courses

COURSE	DATE(S)	VENUE COUNTRY/CITY	FEES (BWP)	FEES (USD)
ISO/IEC 17025 Requirements & Internal Auditing	February 2016 (TBA)	Tanzania (Dar es Salaam)	-	850
ISO 15189 Requirements & Internal Auditing	February 2016 (TBA)	Namibia (Windhoek)		900
ISO/IEC 17025 Requirements & Internal Auditing	February 2015 (TBA)	Namibia (Windhoek)		850
ISO/IEC 17025 Requirements & Internal Auditing	March 2015 (TBA)	Tanzania (Mwanza)	-	850
ISO/IEC 17025 Requirements & Internal Auditing	March 2015 (TBA)	Botswana (Gaborone)	8,000	-
ISO/IEC 17025 Requirements & Internal Auditing	March 2016 (TBA)	Zimbabwe (Harare)		750
ISO/IEC 17025 Requirements & Internal Auditing	March 2016 (TBA)	Zambia (Lusaka)	-	850
ISO/IEC 17020 Requirements & Internal Auditing	March 2015 (TBA)	Tanzania (Mwanza)		850

To register for any of the above courses please download SADCAS F 70 (b) - Training Booking Form from SADCAS website: http://www.sadcas.org/sadcas_forms.php or contact SADCAS at info@sadcas.org for more information.

SADCAS Training Programmes

The Southern African Development Community Accreditation Service (SADCAS) provides training for conformity assessment bodies' management and staff. Conformity assessment bodies (CABs) include calibration/testing laboratories, medical laboratories, certification and inspection bodies.

SADCAS Trainers

SADCAS draws its trainers from a pool of qualified and experienced experts from the SADC region who have up to date involvement in accreditation matters be it system implementation and/or assessments.

Training Programmes

SADCAS currently offers the following accreditation training courses:

Five-Day Requirements and Internal Auditing Training Courses on the Various Key Accreditation Standards

- ISO 15189 Requirements and Internal Auditing **for medical laboratories**
- ISO 15189:2012 Requirements and Internal Auditing [Bridging course] **for medical laboratories**
- ISO/IEC 17020 Requirements and Internal Auditing **for inspection bodies**
- ISO/IEC 17021 Requirements and Internal Auditing **for management systems certification bodies**
- ISO/IEC 17025 Requirements and Internal auditing **for calibration/testing laboratories**

The objective of the 5 days courses is to provide an insight into the respective system standard's requirements and implementation as well as to guide CAB's personnel on how to prepare and carry-out an internal audit so as to monitor compliance with the system standard. These courses are made relevant and practical as they include case studies and exercises that reflect the respective professional disciplines. In order to objectively assess participants, an examination is written at the end of each course. Participants are also evaluated throughout the course.

Three-Day ISO/IEC 17025 International Auditing

The objective of the 3-day training course is to impart internal auditing knowledge and skills to laboratory staff. The course covers the following main topics:

- ✓ Introduction to Auditing
- ✓ The Audit process
- ✓ Reporting and corrective actions
- ✓ Auditor competence
- ✓ Benefits of an auditing

One-day Awareness Training Courses on the Various Key Accreditation Standards

- ISO 15189 **for medical laboratories**
- ISO/IEC 17020 **for inspection bodies**
- ISO/IEC 17025 **for calibration/testing laboratories**

The objective of the one day awareness training courses is to create awareness on the benefits and importance of accreditation and the requirements of the respective accreditation standards.

The SADCAS courses can be conducted in-house. In-house courses have the following benefits:

- ✓ You choose the venue of the course in
- ✓ You choose the date of the course
- ✓ Cost effective as a number of staff can be trained at the same time
- ✓ Promotes team work as members have access to the same consistent information

