

Highlights from 2014 IAF/ILAC over Meetings

The 2014 joint annual meetings of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) were held at the Sheraton Hotel, Vancouver, Canada from 8 to 17 October 2014. Although the meetings had originally been scheduled to be held in Bangkok, Thailand the venue was changed due to political instability in that country. However the Thailand Accreditation Body was the honorary host of the 2014 ILAC/IAF annual meetings. Over 350 delegates attended the meetings with the following economies from the Africa region attending the meetings: SADC countries serviced by SADCAS; Egypt; Ethiopia; Kenya; South Africa; and Tunisia. The meetings started on 8 October 2014 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 15 to 17 October 2014.

Membership of the Secretariat Issues

- **IAF** - Since the last IAF General Assembly 2 new members the GCC Accreditation Center (GAC) and Quality System for Feed Additives and Premixtures (FAMI-QS) were admitted to the IAF Memorandum of Understanding (MoU). One member was suspended for non-payment of annual dues. This brought the total membership of the IAF to 70 accreditation body members, 18 associate members and 6 regional group members and 3 observer members. The GAC is another multi - economy accreditation body established in the Gulf States to meet the accreditation needs of 7 Member States. Other applications are under process.

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- ❑ **ILAC** - Since the last ILAC General Assembly, 6 accreditation bodies were admitted as full members. Two members including the GAC membership were upgraded to associate category and one stakeholder member admitted. The total ILAC membership of 148 bodies now covers 112 different economies worldwide broken down as 81 full members from 66 economies, 17 associate members from 34 economies, 16 affiliates from 16 economies, 6 regional co-operations and 24 stakeholder members. Approximately 45,000 laboratories and over 7000 inspection bodies are accredited by the ILAC Full Members who are signatories to the ILAC Arrangement.

Various ILAC documents were published since the 2013 General Assembly including: **ILAC P9:06/2014** ILAC Policy for Participation in Proficiency Testing Activities, **ILAC P15:06/2014** Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies and **ILAC G19:08/2014** Modules in a Forensic Science Process.

New IAF Multilateral Arrangement (MLA) and ILAC Mutual Recognition Arrangement Signatories

- ❑ **IAF MLA** - Since the 2013 annual meetings, the IAF welcomed 26 new IAF MLA signatories for the sub scope Global Gap under the main scope of ISO/IEC 17065 and 3 scope extensions of which 2 fall under the main scope Product Certification ISO/IEC 17065 and one under the main scope Management System ISO/IEC 17021, sub scope ISO 9001 and ISO 14001. This brings the number of IAF MLA signatories to 60, The IAF approved 2 new sub-scopes Food Safety Management Systems and Green House Gas under the main scope of ISO/IEC 17021. The IAF MLA is being extended to cover the schemes owned by the Global Food Safety Initiative (GFSI).
- ❑ **ILAC MRA** - The ILAC General Assembly welcomed 6 signatories to the ILAC Arrangements. 2 of which are new signatories in the scope for testing (2) and calibration (2) and 4 extensions into the scope calibration (ISO/IEC 17025) (1), testing (ISO 15189) (1) and Inspection (3). This brings the number of ILAC MRA signatories to 81 from 66 economies. Representatives of the signatory accreditation bodies signed their respective MLAs /MRAs at a ceremony held during the joint ILAC/IAF General Assembly held on 16 October 2014. The ILAC Arrangement covers recognition for accreditation in the areas of calibration (ISO/IEC 17025), testing (ISO/IEC 17025), medical testing (ISO 15189), and Inspection (ISO/IEC 17020). The ILAC MRA was extended to include accreditation of proficiency testing providers. Various ILAC Regional Cooperation Bodies are in process of developing mutual recognition arrangements for Reference Materials (ISO Guide 34) and it is expected that this field of recognition will be added to the ILAC Arrangement in the future.

Transition Periods

The IAF General Assembly acting on the recommendation of the Technical Committee (TC) endorsed the following:

- ❑ **ISO 14001: 2015: Environmental management systems – Requirements with guidance for use**, as a normative document and agreed that the transition period of the revised document to be published in 2015 will be 3 years from the date of publication.
- ❑ **ISO /IEC 17021: Part 1: 2015: Conformity assessment – Requirements for bodies providing audit and certification of management systems**, as a normative document and agreed that the transition period of the revised document to be published in 2015 will be 2 years from the date of publication.
- ❑ **ISO 50001: 2015: Energy management systems – Requirements with guidance for use and ISO 50003: Energy management systems – Requirements for bodies providing audit and certification of energy management systems**, as a normative document and agreed that the transition period of the revised document to be published in 2015 will be 2 years from the date of publication.

SADCAS Value Proposition

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

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IAF TC meeting in progress



Morning break during Joint Development Support Committee meeting



ILAC General Assembly in session



Afternoon break during the joint IAF/ILAC General Assembly

Joint Working Group (WG) on Maintenance of A - Series

This Joint WG is responsible for the IAF/ILAC Joint publications including IAF/ILAC A1, A2 and A5.

- ❑ As part of the revisions of **ILAC A1**, the evaluation forms were finalized and a procedure for monitoring ILAC/IAF and regional evaluators was added to A1. Reporting format for evaluations was also revised so that reports at each stage of the evaluation process are provided to ILAC/IAF Secretariats rather than the Management Committees. To facilitate this process a new regional report template was developed and section 2.6.9 of ILAC A1 was clarified together with the reporting timelines. A procedure for decision making on joint ILAC/IAF regional evaluations was also added.
- ❑ Revisions made to **ILAC A2** now require evidence of management reviews and internal audits to be provided at application stage and surveillance assessments can now be used during witnessing of accreditation bodies for peer evaluation purposes.
- ❑ **ILAC A3** was revised to encourage accreditation bodies to start working on corrective action based on the summary report rather than wait for draft report.

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- ❑ All the 3 documents **ILAC A1, A2 and A3** were reviewed to take into account the proficiency testing and reference materials providers MRAs. The revised documents ILAC A1 and A2 will be circulated for comment early 2015. Since the changes in A3 are editorial the process may not need to go through the 60 day comment period. The WG is also working on a unified template report for the evaluation of a single accreditation bodies that are not affiliated to any region.

ILAC Inspection Committee (IC)

The IC meeting held in Vancouver was attended by 78 participants.

- ❑ **Transition to ISO/IEC 17020: 2012** - Most of the countries in attendance and through their regional representatives confirmed that generally transition to ISO/IEC 17020: 2012 was going on well with approximately 60% of the inspection bodies having completed their transition.
- ❑ **ILAC P 15:** Application of ISO/IEC 17020:2012 for the accreditation of inspection bodies was published in June 2014 and replaces ILAC A4. However in the short period of its implementation concerns were expressed on the application of Clause 8.1.3 on Management system requirements - Options on whether or not an accreditation body shall assess the management system where an inspection body is already certified to ISO 9001 and particularly in the case of self-declaration and where the certification audit did not fully cover inspections aspects of the management system. Working Group 1 of the IC was tasked to review 8.1.3 of ILAC P15.
- ❑ **Inspection scopes** - Not much progress was made by WG 3 which is drafting a guidance document on inspection scopes and 1st draft will only be ready in April 2015.
- ❑ **Guidance for testing performed as part of inspection** -WG 4 of the IC is working on a guidance document for testing performed as part of inspection and a committee draft will be available for discussion at next IC meeting in April 2015.
- ❑ **Sampling as a standalone activity** - Discussion were also held on accreditation of sampling as a stand - alone activity in accordance with ISO/IEC 17020. Since a Task Force of the European Cooperation in Accreditation (EA) is already looking at this issue, the IC decided to wait for their report then decide on the next step after reviewing the EA Task Force report.
- ❑ **Accreditation of NDT** - Regarding accreditation of NDT it was reported that some accreditation bodies have been accrediting NDT using either ISO/IEC 17025 or ISO/IEC 17020. Noting the work under way in the EA on EA 4/15, the IC decided to wait for the EA revision then decide whether or not to adopt the document as an ILAC document.
- ❑ **Other areas of inspection accreditation** - Discussions were also held on new areas of inspection such as Halal inspections and risk assessment in the railway sector, healthcare and inspection of care givers (social care).

ILAC Accreditation Committee (AIC)

The ILAC AIC is supported by 12 working groups (WG). The highlights of the meeting discussions and decisions are as follows:

- ❑ **Calibration and traceability - ILAC-G17:** Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025 was published in 2002 following its approval by the ILAC General Assembly in 2001. With the pending revisions of ISO/IEC 17025 and the unpredictability of what will happen it was agreed that the revision of ILAC G 17 be put on hold. It was however suggested that all the learning (to show where reporting on uncertainty has helped) be listed and submitted to the WG dealing with the revision of ISO/IEC 17025. The listings could also be used for promotional



ILAC Inspection Committee in session on 11 October 2014

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purposes in the meantime. Survey on Internal Calibrations - Based on the survey on internal calibrations undertaken by the Committee in which most of the respondents said that the creation of an ILAC policy or guidance document would be worthwhile for clarification or standardization, it was agreed that more information on the responses is needed before deciding whether or not to develop a guidance document.

- ❑ **Revision of ISO/IEC 17025: 2005:** General requirements for the competence of testing and calibration laboratories - The ballot for the New Work Item Proposal (NWIP) for the revision of ISO/IEC 17025:2005 closed on 19 September 2014 and was successful. Forty nine members approved the ballot with 7 members not approving and 12 abstaining. The ISO policy Committee on Conformity Assessment (ISO/CASCO) has established a Working Group to revise the standard. ILAC is represented on the ISO/CASCO Working Group by 2 members. It is expected that the first meeting of this group will be held in mid-December 2014 or late January 2015. The revised standard is expected to be published after 3 years at maximum. A joint Working Group of the ILAC AIC and Laboratory Committee (ILAC LC) was established during the 2014 ILAC General Assembly to coordinate ILAC's input into the revisions. A paper will be prepared for submission to ISO CASCO Working Group on issues to address in the revision of ISO/IEC 17025. Clause 5 was identified as an important clause for the revision taking into account the technological developments that have taken place. Members were invited to nominate representatives to participate in the WG.
- ❑ **Reference Materials** - ISO Guide 34 is going to be revised and published as a standard instead of a guide. The revisions will be managed jointly by ISO CASCO and REMCO through JWG 43 which is scheduled to meet in December 2014 to start the work. Members were invited to make submissions on ISO Guide 34 to be taken into account during the revisions. Other related documents ISO Guide 80 is now being finalized whilst the revised text for ISO Guide 33 was finalized and is ready for publication. With the publication of ISO Guide 33, ISO Guide 32 will be withdrawn. Noting the developments in Guide 33 which was revised taking into account ILAC G9: 2005: Guidelines for the selection and use of reference materials, the meeting agreed to withdraw ILAC G9. The meeting also agreed to withdraw ILAC G 12: 2000: Guidelines for the requirements for the competence of reference materials producers.
- ❑ **Accreditation of sampling** – As reported under the IC highlights.
- ❑ **Accreditation in the medical field** – Some accreditation bodies have started accrediting to ISO 22870: 2006: Point of care testing - Requirements for quality and competence of which 13 accreditation bodies have already accredited to this standard. Regarding medical imaging CNAS (China) has determined that the base standard for accrediting be ISO 15189 but are undertaking a study to look at what elements of ISO/IEC 17020 would be also be applicable. New Zealand offers a scheme based on ISO 15189. In the UK and Australia, a professional standard is being used as they felt that ISO 15189 is too much of a pathology standard. Noting the heterogeneous approach to accreditation in the medical imaging area, it was agreed that the matter be taken up with ISO TC 212 and have it on AIC WG 6 agenda so as to ensure harmonious activities in this area. Following the publication of ISO 15189 in July 2012 and taking into account the new requirements added in ISO 15189:2012 such as risk management, automated selection and reporting of results, laboratory information management etc., the AIC agreed to revise ILAC G 26. A draft of the revision will be circulated to AIC members for 60 days comment, then ILAC members comment in the near future. Based on the EA report of activities in the health care sector it was suggested that an experience sharing be provided for regional benchmarking in the area. The EA has a standard for certification of medical professionals.
- ❑ **Accreditation in the Forensic Science area** – ILAC G 19:08/2014 Modules in a forensic science process was published in 2014. The document provides guidance for forensic science units involved in the examination and testing in the forensic science process by providing application of ISO/IEC 17025 and ISO/IEC 17020.

Arrangement Committee Report (ARC)

- ❑ **Cross frontier accreditation survey** - WG 8 of the ARC has now finalized the survey questionnaire on the implementation of ILAC G 21 -09/2012: Cross frontier accreditation – Principles for cooperation and the survey will be launched and circulated to all ILAC members after the General Assembly. The survey which is voluntary will be treated as confidential and not in a way that promotes competition amongst accreditation bodies.

