



ETHIOPIAN NATIONAL ACCREDITATION OFFICE

Dec/ 2021



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ETHIOPIAN NATIONAL ACCREDITATION OFFICE



Magazine Production

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Araya Fesseha
Director General of ENAO

As the General Director of Ethiopian National Accreditation Office it gives me a great pleasure to convey a message on the office 10 years Journey from 2011 to 2021. In Ethiopia, accreditation, standard, metrology and conformity assessments are well structured and coming operational since 2011 that suits to the international practice used as an acceptable quality tools which enables to establish and maintain a safer nation in particular and harmless world in general.

This can be realized when the stipulated standard requirements or code of practices or regulatory requirements of raw materials, semi and finished products, services and personal competences have been checked for the compliance by ENAO accredited conformity assessment bodies for their safe for use by the users. Because ENAO is the independent

evaluator of the conformity assessment bodies against recognized standards to carry out specific activities to ensure their integrity, impartiality and competence in that particular accredited scope in principle and the lesson from experience of develop economic showed us government and regulatory bodies should work to ensure the businesses are providing safe working environment because government set policies and regulatory bodies develop and control the implementation of technical requirement for product and service placed in the market that enables to rely on accreditation conformity assessment bodies which verify the compliance of the stipulated requirements of product and services to ensure safety and health of the users.

For the last ten years ENAO provided accreditation service in testing laboratory (ISO/IEC

17025) 32 facilities in 36 scopes of accreditation, 50 medical laboratories (ISO 15189) in 84 scopes, 9 inspection bodies (ISO/IEC 17020) in 11 scopes and also one certification body was accredited in system certification according to ISO/IEC 17021-1.

Within the last ten years ENAO deserving the full membership on African Accreditation Cooperation and at International Laboratory Accreditation Cooperation (ILAC). ENAO has also developed the necessary documents that enable to provide an accreditation service on management system, product certification and certification for person.

With regard to creating accreditation market ENAO conducted awareness all over the country in different accreditation themes.



MESSAGE

FROM THE DIRECTOR GENERAL

If the Ethiopian government and regulators properly promote and insist conformity assessment bodies to utilize the Ethiopian National Accreditation Office service, then investors will be highly encouraged and motivated to invest in our country because the requirement of products and service will be verified by accredited conformity assessment bodies which ultimately creates consistence and similar supply of agricultural products for agro processing; Industry products can also timely deliver products to the market because of the close distance and relatively cheap and globally acceptable accredited conformity assessment service that avoids the rework of conformity assessment by the recipient country. This condition helps to attract investment and ultimately creates employment opportunity that benefits youths in getting job and hinders dream of illegal immigration which is the most unsafe to human.

ENAO is also working by giving

priority attention to the scopes that supports the AfCFTA on the economic sectors like manufacturing, communication, Agro processing, mining, pharmaceuticals and traded products and services and to be effective and competitive in the African Continent Free trade Area, AfCFTA it needs to work jointly with other relevant actors on the value chain of Ethiopian exported products.

As Ethiopians, we need to work hard on the selective and economically viable value chains of agricultural products stretching from agriculture to fork that starts from soil characterization that enables us to know the deficiency and to build the require formulation of fertilizer which the soil required, to use optimum herbicide and pesticide for the acceptable residual characters expected to remain on the product, develop and implement requirements for safe transportation and storage of agricultural products to avoid biohazard contamination

within the products. Therefore, it is essential to apply those stated on the above and other unstated processes which support to ensure the sustainable quality supply chain for agro processing industries.

In the manufacturing industry we also need to gear the small with medium and medium with large enterprises along the value chain using quality infrastructure units across the value chain unless we cannot transform our economy by exporting the natural resources without value addition.

Finally, ENAO is working on the human capital development by providing training on the standard requirements and audit principles on ISO/IEC 17025: 2017, ISO/IEC 17020:2012, ISO/IEC 17021-1:2015 including sub- scopes (ISO 9001, ISO 14001,45001,27001, etc.) ISO/IEC 17065: 2012, ISO/IEC 17067: 2013, ISO/IEC 17024:2012, ISO 15189 and on the upcoming accreditation standards



QUALITY INFRASTRUCTURE

What "Quality" means

"Quality" means ensuring that products and services meet the requirements of the customers. And also quality is the degree of excellence and its conformance to specifications and requirements. However, for a manufactured product, the consumer as a user recognizes its quality in relation to its fitness for purpose (appearance, function, performance, etc.). The quality of service may be rated based on the degree of satisfaction by the customer receiving the service. All of these have shown the concern that there must be a standard scientific more universal definition of quality.

To this effect, the international organization for standardization (ISO), adopted, based on international consensus, the most popular and complete definition is stated as "Quality is the degree to which the innate characteristics of a product, process, or person fulfill stated and unstated customer requirements and expectations; with stated norms, regulations, and laws; or both."

An organization focused on quality promotes a culture that results in the behavior, attitudes, activities and processes that deliver value through fulfilling the needs and expectations of customers and other relevant interested parties.

The quality of an organization's products and services is determined by the ability to satisfy customers and the intended and unintended impact on relevant interested parties.

The quality of products and services includes not only their intended function and performance, but also their perceived value and benefit to the customer.

Another way of understanding, quality is that products and services should be fit for the purpose for which they are intended. For example, expensive leather shoes can be regarded as luxury products, but failing to meet the quality requirements of a farmer who really needs a pair of much less expensive rubber boots fit for his purpose of working in muddy fields.

This understanding of quality as being fit for purpose and meeting customer requirements allows a QIS to be used for producing effective results in meeting a broad range of challenges, in addition to product or service quality. Examples of particular interest to developing countries are food safety, health, the environment, tackling climate change, social responsibility and gender issues.

What is Quality Infrastructure?

International Network on Quality Infrastructure (INETQI) have adopted quality infrastructure definition as the system comprising the organizations (public and private) together with policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety, and environmental soundness of goods, services and processes.

The Quality infrastructure is required for the effective operation of the domestic markets, and its international recognition is important to enable access to foreign markets. It is critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. It relies on metrology, standardization, accreditation, conformity assessment and market surveillance.

In this ever changing world the issue of Quality Infrastructure has become the prime agenda of every government and every private firm for that matter it has got global acceptance. There are several factors that push the world to integrate Quality infrastructure in their system. The first and the most important factor is enhancing market access, facilitating product diversification and increase investment opportunities.

What is more, having Quality Infrastructure reduces cost of trade by avoiding duplication in testing and inspection, streamlining operations and eliminating restrictive regulations. Enhancing innovation and technological diffusion is the other significant part of Quality Infrastructure.

National Quality Infrastructure (NQI)

Now-a-days it has become the most imperative to give careful attention to raising the level of competitiveness and market acceptance of products and services originating from a country. This

depends on an NQI which is built on credible system comprising of accurate measurements based on internationally recognized measurement capabilities, standards that reflect international consensus as far as possible, accredited testing laboratories, inspection and certification establishments that are based on international standards and efficient technical regulatory framework based on good regulatory practice. The term 'national quality infrastructure' (NQI) denotes the complete public and private institutional framework required to establish and implement standardization, technical regulation, metrology, conformity assessment and accreditation, needed to ensure quality improvement and its outcomes.

Because it is a multi-stakeholder system a National quality infrastructure (NQI) is, therefore, defined as "the totality of the institutional framework (public or private) required to establish and implement standardization, metrology (scientific, industrial and legal), accreditation and conformity assessment services that products and services meet defined requirements, be they demanded by authorities (technical regulation) or the market place (contractual or inferred).

The concept of NQI is a recent development as nation-

al infrastructure and it is a special kind of infrastructure which is dedicated for a national benefit and used country-wide to ensure the competitiveness of goods and services of the country in the global market by helping to underpin its effort to establish internationally recognized, reliable and sustainable quality assurance system through strengthening quality related services and legal information. This requires collective responsibility in order to archive the quality objective of the country and it is the result of the strong coordination of the players and creates the synergy for integrated series of activities of both the technical and administrative governance of the system.

Based on the economy of a country, regional and international situation, as well as current needs of the public and private sectors, the overall system of NQI is to be established around a core made up of the National Standard Body (NSB); National Metrology Institute (NMI); National Accreditation Body (NAB); Conformity Assessment Service providers and market surveillance, while its holistic coordination management and responsibility for handling its oversight function is given to one lead implementation authority legally appointed.

Elements of National Quality Infrastructure

The core elements of NQI are Standards, Metrology, Conformity assessment and Accreditation that falls under the technical wing of the overall infrastructure system. These are closely interrelated and cannot be reliably implemented without all of them being actively working together, integrated, and internationally recognized.

Standards

One of the elements of the NQI is standard. It is document developed based on consensus and approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of optimum degree of order in a given context. For the purpose of the TBT agreement, standards are defined as voluntary and technical regulations are defined as mandatory. The standard can be applied by a manufacture or supplier or by a user or by an independent body. As our world change, new standards are introduced to reflect the latest technologies, innovations and community needs.

Metrology

Metrology is the technology or science of measurements and the service is required



to ensure internationally recognized traceability of measurements and calibration of measuring instruments. It is the earliest among the NQI elements. There are three types of metrologies. Such as scientific, industrial and legal metrology. Scientific metrology is defining of internationally accepted units of measurement and realiza-

tion of units of measurement by scientific methods. Industrial metrology involved in calibration of measuring instruments. Legal metrology which involves in verification of measuring instrument. it is part of technical regulation, service implements on areas trade, health, environment and safety.

Conformity Assessment

Conformity assessment bodies means a body that performs conformity assessment activities testing, inspecting, certifying product, process and services, certification for person, management system certification to the objective of accreditation. It can be government or private.

Testing: -Testing means determination of one or more characteristics of an object of conformity assessment, according to a procedure. There are different types of testing: veterinary, chemical, biological, forensic, non-destructive, mechanical, material and physical, environment, optics radiometry & radiation, construction material, electrical, fuel, etc

Medical Testing also includes: biological, microbiological, immunological, chemical, immunohaematological, haematological, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings



Calibration

Physical measurement and comparison against known standards traceable to national and international standards.

Inspection

Examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professional judgment, with general requirements. It includes agricultural product inspection, pharmaceutical products inspection, con-

struction inspection, cargo inspection, labor inspection, warehouse & cleaning plant safety inspection, textile end-Products inspection, abattoir inspection, pressure equipment inspection, mechanical equipment inspection, lift and escalator inspection, vehicle inspection, etc

Certification

Third-party attestation related to an object of conformity assessment, with the exception of accreditation and it is a procedure by which a third party gives written as-

surance that a product, process or service conforms to specific requirements." Engaged in: product certification, management system and person certification. Product certification bodies (ISO/IEC 17065) it is the most visible form of certification, as so many products carry the various marks of conformity issued by product certification bodies.

Management system certification (ISO/IEC 17021): accreditation of management system is assessed against (ISO/IEC 17021). The certi-



fication body provided management system certification to sub scope quality management system (ISO 9001), environment management system (ISO 14001), energy management system (ISO 50001), information security management system (ISO /IEC 27001), food safety management system (ISO 22000), etc.

Personal certification bodies (ISO/IEC 17024): accreditation of personnel certification bodies are assessed against (ISO/IEC 17024) –general requirement for bodies operating certification of persons.