For more details please contact SADCAS
Email: info@sadcas.org

Status of Key Accreditation Standards and IAF/ILAC Documents

STANDARD	STATUS
ISO/IEC CD 17011 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies	Close of comment period
ISO/IEC CD 17025:2005 General requirements for the competence of testing and calibration laboratories	Close of comment period
ISO/IEC NP 17028 Conformity assessment - Example of a certification scheme for tangible products	New project approved
ISO/DIS 17034 General requirements for the competence of reference materials producers	DIS ballot initiated
ISO/IEC 17043: 2010 Conformity assessment – General requirements for proficiency testing	International standard confirmed
ISO/IEC 27006:2015 Information Technology – Security Techniques – Requirements for bodies providing audit and certification of information security management systems	International standard published on 2015-09-30
IAF PL 2:2015 Bylaws on the International Accreditation Forum	Issue 7, issued on 26 November 2015
IAF PR 1:2015 Procedure for the investigation and resolutions of complaints	Issue 3, issued on 27 July 2015
IAF PR 4:2015 Structure of the IAF MLA and list of IAF endorsed normative documents	Issue 7, issued on 24 October 2015

Training on Validation/Verification of Methods and Measurement Uncertainty

SADCAS also offers training on Validation/Verification of Methods and measurement Uncertainty.

The objective of the **Validation & Verification of Methods** is to:

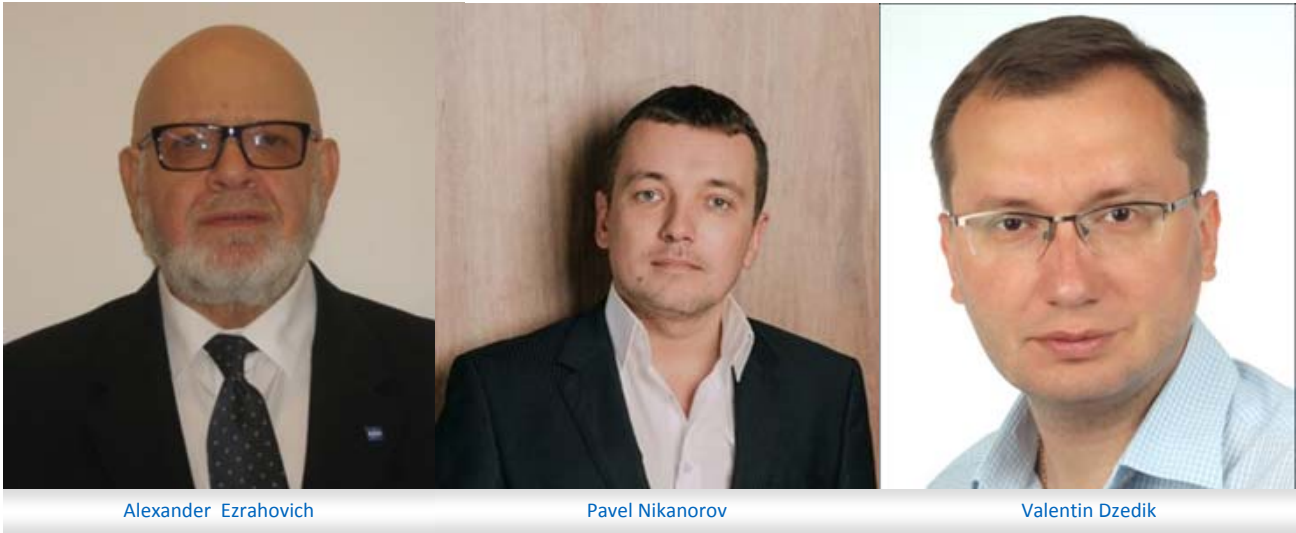
- Bring the participants from fundamental principles of descriptive statistics with the emphasis on hypothesis testing for the determination and verification of:
 - Trueness (Bias)
 - Precision
 - Linearity of calibration curves
 - Working Range
 - Selectivity/specificity
 - Ruggedness & Robustness
 - Sensitivity
 - Limit of Quantification
 - Limit of Detection

The objective of **Measurement Uncertainty** is to:

- Remove the mystique surrounding the concept of *Measurement Uncertainty*;
- Promote a practical methodology, based on GUM requirements to calculate measurement uncertainty over the working range of the method;
- Promote acceptable forms of expression of *Measurement Uncertainty*
- Create an understanding of the requirement of validation and verification and their respective applications in terms of both ISO/IEC 17025 and ISO 15189
- Ability to design a validation or verification programme

New Era of ISO 9001:2015

This article is devoted to the development of the new version of the International Standard ISO 9001:2015 "Quality management systems – Requirements" which was produced by the ISO/TC 176/SC2. In this article the new terms introduced in ISO 9001:2015 are analyzed and the main changes in the standard are provided. The article also outlines the Transition Planning Guidance for ISO 9001:2015 approved by the International Accreditation Forum (IAF). The article was compiled by Ezrakhovich Alexander - Head of Australian Delegation to ISO/TC176 and member of ISO TC176/SC2 WG 24 Coordinating Group, Pavel Nikanorov and Nalentin Dzedik Certification Association Russian Register.