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- ❑ **Management of extra ordinary events** - Another draft of the document on the management of extra ordinary events was presented and discussed at the Vancouver meeting and will be circulated to ARC members for 60 day comment. Although originally the scope covered accreditation bodies it has been extended to cover accredited facilities as well.
- ❑ **New MRAs** - Discussions were held on ILAC's readiness to launch the Proficiency Testing Providers (PTP) and Reference Materials Providers (RMP) MRAs for which a resolution was subsequently passed at the ILAC General Assembly to launch the PTP MRA only for now.
- ❑ **Accreditation/regulators** - Working Group 3 of the ARC is undertaking an exercise to find out and give an outline of how regulators are using accreditation and specifying it in their requirements. The idea is to come up with a model that can be used for benchmarking purposes. The exercise will be approached on a prioritized sector basis. The exercise is a major promotional tool and the information which will come out of it will be posted on the ILAC website. The information will also be useful to customers as it will provide a list of regulatory requirements for accredited testing/inspection.

ILAC Marketing and Communications Committee (MCC) and the IAF Communications and Marketing Committee (CMC)

The theme for 2014 World Accreditation Day is "Accreditation: Supporting the delivery of health and social care" and promotional material will be distributed by ILAC/IAF well in time for the commemorations. The ILAC website was re-vamped and is much more user friendly and even now allows for electronic balloting. Website visitations have increased by 8% over the last year's figures and so has the readership of the ILAC news. Promotional brochures, 85 in total have been translated into 13 languages and are available from the ILAC website. The ILAC MCC has also developed the rules for the use of the ILAC/IAF logos which will be circulated for members' comments. A guide to using social media published and uploaded on website. IAF/ILAC welcome pack is now available and can be used for induction of new staff in an accreditation body. Case studies are being worked on and will be grouped by sector.

IAF/ILAC Joint Development Support Committee (JDSC)

- ❑ In a review of activities undertaken since the last meeting the Chairs of the JDSC reported on their participation at the DCMAS meeting held in April 2014. Presentations were made by KENAS (Kenya), MOLDAC (Moldavia), ARAC (Arab region) all of which are working towards signatory status, CASCO and United Nations Industrial Development Organization (UNIDO).
- ❑ **ISO/CASCO issues** - The meeting was informed of ISO CASCO intention to develop an educational brochure on certification of personnel noting that a lot of schemes being developed are not in accordance with ISO /IEC 17024.
- ❑ **UNIDO** - The UNIDO presentation outlined the various projects that they are working on worldwide in the area of accreditation. In the SADC region UNIDO is working in Malawi, Zambia, Mozambique and Namibia to improve the quality infrastructure and specifically in the accreditation area is assisting conformity assessment bodies to work towards accreditation. As a result of the extensive work that UNIDO has undertaken in the SADC region UNIDO would like to have an experiencing sharing workshop in the SADC region.
- ❑ **JDSC Survey** - The results of a survey undertaken by the JDSC were presented. The survey questionnaire was circulated to 71 JDSC members with a response rate of 55%. The objective of the survey was to get information to improve supporting actions to support developing countries. In breakaway groups the delegates discussed key aspects of the survey results on participation in revision and commenting on documents, capacity building of peer evaluators, tools to improve participation in ILAC/IAF and which activities need to be funded by JDSC. The Chairs of JDSC and the ILAC/IAF Secretariats will review the inputs from the breakaway discussions.

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IAF/ILAC Strategic Plans

- **IAF Strategic Plan** – The new IAF strategic plan was published in September 2014 and is available on the IAF website. The strategic plan mission re-enforces the principles upon which the IAF was established which is to facilitate trade and support regulators by operating a MLA among accreditation bodies. IAF vision is, together with ILAC, to be the preferred partners for worldwide recognition of accredited conformity assessment results that meet the market and regulatory and public needs. The IAF MLA has been extended to cover global gap and is now being extended to cover schemes under the GFSI. There are 6 strategic objectives 2 of which are on expansion of MLA and to improve the peer evaluation process. The others are on stepping up communications for wider acceptance of the MLA and fighting against counterfeit certificates. Increase support to developing countries and reduce duplication and variation of work between IAF and regions are also amongst the 6 strategic objectives.
- **ILAC Strategic Plan** - The 2nd draft of the ILAC strategic plan was considered at the April 2014 meeting during which the vision was not changed, mission was shortened thus more memorable and strategy components were updated and retained. Specific strategies considered to be critical in achieving strategic objectives were identified and incorporated together with an activity plan and progress tracking supplement which will be managed by the ILAC Executive Committee. The activity plan and tracking document can also be used by the Committees to track their supporting activities. It is anticipated that the 30 day ballot (vote) period will take place soon after the Vancouver meetings, taking into account any final minor adjustments arising from Vancouver meeting after which the strategic plan will be published early 2015.

ILAC Joint General Assemblies

The Joint ILAC/IAF General Assemblies were held on 17 October 2014 during which 5 resolutions were passed. Various reports were presented by international organizations IEC, ISO and ISO CASCO, European Commission, OIML and UNIDO during which members were updated on developments in their respective organizations. In his presentation to the joint ILAC/IAF General assembly the IEC representative informed the meeting of the launch of the certification scheme for renewable energy (IECRE) and that the scheme management committee had held its 1st meeting. From the presentation by ISO CASCO it was noted that various standards some of which have already been mentioned in this report including **ISO/IEC 17011 is being revised**. ISO/IEC 17011 is the international standard which accreditation bodies have to comply with for international recognition. The revision will be undertaken by ISO CASCO WG 42. The Working group comprises of 29 ISO members bodies, 6 "A" Liaison members and a representative of ISO TC 176. The first meeting of CASCO WG 42 took place from 11 to 13 November 2014 and it is expected that the revision will be completed in 3 years at maximum. ILAC is represented on the WG. Management and coordination of ILAC input into the revisions will be managed by the Arrangement Committee (ARC) which has established a WG for this purpose. Discussions were also held following the EU Commission presentation on the restrictions imposed by the interpretation document of the EU regulations on accreditation. The restrictions have serious implications on certification bodies that operate worldwide and who are accredited by respective countries accreditation bodies who are members of the IAF/ILAC. The EU reiterated that the intention of the EU accreditation policy was to avoid competition amongst accreditation bodies and to work within the context of the IAF/ILAC MLA/MRA.

A report on the progress of work on harmonization of activities within the IAF, ILAC and the Regions was presented to the joint General Assembly. The report contains the initiatives which ILAC and IAF have to take to ensure that regional and international cooperation structures are fit and suitable to serve the future market for accreditation and conformity assessment. The regions were tasked to consider the key issues identified in the report and to report to the joint ILAC/IAF Executive committees and the Joint ILAC/IAF general assemblies in 2015.

Election of Directors

- **IAF** - Messrs R Dougherty (ANAB, USA) and Jian Hua (CNAS, China) will complete their second terms as IAF Chairman and Vice Chairman respectively at the 2015 General Assembly. Dr T Facula (Dakk's, Germany) will complete his

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second term at the 2015 General Assembly, as Director representing Accreditation Body members located in a high income economy. Mr. M Staler (BDI) will complete his second term at the 2015 General Assembly, as Director representing industry and user association members. Mr. Trevor Nash (ABCB) was appointed as Director representing Conformity Assessment Bodies Association members replacing Mr Roger Bennett (IIOC) who completed his second term at the 2014 General Assembly. The IAF General Assembly appointed Mr Eric Janssens (EOQ) for a second term as an Association member for the years 2015 and 2016 and Mr Marcos Oliveira (CGCRE) for a final term as an Accreditation body member and as Chairman of the Financial Oversight Committee for 2015 and 2016.

- **ILAC** – the ILAC General assembly endorsed the election of Mr P Unger, Chairman ILAC, Ms M Malqvist Nilsson Vice Chairman respectively; Ms I Martinez, Chair Arrangement Committee; Ms R Robertson, Chair Accreditation Committee; Mr J Murthy, Chair Marketing and Communications Committee; Ms I Somma, Chair JDSC; Mr E Feller Unaffiliated Representative; and Mr S Sidney, Chair Laboratory Committee. Ms Ety Feller (ISRAC) was appointed Chair of the Arrangement Management Committee to serve for 2 years. Mr Arne Lund was appointed Chair of the Inspection Committee to replace Mr Lal Ilan who is going to retire from UKAS.

Highlights from the 5th AFRAC General Assembly

The African Accreditation Cooperation (AFRAC) held its 5th General Assembly meeting on 26 September 2014 at the Ellily International Hotel in Addis Ababa, Ethiopia. The meeting was hosted by the Ethiopian Accreditation Office (ENAO). Before the General Assembly meeting, a number of workshops were held on 20, 21 and 23 September 2014 followed by AFRAC Committees meetings on 23 to 25 September 2014.

The 5th AFRAC General Assembly meeting was officially opened by the Ethiopian State Minister of Science and Technology, Honourable Mahamouda Ahmed Gaas at a ceremony held on Monday 22 September 2014 and attended by over 100 dignitaries from African countries, regional trading blocs, diplomats, international development partners such as Physikalisch- Technische Bundesanstalt (PTB) Germany and the ACP Group, accreditation cooperation partners such as the Arab Accreditation Cooperation (ARAC). The New Partnership for African Development (NEPAD) was also represented at the meeting.



Delegates attending the opening ceremony of the 5th AFRAC General Assembly

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The Director General of ENAO Mr Araya Fisseha welcomed delegates to the 5th AFRAC Annual meetings and thanked the AFRAC for the opportunity afforded to ENAO to host this special event in Addis Ababa the political city of Africa where the African Union (AU) Secretariat is hosted. He thanked GIZ for supporting ENAO in its development and also thanked PTB Germany for its support to AFRAC and to many other African Countries in the development of quality infrastructure. In his opening speech Honourable Mahamouda Ahmed Gaas noted that only 25.3% of Ethiopian exports are to African countries and that most Ethiopian exports are unprocessed products. "This is typical of many African countries" he said. He noted that African countries have a lot of to do in building their quality infrastructure in order to support value addition and promoting trade amongst themselves. Acknowledging the role of accreditation in enhancing trade and regional integration amongst African countries and in improving the competitiveness of African goods and services, Honourable Mahamouda Ahmed Gaas said, "If Africa progresses with value addition, meet standards and authenticate products and services' compliance to standards by competent conformity assessment bodies, it will create a good trade environment and linkage among African countries for an improved share of global trade".

In his remarks during the opening ceremony Mr Nadir Merah the Head of Trade at the African Union Commission (AUC) mentioned that the AU gives high importance to SQAM issues and that the AU Agenda 2063 covers all the areas of SQAM including accreditation. He noted that although the Pan African Quality Infrastructure (PAQI) had been established and now exists there is a need for a new impetus to progress the work on harmonization of standards and working towards international recognition so as to contribute towards the growth of economies in Africa. "Africa trade constitutes less than 3% of world trade mainly because of quality issues. Eighty percent of African exports are raw materials hence the need to value add", he said. He then urged all to play their part in order to achieve Africa's dream to be the 3rd power house in the world. In his remarks Mr Ron Josias the Chairman of AFRAC noted that over the last decade Africa has been home to 60% 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 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 then thanked Ethiopia for hosting the 5th AFRAC General Assembly meeting and also thanked PTB Germany for the support provided to AFRAC thus far. In her presentation to the General Assembly Dr Tsehaynesh Messele, Chief Executive Officer of the African Society for Laboratory Medicine (ASLM) a professional body established to advance laboratory medicine across the African continent, briefed delegates on ASLM's achievements thus far in preparing medical laboratories for accreditation. She highlighted the need to consolidate fragmented efforts, pool limited resources, and promote result oriented collaborative efforts and to engage partners outside the laboratory health sector so as to achieve the objective of having 250 medical laboratories accredited.

A series of workshops were held in the run up to the General Assembly meeting starting with the workshop on MRA decision making held on 20 September 2014, followed by an orientation for new members of AFRAC hosted by the AFRAC Chairman and Vice Chairman and a workshop for new and emerging accreditation bodies on 21 September 2014. On 22 September 2014 a National Accreditation Focal Point (NAFP) Toolkit workshop was held.

Technical Committee and MRA Committee Documents Working Groups met on 23 September 2014 after the NAFP Toolkit workshop. From 24 to 25 September 2014 the AFRAC MRA Committee and the Technical Committee held their respective meetings.

The MRA Committee meeting was attended by 7 members and the Secretariat. In confirming membership to the MRA Committee Mrs Yolanda Vinnicombe was appointed member of the MRA Committee member representing SANAS noting the pending retirement of Mrs Christinah Leballo. In reviewing its terms of reference (TORs) the MRA Committee noted the need to revise Clause 7.7 and add a new Clause 7.8 of the TORs and make explicit the requirements for confidentiality and impartiality declarations by MRA Committee at the beginning of each meeting. The meeting then reviewed progress in implementation of the 2013/14 work plan and noted that peer evaluation teams for SANAS, ENAO and MAURITAS were being set up. Four evaluations were undertaken for KENAS, SADCAS, EGAC and TUNAC during the period of review. The peer evaluators training course was not held as scheduled in June 2014. Members noted the need to train more evaluators especially for medical laboratories, certification and inspection bodies arrangements. Noting that the Peer Evaluator Guide had not yet been developed, the meeting resolved to engage Mr Mahmoud el Tayeb to

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review the available peer evaluator guidance documents and to develop a guidance document for use by AFRAC evaluators. A Task Force comprising of Mr Araya Fisseha, Mrs Yolanda Vinnicombe and Mrs Maureen Mutasa was also established to monitor progress in the preparation of the guide which should be considered at the next meeting of the MRA Committee. The proposed approach of subcontracting team leader for peer evaluations was looked at and deemed not feasible in the foreseeable future.