The certification bodies include Occupational Competency Assessment Certification Center, like medical persons, engineers, civil servant, welders, etc.

Accreditation

Third-party attestation related to an object of conformity assessment, with the exception of accreditation and it is also an activity carried out for providing independent attestation as to the competency of organizations providing conformity assessment services,

there by facilitating international recognition of claims of conformity. Accreditation is third party attestation related to a conformity assessment body Conveying formal demonstration of its competency to carry out specify conformity assessment tasks. It is carried out based on international standards and by an independent third party competent to perform the duty. It is means of building confidence in the work and the findings of testing and calibration laboratories and of inspection and certification bodies.

Quality Infrastructure in Ethiopia

In Ethiopia, the functions of standardization, metrology, inspection, testing and certification were used to be operated by the same organization, namely the Quality and Standards Authority of Ethiopia (QSAE). QSAE was also responsible for the administration of mandatory standards on behalf of other regulatory institutions such as Ministry of Trade etc. Despite commitment and initiation to play a meaningful role in enhancing exports of Ethiopian industry, the NQI was not developed in a way that enables local business meet the requirements for the international market.

Studies have confirmed that the absence of an effective and internationally recognized NQI had not only limited Ethiopia's share in the export market, but had also indirectly exporters to additional transaction costs such as inspection and testing by recipient countries. Hence, this has led to the approval of the national quality infrastructure of Ethiopian since February 2009.

With the newly approved Ethiopian National quality infrastructure strategy comprising four organizations / institutions namely:

- Ethiopian Standards Agency;
- National Metrology Institute of Ethiopia;
- Ethiopian Conformity Assessment Enterprise and
- Ethiopian National Accreditation Office.

● Ethiopian Standards Agency/ESA/

Ethiopian Standards Agency was established as Ethiopia's National standards body (NSB) in February 2010 by council of Ministers regulation No.193/2010.

Ethiopian Standards Agency has many powers and duties. Such as develop implement and follow up standardization strategy for the purpose of quality promotion activities which are in line with the country's developmental programs and develop, through stakeholders' involvement, approve and publicize Ethiopian standards.

Moreover, recognize any standard published by a national, regional, international or any other standardization body as Ethiopian standard, as may be relevant.

- Determine the shape and content of the national standard mark and authorize its use
- Establish national enquiry point and deliver services on standardization, conformity assessments and technical regulations;
- Developed and implement awareness creation strategies for consumers on quality and standards;
- Enable domestic industries to benefit from technology transfers through providing technical support, training and consultancy services in the implementation of standards;
- Build the capability of companies through technical support, training and consultancy service for developing their own company standards;
- Promote the use of technologies, and the industries, which help to reduce pollution and



wastage during production process;

- Work in collaboration with the concerned national and international institutions to ensure that technical regulations are developed in line with world trade legal requirements are the ESA duties and powers.

ESA safeguards Ethiopia's interest in international standardization when new standards developed and the existing are revised through the participation in technical committees, especially in the fields of agriculture and food. ESA is a member of the International Organization for Standardization (ISO), and Codex Alimentarius Commission (CAC). It is also a founding member of the African Regional Organization for Standardization (ARSO), and has close relations with the International Electrotechnical Commission (IEC). Using its mandate ESA strives to develop Ethiopian Standards and establish a system that enable to check whether goods and services are in compliance with the required standards. What is more using all the available resource ESA strives to make Ethiopian goods competitive in the international markets.

National Metrology Institute of Ethiopia/ NMIE/

The NMIE is established as an autonomous federal government office having its own legal personality in accordance with the National Metrology Institute Establishment council of Ministries Regulations No. 194/2010. Its accountability shifts to Ministry of Trade and Industry as of 2018. The Government of Ethiopia has authorized NMIE as the custodian of National Measurement standards for the base units (Length, Mass, Temperature etc.) and some derived measurement quantities of the system international (SI). It provides support to the testing, inspection and certification activities of Ethiopian Conformity Assessment services, to industry, universities, research institutes, service giving organizations and others within the country. NMIE also supports education and research activities in the field of metrology. It builds national capability for maintenance of scientific instruments and provides maintenance services. It provides technical, training consultancy and information services on scientific equipment with a view to supporting users to carry out their duties effectively

Ethiopia Conformity Assessment Enterprise/ ECAE/

ECAE is established in February 2011 as federal owned public enterprise governed by the ministry of trade and industry. ECAE is the major conformity Assessment body providing testing, inspection and certification services and operating in more than 8 branch offices throughout the country third-party attestation related to an object of conformity assessment, with the exception of accreditation. However, it is important to note that conformity assessment service is open to all private and government bodies hence, ECAE is one out of many conformity assessment bodies operating in Ethiopia.

ECAE mission is to provide internationally accepted and recognized laboratory testing, inspection and certification services for exporters, producers, service providers, efficient credible and accessible manner to ensure the availability of quality products and services.

The major services provided by ECAE include:

Laboratory Testing:- is determination of products or services quality features by means of physical & chemical testing to check it complies or performs in accordance with the specified requirements.

Inspection:- is checking of products design, products services and manufacturing processes to ensure their conformity with specific requirement.

Certification:- is a third party license given for a product, service system and persons after proving their conformance with the specified requirements.

Ethiopian National Accreditation Office/



ENAO was first established by the council of minister's regulation No. 195/2010. The government of Ethiopia has authorized ENAO as the sole National Accreditation body to offer accreditation services. It operates as an autonomous body under Ministry of Trade and Industry, government of Ethiopia. The mandate of ENAO is to accredit, by formal third party recognition, the competence of conformity assessment bodies (CABs) to perform specific activities.

The office shall have the power and duties to Act as sole independent body to provide accreditation service to conformity assessment bodies based on national and international standards and requirements and Promote accreditation by providing training on accreditation standards, assessment techniques and related requirements in an internationally acceptable manner. Moreover, Issue rules on how to use National Accreditation symbol and ensure its implementation, promote and protect other legally granted regional and international umbrella organization symbols in an internationally acceptable way and Promote and encourage conformity assessment bodies to obtain accreditation service are

powers and duties of ENAO.

In addition, promote the service it provides and create awareness to clients on the benefit of accreditation and Keep register and publicize the list of accredited bodies and those whose accreditation have been suspended and withdrawn, and notify same to the concerned regulatory bodies.

Issue and implement directive governing the accreditation process, in particular, the assessment of applicants and the granting suspending and withdrawing of accreditation, and handling of grievances relating thereto and Conduct planned and surprise surveillance visit to verify continuation of scope of competence of accredited conformity assessment bod-



National, Regional and International Quality Infrastructure Linkage

ies and fulfillment of mandatory requirements issued by the office are the duties. And also Conduct supervision to protect misuse of accreditation certificate, accreditation symbol including misrepresentation of data from an accreditation: and take administrative measure to rectify problems identifies: etc. is the powers and duties of ENAO's.

Regional National Quality Infrastructures

1. African Organization for Standardization (ARSO)

ARSO is a member of inter-governmental organization with the principal mandate to harmonize African standards; conformity assess-

ment and procedures in order to reduce technical barriers to trade and therefore, promote intra African and international trade as well as enhance the industrialization of Africa. ESA is founding and council member of ARSO and it also contributes to regional standards harmonization activities of the Common Market for Eastern and Southern Africa (COMESA) also an Affiliate plus member of IEC and participating member of the Codex Alimentarius Commission (CODEX).

2. African Accreditation Cooperation /AFRAC/

AFRAC was established to facilitate the use of accreditation as a tool to support trade and industrial development, improve competitiveness of African products

and enhance the protection of the health and safety of the public and the environment and also facilitate trading system and acceleration of economic growth within the continent, as it supports regional and international trade by promoting confidence and acceptance of results generated by accredited laboratories, inspection and certification bodies. The main function includes the following:-

- Fostering collaboration among accreditation bodies in Africa and facilitating collaboration between member States having accreditation bodies and those without;
- Assisting and supporting the establishment of national or multi-economy accreditation bodies in Africa with-

out compromising AFRAC's impartiality;

- Creation and maintenance of a system for the recognition of accreditation bodies in Africa within the framework of and consistent with global MRA/MLA international requirements;
- Coordination and facilitation of liaison with other regional and international organizations concerned with accreditation such as International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF), Inter American Accreditation Cooperation (IAAC), Asia Pacific Accreditation Cooperation (APAC), Arab Accreditation Cooperation (ARAC) and European Accreditation (EA);
- Representation of Africa in international accreditation and other quality infrastructure fora;
- Promotion and expansion of the recognition and acceptance of the MRA in Africa internationally in both the voluntary and regulatory areas; ;
- Development of and managing training and technical assistance programs for transferring expertise and technical information, sharing of information and activities identified to assist new or developing accreditation

programs, among present and potential members;

- Harmonisation of accreditation practices within Africa in compliance with international requirements;
- Establishment of an information system such as a database on accreditation bodies, Proficiency Testing (PT) schemes and qualified technical assessors, etc.; and
- Finding ways to reduce costs incurred by African accreditation bodies associated with obtaining and maintaining full membership to ILAC/ IAF, in particular pre-peer and peer evaluation processes.

3. Intra-Africa Metrology System /AFRIMETS/

The sub-regions and nations of Africa came together to establish an Intra-Africa Metrology System, Intra-Africa Metrology System /AFRIMETS/, with as main goal to harmonize accurate measurement in Africa, establish new measurement facilities and gain international acceptance for all measurements critical to export, environmental monitoring and sanitary and phyto-sanitary issues. ENMI from Ethiopia signed on as individual members.

4. African Electro Technical Standardization Commission /AFSEC/

AFSEC was established as a subsidiary body of the African Energy Commission (AFSEC), to promote for everything related to electro-technical standardization aiming to support electro-technical industrialization of Africa and its main function is to enhance Africa's development and competitiveness through excellence in electro-technical standardization. ESA is a statutory member of AFSEC.

5. Pan African Quality Infrastructure /PAQI/

Established by members comprising of, the African Accreditation Cooperation (AFRAC), the Intra-Africa Metrology System (AFRIMETS), the African Electro Technical Standardisation Commission (AFSEC) and the African Organisation for Standardisation (ARSO).

PAQI fits well in the strategy for the implementation of the Action Plan for the strategic framework for the establishment of the Continental Free Trade Area (CFTA) as is being fast tracked by the African Heads of State, as an efficient and value-adding institution driving the African integration and development process in close collaboration with African Union Commission.



International Quality Infrastructure

1. International Organization for Standardization /ISO/

ISO is an independent, non-governmental international organization with a membership of national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

2. Bureau International des Poids et Mesures / BIPM/

The intergovernmental organization through which Member States act together on matters related to measurement science and measurement standards

The unique role of the BIPM enables it to achieve its mission by developing the technical and organizational infrastructure of the International System of Units (SI) as

the basis for the world-wide traceability of measurement results. This is achieved both through technical activities in its laboratories and through international coordination.

Its objectives include to:

- Establish and maintain appropriate reference standards for use as the basis of a limited number of key international comparisons at the highest level.
- Coordinate international comparisons of national measurement standards through the Consultative

Committees of the CIPM; taking the role of coordinating laboratory for selected comparisons of the highest priority and undertaking the scientific work necessary to enable this to be done.