Alexander Ezrakhovich

Pavel Nikanorov

Valentin Dzedik

The latest versions of ISO 9001 and ISO 9000 were published on 23 September 2015 marking the beginning of a new era of the revised documents. The work on developing and updating international standards in the International Organization for Standardization (ISO) is a continual structured process which ensures maximum involvement of interested parties, achieving consensus by working through the feedback and comments received. The output of this process is the creation of a document which through incorporation of best practices in a certain scope, meets expectations of its users, their customers and other stakeholders.

For more than 2 years, ISO TC 176 SC 2 Working Groups (WG) 24 -Revision of ISO 9001 prepared the primary international document whilst other WG such as WG 23 - Communications and product support carried out large-scale activities on the development of methodological materials, matrixes of interactions between the current and the new version and answers to the frequently asked questions. Sub Committee (SC) 1 – Concepts and terminology, worked on the new ISO 9000 and SC 3 - Supporting technologies worked on interpretation of ISO 9001 requirements for the various user groups.

No significant changes were made in the text of the published standard compared to the DIS. The following are the most significant issues discussed and changes made:

- ❑ **Innovations** - The word "innovation" was practically removed from the requirements of the standard. A significant number of comments were raised regarding this issue by the national standardization bodies. As a result of this discussion the main problem was recognized to be practical absence of a common, or if preferable, a "consensus" definition for "innovation". In this respect it was decided that the requirement for the need to consider the innovations issue by top management (which was included in the DIS) can lead to difficulties both during implementation of the standard requirements and during certification audits. The word "innovation" in the final text of the standard will only be used as an example for improvement of a company's activities in the form of the annex to the standard Clause 10.1.

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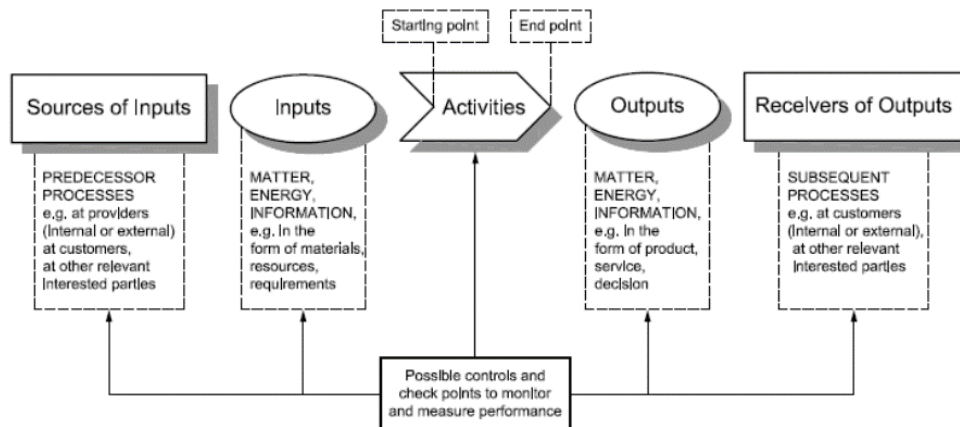
- ❑ **Use of the term “documented information”** Final decision was made in respect of the procedure for control of documented information. This term was introduced instead of the concepts “document” and “record” in ISO 9001:2008. A number of countries requested to provide the standard users with maximum freedom in control of the documented information. Such proposal met strong objections from a number of countries and as a result the following consensus a decision was made:
 1. Documented information, depending on its nature, can be controlled in two ways:
 2. Documented information is **retained** – control is carried out the same way as control of records in ISO 9001:2008
 3. Documented information is **maintained** – control is carried out the same way as control of documents (e.g. manuals, policies, procedures) in ISO 9001:2008

Application of the requirements for retention /maintenance of documented information depends on a justified decision on applicability /non-applicability of a requirement of ISO 9001:2015.