AFRAC MRA Committee meeting in session

Based on the recommendations from the MRA Committee Documents Working Group The MRA Committee reviewed the scopes listed in MR 002 to ensure that the scopes listed are within our current competence range and taking into account Africa's development plans. The MRA Committee agreed to recommend the following prioritized scopes for the AFRAC MRA: Calibration Laboratories, Testing Laboratories, Medical Laboratories, Inspection, QMS certification and EMS certification. Although AFRAC does not have an MRA in the following: Product certification, Persons certification and FSMS certification AFRAC will accept applications for evaluation. The Document WG was tasked to review the rest of the AFRAC documents and align them to the prioritized scopes of the MRA and in particular draft M003 which will also have an additional clause on the procedure to extend the scope of the MRA. In revising M003 the meeting noted the need to take into account ILAC R6 and IAF PR 4. Revised documents shall be circulated to members electronically for approval. The MRA Committee acting as

the MRA Council and having reviewed and verified the supporting documents resolved that EGAC, TUNAC and SANAS be accepted as AFRAC MRA Signatories for the scopes:

- Testing;
- Calibration;
- Medical;
- QMS certification; and
- EMS certification.

The MRA Committee once again acting as the MRA Council and having approved TUNAC's scope for inspection noted that the inspection scope meets the criteria for the AFRAC Inspection MRA and having verified the signatory status of EGAC and SANAS in the ILAC MRA, approved that EGAC, SANAS and TUNAC be the first signatories in the AFRAC MRA for inspection. With these signatories to the AFRAC MRA the MRA Committee resolved to urge AFRAC to now submit its application for the evaluation as a region in the scopes of Testing, Calibration, Medical, Inspection, QMS and EMS certification. The MRA Committee also reviewed the KENAS and SADCAS draft pre peer evaluation reports and noted that the SADCAS application was progressing timeously. Based on the final evaluation report the MRA Committee acting as the MRA Council reaffirmed that TUNAC be admitted as an AFRAC MRA signatory for Calibration, Testing, QMS and EMS certification and that TUNAC's scope be extended to include inspection. Based on the joint peer evaluation report the MRA Council approved that EGAC scope be extended to FSMS certification for which an AFRAC MRA is yet to be launched. The MRA Committee also agreed to recommend to the General Assembly that AFRAC applies to ILAC and IAF for its evaluation in the prioritized scopes by March 2015 and that the first round of AFRAC's cycle be aligned to the ILAC and IAF four year cycle. An additional 2 peer evaluators were qualified Mr Moslem Barrack (TUNAC) in the scope certification bodies and testing laboratories and Mr Neville Tayler (SANAS) in the scope calibration laboratories whilst Mr Mahmoud El Tayeb (EGAC) was upgraded to Lead Evaluator. AFRAC now has 6 qualified peer evaluators and one Lead Evaluator. In order to develop the pool of evaluators further the meeting agreed to train more experts for which an invitation shall be send by the AFRAC Secretariat to all accreditation bodies to submit nominations for training as peer

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evaluators. A number of forms were approved for publication following their revision and a number of documents were identified for revision. The meeting then developed the work plan for the 2014/15 year in which 2 pre-peer evaluations for ENAO and MAURITAS and 3 peer evaluations for SANAS and KENAS and SADCAS are scheduled with the latter 2 being carried out subject to approval of the final pre-peer evaluation reports which are yet to be submitted and considered. The work plan also includes the training mentoring and qualification of peer evaluators and updating of MRA documents amongst other activities programmed. A total of 22 resolutions were passed during the meeting some of which were for endorsement by the General Assembly.

The Committee meetings were followed by the 5th AFRAC General Assembly Meeting during which a total of 33 resolutions were adopted. The General Assembly was attended by representatives of EGAC, ENAO, KENAS, SANAS, MAURITAS, SADCAS, TUNAC, SOAC, EAC, SADCA, ECOWAS, ARAC, Nigeria, Senegal, Russian Federation, PTB Germany, ACP EU TBT programme, Africa Eco Labelling Mechanism, AFRIMETS, ARSO, AFSEC and the AUC. In his report to the General Assembly the AFRAC Chairman, Mr Ron Josias reviewed the progress made since the 4th annual general meeting held in Kenya. On membership he advised that AFRAC had 7 full members, 1 stakeholder member. He also updated members on developments in PAQI for which an MOU was signed thus PAQI is now recognized by the AU as the technical infrastructure partner. On technical co-operations, AFRAC signed a Memorandum of Understanding (MOU) with IAAC at the IAAC annual meeting held in Guatemala in August 2014 with MOUs also having been signed with ARAC, APLAC and SADCA. AFRAC participated at the 2013 ILAC and IAF annual meetings and mid-term meetings. The Chairman thanked PTB Germany who funded AFRAC attendance to the APLAC, PAC, IAAC, ARSO and AFRIMETS General Assembly meetings and mid-term ILAC meetings, AFRAC website improvements and maintenance and delegates attendance to the 5th AFRAC Annual meetings. During the meeting SOAC (UEMOA) was accepted as full member of AFRAC whilst ASLM, FH 1360 and LSAHE (Senegal) were admitted as stakeholder members of AFRAC. The General Assembly received the report of the MRA Committee and approved the 2014/15 work plan as presented by the MRA Chairman. The General Assembly also received the Technical Committee report which covered the outcome of the NAFP Toolkit workshop held on 23 September 2014, the activities carried in the year including the development and dissemination of calibration traceability database, attachment of Cote D'Ivoire and ENAO staff at KENAS for requisite capacity building. The Technical Committee encouraged members to enter into Twinning Partnership Agreements for skills development and transfer. The General Assembly approved the establishment of 3 additional Working Groups by the Technical Committee namely: WG for Inspection (IWG) with Mr Mpho Phaloane (SANAS) as the convener; WG for Testing and Calibration (TCWG) with Mr Thabo Chesalokile (SANAS) as the convener; and Working Group for Certification (CWG) with Mr Adel Rezk (EGAC) as the convener. These WG are expected to input into the revision of ISO/IEC 17011. The Technical Committee Chairman presented 7 resolutions of which 2 were recommendations and approved by the General Assembly including the 2014/15 work plan. In a report by the Executive Committee it was noted that all the outcomes on marketing in the 2013/14 work plan had been achieved with the AFRAC Newsletter published, calendar of events uploaded on AFRAC website and improvements made on the AFRAC website. A recommendation by the Executive Committee to establish a Marketing and Communications Working group with Mrs Susan Muniyiri (KENAS) as the convener was approved by the General Assembly together with the 2014/15 work plan. The General Assembly approved the financial statements for the years 2012 and 2013 and also approved the 2015 budget as presented. Noting that AFRAC does not yet generate income as it is still developing a formula for membership fees the General Assembly agreed to pay a flat fee of US\$ 250 per delegate for participation in meetings from 2015 onwards.

Various reports were presented to the General Assembly by PTB Germany, ARAC, SADCA, EAC, IAAC, APLAC, ILAC, IAF, ARSO, AFSEC, PAQI, AEM/EMA and ACP Group. The representative of ACP group urged members to submit proposals for funding under the ACP EU TBT Programme.

The General Assembly re-elected Mr Ronald Josias the Chief Executive Officer of SANAS as Chairman of AFRAC for a second term of office in accordance with the AFRAC Bylaws. Mr Mahmoud el Tayeb (EGAC) was re-elected as Vice Chairman of the MRA Committee whilst Mr Mohamed Adel Rezk (EGAC) was re-elected as Vice Chairman of the Technical Committee for second terms in accordance with the AFRAC Bylaws. The General Assembly thanked ENAO for hosting the 5th General Assembly of AFRAC, for the excellent arrangements and hospitality. The General Assembly concluded with the SADCAS/TUNAC Twinning Partnership handover ceremony and a membership signing ceremony during which SANAS, EGAC and TUNAC who had been approved by the MRA Council as the first signatories to the AFRAC MRA for Calibration

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laboratories, testing laboratories, medical laboratories, inspection bodies, quality and environmental management systems certification. Newly admitted members of AFRAC also signed their respective MOU as commitment to abide with AFRAC by laws and the various members' obligations.



Representatives of SANAS, TUNAC, EGAC and LSHE showing off their signed MoUs

To mark the end of the 5th AFRAC Annual meetings a dinner was hosted by ENAO on 26 September 2014 which coincided with the celebrations of the finding of the Cross a national holiday in Ethiopia. The dinner was held at a cultural restaurant where delegates were treated to some traditional Ethiopian music and dance. The AFRAC General Assembly was a success and great strides were made during the 2013/14 year towards the achievement of the 2012 to 2017 strategic plan. The meetings were not only a good platform for learning and sharing experiences but also for networking with other peers. The meeting was also an opportunity to keep abreast with developments in SQAM in the region, network with cooperating partners working in the SQAM area.

Upcoming Training Courses

NO.	COURSE	DATE(S)	VENUE COUNTRY/CITY
1	ISO/IEC 17020 Requirements & Internal Auditing	24 to 28 February 2015	Swaziland (Mbabane)
2	ISO/IEC 17025 Requirements & Internal Auditing	2 to 6 March 2015	Swaziland (Mbabane)
3	ISO/IEC 17025 Requirements and Internal Auditing	24 to 28 February 2015	Tanzania (Dar es Salaam)
4	ISO/IEC 17025 Requirements & Internal Auditing	9 to 13 March 2015	Namibia (Walvis Bay)
5	ISO 15189 Requirements & Internal Auditing	23 to 27 March 2015	Zimbabwe (Harare)

Workshop for New and Emerging Accreditation Bodies in Africa

As part of its 5th General Assembly programme AFRAC held an orientation for new members on Sunday, 21 September 2014. The orientation was hosted by the AFRAC Chairman Mr Ron Josias of SANAS and Vice Chairman, Mr Robin Gopee of MAURITAS. This was followed by a workshop for new and emerging accreditation bodies. The aim of the workshop was to provide a platform of experience sharing among developed, emerging and new accreditation bodies in Africa and to clarify any issue related to accreditation. The workshop focused on seven key requirements ISO/IEC 17011 namely: Legal identity; Legal status; Impartiality; Conflicting activities; Related bodies; Confidentiality; and Liability and finance. To encourage participation and address the pertinent issues the workshop was conducted in the form of panel discussions with representatives of EGAC (Egypt), ENAQ (Ethiopia), KENAS (Kenya), MAURITAS (Mauritius), SADCAS (SADC), SANAS (South Africa) and TUNAC (Tunisia) making brief presentations on their respective accreditation body experiences in the areas of focus and answering any questions from participants.



Panelists of the workshop for new and emerging accreditation bodies and participants at the workshop

The panel discussion was then followed by breakaway sessions during which the participants in group work considered the above mentioned key requirements in detail. The workshop was chaired by Mrs Maureen Mutasa, SADCAS CEO and the panel discussion was facilitated by Dr Elsabe Steyn, SANAS. From the discussions, the following key success factors were identified for the establishment of an accreditation body: Awareness and marketing of accreditation to stakeholders; Coaching of CABs to prepare them for accreditation; Training and development of a pool of competent assessors; Government commitment and recognition; Legal identity and impartiality in accreditation decisions; and The need for regulators to support and use of accreditation.

AFRAC Workshop for National Accreditation Focal Points

On 22 September 2014 a National Accreditation Focal Point (NAFP) Toolkit workshop was held in conjunction with the 5th AFRAC General Assembly meeting in Addis Ababa, Ethiopia. The workshop was organized by the AFRAC Technical Committee. The Vice Chairman of the AFRAC Technical Committee Mr Adel Rezk gave a background to the workshop. AFRAC aims at encouraging the establishment of NAFPs in those countries where accreditation bodies do not yet exist. To this end AFRAC aims to provide tools for new members based on the workshops held and being held. AFRAC has already developed a tool kit for the establishment of accreditation bodies but the tool kit requires further work before publication. It was noted that AFRAC Associate membership category includes NAFPs for those countries which do not have accreditation bodies. Although according to the AFRAC By laws Associate members can participate in AFRAC and its committees and comment on AFRAC documents they do have voting rights. The NAFP should have knowledge and an understanding of WTO TBT, PAQI, AFRAC and general awareness on accreditation.

This was followed by a panel discussion of the various models of NAFPs operational in the region namely the SADCAS and EAC models which were presented by Mrs Maureen Mutasa, SADCAS Chief Executive Officer and Mr Willy Musinguzi, the Representative of the East and Central African Community (EAC) respectively. A discussion was then held on the various models.

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The workshop was also appraised of developments in Ghana where as part of an EU funded programme for building quality infrastructure, Ghana had made some progress in the establishment of a national accreditation body and where in developing a market for accreditation, 28 laboratories are already being coached. In Nigeria the accreditation body initiative was being driven by the Standards Organization Nigeria (SON) and a roadmap has been drawn up on the establishment of the accreditation body NINAS. Currently NINAS was being registered. Accreditation promotional activities are already underway in Nigeria and NINAS intends to apply to AFRAC as an Associate member in the near future. In UEMOA, SOAC is being set up as a multi economy accreditation body to service the accreditation of 8 French speaking countries in West Africa namely: Benin, Mali, Cote d'Ivoire, Niger, Burkina Faso, Togo, Senegal and Guinea Bissau. Although NAFPs have been set up in the 8 countries to be serviced by SOAC they are not yet operational. The representative of SOAC advised the meeting that they intend to set up SOAC and operationalize NAFPs based on the SADCAS model. He also advised the workshop that a new regulation is now in place to set up SOAC as an autonomous organization. SOAC has trained assessors and established accreditation committees to advise SOAC on technical issues.