- Provide selected calibrations for Member States.
- Coordinate activities between the NMIs, such as through the CIPM MRA and to provide technical services to support them. To liaise as required with relevant inter-governmental organizations and other international bodies both directly and through joint committees.
- Organize scientific meetings to identify future developments in the world-wide measurement system required to meet existing and future measurement needs in industry, science and society.
- Inform, through publications and meetings, the science community, the wider scientific public and decision makers on matters related to metrology and its benefits.

Its mission is to work with the NMIs of the BIPM's Member States, the RMOs, and strategic partners world-wide, and to use international and impartial status to promote and advance the global comparability of measurements for: scientific discovery and innovation, industrial manufacturing and international trade

and improving the quality of life and sustaining the global environment.

3. International Electro Technical Commission /IEC/

Millions of devices that contain electronics, and use or produce electricity, rely on IEC International Standards and Conformity Assessment Systems to perform, fit and work safely together

is the world's leading organization for the preparation and publication of International Standards for all electrical, electronic and related technologies. These are known collectively as "electrotechnology". IEC provides a platform to companies, industries and governments for meeting, discussing and developing the International Standards they require.

All IEC International Standards are fully consensus-based and represent the needs of key stakeholders of every nation participating in IEC work. Every member country, no matter how large or small, has one vote and a say in what goes into an IEC International Standard. Experts from industry, commerce, government, test and research labs, academia and consumer groups participate in IEC Standardization work. IEC complements its standards development activities with international conformity assessment activities and

thus creates greater value.

The IEC is a global, not-for-profit membership organization, whose work underpins quality infrastructure and international trade in electrical and electronic goods. Its work facilitates technical innovation, affordable infrastructure development, efficient and sustainable energy access, smart urbanization and transportation systems, climate change mitigation, and increases the safety of people and the environment. Ethiopia is an associate member for IEC.

4. International Laboratory Accreditation Cooperation/ILAC/

ILAC is the international organisation for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189), inspection bodies (using ISO/IEC 17020), proficiency testing providers (using ISO/IEC 17043) and reference material producers (using ISO/IEC 17034).

The arrangements support the provision of local or national services, such as providing safe food and clean drinking water, providing energy, delivering health and



Quality

Assurance

social care or maintaining an unpolluted environment. In addition, the arrangements enhance the acceptance of products and services across national borders, thereby creating a framework to support international trade through the removal of technical barriers where ENAO is a mutual recognition arrangement signatory member of ILAC in the scope of testing laboratory: (ISO/IEC 17025), medical Testing Laboratory (ISO 15189) and Inspection: ISO/IEC 17020

5. International Accreditation Forum /IAF/

The International Accreditation Forum (IAF) is a worldwide association of accreditation bodies and other bodies interested in conformity assessment in the fields of management systems, products, processes, services, personnel, validation and verification and other similar programmes of conformity assessment.

Its primary function is to develop a single worldwide program of conformity assessment which reduces risk for businesses and their customers by assuring them that accredited certificates and validation and verifi-

cation statements may be relied upon. ENAO signed International Accreditation Forum memorandum of understanding in the scope of certification.

6. Organisation Internationale de Métrologie Légale/ OIML/

The International Organization of Legal Metrology is an intergovernmental treaty organization which

- develops model regulations, standards and related documents for use by legal metrology authorities and industry,
- provides mutual recognition systems which reduce trade barriers and costs in a global market
- represents the interests of the legal metrology community within international organizations and forums concerned with metrology, standardization, testing, certification and accreditation
- promotes and facilitates the exchange of knowledge and competencies within the legal metrology community worldwide
- cooperates with other metrology bodies to raise

awareness of the contribution that a sound legal metrology infrastructure can make to a modern economy

7. International Network on Quality Infrastructure /INetQI/

Responding to the challenges of globalization and sustainable development, international organizations (BIPM, IAF, IEC, IIOC (Independent International Organisation for Certification), ILAC, IQNET Association (The International Certification Network), ISO, ITC (International Trade Centre), ITU (International Telecommunication Union), OIML, UNECE (United Nations Economic Commission for Europe), UNIDO, WBG (World Bank Group), and WTO (World Trade Organization) involved with quality infrastructure, trade, and international development to enhance their cooperation in promoting the understanding, value and acceptance of the quality infrastructure and providing guidance and support for its effective implementation and integration worldwide established the International Network on Quality Infrastructure (INetQI).





Accreditation

Back bone of Quality service

What is Accreditation?

Accreditation is the third party attestation related to conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. It is a benchmark for performance that assures high standards in organization system by conformity assessment body.

Moreover, accreditation is independent evaluation by an authoritative body of conformity assessment bodies, against recognized national international standards, to carry out specific activities in order to ensure their integrity, impartiality and competence. As the result of this process, governments and private sector procurers and consumers can have confidence in the calibration and test results, inspection reports, and certifications providers.

Accreditation provides peace of mind and assurance to both business and consumers that the products and

services they are using in daily life have been verified by conformity assessment bodies against national and international standards. The on-going work of the AFRAC, IAF and ILAC as the appointed authorities, to which accreditation bodies comply, provides additional re-assurance and confidence that transcends frontiers and the subsequent acceptance of accredited certification in multiple markets, based on one accreditation.

To sum up, Accreditation is a process in which certification of competency, authority, or credibility is presented.

Accreditation witnessed competence

The reason why we trust accredited conformity assessment bodies is that they provide reliable and accurate test results or certificates. During the accreditation assessment process, all parameters, any working attachments that can affect the outcome result of the test sample like sampling representation, transporting stor-

ing, working environment, personnel, equipments, measuring devices, reagents, consumable chemicals are checked and verified to ensure for not having any effect to the outcome result. This is the bases of accreditation bodies that enable them to give the witness of competence to conformity assessment bodies for their specific scope of activity. Therefore, accreditation is a means of determining the technical competence of testing, calibration and medical laboratories to perform specific types of testing measurement and calibration. It provides formal recognition that laboratories are competent, impartial and independent, therefore, providing a ready means for customers to identify and select reliable testing, measurement and calibration services that are able to meet their needs. To maintain this recognition, laboratories are re-evaluated regularly by recognized accreditation body to ensure their continued compliance with requirements, and to check that their standard of operation is being maintained.

The laboratory is also required to participate in relevant proficiency testing programs between reassessments, as a further demonstration of technical competence. Accredited laboratories usually issue test or calibration reports bearing the

accreditation body's symbol or endorsement, as an indication of their accreditation. Clients are encouraged to check with the laboratory as to what specific tests or measurements they are accredited for, and for what ranges or uncertainties. This information is specified in the laboratory's scope of accreditation, issued by the accreditation body, which provides the customers seeking laboratory services with clear information about the range of testing or calibration services that the laboratory can provide under accreditation.

Accreditation benefits

Accreditation is a means of reducing technical barriers to trade hence leading to increase in trade and creation of wealth.

For Government and/ or Regulatory

Accreditation provides a reliable and impartial basis for sound decision making. Regulators can set policy requirements or detailed technical requirements and rely on accredited laboratories, inspection bodies or certification bodies to verify compliance with those requirements.

Regulators are therefore, able to reduce costs by reducing their in-house personnel and targeting their inspections more reliably and effectively.

The use of accredited service can also moderate the need for additional legislation, as well as reducing the risk of unintended consequences. International accreditation arrangements provide regulators with a robust and credible framework to accept test results, inspection reports, and certifications from multiple foreign Service providers that have been accredited by the signatories to these IAF and ILAC arrangements, with an equivalent level of confidence as if they had been carried out in the local economy. Accreditation ultimately provides a reliable monitoring tool to support the industries and economies.

For Medical Laboratory

The general criteria for accreditation of medical laboratories are contained within the ISO 15189: 2012 Medical laboratories – particular requirement for quality and competence. Medical laboratory accreditation is means of determining the technical competence of a medical laboratory to perform specific type of testing.

Medical laboratory accreditation also provides a formal recognition to competent laboratories, thus providing a ready means of customers to identify and select reliable testing and measurement service able to meet the customers' needs.



ISO 15189
ACCREDITATION

MEDICAL LABORATORY ACCREDITATION

The essential aspect of accreditation is that it promotes confidence in results and services because it is a valid means of verifying claims about quality, performance and reliability. The use of internationally recognized standards as the reference criteria for laboratory accreditation is key to building trust across and promoting best practice worldwide.

The outcomes of accreditation in medical laboratories are measurement of the strength and integrity of the quality system, continual monitoring of the quality system and recognition for your efforts. Accredited laboratories tend to perform better on proficiency testing and are likely to have a working quality management system.

For Health and Social Care Providers

Accreditation provides objective proof that the service operates competently and safely, is patient focused and delivers outcomes that can be relied upon. Accreditation supports continuous improvement which can boost morale, deliver cost savings and, in some cases, can act as leverage for change. Accreditation provides market differentiation and therefore, may result in an increase of commissioned service and advantages during any tender process.

Accreditation is gaining increasing recognition from regulators, and so providers can demonstrate compliance through accreditation. In some cases, this can result in reduced audits.

For Clients

Clients are the biggest beneficiaries. The clients get high quality of care and patient safety and they get services by credential medical staff. On the other hand, rights of patients are respected and protected. Patient satisfaction is at center and paid due heed.

For laboratory

Laboratory accreditation provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and select reliable testing. Measurement and calibration service. To maintain this recognition, laboratories are re-evaluated regularly by the accreditation body to ensure their continued compliance with requirements, and to check that their standard

of operation is being maintained. The laboratory is also required to participate in relevant proficiency testing (PT) programs between reassessments, as a further demonstration of technical competence. Accredited laboratories usually issue test of calibration reports bearing the accreditation body's symbol or endorsement. As an indication of their accreditation. Client are encouraged to check with the laboratory as to what specific tests or measurements they are accredited for. And for what ranges or uncertainties. This information is specified in the laboratory's scope of accreditation, issued by the accreditation body. The description in the scope of accreditation also has advantages for the customers of laboratories in enabling them to find the appropriate laboratory or testing service.

Accreditation is an effective marketing tool for testing, medical, calibration and measurement laboratories, and passport to submit tenders to contractors that require independently verified laboratories. Laboratory accreditation highly regarded both nationally and internationally as a reliable indicator of technical competence. Many industries, from clinical, chemical, construction, forensic science, electrical and food sectors, routinely specify laboratory accreditation

for suppliers of testing or calibration services.

Unlike certification to ISO 9001, laboratory accreditation uses criteria and procedures specifically developed to determine technical competence, thus assuring customers that the test, calibration or measurement data supplied by the laboratory or inspection service are accurate and reliable. Many accreditation bodies also publish a directory of their accredited laboratories, which includes the laboratories' contact details and information on their testing capabilities. This is another means of promoting a laboratory's accredited services to potential clients. Finally, through a system of international agreements accredited laboratories receive a form of international recognition, which allows their data and results to be more readily accepted in overseas markets. This recognition helps to reduce costs for manufacturers and exporters that have their products or materials tested in accredited laboratories, by reducing or eliminating the need for re-testing in another country.