- ❑ **Definition of “risk”** - The definition “risk” which can relate to both negative and positive consequences of an event was finally approved. A number of delegates expressed doubts regarding correctness of this term and its adequacy to the definition of “risk” used in activities of the business community. However, this term (which accords with the definition of risk provided in ISO 31000, Risk management – Principles and Guidelines) was approved without changes. At the same time final version of the standard does not include requirements for mandatory risk analysis, development of a risk registrar or a documented procedure of its management – the standard focuses organizations on “risk based thinking” in making decisions and operation of a management system.
- ❑ **Continual improvement** - The term “continual improvement” which had been previously used in DIS wherever improvement was mentioned, was recognized to be only one example of a company’s activity improvement. Thus these terms were distinguished in the text of the standard – in a number of clauses improvement of organization’s activity is addressed, in other clauses – continual improvement is described.
- ❑ **New graphical illustrations** - New process flowchart (Figure 1) and an illustration of the structure of ISO 9001, showing how the parts of the standard are grouped as PDCA cycle (Figure 2). It is important to note that this illustration is similar to the illustration adopted in the new version of ISO 14001, which will be also published in September 2015.

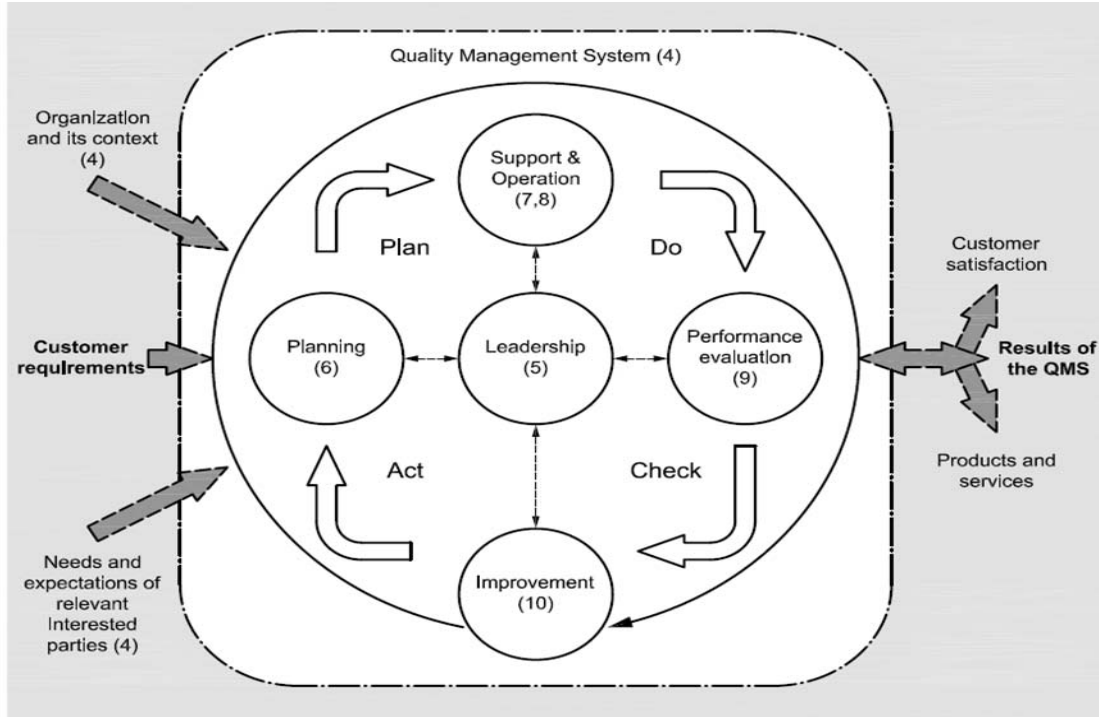
Other changes were effected including editing of a number of terms and definitions, proofreading of the standard text. Pictures clarifying operation of a system through the example of a person were removed from the text.

Figure 1. Scheme of processes interaction in ISO 9001



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Figure 2—Representation of the Structure of this International Standard in the PDCA Cycle

Note: Numbers in brackets refer to the clauses in this International Standard.