In the concluding discussions it was noted that in Africa which comprises of 54 countries, 21 countries which do not have national accreditation bodies are covered by SADCAS and SOAC, 11 accreditation bodies have been established and are operational of which 7 are member bodies of AFRAC. There is therefore a mass out there of 21 NAFPs under UEMOA and SADCAS, 4 under EAC and those countries who have not established ABs that can be tapped into in terms of membership in AFRAC. The workshop therefore resolved that AFRAC should invite already existing NAFPs to apply for membership into AFRAC and to encourage those member states who do not currently have an accreditation body to establish NAFPs.

AFRAC Workshop on MRA Decision Making

The African Cooperation in Accreditation (AFRAC) workshop on MRA decision making was held on 20 September 2014 in conjunction with the 5th AFRAC General Assembly in Addis Ababa, Ethiopia. The workshop was attended by over 33 participants from accreditation body members of AFRAC and representatives from Uganda and Ghana who intend to set up accreditation bodies.



Chairman of the AFRAC Mr B Moez speaking during the workshop

The workshop started with a presentation on ILAC A3 and A5 by Mrs Yolanda Vinnicombe, the SANAS Quality Manager. ILAC A3 provides a framework for the evaluation team and is compiled by the accreditation body. It is a self-evaluation tool for improvement purposes. Self-evaluation report has to be submitted as part of the evaluation application documents. During evaluation the team reviews the report and facts provided by the accreditation body and provides comments on the reviews and evaluation. After on site evaluation the team provides summary report to the accreditation body containing the findings raised. Within a specified period of receipt of report, the accreditation body shall respond to the team where after and upon clearance of the findings by the team, a final report is prepared.

This was followed by a presentation by Mr Mahmoud El Tayeb on ILAC A2 and AFRAC M001: Accreditation process for evaluation of accreditation bodies. ILAC A2 was revised

and the new edition was published in February 2014. The workshop noted the need to update AFRAC M001 in line with the 2014 version of ILAC A2. He highlighted the Clauses 2.1 which says that experience of an accreditation body may be obtained by having accredited at least one conformity assessment body and having carried out surveillance and reassessment. He then walked delegates through the AFRAC evaluation process which involves a number of stages as follows: application; pre evaluation; full evaluation; and re- evaluation.

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In a presentation on the MRA decision making process, Mr Bhoughalmi Moez outlined the TORs of the MRA Committee and Council and defined their respective timelines. He reiterated the need for mid-term meetings for timeous handling of applications. On the findings raised during an evaluation, Mr Moez informed delegates that for nonconformities, the accreditation body shall provide corrective action report and evidence of implementation whilst for concerns it is adequate for the accreditation body to provide a corrective action plan including schedule of implementation and for comments the accreditation body is encouraged to respond. A number of recommendations were made during the workshop and considered at the MRA Committee meeting subsequently held on 24 to 25 September 2014:

- ❑ AFRAC MRA Committee to consider having a workshop on how to compile the self-evaluation report in accordance with A3;
- ❑ Review AFRAC M 001;
- ❑ Review AFRAC P 002;
- ❑ Consider coming up with an AFRAC template for the final evaluation report; and
- ❑ Reiterated the need for mid-term meetings.

Advisory Committee for Inspection Bodies in Zimbabwe Holds Fourth Meeting

The fourth Advisory Committee for inspection bodies in Zimbabwe was held on 29 October 2014 at National Social Security Authority (NSSA) House in Harare. The meeting was chaired by Mrs Maureen Mutasa the SADCAS Chief Executive Officer and attended by 19 participants from accreditation bodies, inspection bodies, regulators, manufacturers, users, academic institutions and Ministry of Industry and Trade. The purpose of the meeting was to review the composition of the Advisory Committee vis a vis the scope of the Advisory Committee; appoint the Chairman of the Advisory Committee; familiarize with the terms of reference of the Advisory Committee and familiarize members with the accreditation process for inspection bodies operating in the regulatory domain under the Factories and Work Act noting that six new members were present at the meeting; consider the output of Working Group which was tasked to develop national criteria for accreditation of Independent Inspection Authorities involved in the inspection of tanks; review progress with the development of regulations for lifting equipment; and identify and prioritize additional accreditation scopes for inspection bodies operating in the regulatory domain under the Factories and Works Act.

Regarding the composition of the Advisory Committee, new members attended the meeting: Mr Rubben Seva from Triangle Ltd; Mr Kudzai Musiwa from University of Zimbabwe; Engineer Zwelibanzi Brian Dlodlo from the National University of Science and Technology (NUST); Mr Admire Maradzika from Chinhoyi University of Technology; Mr Ngoni Chirinda from Harare Institute of Technology (HIT); and Mr R Manibhai Naik from Engineers Council of Zimbabwe (ECZ). Mrs Mutasa explained that since its establishment the Advisory Committee has been chaired by the SADCAS Chief Executive Officer. According to SADCAS AP 11, Clause 4.3.3 the SADCAS Chief Executive Officer in consultation with the Technical Manager shall appoint a Chair of the Advisory Committee for a period of two years which may be extended. The prerequisites for Chair include: impartiality, requisite skills, confidence of members, ability to focus discussions and come up with appropriate resolutions. Following a proposal from Mrs Mutasa and having outlined candidate's experiences and skills members unanimously agreed that Mr Ngoni Chirinda be appointed as the Chairman of the Advisory Committee for Inspection Bodies in Zimbabwe. Mr Chirinda was appointed as the Chairman of the Advisory Committee for Inspection Bodies in Zimbabwe for a period of two years.

Mr Eben Smit then explained SADCAS AP 12: Part 2 – Accreditation of Inspection Bodies Operating in the Regulatory / Voluntary Area. This document was developed and published on 5 June 2012 and was revised and issue 2 was published on 24 April 2013. He highlighted that the accreditation procedure for inspection bodies operating under the Factories and Works Act in Zimbabwe have to undergo a pre-assessment with the timeline between pre-assessment and initial assessment set at six months with possibilities of extension. Upon a successful pre assessment, an Indicative Letter is issued to serve as the basis for the provisional approval of inspection bodies by the Regulator.

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Mr Eben Smit addressing members during the AC meeting

Mr Danmore Mabambe presenting a report of the WG on "Storage Tanks" output

Mrs Mutasa reminded members that during the last Advisory Committee meeting AC 01.M 3, members agreed to extend the scope of the Advisory Committee to include "Storage Tanks" and "Lifting Equipment". It was agreed to put on hold the scope "Lifting Equipment" until the Regulator has promulgated new regulations at which time the Advisory Committee membership will be reviewed. To this regard, Mr Mabambe the Convener of the Working Group for "Storage Tanks" presented the proposed criteria for the inspection of tanks. Following discussions on the proposed criteria it was agreed that the WG revisit the draft criteria taking into account the Advisory Committee deliberations including streamlining the scope to "Metallic Tanks". The WG will come up with a 2nd draft by end of January 2015 which will be circulated to members for comment within one month after which a 3rd draft will be prepared and submitted for consideration by NSSA. Thereafter, a final draft will be circulated to members by July 2015 and presented to the Advisory Committee members for approval at its 5th meeting scheduled to be held in September 2015.

The "Lifting Equipment" scope was put on hold because the new regulations have not yet been set. The Ministry of Labour & Social Health deals with the promulgation of laws and there was a delay in the promulgation of the new law.

This meeting was also an opportunity to appraise members of developments in accreditation of inspection worldwide following the ILAC Inspection Committee meeting held on 11 October 2014 and where SADCAS was represented by Mrs Mutasa.

OCC Delegation Visits SADCAS

On 4 December 2014, SADCAS Management welcomed 3 delegates from the Office Congolais de Contrôle (OCC), Democratic Republic of Congo (DRC) at SADCAS offices in Gaborone, Botswana. The OCC delegates were Mr Viki Mbuya Kanama who apart from being a member of the SADCAS Board of Directors is also the NAFP-DRC, Mrs Adrienne Bokabo who is Director Standardization and Mr Albert Yuma Ntambo, Director of the Kinshasa Province and is also a registered technical assessor with SADCAS.

The visit was a courtesy call to SADCAS since the delegation had come to Gaborone for a meeting with the SADC Secretariat to prepare for the 2015 Annual SADC SQAM meeting which will be hosted by OCC in Kinshasa, DRC. SADCAS took the opportunity to update the delegation of developments in SADCAS and in particular to update the delegation on progress with the implementation of the SADCAS/TUNAC Twinning Partnership Agreement under which all applications from French speaking countries including DRC will be processed. After the briefing the delegation was taken around the office and introduced to all SADCAS staff.

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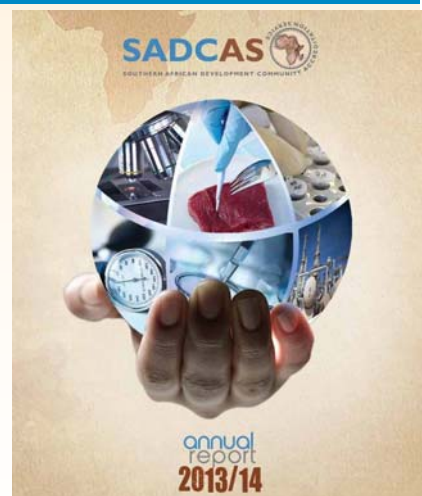
From left to right: Mr Kanama, Mrs Bokabo, Mrs Ranorovelo, Mrs Mutasa, Mrs Gudo and Mr Ntambo at SADCAS Offices in Gaborone, Botswana

SADCAS Publishes Sixth Annual Report

The SADCAS Board of Directors at its 38th meeting held on 27 November 2014 approved SADCAS' 6th annual report. Some of the highlights contained in the annual report which covers the 2013/14 financial year are as follows:

- ❑ Encouraging results with a 50% growth in the number of accreditations, 29% growth in training services and 25% increase in operating income over 2012/2013.
- ❑ Summary of the achievements in each of the key 5 result areas agreed for the 2013/14 financial year.
- ❑ Reports from the two Board Committees namely Human Resources and Remuneration Committee and the Finance, Risk and Audit Committee.
- ❑ Auditor's report and audited financial statements.

The full Annual Report is available to all stakeholders from NAFFPs, the SADCAS offices and on the SADCAS website on www.sadcas.org/annual_report.php



SADCAS Participate at the 2014 SLMTA/SLIPTA Symposium

The Strengthening Laboratory Management Towards Accreditation (SLMTA)/Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) Symposium was held from 28 to 29 November 2014 at the Cape Town International Conference Center in Cape Town, South Africa. The theme of the conference was "To go higher, faster, farther and longer". The conference was attended by over 135 participants from 27 countries including France, Germany, Netherlands, Switzerland, Trinidad & Tobago, USA, Vietnam as well as 20 African countries.

The symposium started off on Friday, 27 November 2014 with updates on SLMTA and SLIPTA programmes and showcasing of the South African Experiences on SLMTA. This was followed in the afternoon by a session on accreditation during which a panel discussion of SLMTA laboratories that had achieved accreditation was held. The panel discussion was chaired by Professor Killian Songwe the Regional Director for Africa Global Healthcare Public Foundation. In her presentation which came very appropriately after the panel discussion by medical laboratories' representatives, Mrs Maureen Mutasa the SADCAS CEO shared with delegates SADCAS experiences from the Medical Laboratory Accreditation Programme (MLAP). In her presentation she gave an overview of SADCAS, introduced the SADCAS MLAP and the accreditation process and shared with delegates the trends which SADCAS has noted from the assessments undertaken thus far and the lessons learnt. During the morning session of day 2 of the Symposium a presentation was made by representatives of a hospital in Cameroon which had successfully implemented the SLMTA programme with financial assistance from the World Bank. In the following morning session presentations were made on the various tools that can be used to facilitate data collection, analysis, management and reporting. The Symposium ended with country case studies from Botswana and Vietnam followed by an Award ceremony.



Delegates at the SLMTA/SLIPTA Symposium



SADCAS CEO addressing delegates during the symposium



Delegates pose at the SADCAS Stand

Pamphlets for Accreditation Programs published in French and Portuguese

- ✓ Calibration Laboratories Accreditation Programme (CLAP)
- ✓ Inspection Bodies Accreditation Programme (IBAP)
- ✓ Medical Laboratories Accreditation Programme (MLAP)
- ✓ Testing Laboratories Accreditation Programme (TLAP)

To download visit: www.sadcas.org/promotionalMaterial.php

SADCAS/SANAS Joint Communiqué - SADCAS Accreditation Services

The Southern African Development Community Accreditation Services (SADCAS) is a multi-economy accreditation body established in terms of Article 17 (3) (b) of the Technical Barriers to Trade (TBT) Annex to the SADC Protocol on Trade with the primary purpose of ensuring that conformity assessment service providers operating in those SADC Member States which do not have their own national accreditation bodies are subject to an oversight by an authoritative body. Within the Southern African Development Community (SADC) region, only South Africa and Mauritius have their own national accreditation body. The remaining 13 countries namely: Angola; Botswana; Democratic Republic of Congo (DRC); Lesotho; Madagascar; Malawi; Mozambique; Namibia; Seychelles; Swaziland; Tanzania; Zambia; and Zimbabwe do not have national accreditation bodies hence serviced by SADCAS. SADCAS is recognized by the SADC Council of Ministers as a subsidiarity organization of SADC. The relationship between SADCAS and SADC is formalized through a Memorandum of Understanding (MOU) on general cooperation which also serves as the basis for the recognition of SADCAS, by SADC Member States as a multi economy accreditation body.