Laboratory accreditation benefits laboratories by allowing them to determine whether they are performing their work correctly and to appropriate standards and provides them with a benchmark for maintaining that

competence. Many such laboratories operate in isolation to their peers, and rarely, if ever, receive any independent technical evaluation as a measure of their performance. A regular assessment by an accreditation body checks all aspects of a facility's operation related to consistently producing accurate and dependable data. Areas for improvement are identified and discussed, and a detailed report provided at the end of each visit. where necessary, follow-up action is monitored by the accreditation body so the facility is confident that it has taken the appropriate corrective action.

In addition to commercial testing and calibration service, manufacturing organizations may use laboratory accreditation to ensure the testing of their producing by their own in-house laboratories are being done correctly.

For Inspection Bodies

Accreditation uses criteria and procedures, specifically developed to determine technical competence, thus assuring customers that the inspection reports supplied by the inspection service are accurate, reliable and impartial.

Accreditation to ISO / IEC 17020, "conformity assessment _ Requirements for the operation of various type of

bodies performing inspection", is gaining momentum in industries around the globe. the broad definition of inspection in the standard allows great flexibility in application from systems to services and raw material to finished products.

It is key in demonstrating that products, equipment, structures, and systems meet required specifications. Governments and industries around the world are increasingly requiring use of accredited inspection service.

Throughout the world today, businesses and customers seek reassurance that the design, product, service process or installation they produce or purchase meet their expectations or conform to specific requirements. This often means that the item is inspected to determine their characteristics squints a standard or a specification. For the manufacturer or supplier, choosing a technically competent inspection body minimizes the risk of producing or supplying a faulty product.

Inspecting products and materials can be expensive and time consuming. If the quality of the inspection is poor, the consequences can be much more expensive if a product has failed to meet specifications or customer

expectations, it may lead to product recalls, rework, litigation and reimbursement. If reinsertion is required, it is invariably damaging the reputation of the supplier or manufacturer too. Choosing a technically competent inspection body minimizes the chance of additional inspection being required.

Confidence in a product is enhanced if clients know it has been thoroughly evaluated by an independent, competent inspection body. This is particularly so if a product supplier can demonstrate to their customers that the inspection body itself has been evaluated by a third party. Increasingly customers are relying on independent inspection evidence, rather than simply accepting a supplier's word that the product is "fit for purpose".

For Certification Bodies

Accreditation is the independent evaluation of certification bodies against recognized standards. Accreditation for certification bodies working according to ISO/IEC 17021; ISO/IEC 17065 or ISO/IEC 17024 standards to ensure their impartiality, competence and consistency. The standard sets out the principles and requirements for the competence, consistency and impartiality of bodies providing audit and certification of management systems services.

In many countries, accreditation is not mandatory. It should be noted that the fact that a certification body is not accredited does not, by itself, mean that it is not a reputable organization. However, many certification bodies choose to seek accreditation in order to be able to demonstrate an independent confirmation of their competence and independence.

There are many reasons why you should use the services of an accredited certification body;

- de-risk your procurement by taking the guesswork out of choosing a certification body by giving you confidence that you will get the service that closely meets your requirements
- win new business particularly since the use of accredited conformity assessment services is increasingly a stipulation of specifies in both the public and private sector;
- gain access to overseas markets since certificates issued by bodies that are accredited by an IAF MLA signatory are recognized and accepted throughout the world;
- help to identify best practice since the certification body is required to have appropriate knowledge of your business sector;

- control costs with the help of knowledge transfer since accredited certification bodies can be a good source of impartial advice;
- offer market differentiation and leadership by showing to others credible evidence of good practice;
- demonstrate due diligence in the event of legal action;
- Reduce paperwork and increase efficiency by reducing the necessity to re-audit your business.

Areas of Management Systems Certification:

While quality Management system certification (to ISO 9001) accounts for a large proportion of work undertaken by certification bodies, there are other equally important areas of work, namely: Information security management systems certification ISO/IEC 27001, Environmental management system certification (ISO 14001), Food safety Management systems certification (ISO 22000) and Supply chain security management systems certification (ISO 28000) .

For Trade

Accreditation facilitates trade and eliminates the need for repetitive testing, certification and inspection.

International trade is the exchange of capital, goods, and services across international borders or territories. Globalization means that we all enjoy and rely on a vast number and range of products and services supplied from overseas. Most of us would find it impossible to imagine, let alone survive, in a world in which our choice of goods and services was limited to those products within the country in which we live.

Every year sees an increase in global trade figures which now run into many trillions of dollars. International trade represents a large share of the gross domestic product of most countries. Supporting the continued movement of capital, goods and services between countries is therefore of huge importance not only to the health and wellbeing of individuals but also to the economic health of entire nations around the globe.

As international trade has grown, the number of national and international voluntary and mandatory technical regulations, standards, testing, inspection and certification procedures across all market sectors which apply to samples, or products, service, management systems or personnel.

Generally, these are introduced to meet the legitimate requirements of quality and

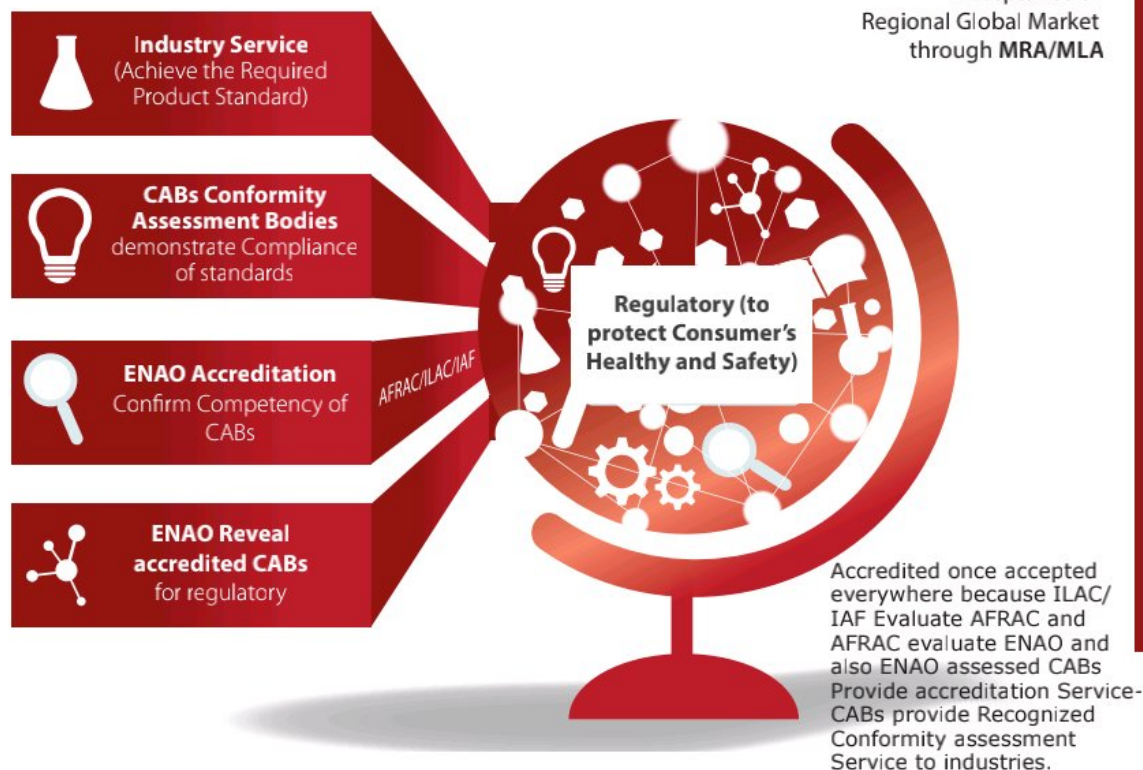
safety that consumers, businesses, regulators and other organizations demand of goods and service, whatever their country of origin.

It is vital, not only for national and international economic health, that products and services can cross borders to meet global demand without causing undue risk to the health and security of individuals or the environment. But in these challenging economic conditions, it is also vital that regulations and standards-which can vary from country to country- are not prohibitively costly or burdensome to businesses and that they do not represent technical barriers either to domestic markets or to export opportunities.

In many economies there is an accreditation body recognized by government and industry to carry out the assessment and verification against international standards of testing, calibration, inspection and certification activities in both the private and public sectors.

ILAC is an organization that counts as its member accreditation bodies, regional organizations and stakeholders representing over 110 economies. The ILAC MRA allows you to make use of a global network of testing and calibration laboratories and inspection bodies that have been accredited to provide accurate and reliable results.

Facilitating National & International Trade



The MRA supports international trade by promoting international confidence and acceptance of data generated by accredited laboratories and inspection bodies. Technical barriers to trade, such as the retesting or inspection of products each time they enter a new economic would be reduced. For example, the MRA supports international trade by helping regulators to recognize and accept data that is driven by regulatory or public policy frameworks in sectors such as health, environment and others.

Operating in the public interest across all market sectors, accreditation determines the technical competence, reli-

ability and integrity of conformity assessment bodies. These are organizations that check conformity and compliance with standards and regulations and through testing verification, inspection and calibration.

Accreditation works through a process of these organizations against internationally recognized standards and other requirements.

Accredited conformity assessment is one tool that is helping businesses not only to comply efficiently and effectively with regulations and standards around the globe but also to gain competitive advantage from doing so and to expand into new

markets, including those overseas. It is the primary purpose of both ILAC (in the accreditation of laboratories and inspection bodies) and IAF (in the accreditation of managements systems, products, services and personnel) to establish multilateral arrangements between their member accreditation bodies based on mutual evaluation and acceptance of each other's accreditation systems. In this way the acceptance of products and services across national borders is made easier by removing the need for them to undergo additional tests, inspections or certification in each country into which they are sold.



ENAO'S

**TEN YEARS OF RELIABLE
ACCREDITATION SERVICES**

Background

For centuries, our world has long been a competitive arena. And, competition is growing and taking an upward trajectory from time to time. Countries are trying to change the lives of their citizens, create better people, a healthier and prosperous environment, and build economies. The issue of quality has also become a widely known issue of concern quite a while now.

In Ethiopia, according to special bulletin published in September 2009 by former QSAE the issue of quality was started in 1956 government structure of the Ministry of Trade, Industry and Tourism under quality standardization department.

The quality assurance work started under the "standard allotment department", was later expanded to include various organizations. It was established by Proclamation No. 328/1979 in August 10, 1979 as the "Ethiopian Standardization Authority". This only lasted until 1996. Being accountable to the Ministry of Trade and Industry, it was reorganized as the Ethiopian Quality and Standards Authority under the proclamation No. 413/1996 in 1996.

According to the BPR evaluation, the Authority was restructured to make it suitable to country's economic growth in line with international trade Organizations standards development, testing, inspection and certification directorate comes to independent organizations.

This structure created the Ethiopian Standards Agency, the Ethiopian National Metrology Institute, and the Ethiopian Conformity Assessment Enterprise. The Ethiopian National Accreditation Office is created as a new institution, which has been expanded to make it more accessible to the public.

How it all begins

With the approval of the Ethiopian National Accreditation Office and the infrastructure development plan and in line with the implementation of the BPR study, the office is entrusted with contributing to the country's economic growth.

Before, the Ethiopian National Accreditation Office established CABs seeking accreditation and receiving the service from other countries.