The publication of ISO 9001 on 23 September 2015 marked the beginning of the transition period for its users and especially for the certified organizations during which they will need to change their quality management systems and bring them in line with the new requirements. Currently the International Accreditation Forum IAF – an organization which regulates the procedure of the internationally recognized management system certification has already published the information document IAF ID 9:2015, Transition Planning Guidance for ISO 9001:2015. This document identifies a three-year period of transition to the new version of ISO 9001. Certificates of conformity to the requirements of ISO 9001:2008, according to IAF ID 9:2015, will become invalid after three years since the date of ISO 9001:2015 publication. Expiration date of certificates against ISO 9001:2008 issued during the transition period shall correspond to the end of a three year transition period.

Depending on an agreement with a certified organization a certification body can carry out transition activities during a scheduled surveillance audit, recertification audit or a special audit. In the cases when transition audits are carried out simultaneously with a planned surveillance or recertification (i.e. in case of a gradual or a stage-by-stage approach), additional time may be required to ensure that all activities are covered by both current and new versions. The transition will be completed in September 2018, when all organizations maintaining certification against this standard will have certificates of conformity.

It is also important to note that WG 24 are now developing ISO TS 9002: Quality management systems - Guidelines for the application of ISO 9001. This Technical Specification (TS) will be a companion document to ISO 9001:2015. Whilst it will present guidance with a clause by clause correlation to clauses 4 to 10, the emphasis of the TS will be on application of process approach and to explain the intent of the ISO 9001:2015 requirements. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes. The TS is designed to assist users of the new 9001:2015 standard.

Diary of Upcoming Events

DATES	MEETINGS	VENUE
23-25 November 2015	53 rd ARSO Council Meeting	South Africa
2-3 December 2015	UNECE 25 th Working Party on Regulatory Cooperation and Standardization Policies	Geneva, Switzerland
3-4 December 2015	JCGM WG 2(VIM) Meeting	Paris, France
3 December 2015	ISO-CASCO-TIG Meeting	Geneva, Switzerland
3 December 2015	ISO-CASCO-STAR Meeting	Geneva, Switzerland
4 December 2015	ISO-CASCO-CPC Meeting	Geneva, Switzerland
7 - 8 December 2015	SADCA Strategic Planning Session	Pretoria, South Africa
8 - 11 December 2015	ISO-CASCO-WG 42 Meeting on the Revision of ISO/IEC 17011	Geneva, Switzerland
9 December 2015	23 rd SADCAS/SANAS TPA Meeting	Pretoria, South Africa
6 - 9 January 2016	APLAC Mid-term Meetings	Bangkok, Thailand
11 - 15 January 2016	ISO/IEC 17020 Assessor Training Course	TBC
12 - 14 January 2016	ISO-CASCO-WG 44 Meeting on the Revision of ISO/IEC 17025	Geneva, Switzerland
25 - 29 January 2016	ISO 15189 Assessor Training Course	TBC
28 January 2016	SADCAS Budget Meeting	Gaborone, Botswana
3 February 2016	24 th SADCAS/SANAS TPA Meeting	Pretoria, South Africa
8 February 2016	SADCAS FRAC Meeting	Pretoria, South Africa
18 February 2016	SADCAS HRRC Meeting	Pretoria, South Africa
18 February 2016	SADCAS Board Meeting	Pretoria, South Africa
16 -18 February 2016	ISO-CASCO-WG 44 Meeting on the Revision of ISO/IEC 17025	Geneva, Switzerland
24 - 26 February 2016	ISO-CASCO-JWG 43 Meeting on the Revision of ISO Guide 34/17034	Geneva, Switzerland

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DATES	MEETINGS	VENUE
February 2016	SADCAS Assessors Conclave	Walvis Bay, Namibia
March 2016	SADC SQAM Meetings	TBC
March 2016	SADCAS AGM Meeting	TBC
2 1- 24 March 2016	CAFMET 6 th International Metrology Conference	Dakar, Senegal

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SADCAS

Plot 50669 Unit 2A,
 Tholo Office Park, Fairgrounds
 Gaborone, Botswana
 Tel: +267 3132909/ 3132910; Cell No: +267 71250042
 Fax: +267 3132922
 Email: info@sadcas.org
 Website: www.sadcas.org

Editors:

Maureen P Mutasa
 Jeanne Françoise Ranorovelo

Layout & Design

Linda Dirorimwe