SADCAS is now in its sixth year of operation as a multi economy accreditation body. Having been incorporated in December 2005, the SADCAS office was set up by October 2008, launched in April 2009 and started to offer accreditation services in October 2009. Up to date SADCAS has issued 35 accreditation certificates to 26 accredited facilities in 6 SADC Member States. SADCAS accreditation services were kick started through a Twinning Partnership Arrangement with the South African National Accreditation System (SANAS). The Twinning Partnership Arrangement is meant to ensure the credibility of SADCAS accreditation services whilst at the same time benefiting from skills transfer from SANAS as SADCAS works towards signatory status in international accreditation arrangements.

In working towards signatory status in the International Laboratory Accreditation Cooperation (ILAC) as well as the African Accreditation Cooperation (AFRAC) Mutual Recognition Arrangements (MRA) for the accreditation of testing and calibration laboratories, the SADCAS application for peer evaluation was reviewed and accepted by the ILAC Arrangement Management Committee (AMC) and AFRAC MRA Committee. SADCAS subsequently underwent a joint ILAC/AFRAC pre peer evaluation from 23 to 27 June 2014. The purpose of the joint pre peer evaluation was to:

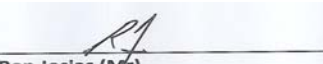
- Provide SADCAS an opportunity to submit its accreditation system for an evaluation process that applies the same requirements and competences used in a peer evaluation for the AFRAC MRA and ILAC MRA; and
- Provide SADCAS an opportunity to identify findings in its accreditation system through an independent peer evaluation process.

Whilst the evaluation team confirmed that the overall system of SADCAS is in accordance with the requirements of AFRAC M002-01 and ILAC-P5:10/2013, that SADCAS operates its testing laboratory and calibration laboratory accreditation programmes substantially in accordance with the requirements of ISO/IEC 17011:2004 and IAF/ILAC-A5:11/2013 and that laboratories accredited by SADCAS have been assessed against and found to comply with the requirements of ISO/IEC 17025: 2005, a finding was raised on the Joint Communiqué on SADCAS Readiness to Offer Accreditation Services signed by SADCAS and SANAS and issued on 12 April 2010. The Communiqué includes the following statement: "3. Through the SADCAS/SANAS Twinning Partnership Arrangement, the accredited facility will be able to maintain international recognition". The facilities accredited under the SADCAS/SANAS TPA are currently only listed in SADCAS directory of accredited facilities available on the SADCAS website and not in SANAS directory of accredited facilities. This, as the pre peer evaluation team noted, may mislead the International recognition of SADCAS.

To address this finding, all facilities accredited under the SADCAS/SANAS TPA will now be issued with separate SADCAS and SANAS accreditation certificates and will be listed on both the SADCAS and the SANAS directories of accredited facilities available on the respective accreditation body's website. All certificates issued under the SADCAS/SANAS TPA will contain a note to that effect.

SADCAS is well on its way to signatory status in the ILAC MRA for the testing and calibration laboratories accreditation programs and aims to achieve the said status in the 2015/16 financial year after which only SADCAS certificate will be issued. SADCAS is also working towards signatory status for its medical laboratories, inspection bodies and management systems certification bodies' accreditation programmes.


Maureen P Mutasa (Mrs)
SADCAS Chief Executive Officer


Ron Josias (Mr)
SANAS Chief Executive Officer

Date of Issue: 2014-09-12

CIMAS Medical Laboratories Road to Accreditation

The challenges facing medical laboratories worldwide are to provide accurate and reliable medical results timeously. Resources are often limited hence the need to use them as efficiently and effectively as possible.

The Zimbabwe government reiterated the need to provide its citizens with quality medical services by strengthening evidence based medicine. One way to achieve this was through ISO 15189 accreditation for medical laboratories. Accreditation is a procedure by which an authoritative body gives formal recognition that an organization is compliant and competent to carry out specific tasks according to predetermined standards. An initiative was rolled out by the Zimbabwe Government in collaboration with ZINQAP, CDC, and WHO-AFRO where the SLMTA/SLIPTA program was unveiled. Strengthening Laboratory Management towards Accreditation is a management tool that allows laboratories to progressively improve on their quality management system through a five tier rating system as they work towards ISO 15189 accreditation. **Stepwise Laboratory Improvement Processes towards Accreditation (SLIPTA)** is a framework to encourage, support and recognize the implementation of a management system in medical laboratories in a stepwise manner.

In CIMAS Medical laboratories' journey towards accreditation it was important to get buy in from management and staff. Initially this proved difficult because change is never easy and always is painful. A quality steering committee was formed with a representative from each department chosen by staff members so as to get buy in from staff by actively involving them. The committee then drew up a plan of activities which included internal audits and structured meetings. Training requirements were identified and trainings were carried out. All support staff participated in the accreditation process even though they were not directly involved. CIMAS Medical Laboratories management was totally committed. The Managing Director Mr Mafingei Nyamwanza being the champion of accreditation was astute in identifying skills in his staff which resulted in persons being given tasks aligned to their skills in an effort to utilize talent towards achieving Accreditation.

The road towards accreditation enabled CIMAS Medical Laboratories to improve quality of service, improve customer care, ensure customer satisfaction, ensure staff competence and that there is ongoing staff development, verify conformance with regulatory and accreditation requirements, and ensure that staff is aware of their health and safety needs.

Total commitment and dedication by all staff resulted in CIMAS Medical Laboratories becoming the 4th medical laboratory to be accredited by SADCAS and the first pathology laboratory to be accredited by SADCAS in Zimbabwe. CIMAS Medical Laboratories was accredited in a record 12 months from the application date and accreditation by SADCAS a process which included a pre assessment. The CIMAS Medical Laboratories certificate which was issued on 11 July 2014 is valid for 5 years until 10 July 2019. The accreditation certificate handover ceremony was held on 12 September 2014 at Medical Chambers, in Harare, Zimbabwe.

This article was compiled by Mrs Erica Chidziva CIMAS Medical Laboratories' Quality Manager.

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.

CIMAS Medical Laboratories Celebrates its Accreditation

CIMAS Medical Laboratories is the 4th medical laboratory to be accredited by SADCAS and the first pathology laboratory to be accredited by SADCAS in Zimbabwe. The CIMAS Medical Laboratories has been accredited in the scopes: Serology; Hematology and Chemistry in accordance with ISO 15189. Through this accreditation, CIMAS Medical Laboratories housed at Medical Chambers in Harare has been granted the unique accreditation number: MED 004; indicating that CIMAS Medical Laboratories is now a SADCAS accredited medical laboratory. The CIMAS Medical laboratories certificate which was issued on 11 July 2014 is valid for 5 years until 10 July 2019.

The accreditation certificate handover ceremony was held on 12 September 2014 at Medical Chambers, in Harare, Zimbabwe. Professor Cakana the CIMAS Pathologist gave the welcoming remarks. In her remarks Mrs E Chidziva, a member of the CIMAS Quality Team outlined the road leading towards accreditation highlighting the importance of top management commitment and the need for involvement of all staff in the process.



In her remarks Mrs Maureen P Mutasa, the SADCAS CEO noted the role of medical laboratories in providing 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 Zimbabwe have embraced accreditation as a strategy for the competence of medical laboratories and this has spurred interest in the SADCAS Medical Laboratories Accreditation Programme with 33% of the applications under process being medical laboratories. At the time of the certificate presentation SADCAS had accredited 6 medical laboratories 4 of which are from Tanzania, one from Swaziland and one from Zimbabwe. Mrs Mutasa encouraged CIMAS Medical Laboratories to maintain their accreditation throughout the validity period of the accreditation certificate during which SADCAS would undertake surveillance assessments annually to ensure continued compliance. She also reminded CIMAS Medical Laboratories of the need to transition to the 2012 version of ISO 15189 within the stipulated timelines failing which the accreditation will be suspended.

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Speaking during the certificate handover ceremony, the guest of honor Dr David Parirenyatwa the Minister of Health and Child Welfare congratulated CIMAS Medical Laboratories for the achievement. "This is a living example of hard work and commitment by the staff and management of CIMAS. The attainment of accreditation by CIMAS Medical Laboratories raises the standard of laboratory services to international status" he said. With the recent successful separation of Siamese twins performed at one of the major government hospital in Zimbabwe, the Minister expressed the hope that the recent trends of medical tourism which has seen Zimbabweans seeking medical attention in other countries will soon be a thing of the past as quality services can be offered locally with the support of credible medical laboratory services.



Mrs Maureen P Mutasa handing over the certificate to Mr Mafingei Nyamwanza, Managing Director CIMAS Medical Services Division with Honorable Minister of Health and Child Welfare Dr David Parirenyatwa witnessing the handover

Seated from left to right: Mrs Maureen Mutasa; Honorable Dr David Parirenyatwa; and Mr M P Mahlangu CIMAS Main Board Chairman and CIMAS top management standing

Following the Minister's remarks long standing clients of CIMAS were recognized and a cake cutting ceremony held to celebrate the notable achievement. A tour of the CIMAS Medical laboratories was also undertaken as part of the ceremony.

SADCAS Accredits More Facilities under MLAP

The Southern African Development Community Accreditation Service (SADCAS) is proud to announce the accreditation of 2 medical laboratories namely **Muhimbili National Hospital Central Pathology Laboratory** in the scope of Blood Transfusion and Clinical Chemistry and **Lancet Laboratories (Swaziland)** in the scopes of Chemistry, Hematology and Microbiology both in accordance with ISO 15189.

- ❑ **Muhimbili National Hospital Central Pathology Laboratory** accreditation covers Serum and Whole Blood EDTA under Blood Transfusion and Serum under Clinical Chemistry and the certificate is effective from 22 August 2014. Through this accreditation, **Muhimbili National Hospital Central Pathology Laboratory** has been granted the unique accreditation number **MED 005** indicating that Muhimbili National Hospital Central Pathology Laboratory is a SADCAS accredited medical laboratory.
- ❑ **Lancet Laboratories (Swaziland)** accreditation covers Serum and CSF under Chemistry, Plasma under Hematology, Blood Cultures, CSF, ENT, Fluids, Rectal Swabs, Semen, Sputum, Stool, Tissue, Urine, Genital and Pus under Microbiology and the certificate is also effective from 22 August 2014. Through this accreditation, **Lancet Laboratories (Swaziland)** has granted the unique accreditation number **MED 006** indicating that Lancet Laboratories is a SADCAS accredited medical laboratory.

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Figure 1—Accreditation by Country

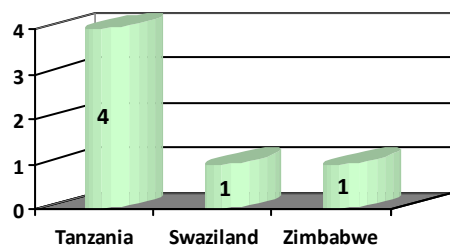


Figure 2—Accreditation by Scope

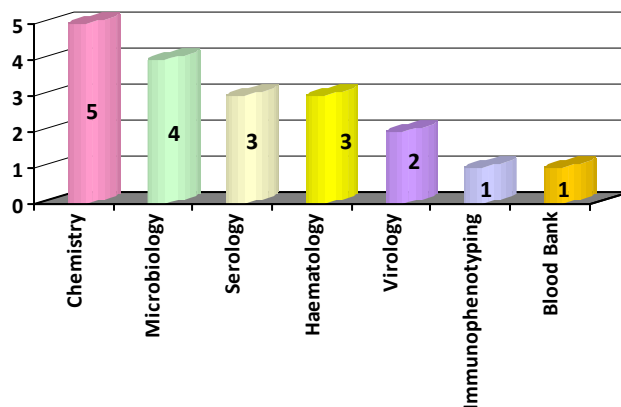


Figure 3—Applications by Country

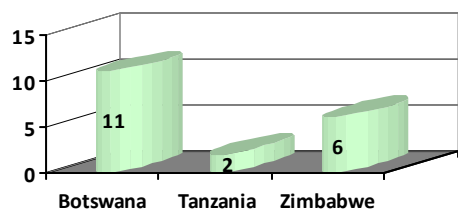
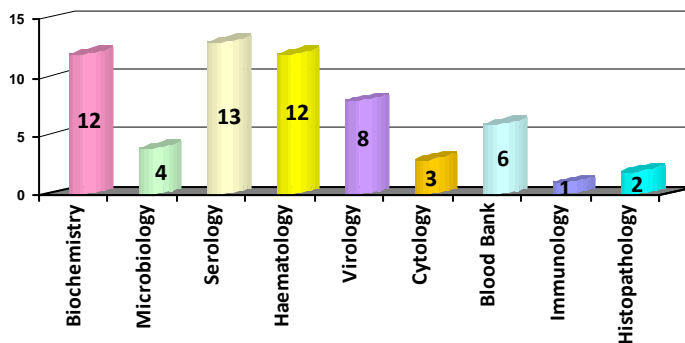


Figure 4—Applications by Scope



Good Professional Practice—Observations from Witnessing Activities



Mr Benson Gabi

Laboratories seeking accreditation are often engrossed in demonstrating their compliance to the ISO/IEC 17025. Often times, high level technical aspects such as method validation, proficiency testing and quality controls are well addressed leaving basic laboratory techniques unaddressed.