When the office started its work, it was staffed by 27 employees drawn from former Quality and Standards Authority. But, three of the seven experts who had been assigned to the technical department had resigned before starting work. Similarly, from the support staff, two out of 20 employees resigned and the office started its activities by 22 employees.

The office had begun its services by four experts and 20 support staff, who worked

hard to make the facility a living entity. These four technicians combined the concept of accreditation with information from international experience preparing documents necessary for the office. The test at the time was a clear indication of the institution's ambitious dream of establishing an institution from scratch without any information or experience.

A total of more than 200 documents have been prepared and implemented in accordance ISO/IEC 17011:2004 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies, International Laboratory Accreditation Cooperation policy, rules, and guidance documents.

Besides, the office's five-year strategic plan, organization of the office, the preparation and presentation of program budget were submitted to the government and were later approved by pertinent body. Accordingly, the responsibility to preparing and submitting the draft of the legal framework for the office's approval to the Council of Ministers had fallen on the shoulder of these experts.

The Ethiopian National Accreditation Office is authorized to provide accreditation services in accordance with the relevant national and international standards.

This power is emanated from the Ethiopian National Accreditation Office in accordance with the Council of Ministers Regulation No. 195/2010, this regulation was lasted for two years because in the regulation statement includes

1. 'Accreditation' means evaluation and certification of conformity assessment bodies and management system consultants that they meet predefined competency requirements.

2. "Regulation" means an authorization given to a conformity assessment body accredited by a foreign accreditation body to operate in to country,

3. establish and implement a system that enable to develop conformity assessment and management system consultancy service compatible with international practices, and

4. Provide recognition service to foreign conformity assessment bodies that wish to operate in the country the above statements which was includes in regulations was not alien with the international practice so the regulations was re-established in Regulation No. 279/2012. For the third time, the Office was reestablished under the Regulation No. 421/2017 to make it as the sole accreditation institution in the country and give power to the of-

face to provide training and additional accreditation services to the office.

ENAO was therefore established to providing assurance to trading partners in Ethiopia that are competent for testing, calibrating, inspecting or certification per of requirements, while at the same time overcoming trade barriers by assuring compliance to the WTO agreement.

It became clear later that unless there is a Accreditation, the import and export process could face market failure as their will be no competition among the manufactures and providers. In 2010 however, a big millstone was laid with the establishment of ENAO. Having only few experts and limited facilities, ENAO began initial works to prepare the required documents and fulfill other necessary preconditions. First, a review has been done to explore the services of the Office. This process was done in collaboration with the help of the GIZ. Consequently, a strategic plan was prepared. In fact, it was hard to exactly prepare the strategy without proper mechanism and expertise.

Preparing demand driven services has been one of the primary tasks of the Office. The primary task was to prepare System document. Besides, the Office has been offering Awareness to organizations that most need it. Unless the clients are applied for accred-



Vision

To be become an internationally recognized accreditation body by 2030 on all AFRAC MRA scopes.

Mission

To provide credible accreditation service for conformity assessment bodies.

Objectives:

- To contribute acceptance and appreciation of Ethiopian products and services in domestic and international markets
- To establish and expand internationally accepted accreditation services for Ethiopian CABs.
- To Provide awareness to authorities and customers
- To work for optimum customer satisfaction and also to become cost-effective, national accreditation service is aimed at supporting the credibility of the National Quality Infrastructure of Ethiopia, assisting regional and international trade, enhancing the protection of consumers and improving the competitiveness of Ethiopian produced products and services.

Core Values:

- Competence
- Impartiality
- Transparency
- Non- discrimination
- Accountability
- Responsiveness
- Confidentiality

itation ENAO system documents' would not be implemented.

Along the courses, the Office has been providing capacity building trainings, Awareness and other services to facilitate the implementation of the documents.

In general terms, the mandate of ENAO is to accredit, by formal third-party recognition, the competence of Conformity Assessment Bodies (CABs) to perform specific activities, such as test, calibrations, certifications or inspections.

Accreditation body helps to promote the country's goods and services through providing standardized products for local consumption and for the global market as well. The accreditation service which is being given locally will enable to provide quality products and services by passing them through standardized laboratories, inspections, and certifications process.

Power and Duties

ENAO shall have the power and duties to Act as sole independent body to provide accreditation service to conformity assessment bodies based on national and international standards and requirements and Promote accreditation by providing training on accreditation standards, assessment tech-

niques and related requirements in an internationally acceptable manner. Moreover, Issue rules on how to use National Accreditation symbol and ensure its implementation, promote and protect other legally granted regional and international umbrella organization symbols in an internationally acceptable way. Promoting and encouraging conformity assessment bodies to obtain accreditation service are powers and duties of ENAO.

In addition, to promote the service, the office provides and creates awareness among clients regarding the benefit of accreditation, It also registers and publicizes the list of accredited bodies and those whose accreditation have been suspended and withdrawn, and notify same to the concerned regulatory bodies.

The other ones are issuing and implementing directive governing the accreditation process, in particular, the assessment of applicants and the granting, suspending and withdrawing of accreditation. Handling grievances relating thereto and conducting planned and surprise surveillance visit to verify continuation of scope of competence of accredited conformity assessment bodies and preparing mandatory requirements issued by the office are the other duties. And also conducting super-

vision to protect misuse of accreditation certificate, accreditation symbol including misrepresentation of data from an accreditation: and taking administrative measure to rectify problems identifies and others are the powers and duties of ENAO's.

ENAO's Services

ENAO is third- party body that performs accreditations according to various international standards, ensuring an unbiased and objective assessment of CABs. ENAO provides accreditation services using international standards for the following scopes.

1. Testing and calibration laboratories accreditation service according to ISO/IEC 17025
2. Medical laboratory accreditation according to ISO 15189
3. Inspection body accreditation service according to ISO/IEC 17020
4. Product certification body accreditation service according to ISO/IEC 17065
5. Person certification body according to ISO/IEC 17024
6. Management System Certification according to ISO/IEC 17021
7. Person certification body according to ISO/IEC 17024



ENAO Milestones

ENAO have been established and implemented six milestones. Developed and implemented quality management system as per ISO/IEC 17011, ILAC, IAF, AFRAC and national regulatory requirements. Task force was established comprises five to seven members as per the scope of accreditation and developed different documents and after thoroughly discussion and considering the need from conformity assessment bodies, National interest and market assessment all the required documents have been approved by the director general. Currently the office has international standard working management system which is under continual improvement by taking corrective action while collected from customer feedback, internal audit finding, management review decisions and inputs, AFRAC/ILAC peer evaluation.

1

Preparation & Implementation of Quality Management System documents

The office conducts Market assessment basically to identify the market in each scope testing, medical, inspection and certification based on the market surveillance the office begins the service in two scopes testing and medical laboratories accreditation. Next to this assignment the office also identifies the gap, the national interest of the policy, developing procedures also need to develop TOR based on the TOR the office assign team which comprise of five members based on the per the nature of the scope. These team develops all required documents which is totally over

200 different required documents which was endorsed by the director general in a controlled document format. Document control is one of the elements of QMS, after all the required documents developed the office started training for assessors and also for internal staffs and interested parties.

The training was basically two types general and technical awareness training. The general awareness basically focused on including the office Vision, mission and objectives the definition of accreditation and the importance of accreditation, on the training most of the time the participants are non-technical staffs includ-

ing government officials while in technical training the trainee was technical staffs, who supports their own office to bring to accreditation.

ENAO developed and implemented a quality management system as per to ISO/IEC 17011, ILAC, IAF, AFRAC and national regulatory requirements that enables to provide the accreditation service. The office has an international-standard working management system that continually improve by taking corrective actions that has to be collected from customer feedback, internal audit findings, management review decisions and inputs and managing continual improvement.

2

Competence Development

ENAO ensures to have sufficient number of competent personnel such as internal, external, temporary or permanent, full time or part time assessors/experts having the necessary education, training, technical knowledge, skills and experience to carry out their assigned work. ENAO assessors/experts, personnel who reviews the application, reviewer of assessment reports, accreditation approval committee members have all needed competence, skills and knowledge for assessment and on ENAO's policies, rules, processes, accreditation scheme requirements, conformity assessment scheme and regulatory requirements. Beside this they are familiar with risk-based assessment principles. Assessor's/ experts' assessment abilities, consistent depth of expertise, consistent and correct interpretation and application of the relevant standard/guides is monitored at least every 3 years if they do at least one assessment every year. Otherwise, the monitoring shall be every 2 years by a team leader and members of the assessment team and permanent ENAO staff represented in the team during the assessment.

ENAO's internal & external staffs built competence on different schemes and scopes. ENAO regularly conducts assessor's calibration in order to address how it can continuously enhance service delivery, which ensures that all assessors have access to the same information. ENAO has total of 101 assessors from the total number of assessor 25 assessors for testing, 33 assessors for medical, 10 assessors for inspection & 33 assessors for certification. and accreditation of assessments are undertaken by registered pool ENAO assessors. Consistence communication between ENAO and the CABs on the competence of assessors is a key ensuring consistency, integrity and continuous improvement of ENAO's services.

3

Building Accreditation Market

Building accreditation market as accreditation was a new concept to the country and voluntary by its nature unless or otherwise the regulatory embarked by its nature, it is undeniable fact for its measureable challenges to create accreditation demand. Initially, there was misconception to the scheme requirements which accreditation demands to be fulfilled by conformity bodies though as impossible to comply. Accreditation market is the most challenging task that ENAO had faced and still facing. But, in 2012—streaming of collaboration among co-operative partners and conformity assessment bodies towards accreditation on testing, medical and inspection addressed using ENAO's budget, then a year after that was 2013 many applicants applied for accreditation.

So far four TV documentary films had been broad casted, six radio spots also advertising reputedly over 50 times, and awareness training session conducted 87 different sessions and over over four thousand four hundred attendances on different accreditation topics for the last 10 years. Every three months newsletters published and also ten thousands of brochures and leaflets were distributed and also every year ENAO celebrated world accreditation day with panel discussion for the last 8 years in each world accreditation day more than 90 attendants with panel discussion.

Provide Accreditation Service Even though ENAO had designed to provide an accreditation service for 60 scopes in GTP 1 and 150 in GTP 2 on testing laboratories according to ISO/IEC 17025 ,medical laboratories as per ISO 15189, inspection as per ISO/IEC 17020 , product certification as per ISO/IEC 17065, and certification for person as per ISO/IEC 17024, conformity assessments bodies are not seeking accreditation to the level of ENAO's expectation because of less attention and commitment to the quality within the institution engaged to provide verification of stipulated requirements of services and / or products, regulatory bodies have neither system nor thought to encourage accredited conformity assessments bodies, challenges of proficiency testing provider, certified reference materials and calibration still continue as problem for conformity assessment bodies.

Speaking to the process, institutions will send their application to the Office. The application should include all the information about the capacity/ resources and other relevant information of the applicant. This should be done in accordance with the checklists/procedures provided by the office.

In general, the documents included in the application must show information which supports the claim that the institution is ready to meet the standards set by the Office. The application document will be assessed to check whether all the necessary documents are included. If complete information is not provided, the applicant will be asked to provide additional information. Then, the Office will notify the applicants about the document in five days times. There will consequently be an agreement between the Office and the applicants. The documents will be assessed by external assessors before given a green light.

