



## NATIONAL LABORATORY ASSOCIATION OF ZIMBABWE

### Awareness Seminar on ISO 15189: 2007 Medical Laboratories – Particular requirements for Quality and Competence held at SAZ Head Office on the 14<sup>th</sup> of May 2009.

#### Present:

For the participant's list see Appendix 1

#### 1. Registration

The registration desk was manned by Mrs. Julia Brebner and Mrs. Cabinet Musuna who were responsible for the registration of participants and providing them with the necessary materials such as the programme and presentation handouts.

#### 2. Welcome

Mr. Petros Ndanga the Secretary of NLAZ gave the welcoming address and allowed each participant present to introduce themselves. Each participant stated their expectations from the seminar and the following points were noted:

- To improve understanding on ISO 15189 and the benefits of implementing it in a Medical Laboratory.
- To gain understanding on ISO standards.
- To learn the approach to take on the journey to Accreditation.
- To increase knowledge on Quality Management Systems.

#### 3. Key Note Address

Mrs. Eve Gadzikwa, the Director General of the SAZ and Immediate Past President of NLAZ gave the key note address. She gave a brief background on NLAZ operations and of interest noted that NLAZ is an umbrella representative body for all laboratory practitioners in Zimbabwe. Some of the objectives of NLAZ highlighted were to:

- Provide a forum which represents the local laboratories in National and International affairs of concern.
- Contribute to the growth of the Zimbabwean economy.
- Magnify the voice of laboratories in communication with suppliers.
- Foster cooperation and resource sharing amongst laboratories.
- Provide a forum to exchange information.

All participants were urged to become members of NLAZ in order to improve the quality standards in their respective workplaces. She reiterated the fact that joining fees are reasonably affordable. The presentation also highlighted the NLAZ Constitution, Code of ethics, Classification of Members in NLAZ and the Structure of Council. NLAZ aims to train staff and members in workshops and seminars, transfer technology and promote regional integration. NLAZ key result areas include the identification of training needs of members, fostering partnerships with NLA, ESALAMA, SADC and addressing key laboratory concerns.

Mrs. Gadzikwa talked on conformity assessment and benefits of accreditation. She stressed that Accreditation is process which provides recognition for technical competence of a conformity assessment body or laboratory by a third party and is necessary to give confidence to users of these services. It eliminates the need for retesting. At the end of her presentation she informed participants that SAZSISO 15189 and other standard documents could be obtained from the SAZ at the Standards Information and Development Division. Her concluding note highlighted the reason why Medical Laboratories should go for ISO 15189. **Please see attached full presentation.**

#### 4. Tea break

Tea break was at 0950 and during tea the participants were urged to visit the exhibitions by Isocal Calibration Laboratories and Multi-Manufacturers. A group photograph was taken (see attached).

#### 5. Accreditation

Mr Christopher Ngwenya and Mrs Machiri, the National Accreditation Focal Point (NAFP) and who act as the satellite for Southern African Development Community Accreditation Service (SADCAS) in Zimbabwe were the present and delivered a brief presentation on Accreditation. NAFP facilitate training for laboratory and other organizations in conjunction with SADCAS as well as facilitating trade and development. NAFP is still building a data base of its clients. It was reiterate by participants that, as different professional Associations are resuscitated in Zimbabwe due to positive economic changes; NLAZ should work hand in hand with NAFP to produce a relevant data base for members interested in Accreditation. Mr. Ngwenya invited all participants to submit their application for the upcoming

technical assessors' courses on time for the PE2 training course to be held in the second half of the year which will be held in Gaborone, Botswana. Mrs Machiri shared the contact details with the participants

#### Contact details

- [fbkarani@mweb.co.zw](mailto:fbkarani@mweb.co.zw)
- [chnqwenya@yahoo.com](mailto:chnqwenya@yahoo.com)
- [trademeasureszim@yahoo.com](mailto:trademeasureszim@yahoo.com)

#### 6. Isocal Laboratories

Mr. Z. Mafaiti of Isocal Laboratories gave a presentation on "Choosing the right calibration provider". Calibration was noted to be of great relevance and importance within the testing laboratories so as to produce satisfactory results. Some of the consequences of not calibrating equipment especially in medical laboratories include: Death of patients, wrong diagnosis, and inefficiency, loss of time and loss in financial value. When choosing a calibration service provider one should consider the accreditation status, traceability of standards, calibration laboratory facilities and the calibration competence of the personnel. Courses offered by Isocal which assist in the Accreditation process, include:

1. Setting up an internal calibration system.
2. Good measurement practice
3. Equipment management software such as *Cal-Assist-Version 2* which logs in all equipment and notes instrument history and maintains a data base on it. **Please see attached full presentation.**

#### Contact details

- [consolte@mweb.co.zw](mailto:consolte@mweb.co.zw)
- Telephone no. (04)774415

#### 7. Multi-Manufacturers

Mr. Samuel Alferi of Multi-Manufacturers, a company which produces cleaning products for many industries, delivered a presentation on their products and services. The fully Zimbabwean owned company was established in 1983 and its headquarters are in Msasa.