Sub – clause 4.2.2 (a) of ISO/IEC 17025:2005 requires laboratory management’s commitment to good professional practice. Good professional practice is a broad area covering all aspects of laboratory leadership and operations where basic laboratory techniques apply. It is therefore necessary for laboratories to minimize or eliminate the risk of failure by ensuring strict adherence to basic laboratory techniques.

To illustrate the above, some typical workbench scenarios are given. The list is not exhaustive but is indicative of common pitfalls that may be observed during witnessing of activity:

- ❑ Rinsing a pipette with distilled/de-ionized water and drawing an aliquot of test solution without rinsing with the test solution;
- ❑ Handling a burette tap with the right hand (for a right handed analyst);
- ❑ Shaking or agitating the contents in an Erlenmeyer flask during titration instead of swirling the contents;

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- Reaching the end point of a titration without rinsing-in the contents in the Erlenmeyer flask;
- Leaving solutions uncovered when they are left to stand;
- Lack of policemen rubber when transferring a precipitate.
- Using inappropriate glassware such as measuring cylinders or beakers to accurately measure an aliquot of a test sample;
- Blowing the last drop of aliquot from a pipette;
- Wiping a spatula using a laboratory coat; and
- Not using the white mark on glassware during titration and so on.

Laboratory management is therefore reminded to ensure that basic laboratory techniques are addressed during the day to day operations of their respective laboratories. That will enhance the effectiveness of implementing the requirements of ISO/IEC 17025 and create value with respect to minimizing risk.

This article was compiled by Mr Benson Gabi a SADCAS qualified and registered lead and technical assessor.

Two ISO 15189 Courses held in Botswana

Between August and November 2014, SADCAS held two five-day ISO 15189 courses all of which were held in Botswana. The courses are based on ISO 15189: Medical Laboratories – Requirements for quality and competence which was published in 2012. This 3rd edition of the standard replaces the second edition of ISO 15189: 2007.



Participants pose for a photo during the ISO 15189 held in Gaborone, Botswana,

The first course was held from 27 to 31 October 2014 in Gaborone as an open course. The course was attended by Laboratory staff from various government and privately owned laboratories. Open courses tend to provide a good platform for participants to share experiences and learn from each other as was noted by the Trainer who was impressed by the fruitful interaction.

The second course was held at Nyangabgwe Hospital in Francistown from 24 to 28 November 2014. The course was attended by 25 participants from a number of sections within the hospital. In houses courses have the advantage of allowing participants to focus on clauses of the standard which they feel that they are not implementing properly depending on their own systems and stage in preparing or maintaining their accreditation.

The objective of the intensive 5 day ISO 15189 requirements and internal auditing course is to promote a thorough and consistent understanding of ISO 15189 standard requirements, implementation and to impart internal auditing knowledge and skills to medical laboratories staff so that they can monitor compliance of their respective systems in accordance with ISO 15189. During the course group work and practical exercises are given to participants to improve understanding of the material with a written examination on the final day used to assess overall understanding on the knowledge imparted.

Based on the feedback from participants from both courses, several participants expressed their gratitude to SADCAS for organizing the course which was very fruitful and in particular they expressed their gratitude to the Trainer who, whilst making the understanding of the ISO 15189 standard easy, illustrated many clauses with real life examples in laboratory practice.

SADCAS Conducts Another ISO/IEC 17020 Training Course in Namibia

SADCAS conducted another five-day open training course on ISO/IEC 17020 requirements, implementation and internal auditing in Namibia. The training course which was on the 2012 edition of ISO/IEC 17020 was held at Alte Brucke Resort and Conference Centre in Swakopmund, Namibia from 8 to 12 September 2014. A total of thirteen (13) participants from 3 organizations namely Namibia Standards Institute, Metrotech Calibration Services and Rentech attended the course. This was the 2nd course on ISO/IEC 17020 to be conducted in Namibia by the SADCAS.

The training course was opened by Mrs Jaanda Maharero the NAFP – Namibia's representative. A comprehensive elaboration on each of the 8 clauses stated in ISO/IEC 17020:2012 was made by the Trainer with various examples being given by the Trainer referencing to the participants' respective workplaces. Participants were made to understand the importance of competence evaluation of personnel, facilities, traceability of measurements, environment conditions, inspection methods and procedures as vital tools towards accreditation. Participants



Participants pose for a photo during the training

were also appraised on why procedures need to be documented by all the staff performing specific tasks and why they are consolidated into a single document called a Quality Manual and why procedures should be available at all locations of their work places. Throughout this training, the participants understood why the quality system requires a quality policy which is the overall intentions and direction of an organization to inspection as formerly expressed by the top management. Participants were also able to understand why the quality policy contains objectives which require commitment, understanding, implementation and maintenance by all staff in an organization. On Internal auditing, the Trainer covered the reasons for carrying out internal audits, the audit process and the competence requirements for auditors.

The enthusiasm to learn was very much felt during the training and the daily attendance of the participants was very good. Judged by the feedback from participants, the course was well organized and met participants' expectations.

Zambia Bureau of Standards Staff Trained on ISO/IEC 17020

Fifteen staff from the Zambia Bureau of Standards (ZABS) were trained on the latest version of ISO/IEC 17020 the international accreditation standard for inspection bodies. The training course which was attended by inspectors from different border posts (Livingstone, Chirundu, Sesheke, Nakonde, Chanida, and Mwami) and ZABS Headquarters (Domestic Quality Inspections) was held at Chrisma Hotel in Lusaka, Zambia.

The course which started on Monday, 15 September 2014 and ended on Friday, 19 September 2014 was opened by Mr Hamutunda, the ZABS Inspections Manager who wished all participants the best during the five days of training. He recommended the participants to fully take part and be fully involved in the training as ZABS greatly valued the course. Mr Hamutunda said that this was the first of a series of training ZABS intended to take the inspectors through.

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ZABS staff who attended the ISO/IEC 17020 course at Chrisma Hotel

A comprehensive elaboration on each clause of the 8 clauses stated in ISO/IEC 17020:2012 was made by the Trainer who on internal auditing, also covered the reasons for carrying out internal audits, the audit process and the competence requirements for auditors. The practical exercises and group work generated a lot of interest and participation from all the attendees. There was a lot of debate in the groups and during the question and answer sessions. The exercises were challenging enough for the participants and were a source of invaluable practical experience and information on the development, implementation, maintenance and improvement of a quality management system that meets ISO/IEC 17020: 2012 requirements. Judged by the feedback from participants, the course was well organized and met participants' expectations with requests for training on other related topics.

SADCAS also held training courses on ISO/IEC 17020 in Botswana from 7 to 10 July 2014 and Zimbabwe from 20 to 24 October 2014 bringing to 15 the total number of ISO/IEC 17020 training courses conducted by SADCAS.

National Fish Quality Control Laboratory Trained Staff on ISO/IEC 17020

The Southern African Development Community Accreditation Service (SADCAS) was engaged by the National Fish Quality Control Laboratory (NFQCL) to conduct training on ISO/IEC 17025: 2005 and ISO/IEC 17020: 2012. The ISO/IEC 17025 Requirements, Implementation and Internal Auditing course was held from 13 to 17 October 2014 whilst the ISO/IEC 17020 Requirements, Implementation and Internal Auditing course was held from 20 to 24 October 2014. Both training courses were held at Adkam Hotel in Mwanza, Tanzania.

The NFQCL has one laboratory in Nyegezi and is in the process of establishing another laboratory in Dar es Salaam. The Microbiology section of the Nyegezi laboratory was accredited by SANAS in 2007 and the laboratory is preparing to have the Chemistry section accredited. The Nyegezi laboratory works in collaboration with Fisheries Inspections Services and is under Ministry of Livestock and Fisheries Department. A total of 15 participants from NFQCL attended the ISO/IEC 17025 training courses whilst 17 participants attended the ISO/IEC 17020 training course.

The objective of the courses was to promote an understanding of the respective key standard requirements and guidance document ILAC P 15 in the case of ISO/IEC 17020 course and to impart internal auditing knowledge and skills to laboratory and inspection staff so as to monitor compliance with the respective standard.



A Multi-economy Accreditation Body!!



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Participants pose for a photo during training



Examination in session

All the participants enjoyed the training which they all found useful and provided sufficient knowledge and skills which they will use to improve their systems so as to satisfy their customers.

ZABS Staff Trained on ISO/IEC 17021

Sixteen (16) participants from the Zambia Bureau of Standards (ZABS) Certification Services participated in a 5 days' training course on ISO/IEC 17021. This was the first course on ISO/IEC 17021 to be conducted in Zambia by SADCAS. The training course was held at Palmwood Lodge in Lusaka, Zambia from 3 to 7 November 2014.

The 5 days' course covered an overview of accreditation, ISO/IEC 17021 requirements, implementation and internal audit principles, process and competence requirements for auditors. The course comprised of 5 exercises aimed at providing the participants an opportunity to put into practice what they had learnt.

The ZABS' management systems certification division is planning to be accredited to the International Standard ISO/IEC 17021:2011 and have so far developed their Policy Manual and some procedures and will be coming up with their accreditation plan to help get buy-in from their top management. Accreditation which is the process of providing recognition for competence in undertaking, in this case management system certification services, is now increasingly accepted as the most transparent, non discriminatory mechanism to assure competence of conformity assessment bodies.

SADCAS Core Values

Impartiality	We are organized and operate so as to safeguard objectivity and impartiality of our services.
Transparency	We are dedicated to provide complete transparency in our work by communicating effectively with our clients.
Non-discrimination	We treat our clients fairly and in an equitable manner
Integrity	We act with honesty and integrity.
Innovation	We generate new ideas and utilize creative approaches to problems for continuous improvement
Diversity	We respect the diversity of our clients and ensure balance of interest in representation.

ISO/IEC 17025 Requirements & Internal Auditing Courses held from September to November

SADCAS continue to offer a generic 5-day ISO/IEC 17025 Requirements and Internal Auditing course. The course is designed to promote a thorough understanding of ISO/IEC 17025 standard requirements and to impart internal auditing knowledge and skills to calibration/testing laboratories staff so as to monitor compliance with ISO/IEC 17025. The course covers the following main topics:

- ❑ An understanding of ISO/IEC 17025 standard requirements
- ❑ Developing a suitable Quality Manual
- ❑ Improvement and maintenance of laboratory quality management system
- ❑ Understanding method validation and uncertainty of measurements
- ❑ Internal auditing tools and techniques and process

The following courses were conducted from September to November 2014 in 4 SADC Member States as follows:

Democratic Republic of Congo - Realizing the need for accreditation Kamoto Copper Company (KCC) SARL invited SADCAS to train its laboratory personnel on ISO/IEC 17025 requirements and internal auditing (French). The course was held from 8 to 12 September 2014 at KCC in Kolwezi. Twelve participants attended the training.

Botswana – An open course was held from 27 to 31 October 2014 at Oasis Motel, Gaborone. Six participants attended the course i.e. 3 participants from Lamworld Technologies, 2 from Gaborone Laboratory Services and one from SADCAS. Lamworld Technologies is a calibration laboratory accredited by SADCAS under scopes of Temperature and DCLF, whilst Gaborone Laboratory Services is a testing laboratory in the process of developing a management system in preparation for accreditation.

Namibia – An open training course was held from 10 to 14 November 2014 2 at Alte Brucke Holiday Resort and Conference Centre in Swakopmund. Eleven participants from the Ministry of Agriculture, Water and Forestry and Walvis Bay Salt works attended the course. Judging by the feedback from participants, the course was a success and was able to meet its objectives with numerous practical examples being undertaken during the course of the week.

Zimbabwe – An open course was held at the Rainbow Towers Hotel in Harare from 24 to 28 November 2014. Six participants from the Standards Association of Zimbabwe (SAZ) (4) and Trojan Nickel Mine (2) attended the training course. Participants from SAZ comprised of two calibration technicians, one quality officer and one analyst from their Bulawayo Laboratory. The two participants from Trojan Nickel Mine comprised of a senior metallurgist and chemist.

All participants enjoyed the training and highlighted that the course was an eye-opener, educative and relevant to their work.



KCC participants pose for a photo during training held in Kolwezi, DRC



Participants who attended the course in Gaborone Botswana



Training in session at the Rainbow Towers in Harare, Zimbabwe

SADCAS Holds Another Training Course on Validation/Verification of Methods and Measurement Uncertainty

SADCAS held its 2nd training course on validation/verification of methods and measurement uncertainty at Konkola Copper Mines in Chingola, Zambia. A total of 15 laboratory staff members from Konkola Mines' various testing laboratories attended the course.