The review team will take an overall view of all the inputs and processes of an institution. This will be done following the checklist/guidelines provided to guide the accreditation process. This process takes one month. They will also be provided with two months to fulfill the required documents. The review team will evaluate the institution if it conforms to the established standards.

The final accreditation decision and recommendation is then provided by the General-Director of the Office based on the information gathered from: application documents presented by the applicant, institutional visit, discussion among assessors team. There are three kinds of Accreditation decision. These are conditional acceptance, unconditional acceptance and Accreditation not granted. Conditional acceptance is done when the applicants are required to meet certain standards.

5

Continual Improvement

It is ENAO's working norms to collect and analyze feedback ultimately after on-site assessment, once a year the system audited against the requirements and the implementation of the developed documents, management review is also carried out once a year to assess all possible improvements and actions taken to the previous management review decisions. So far many actions have been taken in reviewing the documents however, the timeline rule to be maintained by conformity assessment body is still challenging. Peer evaluation and re-evaluation and also extension of scopes were also conducted by African Accreditation Cooperation.

Maintain and increase improvement, ENAO undertakes to collect and analyze feedback after on site assessment. Once a year, the whole system is audited against the requirement and the implementation of the developed documents. Management review are also carried annually to assess all possible improvements and to reconfirm the actions taken as per the previous management review decision

6

Regional and International recognition

ENAO was recognized as affiliate membership of International Laboratory Accreditation Cooperation on July 25, 2011 and become an associate member in April 23, 2013.

In September 26, 2013 granted full membership of African Accreditation Cooperation. ENAO was applied for full membership of ILAC in 25 September 2014 and in April 7, 2015 ILAC Arrangement Management Committee accepts for the application for the full evaluation of ENAO quality management system. And then from 7-11 September 2015 ILAC and AFRAC Jointly evaluate the system of the office and competency of assessors.

In December 2016 the evaluation team accepted the clearance and action taken by ENAO

In September 2016 ENAO signed memorandum of understanding and become member of IAF and in May 2017 the office recognized by African Accreditation Cooperation as Mutual Recognized Arrangement signatory member and in October 2017 recognized as International Laboratory Accreditation Cooperation MRA signatory member and also re-evaluation and expansion of accreditation scopes was conducted from 13 to 17 May 2019 in testing laboratory, medical laboratory and also within the new scope inspection accreditation. And in September 2019 AFRAC recognized ENAO as MRA signatory member on inspection accreditation also and in October 2019 the office become ILAC-MRA on inspection accreditation.



ENAO Office and onsite Competence Evaluation by ILAC & AFRAC team evaluators



Recognition from **AFRAC** September 29/2017 Cairo, Egypt



Recognition from **ILAC** December 26/2019 Vancouver, Canada



5th AFRAC General Assembly from September 20-26/2014 Addis Ababa, Ethiopia



Regional International Recognition

- In July 2011, an affiliate membership of ILAC
- In April 23, 2013 associate member of ILAC
- In September 26, 2013 full membership of African Accreditation Cooperation
- ENAO was applied for full membership of ILAC in 25 September 2014
- In April 7, 2015 ILAC Arrangement Management Committee accepts for the application for the full evaluation
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- In December 2016 the evaluation team accepted the clearance and action taken by ENAO
- In September 2016 ENAO signed memorandum of understanding and become member of IAF
- In May 2017 AFRAC MRA signatory
- In October 2017 ILAC MRA signatory
- In September 2019 AFRAC-MRA on inspection
- In October 2019 ILAC-MRA on Inspection

To get international recognition, applicants should come to the office to get accreditation services. In 2015, the office was evaluated by International Laboratory Accreditation Cooperation (ILAC) a consortium of all accreditation bodies. This was in line with the medium-term goals of the office. For its services to get acceptance the office had a goal to gain full recognition by peer-evaluation of the International Laboratory Accreditation Co-operation (ILAC) and the International Accreditation Forum (IAF). These years of hard work thus paid off. ENAO recognized by ILAC as of 2017 and is working to gain international recognition in other scopes as well.

International recognition and engagement in fact does not only help ENAO, it will also ensure that organizations that are accredited by ENAO will be recognized internationally to produce reliable and traceable conformity assessment services. The process to get ILAC's recognition had begun by submitting applications to the cooperation. ILAC after conducting on-site visits assessing all documents and services, the Office become signatory of ILAC in medical and testing in 2017. This is a great success compared to other accreditation bodies in Africa and beyond. The process only took seven years. And achieved with short period of time as compared to other countries experience. Then in 2017, the Office became ILAC's full membership. In September 2019, we were Renewed the office recognition and extend its scope of recognition

by ILAC then after. Currently, the Office is ILAC's MRA in medical, testing and inspection. This is a worth-praising achievement. The re-evaluation was successfully conducted from May 13-17/2019 according to the new standard ISO/IEC 17011:2017. All revised documents were suitable and applicable. All findings were cleared and ENAO maintain its MRA status on Testing laboratory (ISO/IEC 17025) , Medical laboratory (ISO 15189) and scope extension in Inspection (ISO/IEC 17020) accreditation service in addition.



Success

In the country's development process, the office has contributed to the expansion of trade and the globalization of the world economy, eliminating trade barriers and allowing countries to exchange goods and services.

Such a trading system is acceptable between countries when technical barriers to trade are removed. Trading countries need to trust each other in their products, services, and professionals in order to grow their economies by expanding trade.

Organizing certification, inspection, and laboratory accreditation systems will play a key role in ensuring that countries have confidence in their products and services. Although the office has been using various rental bureaus for the past ten years, it is currently constructing a six-story building with the bud-

get approved by the government for the construction of offices and laboratories.

Since its inception in 2011 E.C, the office has set goals for the coming years and has set a clear road map for introducing accreditation services. Thus, the first accreditation service was started in 2012 in accordance with ISO 15189 standards at the Alert Clinical Laboratory, which became one of the cornerstones of the first accreditation service of the medical laboratory in two scopes.

Similarly, in the inspection category of ISO / IEC 17020, 11 institutions have been Accredited While 9 continued and two dropped out with one institution applied for accreditation once again.

There is only one institution that are accredited in System certification (ISO/IEC

17021) and It is expected that many clients from the government will be benefited from person certification accreditation service.

Though the office provides accreditation services in all four categories, institutions are not benefiting from accreditation.

Over the years, the office has made great strides in manpower training, especially in training and completing part-time managers and trainers, and is one of the cornerstones of the office.

The office has provided training for team leader, technical assessors and experts in ISO / IEC 17025, ISO 15189 and ISO / IEC 17020, ISO / IEC 17024 in Personnel, ISO / IEC 17021 system and ISO / IEC 17065 in product certification Standards.

The event has invited qualified and experienced professionals from universities, research institutes, private medical institutions, and various professional associations across the country, and more than 89 professionals are currently enrolled in part-time pools.

This result did not come easily. Since its inception in 2011, the office has organized more than 87 awareness raising trainings across the country and reached more than 4,412 participants.

This means awareness raising training for the community in addition to the training provided to technicians. Efforts have been made to make the information accessible by participating in various exhibitions in Amhara, Oromia and the Southern Nations, Nationalities and People's Region, as well as in Addis Ababa. These activities are to achieve the road maps set by the office in 2011 and to be carried out on time:

The office is affiliated with the African Accreditation Cooperation and International Accreditation Forum as well as the International Laboratory Accreditation Cooperation. As a full member of the Laboratory Accreditation Cooperation, it has already achieved its goals of making local accreditation services fully acceptable abroad.

The above activities are the major achievements of the office over the past decade since the primary responsibility of the office is to provide accreditation services to third-party accreditation institutions.

Most importantly, to reach its current status, ENAO has gone through a rocky road. To begin with, the concept of

accreditation was new and unfamiliar among the public if not among experts in Ethiopia. In reforming the national accreditation services and as complimentary of quality infrastructure, the Office was established as a legal regulatory body. To implement the reform activities, a bilateral budget was allocated in collaboration with the Ethiopian government. This was the springboard that led to the beginning of proper accreditation services in the country. The work to restructure the Office began with reform agenda in 2010 when a South African Experts was assigned to lead the process. So, he together with the Ethiopian team has been working hard to revisit the service provisions. The early works of collaboration helped got international knowledge about the whole sense of accreditation services.

The expert helped office to boost awareness towards international accreditation services and we were able to acquire the required know-how in terms of service buildup. It then drafted a strategic plan and other pillars by setting up an international management system. It was possible to form an enabling system by taking the experiences of other countries into consideration meeting ISO standards and international laboratory accreditation standards. We



Internationally speaking, accreditation is not profitable and not rewarding. Accreditation requires pure profession.

have completed the system in six months of time earlier than the planned three years' time. The office had then begun offering capacity building training to organizations. Consequently trainers were trained. In cooperation with a South African Accreditation body, the office aggressively worked in training provisions. After some time, we began working independently. ENAO recommended the man to work on other engagements though GIZ doubted it.

Consequently, the office hired Ethiopians to work with the experts as it needed more Ethiopian experts who can do the job. It was possible to give accreditation services within one and half years. In 2014, the office then applied to have its services evaluated by an international body. This body found the document efficient and sufficient.

Without any challenges, the personnel of the International Laboratory Accreditation Cooperation told the office to send them the document and the Office was recognized internationally in 2017. In 2016, ENAO director general was elected as African Chairman of Accreditation Consortium. It has got its accreditation service recognized in testing laboratory. And in 2019, we had our inspection services recognized. It was a tight eval-

uation method. But we had made it. The calibration aspect is yet to get recognition as there was no any calibration laboratory accredited by ENAO.

It was the trust the Office cultivated in the international arena that Director was appointed to represent Africa. Internationally speaking, accreditation is not profitable and not rewarding. Accreditation requires pure profession. That is why; we serve on international platforms without payment. But, the contribution made in international arena is considered as recognition. Management system certifications Accreditation to be recognized application are sent to Evaluator team and are awaiting approval. We have planned to extend our services in scope and diver-

sification. With its achievement, the office is now serving as a benchmark for other neighboring countries.

According to a document obtained from the Office, ENAO developed and implemented a quality management system as per to ISO/IEC 17011, ILAC, IAF, AFRAC and national regulatory requirements that enables to provide the accreditation service, as to a document obtained from the Office,

The office has an international-standard working management system that continually improve by taking corrective actions that have to be collected from customer feedback, internal audit findings, management review decisions and inputs and managing continual improvement.





Future Plans

ENAO's mission is to provide an internationally recognized, cost-effective, national accreditation service within the borders of the Federal Democratic Republic of Ethiopia aimed at supporting the credibility of the National Quality Infrastructure of Ethiopia, assisting regional and international trade, enhancing the protection of consumers and improving the competitiveness of Ethiopian produced products and services, in both the voluntary and regulatory areas.

To become an internationally recognized accredita-

tion body by 2030 G.C on all available scopes of AFRAC is also the vision of the Office.

The non-acceptance of test and inspection data and certification results has been identified as a significant barrier to trade. Non acceptance of conformity assessment results is motivated by lack of confidence in the competence of those bodies producing such results and a lack of assurance that the exporting country complies with the World Trade Organization's (WTO) Technical Barrier to Trade (WTO TBT) agreement.