Their cleaning products are used widely in laboratories, abattoirs and laundry houses. Multi Manufacturers has taken it upon themselves to educate the people on proper usage of their products as an after-sales service. Five of their cleaning products are under the SAZ mark and others are in the process of being tested.

#### Contact details

- [multi@zol.co.zw](mailto:multi@zol.co.zw) or [multiman@ecoweb.co.zw](mailto:multiman@ecoweb.co.zw)
- Telephone no. (04) 487064/5

#### 8. Why seek Accreditation to ISO 15189?

The guest speaker Mrs. Junior Mutsvangwa, who is the head of Laboratories at Biomedical Research and Training Institute (BRTI), gave a presentation entitled "*Why seek Accreditation to ISO 15189?*" Statistics show that there are 8 Accredited laboratories in Zimbabwe, but not a single one of them is a Medical Laboratory. She stressed the importance of having ISO 15189 for all Medical laboratories as it is specific for Medical testing laboratories and elaborates the phases of medical laboratory practices i.e. collection of samples, testing of samples, issuing of results, data management and archiving of samples thereof. All medical labs were encouraged to work towards accreditation so as to improve the health delivery system and be prepared for the opportunities arising from the 2010 World Cup in South Africa. Mrs. Mutsvangwa spoke at length on the benefits of Accreditation, such as the reduction in costs, the improvement in productivity, communications and efficiency and the contributions to economic growth. Her presentation touched on the benefits of Accreditation to BRTI such as the improvements in document location and traceability. Her closing remark was that there is certainly more to gain if accredited than if not. **Please see attached full presentation.**

#### 9. ISO 15189 Awareness Seminar

Rae Ries from the Corporate Quality System gave a presentation on the ISO 15189: 2007 Medical Laboratories – Particular requirements for Quality and Competence. The presentation had touched on major issues such as the role of the laboratory, quality management concepts, the content and benefits of each clause in the standard, accreditation versus certification, benefits of documenting and implementing a Quality Management System (QMS).



Director General of the SAZ Eve Christine Gadzikwa (centre front) standing with ISO 15189 Awareness Seminar participants

### 10. The Approach to Accreditation

The Vice President of NLAZ Mrs. Wedzerai Makaya gave a brief but detailed presentation on “*The Approach to Accreditation*”. Of interest, she noted that the development and implementation of a QMS requires the input of all members of an organization, including the Management and should be looked at as a project, which has a specific budget assigned to it. The role of the Management is to appoint management representatives, allocate resources and to define quality policies and objectives. She also talked about the 5 Phase Approach used in attaining accreditation, which includes; training executive management, training project team, having system documentation, implementing it and then applying for accreditation. In conclusion she said that Attaining accreditation increases your chances of “Getting it right- First time- All the time. **Please see attached full presentation.**”

### 11. Question and Answer

During the course of the seminar various questions were asked and answered and the main ones are as follows:

**1. Does NLAZ represent testing laboratories only? What of research laboratories?**

*NLAZ caters for all sectors including Mining, Agriculture, Medical, Industrial, Regulatory testing/calibration, Tertiary and Research Institute laboratories.*

**2. How does NLAZ relate to all the associations within the economy?**

*NLAZ has a stable structure and represents any body interested but cannot fully address the problems of all associations. Sector specific problems should be addressed at Association level, e.g. Medical Laboratory Associations have a role to play and should cater for problems in medical laboratories. Health Professions Authority should become involved with NLAZ and get an understanding of the quality standards and the benefits of being a part of the Association. Together we can achieve more!*

**3. What kinds of initiatives are available from NLAZ to meet the needs of the mining industry?**

*There is a mining sector representative on the Council who will be responsible for liaising with the mining sector when the mines begin operations as most of them are currently non-operational. The role of the sector representative is to lobby and communicate with members of their sector. At present there is no sector representative for Mining and for the Medical Sector so we are appealing for your active participation in these sectors..*

### 12. Certificate presentation

At the end of the seminar, Certificates were presented to all participants by Wedzerai Makaya, Rae Ries and Eve Gadzikwa.

### 13. Vote of thanks

Petros Ndanga gave the closing remarks and expressed his gratitude to all members of the medical laboratory fraternity who attended the ISO 15189 Awareness seminar. All medical laboratory personnel were encouraged to become a part of NLAZ and work towards achieving accreditation even through economic hardships and challenges. Each participant was urged to take the responsibility of introducing QMS into their organizations, improving and maintaining them.

A special thank you to:

- SAZ for providing the venue free of charge.
- National Focal Point members for their presentations
- Rae Ries of Corporate Quality Systems for providing the awareness presentation free of charge.

#### **14. Lunch**

The seminar ended at 1320 and all participants went for lunch.

**Minutes prepared by:** Ms Vimbai Mukondiwa

**Minutes approved by:** Mrs Eve Gadzikwa