The training programme started on Monday, 22 September 2014 with registration of participants as scheduled at 0800 hours. The training was very intensive and required basic understanding of mathematics and which covers statistical fundamentals before progressing to relatively advanced concepts of statistical techniques that are used in both method validation/verification and in calculating measurement uncertainty of test results. Practical and group work was interspersed throughout the training programme and comprised of exercises on various aspects of the topic. In general participants were extremely focused throughout the week with excellent participation which resulted in some very useful discussions and outcomes.

An examination was written on the last day of the course and all the participants achieved marks of greater than or equal to 60%. Judged from the feedback from participants the training was very detailed and informative, well presented and clarified misunderstandings on statistical tools and their application in the laboratory.

ISO/IEC 17011 Standard Being Revised

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 going to be revised. The revision will be undertaken by Working Group 42 of the ISO Policy Committee on Conformity assessment (ISO CASCO WG 42). The Working group comprises of 29 ISO members bodies, 6 "A" Liaison members and a representative of ISO TC 176. The first meeting of CASCO WG 42 that will revise ISO/IEC 17011 was scheduled to take place from 11 to 13 November 2014 at the ISO Central Secretariat in Geneva, Switzerland. The expected date for the completion of the task is 3 years maximum. A panel consisting of the ISO-Secretary General, the CASCO Chair, the ISO Deputy Secretary-General and the CASCO Secretariat has appointed Cynthia Woodley (ANSI) and Alister Dalrymple (AFNOR) as the co-convenors of the working group.

The ILAC Executive has nominated Ms Jennifer Evans (NATA) and Dr Andreas Steinhorst (EA) as the ILAC representatives on the working group, and Ms Sylvia Lin (TAF/APLAC) as the ILAC reserve. Management and coordination of ILAC input will be managed by the Arrangement Committee (ARC) and a Working Group was established within the ARC to monitor the revision process.

Revision of ISO/IEC 17025 Standard

The key international accreditation standard for testing and calibration laboratories ISO/IEC 17025: 2005: General requirements for the competence of testing and calibration laboratories is being revised. The ballot for the New Work Item Proposal (NWIP) for the revision of ISO/IEC 17025:2005 closed on 19 September 2014 and was successful. Forty nine members approved the ballot with 7 members not approving and 12 abstaining. The NWIP was submitted by the International Laboratory Accreditation Cooperation (ILAC) following a survey which was undertaken by the Accreditation Committee of ILAC (ILAC AIC) in 2013. The survey was designed to collect feedback from Committee members regarding the desired revisions of ISO/IEC 17025. The survey results indicated that Committee members want ISO/IEC 17025 to be revised and in particular the following clauses:

- 5.4 Calibration, Measurement Uncertainty & Validation/Verification

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- ❑ 5.5 Equipment (possibly)
- ❑ 5.6 Traceability
- ❑ 5.7 Sampling
- ❑ 5.9 Quality Assurance including Proficiency Testing
- ❑ 5.10 Reporting Results (opinions/interpretation)

Working Group 44 has been established by ISO CASCO to revise the standard with Mr Warren Merkel of the USA as the convener and Mr Steve Sidney of South Africa as the co convener. ILAC is represented on the ISO/CASCO Working Group by 2 members. It is expected that the first meeting of this group will be in mid-December 2014 or late January 2015. The expected date for the completion of the task is 3 years maximum.

A joint Working Group of the ILAC AIC and Laboratory Committee (ILAC LC) was established during the 2014 ILAC general Assembly to coordinate ILAC's input into the revisions. A paper will be prepared for submission to ISO CASCO Working Group on issues to address in the revision of ISO/IEC 17025.

The conformity assessment bodies, especially the laboratories and accreditation bodies stand to benefit from the revision of ISO/IEC 17025. Laboratories are urged to actively participate in the revision of ISO/IEC 17025 through their respective countries' national mirror committees managed by the respective ISO member organizations whom in the SADC region are respective countries' National Standards Body who have the responsibility for voting to approve standards.

ISO 9001:2015 New Improvements



Ezrakhovich Alexander



Ezrakhovich Alexander



Dzedik Valentin

This Article is devoted to a new version of the International Standard ISO 9001:2015 which is scheduled for publication in 2015. The article was compiled by Ezrakhovich Alexander - Head of Australian Delegation to ISO/TC176 and member of ISO TC176/SC2 WG24 Coordinating Group, Bannykh Julia and Dzedik Valentin, Member of ISOTC176/SC2 WG23.

In 2012 the international standard ISO 9001 turned 25 years. ISO 9001: Quality management systems - Requirements can be considered as the most popular standard in the world. We can proudly say that the Accreditation and Certification industries have been established and developed due to wide acceptance of this standard.

ISO 9001 was first published in 1987 and from that moment its popularity grew constantly from version to version. The subsequent versions were published in 1994, 2000, 2008. Thus average lifetime of ISO 9001 version is 7 years. Therefore

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a release of ISO 9001 new revision is a planned and predictable event. Of course a release of new version of an international standard is a very complex process and the decision of its revision requires consultation with all interested parties and approval by a majority of ISO members. This work has to be done to maintain the usefulness of ISO 9001. Nowadays the world economy is becoming more and more mobile, global and result-oriented. The role of communications and electronic methods of organization, finance and market control has significantly increased. All these facts should be reflected in the requirements for contemporary quality management systems. Furthermore the accumulated experience of using ISO 9001:2008, whether it is positive or not, should be taken into consideration. To do this, a lot of activities have been held, for example, an extensive web-based user survey.

Based on results of international ballot the decision of the ISO 9001 revision has been made and it is the response on the perceived need to: Maintain relevance; Integrate with other management systems; Provide an integrated approach to organizational management; Provide a consistent foundation for the next 10 years; Reflect the increasingly complex environments in which organizations operate; Ensure the new standard reflects the needs of all potential user groups; and Enhance an organization's ability to satisfy its customers'.

The new standard will be published after approval by participating national standardization bodies and thereafter will be reviewed at regular intervals.

Major changes that are intended to occur in the ISO 9001:2015 compared to ISO 9001:2008 can be divided into four categories: removed, replaced, introduced and strengthened requirements.

The requirements regarding following items have been removed:

- Quality manual;
- Six obligatory documented procedures;
- Preventive actions;
- Management representative.

The replaced requirement include the following:

- The term 'documented information' instead of the terms 'document' and 'record'; and
- The term 'external provision' instead of the terms 'purchasing' and 'outsourcing'.

The introduced requirements are as follows:

- Context of the organization;
- Relevant interested parties;
- Actions to address risks and opportunities;
- Quality objectives shall determine what will be done, resources, responsibility, timing and evaluation method;
- Planning of changes;
- Organizational knowledge; and
- Management reviews shall take into consideration strategic direction of the organization.

The requirements regarding the following points have been strengthened:

- Process approach;
- Added value;
- Leadership; and
- Achievement by the quality management processes conformity to product and service requirements in order to enhance customer satisfaction.

In addition, upcoming ISO 9001:2015 has some new features:

- Increased flexibility of documentation usage; and
- Increased applicability in service-providing organizations.

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Unchanged implementation of the customer focus principle remains the same as the basis for the development of the quality management system.

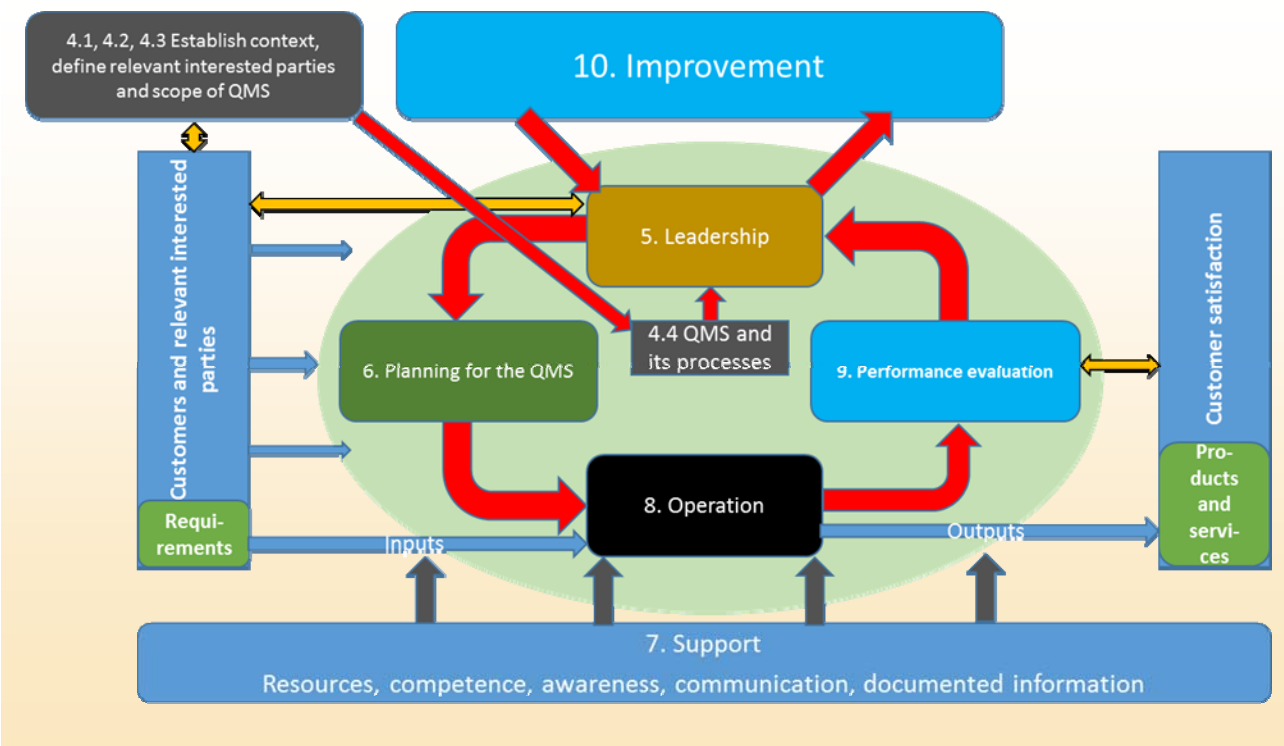
The next point that requires attention is that the so-called 'High-level structure' is applied as the table of contents of the new version of ISO 9001 – It is the standardized enumeration of clauses, based on the cycle of continuous improvement (PDCA). This structure will be applied to all ISO standards, describing management system requirements. This is a huge step towards unification, which will significantly save resources of organizations in the implementation of integrated management systems. It should be pointed out that the new structure of the standard is not in any way connected with the structure of quality management system documentation.

The approximate table of contents of the ISO 9001:2015 is represented in the following way (it should be understood that it could insignificantly change during the further document discussion and approval):

- Introduction.
- Scope.
- Normative references.
- Terms and definitions.
- Context of the organization.
- Leadership.
- Planning for the quality management systems.
- Support.
- Operation.
- Performance evaluation.
- Improvement.

The structure of the ISO 9001:2015 is presented in Figure 1.

Figure 1—Process Model of ISO 9001:2015



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Particular attention should be paid to the fact that developers of ISO 9001:2015 have been doing everything possible to ensure that the organizations which have already implemented and/or certified quality management systems can upgrade their systems to the new version of the standard without making any significant efforts. Organizations have the full right to use such terms familiar to them as a 'document', 'record' or 'documented procedure' instead of 'documented information' or, for example, continue to use the terms 'purchasing' and 'outsourcing' instead of 'external provision'. Organization should not change the structure of its quality management system and should not follow the section numbering of the 'high level structure'.

It is important to realize that most of the changes in the new standard version are aimed at improving the understanding of the requirements and reducing the possibility of misinterpretation. If an organization's quality management system is successfully implemented and effective then the transition to the new standard version will not be difficult.

For a better understanding of future changes, a closer look at some concepts, requirements and terms that have appeared in the new revision is necessary. The context of the organization is the complex of external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result of its quality management system.

Relevant interested parties. Only the organization itself determines its relevant interested parties and also defines their requirements which are related to it based on how one or another interested party with its needs affect the organization's ability to deliver products and provide services in accordance with customer requirements and applicable statutory and regulatory requirements.

Term 'products and services' is used instead of the term 'product' applied in ISO 9001:2008. The term 'products and services' includes all categories of process results such as hardware, services, software, processed materials, components, etc. Introduction to the term of the word "Services" highlights the differences between products and services in the application of certain requirements of the standard. For example, conformity to the requirements cannot be evaluated and validated before providing services.

Actions to address risks and opportunities. In general the concept of risk, i.e. the probability of failure to fulfill the basic goal of any quality management system to provide customers with products and / or services in accordance with their requirements in order to achieve and enhance their satisfaction was covertly presented in the text of previous version of ISO 9001. In the new version the requirement to perform actions to address risk and opportunities is formulated explicitly and is closely linked with the concept of a process approach. This has resulted in the removal of the separate standard clause on preventive actions which has been transferred to the operational level of daily performance of each quality management system process. A risk should be understood not only as a negative phenomenon, but also as an opportunity to find possibilities for improvement within processes. ISO 9001:2015 does not require a formal risk assessment by developing any kind of documented 'risk registers'. ISO 31000 'Risk management – Principles and guidelines' can be used as a useful reference (not mandatory) to risk control methods.