ENAO also aims to provide the assurance to government regulators that a particular organization is technically competent to perform specific conformity assessment activities based on recognized and transparent criteria and procedures. A properly functioning technical regulation system can benefit the economy by balancing regulatory and trade interest, improving quality and consistency of technical regulations and supporting compliance with international requirements which supports good regulatory practices.



Our services are recognized internationally. So far, the support of government is encouraging. The government allocated budget and facilitates experience sharing opportunities.

The World Bank Project has supported Ethiopian National Accreditation Office to expand its accreditation service and build the capacity of its assessors and experts. Twinning arrangement was signed with QCI to through the World Bank project support ENAO activities and began gap assessment on Calibration, Inspection and Certification (System and product Certification) and

developed 11 new guidance documents.

All documents and formats were reviewed according to document control procedure, ILAC/IAF/AFRAC documents and ENAO new structure with top management and technical staff at Adama, Ethiopia. ENAO provided training for internal staff and Medical, Testing and inspection conformity assessment bodies regarding revised, reviewed documents.

ENAO was established to provide assurance to trading partners that accredited Conformity Assessment Bodies in Ethiopia are competent to test, calibrate, inspect or certify to the trading partners' requirements, while at the same time overcoming trade barriers by assuring compliance to the WTO TBT agreement.

Consequently, one of ENAO's medium-term goals was to gain full recognition, by peer-evaluation, of the International Laboratory Accreditation Co-operation (ILAC) and the International Accreditation Forum (IAF) and of which ENAO recognized by ILAC as of 2017 and keep working its recognition in other scopes as well. This recognition will ensure that organizations that are accredited by ENAO will be recognized internationally to produce reliable and traceable conformity assessment services.

Building Competent Accreditation services

Basically, accreditation involves the use of standards minimum quality requirements and conditions that have to be met by an institution or program. When compared to other quality assurance mechanisms, accreditation is expected to represent a more structured discourse where a certain threshold level is established. The final outcome of an accreditation process leads to an official recognition of service providers. In one-way accreditation can help the government of Ethiopia to protect the quality, but if it is focusing solely on quality control and inspection, achieving the goal of long-term improvement could become difficult.

Quality is none negotiable. Quality is not something we should compromise; it is the order of the day and increasingly becoming must-do task. In order to be competent in the world market accreditation is decisive. It is through accreditation that products or services are better sold and earn good sum of hard currency. For services to be accepted in local and international markets, they have to be accredited.

Speaking of health wise, medical errors happen and lives could be lost because of compromised quality services. In

this regard, accreditation is vital to ensure quality in all sectors. The Office has conducted extensive awareness raising activities to encourage accreditation among the public and institutions. Accreditation process takes up to one year time. For institutions to be accredited, they have to go through different stages.

Accreditation services are conducted in terms of scope and institutions. Accreditation is voluntary activities and is very much challenging. The satisfaction of applicants is good. In terms of percentage, the satisfaction of clients is above 95 percent. The quality of assessors is attributable to the achievements made by ENAO. We usually assess the efficiency of our assessors and their services.

To ensure and improve quality accreditation services, monitoring and evaluation works are needed. In this regard, assessor's/experts' assessment abilities, consistent depth of expertise, consistent and correct interpretation and application of the relevant standard/guides has been the areas ENAO worked hard. ENAO regularly conducts assessor's calibration capacity in order to address how it can continuously enhance service delivery, which ensures that all assessors have access to the same information.

The challenges

Having going through a remarkable periods of success, ENAO has not been without challenges. From poor awareness to policy gaps, accreditation is confronted with various barriers. Lack of adequate human resource is the major barrier. It needs one year experience for an expert to be efficient. Turnover of experts is another problem. The structure of the Office also goes against civil service standard. This would continue to pose a big challenge in the future.

According to a survey conducted by the Office, lack of adequate calibration body, and poor commitment of leaderships of institutions are the major barriers affecting accreditation services. Reference material and other facilities used to assess applicants should be exempted from tax. Encouraging accredited institutions is imperative to increase the demand for accreditation services. The fact that accreditation is voluntary services, institutions have no the gut to seek accreditation services. We are now preparing an action plan to bridge the gaps.

The early times of accrediting clients were challenging since the process was very costly and uncommon. The Office had laid a foundation for accreditation in the coun-

try. With our services, we have been able to curb hard currency spent on accrediting services and products. Now clients are able to reliable accreditation services locally. Human resource is a major setback affecting the authority, there is high turnover of employees. We are building new building; hopefully this would help us scale up the size of our manpower pool.

Organizational commitment is imperative to strengthen the Office. The top managers of organization should attach highest attention to ensuring quality services. If the organizations are to compete with other countries, they should have their services accredited. Accreditation is voluntary task. We as a third party cannot put obligation in organization for having accreditation. The regulatory bodies should oblige organizations to have their services accredited. Once the regulatory bodies require organization to have their services accredited, our organization could expand our accreditation services.

Accreditation is voluntary in the eye of third party. ENAO strongly recommend the regulatory bodies to make accreditation mandatory.

We are working on standard and expanding training. The major impediment affecting the efficiency of the office is

that institutions have low interest to get their produces and service accredited.

To improve the quality of its services, the Office conducts surveys. In 2021, the Office conducted a survey to assess the shortcomings organizations face in seeking accreditation services. Even though 80% of the respondent has program to accredited their service, due to the absence of a proficiency test provider in the country, almost half of the respondents did not participated and 30% were not calibrated their measuring equipment by accredited calibration Laboratory periodically.

Majority of the respondents explained that top management has a commitment to accredit their service however, 35% were not included accreditation activities on the strategic plan, annual plan and there is no activity to wards accreditation evaluates and supported by top management.

Another main factor was equipment/reagent calibration Traceability, the supervision result shows that only 55% are calibrating scientific equipment using certified reference materials, the rest 35% not done because of unavailability of CRM, lack of knowledge and 15% were not applicable for their service.

The fact that accreditation is a voluntary activity, it is



ENAO's mission is to provide an internationally recognized, cost-effective accreditation service.

very challenging to create an accreditation market. And, still support of regulatory is needed. Regulatory shall accept and support the use of accreditation because accreditation avoids the burden of rework by the regulatory and mitigates corruption in the regulatory process

During assessor's training, there was a challenge to find CABs with the system emplaced that helps to mentor and monitor assessors which

is part of the process to capacitate and evaluate their competency.

Limited service of calibration scopes, no certified reference material (CRM) and proficiency testing (PT) suppliers have been also the other obstacles in providing accreditation services. Conformity Assessment bodies are challenging to participate on PT and to buy CRM.

The way forward

In response to the predicaments observed over the years such as lack of awareness with top management, shortage of resources, lack of training on implementation of requirement, shortage of hard currency to purchase certified reference material and PT, no PT provider in the country, lack of management support, equipment/reagent calibration traceability and infrastructure. The following are the recommendations which the Office usually prescribes.

To address the problems responsible bodies should give due attention to solving those identified major factors towards achieving accreditation.

- Need to perform training gap analysis and establish a uniform knowledge of accreditation for all technical staff by arranging participation in relevant training.
- Establish a PT provider in the country.

- The government facilitate Tax free system to purchase Certified reference material (CRM) and proficiency testing
- Strengthen purchasing system and fulfill all resources (Equipment's (Reagents, consumable supplies etc)
- Create awareness on the benefits of accreditation within the community.
- Develop a national policy for accreditation processes.
- Need to develop an effective inspection service for imported equipment to ensure they are suitable for the country's environment, have full information provided on validation and traceability along with a sustainable reagent supply.
- Create awareness training and commitment to top management which is greatly helps to increase staff motivation.
- Periodically conduct risk assessments, insist stakeholders to apply for accreditation and follow their strategic plan, annual plan implementation and take action.
- Perform internal audits of current procedures, taking corrective actions where nonconformities are identified and ensur-

ing the effectiveness of actions taken.

- Regulatory bodies should value the competency of Accredited CABs while outsourcing inspection and testing activities. The House of people Representative standing committees should create synergy and harmony among Federal Ministries to make quality an issue in their plan.

Now that ENAO is marking its ten years anniversary, the Office emboldened by its achievement and tested by the challenges is working round the clock to see a planned tomorrow. By investing in its human resource and expanding its facilities. ENAO is looking

to help manufacturers and service providers to be competitive enough in the world market.

"Increasing the size of manpower is on the top list of our future plan. We are currently working on a new structure. We have digitized our activities with the help of South African company. Our daily routines are done our IT capacity. This would be scaled up in the future.

We have part-timers who work as assessors; we now have over 101 assessors. Having efficient employees in quantity and quality is something we should work hard on in the future." Diversifying the number of accreditation services in scope and category is the future plan of ENAO. We are constructing six-story building which would be fit enough to host large-size manpower and expand facilities.

Providing awareness is also in the first rung of the Office's future plan. As mentioned repeatedly, shortage of awareness is making organizations to be reluctant in having their services or products accredited. In this regard, ENAO plan to extensively provide awareness raising forums. Besides, the Office aspires to scale up its presence in regional and international platforms and seek to share its experience to other countries.



**ENAO Recognition by
AFRAC/ILAC event
Celebration
2 May 2018
A.A, Ethiopia**



**ENAO Re-evaluation
by AFRAC team
opening Meeting
May 13/2019
A.A, Ethiopia**



**Evaluator team
witnessed on
site assesment
(testing) A.A,
Ethiopa**



**Evaluator team
witnessed on site
assesment (Medical)
A.A, Ethiopa**



ENAO Gives reliable Accreditation



CABs Experiences

Tip

It's now only years since businesses in Ethiopia have begun being accredited here at home, after all it's a newly introduced business thought with many people still unfamiliar to the concept and blessings of it to quality business exchanges and service delivery. Interestingly, however, few others

knew its paramount significance ahead of many others and even traveled abroad to get their businesses accredited and dealt with problems they encountered back then. It's then so simple to sense how costly their journey was, and at the same time the establishment of Ethiopian National Accreditation Office is of paramount sig-



nificance to quality business engagements alleviating all the headaches of old days.

At its infant stage, though, the home grown office of accreditors, shortly known as ENAO, has already begun attracting customers, and is envisioned to excel in its task of evaluating quality of businesses to pursue in their respective fields. But what are its customers toward such a newly established of-

fice of home grown accreditors. Come on, I have stumbled upon to talk with four of its customers who told me about their areas of engagements, blessings they have earned as the result of being accredited here at home ,channels established to communicate ENAO ,and of course challenges they are facing as they operate their respective areas of engagements. If I should recap their takes about the office,

they are confident of success stories ENAO will be making along, if it commits to tick all the shortcomings off.

Follow me then as I will be navigating through the reactions which heads and experts of the accredited customers of ENAO explained to me recently, some of them engaged in the medical circle and others in the industry of trade and export.