Documented information – as already mentioned above, the term 'documented information' replaces and generalizes the terms "document" and "record" as used in the text of ISO 9001:2008. If the previous version of the standard strictly define the cases in which the organization shall develop a documented procedure, and shall maintain records, in the new version there are only requirements to maintain documented information. The organization decides itself whether this information will be in the form of documented procedures, manuals, records, or in some other form. This change significantly increases the flexibility of the organization to meet the requirements of the ISO 9001 related to the quality management system documentation in the most convenient and cost-effective way.

Organizational knowledge is new term and requirement, which is the result of the evolution of the personnel competence requirement stated in ISO 9001:2008. It implies determination, accumulation and control of knowledge obtained by the organization to ensure conformity to requirements of supplied products and provided services. Determination of knowledge media, such as personnel, computer databases, paper storage means, etc. and methods of their control is the right, choice and responsibility of the organization.

External provision is another generalization that takes into account all forms of obtaining products and services from

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external parties, such as purchasing from third-party suppliers, transferring by agreement with associates, outsourcing, etc.

An important aspect that is certainly of interest to all potential users of the standard ISO 9001:2015 is the possibility to make exclusions from the requirements of the standard. ISO 9001:2008 allowed making justified exclusions from the requirements of clause 7 of the text of the standard. The new version does not provide the possibility to make exclusions from the requirements, but it is recognized that there may be some adaptability justified in applying the requirements based on the size of the organization, organizational culture, activity, nature of the risks and opportunities faced by the organization. However, mentioned adaptability should not lead to an increased probability of failures in a sequential realization of the relevant products and providing services or to reduction of the organization's potential ability to meet customer requirements. In other words, if the requirement can be applied, it shall be applied, and if the requirement cannot be applied, for example, because a process is not carried out in the organization, the requirement does not apply. ISO 9001 revision will affect, of course, a number of international management system standards, for instance the industry standard in the automotive, aerospace, etc. In addition ISO / TC 176 is currently working actively on the revision of a number of related documents, such as ISO 9000 and ISO 9004. Now the guidance documents on process approach, risk management, documented information, etc. are under development. In general everything is doing to ensure the transition to the new version of ISO 9001 in the most easily and intuitive way.

The next steps on the way to ISO 9001:2015 revision are as follows:

- May 2014 – DIS ISO 9001:2014 – is already published and is available for comments and ballot;
- July 2015 – FDIS ISO 9001:2015;
- September 2015 – ISO 9001:2015.

Speaking about the certification process the International Accreditation Forum has approved three-year transition period for the new version of ISO 9001, which will take place from September 2015 to September 2018. IAF welcomes and encourages preliminary readiness reviews of organizations after the publication of the Draft International Standard (DIS) from May 2014.

To summarize we can say that now enormous efforts to enhance the usefulness of ISO 9001 standard for all its users are undertaken. Great efforts are made to ensure the simplest transition to the new version of the standard. ISO 9001:2015 release should allow to make management system of our organizations more effective that will contribute to strengthen the economy and make this world a little better.

New Training Course Introduced

SADCAS has introduced a 5-day course 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* associated with any results.
- 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

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

Xavier Mugari Joins SADCAS



Mr Xavier Mugari has been appointed SADCAS Lead Assessor and joined SADCAS in November 2014. He is a holder of Bachelor of Medical Laboratory Sciences Honours Degree from University of Zimbabwe. Mr Mugari has studied Total Quality Management with University of South Africa and holds certificates in Internal Auditing and Quality Management Systems based on ISO/IEC 17025 and ISO 15189 from SANAS and SADCAS. He underwent assessor training in 2009 under the SADC EU EDF 9 programme and subsequently went through further mentoring under the assessor training/mentoring programme sponsored by PTB Germany. Mr Mugari brings with him a wealth technical expertise and experience in managing laboratory systems.

Prior to joining SADCAS Mr Mugari was Head of Clinical Biochemistry department and Deputy Quality Manager at Diagnostifirm Medical Laboratories, positions he held for 7 years. Diagnostifirm Laboratories are based in Gaborone, Botswana.

In his capacity as Lead Assessor Mr Mugari will be responsible for planning and conducting assessments based on ISO 15189 standard and SADCAS requirements and contributing to the application of the SADCAS Strategic and Annual Implementation Plans.

Mr Mugari is married to Vongai and they have two children. SADCAS welcomes Mr Mugari to a hardworking and dedicated team of staff.

NAFP Appointments



The Malawi Ministry of Industry & Trade appointed Mrs Margret Sauzande as the 2nd National Accreditation Focal Point (NAFP) for Malawi. Mrs Sauzande holds an MBA Business Administration degree and is the Assistant Director of Industry at the Ministry. She replaces Mr Lusungu Mwaungulu and will assist Mr Patrician Kondowe, the 1st NAFP to progress accreditation activities in Malawi.



The Department of Industrial Affairs under the Ministry of Trade and Industry appointed Ms Gofaone Nono Mokalake as the 2nd NAFP for Botswana. Ms Mokalake holds a Bachelor of Arts degree in Social Sciences (Economics and Psychology) and is the Assistant Industrial Officer. She replaces Ms Boikhutso Pheto and will assist Mr Edward Mmatli the 1st NAFP to progress the accreditation activities in Botswana.



NOTICE

Christmas and New Year Holidays!!

SADCAS offices will be closed from Monday, 22 December 2014 and re-opens on Monday, 12 January 2015

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## SADCAS Training Courses

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](mailto:info@sadcas.org)



## Status of Key Accreditation Standards and IAF/ILAC Documents

| STANDARD                                                                                                                                                                                                                                            | STATUS                                                                    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| <b>ISO/IEC 17000:2004</b> —Conformity assessment – Vocabulary and general principles                                                                                                                                                                | Close of review                                                           |
| <b>ISO/IEC 17011:2004</b> —Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies                                                                                                           | International standard to be revised                                      |
| <b>ISO/IEC DIS 17021-1</b> —Conformity Assessment – Requirements for bodies providing audit and certification of management systems - Part 1: Requirements                                                                                          | Close of voting                                                           |
| <b>ISO/IEC DTS 17021-6</b> —Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 6: Competence requirements for auditing and certification of business continuity management systems      | International standard at publication stage                               |
| <b>ISO/IEC 17021-7:2014</b> —Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 7: Competence requirements for auditing and certification of RTS/road traffic safety management systems | International standard published on 2014-10-15                            |
| <b>ISO/IEC 17025:2005</b> —General requirements for the competence of testing and calibration laboratories                                                                                                                                          | International standard to be revised                                      |
| <b>ISO/IEC DTR 17026</b> —Conformity assessment – Guidance on a third party certification system for products                                                                                                                                       | Committee Draft approved                                                  |
| <b>ISO/IEC 17030:2003</b> —Conformity assessment - General requirements for third party marks of conformity                                                                                                                                         | Close of review                                                           |
| <b>ISO/CD 17034</b> —General requirements for the competence of Reference Materials Producers                                                                                                                                                       | Committee Draft approved for registration as Draft International Standard |
| <b>ISO/IEC 17040:2005</b> —Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies                                                                                                | Close of review                                                           |
| <b>ISO/IEC 17050-1:2004</b> —Supplier’s declaration of conformity – Part 1 General requirements                                                                                                                                                     | Close of review                                                           |
| <b>ISO/IEC 17050-2:2004</b> —Supplier’s declaration of conformity – Part 2 Supporting Documentation                                                                                                                                                 | Close of review                                                           |

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| STANDARD                                                                                                                                                                                      | STATUS                                                                                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>ISO/IEC 17050-2: 2004</b> —Supplier's declaration of conformity – Part 2 Supporting Documentation                                                                                          | Close of review                                                                                                                                                                                                                              |
| <b>ISO/CD 18322 – 2</b> — <b>Space</b> systems – Accreditation of space test centers and laboratories - Part 2 General quality and safety requirements                                        | Committee Draft approved for registration as Draft International Standard                                                                                                                                                                    |
| <b>ISO/TS 22475-3:2007</b> —Geotechnical investigation and testing – Sampling methods and groundwater measurements - Part 3 Conformity assessment of enterprises and personnel by third party | Close of review                                                                                                                                                                                                                              |
| <b>ISO/IEC CD 27009</b> —The use and application of ISO/IEC 27001 for 27001 for sector/service – Specific third party accreditation certification                                             | Close of voting / Comment period                                                                                                                                                                                                             |
| <b>ISO 13528:2005</b> —Statistical methods for proficiency testing by inter laboratory comparisons                                                                                            | International standard to be revised                                                                                                                                                                                                         |
| <b>ISO/IEC 27006:2011</b> —Information Technology – Security Techniques – Requirements for bodies providing audit and certification of information security management systems                | International standard to be revised                                                                                                                                                                                                         |
| <b>ISO Guide 27:1983</b> —Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity                                               | Close of review                                                                                                                                                                                                                              |
| <b>ISO/IEC Guide 28:2004</b> —Guidance on a third-party certification system of products                                                                                                      | International guide to be revised                                                                                                                                                                                                            |
| <b>ISO/IEC Guide 53:2005</b> —Conformity assessment – Guidance on the use of an organization's quality management system in product certification                                             | International guide to be revised                                                                                                                                                                                                            |
| <b>ILAC G19:08/2014</b> — Modules in a forensic science process                                                                                                                               | Document published in August 2014. This document is intended to provide guidance for forensic science units involved in examination and testing in the forensic science process by providing application of ISO/IEC 17025 and ISO/IEC 17020. |
| <b>IAF PL 7:2014</b> — IAF Quality Manual                                                                                                                                                     | Issue 2 published on 9 July 2014<br>Application from 9 June 2014<br>Describes the management system established to ensure the effective implementation of the Mission, policies and objectives of the International Accreditation Forum      |

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| STANDARD                                                                                                                                                 | STATUS                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>IAF ID 08:2014</b> Informative document for the transition of food safety management system accreditation to ISO/TS 22003:2013 from ISO/TS 22003:2003 | Issue 1 published on 9 August 2014<br>Application from 15 December 2016<br>Informative document to facilitate the transition from ISO/TS 22003:2013 to ISO/TS 22003:2013                                                                                                                                                                                                                                                  |
| <b>IAF MD 16:2014</b> Application of ISO/IEC 17011 for the accreditation of Food Safety Management Systems (FSMS) certification bodies                   | Issue 1 published on 8 October 2014<br>This document specifies normative criteria for Accreditation Bodies assessing and accrediting CABs which provide audit and certification of FSMS, in addition to the requirements contained in ISO/IEC 17011. It is also appropriate as a requirements document for the peer evaluation process for the IAF Multilateral Recognition Arrangement (MLA) among Accreditation Bodies. |
| <b>IAF PRA: 2014</b> Structure of the IAF MLA and endorsed Normative documents                                                                           | Issue 6, 13 November 2014<br>Application from 13 November 2014 with updated endorsed documents.<br>This document describes the structure of IAF MLA and publishes the list of IAF endorsed documents including international standards, as required by IAF PR2.                                                                                                                                                           |

## 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](mailto:jfranorovelo@sadcas.org); [info@sadcas.org](mailto:info@sadcas.org)

## Diary of Upcoming Events

| DATES                          | MEETINGS                                                                                                                                | VENUE                                  |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| 27 November 2014               | SADCAS HRRC Meeting                                                                                                                     | Pretoria, South Africa                 |
| 27 November 2014               | SADCAS FRAC Meeting                                                                                                                     | Pretoria, South Africa                 |
| 27 November 2014               | SADCAS Board of Directors                                                                                                               | Pretoria, South Africa                 |
| 28 to 29 November 2014         | SLMTA/SLIPTA Symposium                                                                                                                  | Cape Town, South Africa                |
| 30 November to 4 December 2014 | ASLM Conference                                                                                                                         | Cape Town, South Africa                |
| 2 – 5 December 2014            | ARSO – African Harmonization Meeting for THC, African Traditional Medicine                                                              | Nairobi, Kenya                         |
| 1-9 December 2014              | 33 <sup>rd</sup> COMESA Policy Organs Meeting : Administrative & Budget Committee; Intergovernmental Committee and Council of Ministers | Lusaka, Zambia                         |
| 29 January 2015                | SADCAS Budget meeting                                                                                                                   | Gaborone, Botswana                     |
| 9 February 2015                | SADCAS FRAC Meeting                                                                                                                     | Gaborone, Botswana                     |
| 19 February 2015               | SADCAS HRRC Meeting                                                                                                                     | Pretoria, South Africa                 |
| 19 February 2015               | SADCAS Board of Directors                                                                                                               | Pretoria, South Africa                 |
| 25 – 27 February 2015          | NAFP Training on Marketing & Communications                                                                                             | Gaborone, Botswana                     |
| 27 February 2015               | NAFP Annual Meeting                                                                                                                     | Gaborone, Botswana                     |
| 16 to 20 March 2015            | SADC SQAM Meeting                                                                                                                       | Kinshasa, Democratic Republic of Congo |
| March 2015                     | SADCAS Board Meeting                                                                                                                    | Kinshasa, Democratic Republic of Congo |
| March 2015                     | SADCAS Annual General Meeting                                                                                                           | Kinshasa, Democratic Republic of Congo |
| March 2015                     | SADCA EXCO Meeting                                                                                                                      | Kinshasa, Democratic Republic of Congo |





**SADCAS Management and Staff  
would like to wish you a  
a Merry Christmas and  
a Happy New Year!!**

**PUBLISHED BY:**

**SADCAS**

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