Zelalem Fisseha
Managing Director of Arsho
Medical Lab

Areas of engagements

Let's begin with Arsho Medical Laboratory, a medical center of growing reputation, which was medically accredited in January 2015; two or so years after ENAO came into reality. Its establishment meant an offer to the lab, given the difficulty it experienced in its quest to easily access accreditors nearby. This medical lab, whose name is running across Addis, if not nationwide, even beyond is now a solution for medical lab tests. It is chiefly engaged in testing though the medical lab welcomes patients seeking related medical care, says Zelalem Fisseha. She is managing director of Arsho Medical Lab and spoke to me about her lab. Her lab rejects no calls for medical help, and when cases are beyond its limit, it processes requests and finds solutions communicating with its cor-

respondent medical allies of Dubai, of Germany and of England.

Three years after Arsho Medical Lab became medically accredited, Amhara Public Health Institute followed suit in 2018 with a well-defined task of identifying and conducting medical research, including Microbiology, Cholera and Virology. It a year later outshined while being evaluated and acclaimed in international approvals after it met with all the standards set by relevant experts to pursue in the scopes of medical labs for which it applied to get a go ahead, as the result, the institute is now the first of its kind in Ethiopia for being fully accredited.

Whereas, QITS Inspection, another homegrown PLC got approval in 2018 to inspect export quality of oil seeds, cereals and spices, specifically for type A [3rd Party] service delivery. Initially, QITS was accredited in late

2018 for oil seeds, followed by more approvals to inspect pulses, and years later it got accredited for eleven more scopes to engage in, including textiles.

Then comes the Ethiopian Conformity Assessment Organization, one more of the four accredited customers of ENAO. Home to many accredited fields of diverse scopes, the organization is known for being accredited in laboratory, inspection and system certification, respectively with forty, three and three distinctive parameters. It has also applied for more approval and is expecting responses both from the homegrown office of accreditor ENAO, and from a German based accreditor.

Blessings of being locally accredited

It's now only less than a decade since ENAO started witnessing the capability of businesses to engage in their

Kalekirstos Ayele
Manager and Founder of
QITS Inspection plc



areas of interests, but it has already begun proving its relevancy as of its kick start. No more lengthy and costly flights in search of accreditors, right now. The home-grown office of accreditors, coined as ENAO, is now helping save both time and foreign currency of the country as witnessed by customers of the competency recognizer.

My time with customers of the office proved the reality. Let me begin with testimonies Zelelam Fisseha of Arsho Medical Laboratory shared with me as I approached her for exchanges. 'Kind of a big offer ENAO is 'she says, recalling all the ups and downs she had to face back then as her lab journeyed to South Africa in search of accreditors for her medical lab. Being approved by the local office is helping them develop confidence both to the medical lab and to its clients.

Its fame which was already established even before the onset of ENAO, though; the office has undeniably made the lab reform and transform itself, chiefly equipped with the latest medical lab appliances. As a result of being accredited, Arsho has become more consistent and reorganized, paving the way to outsmarting its equals. Right now, she says, the medical lab is frequented by many people seeking solutions, some for lab solutions, some others for general medical checkups and further examinations and medical care. Its consistent medical history and fame supported by the ENAO introduced Accreditation service has further helped sustain Arsho Medical Lab pursuit in the medical industry, and it's now a hub of medical lab solutions. As of its accreditation by the homegrown office of accreditors, the lab remained consistent to medical lab working values. It's,

of course, the best-rated medical lab in town and beyond, if you like. It worries about its reputation, told to me by the managing director. It strictly sticks to medical advice and ethics, with lab tests in focus, not simply because failure results in consequences, but the newly launched service delivery has become rituals of health officials and other staffers. Whoever comes to join Arsho Medical Lab as a staffer, pre service orientation and crash course training are preconditions to go through, which by itself contributes to its consistency and quality. This on one hand helps the medical lab keep its tempo of sustaining quality services, and on the other hand attracts more clients.

The Amhara Public Health Institute Accreditation Nominated representative, Melas-hu Balew says being locally accredited is of paramount importance. Right, asked



Melashu Balew

Amhara Public Health Institute
Accreditation Nominated
representative (Laboratory
Quality Manager)

what benefits it is earning in return of being accredited, the public institute says it is now confident of its verified, standard and internationally traceable medical lab results, mainly because of the recognition by the relevant body. Being accredited requires medical labs to strictly stick to time tables to which they set for results to announce. Also no interruptions and suspensions of medical examinations, and failures of lab equipment encountered as the arrangement by its very nature alerts lab technicians to respond as per requirements set ahead of the launch.

As the result of being accredited, the institute says, its entire staffers have now become professionally efficient, competent and familiar to newly discovered medical researches and thoughts, and the safety of practitioners have been assured, best of all university students of related fields

have been increasingly attracted because of its excellent reputation To conducting feasible medical researches.

The difference is visible. Ahead of the accreditation, the institution was often blamed for rejecting specimen samples, mostly for no reason, but now no more related complaints. Requests of visitors are now being tackled, immediately and professionally. Best of all, one of the breakthroughs of the newly introduced medical arrangement is its experts can timely respond before medical lab appliances go wrong, potentially.

Stepping to other customers of ENAO, we find QITS inspection PLC, a company which hails the benefits of being accredited, or locally accredited in particular. Mr Kalekirstos Ayele of the company has more details, but now about the benefits of being accredited. The manager and Founder of QITS inspection plc Kalekirstos

says ENAO got its life after his company wasted two years of inspections, with no third party out there to approach for approval. Being evaluated, the company has established confidence over its inspection, which in turn helped it confidence and competence to pursue its business.

He recalls that ahead of the launch of ENAO, it took his company lengthy processes even years to persuade and attract clients of oil seeds exporters, of textiles traders, of food warehouse owners. Because of the accreditation, its clients trusted it and established a sense of confidence to partner, and if you like, the company saved both its many and foreign currency as the result of having a homegrown office nearby.

Yet to come is another accredited organization to witness the benefits of being recognized, but this time

Amsalu Eniyew

Ethiopian Conformity
Assessment Enterprise
Certification Director



around a conformity, in its full name Ethiopian Conformity Assessment Enterprise is picked to have its feedback about gains of being recognized by recognized legal bodies.

But how helpful is accreditation, Amsalu Eniyew ECAE Certification Director said that internationally acclaimed documents are reliable and accurate. In testing, for instance, as the result of various multiple factors their may be inconsistent results. For results to be consistent in disregard of time and place, there are agreed and standard parameters to be applied, meaning organizations become certain of the consistency of their results, services and products if and only if they are governed by standards set by acclaimed accreditors. Accreditors are governed by sets of agreed and scientifically proven standards. As an independent third party, accreditors' matter the most both to the service providers and clients,

in other words its confidence and trust are what the former and the latter can respectively enjoy from being accredited. Accredited services and products are logos to carry and delegate tasks on behalf of owners toward end users, he says. Goods and products with names of accreditors branded on, for instance, declare quality of products and services. The approvals sealed off, by his organization in this case, protects customers from financial losses, health related problems, if you like. The more you expertly inspect, assess and taste services and products, the more quality services and products you deliver. Being accredited also avoids risk, develops self-confidence and also a source for decision and policy makers.

Amsalu further says, ahead of ENAO some business operators tried to get accredited in South Africa and certified in Germany, but ENAO changed it once and for all.

The home grown office of accreditors has brought not only internationally acclaimed thoughts, but also has spared the nation from sending losing currencies.

Communication channels

The communication between the accredited organizations and ENAO is somewhat encouraging, all of them told me all along my time with their respective representatives. The exchange is mostly periodical and is composed of a series of reports accompanied by physical inspections made by assessors of both parties. In their inspection, experts of ENAO closely cross check if their respective accredited organizations are acting accordingly, any failure results cancellation of accreditation. Every time the agreement for some kind of engagement expires, each of them are expected to apply for renewal of their target scopes to sustain.

Challenges and recommendations

Difficulty to access calibrators is on top of challenges, Zelalem Fisseha began as I asked her to tell me of shortcomings her lab is facing. The challenge seemingly being alleviated-through, in the year's back, it was one of the headaches for the medical field operators to undergo even minor medical lab equipment grading, medically known as calibrating. Her lab had to travel overseas for the case, which she recalls was time and money consuming.

External Quality Assurances (Proficiency Testing) too are to be blamed in this case. Years before, Arsho tackled the problem through GIZ, which helped sponsor it to pay fees for Thistle QA, South Africa. Arsho, she says. The medical lab then does not hesitate to invest whatever costly it is for the EQA Lack of Proficiency testing provider is a problem to the country, but foreign currency shortage too is negatively affecting her lab as it tries to seek solutions out of Ethiopia.

One more challenge to note. The communication channel witnessed between the regulatory body and the office of the accreditor is attractive. The former is often seen confused with imported medical appliances, as the result of which it was refusing to accept their entrances to the medical industry. The medical lab has paid the price and paved the

way for others to follow suit, though many have failed to join the industry. With its insistence, a policy has been drafted and is now on the table to be ratified and adopted by relevant bodies, just right years after some medical equipment of Arsho were rejected, at least twice. To Kirstos Ayele, QITS founder, Ethiopia is lagging behind in terms of fully exploiting the offer accreditation can have to a given country. Multiple Conformity Assessment Bodies need to get active, otherwise quality will fall, he suggests. She wonders why many lack the appetite to get accredited.

In her fifteen years of medical field, she has witnessed thousands of clinics and hospitals popping up, but few medical labs have undergone approval from the homegrown office of accreditors. No need for each and each clinic and hospital to get accredited lab, but each and each of them need to establish a strong channel to medically communicate with accredited medical labs, making agreements the same way many private and government corporates and institutions have made with Arsho Medical Lab.

Whereas, Zelalem Fisseha suggest that there should be some sorts of platforms for corporates and medical institutions to work closely with standard medical labs, simply because equipping all the clinics and hospitals with standard labs cannot be effective and efficient, and sometimes may

be a hassle to medical centers to accommodate altogether.

What Amsalu Eniyew blames as the bottlenecks of the sector is lack of adequate foreign currency to import medical lab equipment, as the result his organization lacks the opportunity to seat for proficiency tests with international competence. He says that industries of ours today are more production oriented, their priority needs to be consistency. Once they make a reputation, the market willow, top of every business should be quality, he recommends.

In the case of Amhara Public Health Institution, the most blamed one is failure to value accredited institutions, which results in high turnovers. The institution recommends that better to establish a mandatory arrangement for practitioners to be accredited, incentives should be offered to outsmarting ones and periodical capacity building training should be offered to introduce medical professionals with newly discovered thoughts and findings. To do so, their labs should be fitted with calibrated equipment, so that their productions will not suffer from poor quality. Every time they feel there are some odds, industries can cross check against the standard set.

In the case of Amhara Public Health Institute, turnover is the headache of the medical center. Many of its highly trained experts often resign for better opportunities. Shortage of on service trainings and failure to establish ways of offering incentives to high performing staffers are also contributing to its shortcomings.

**Certificate
were presented
to Accredited
CABs**



ABOUT

ACCREDITATION COUNCIL



Mr. Eshetie Asfaw, Former Quality and Regulatory Sector State Minister of Trade and Industry under and also the Chairman of Accreditation council addressed that:

The Accreditation Council works according to regulation no. 421/2017. Its members, not more than 15, including the Chairperson, are taken from the relevant government bodies, private sectors and associations. To avoid undue influence and domination by particular interests, the members of council are selected from different organizations or sectors as per consideration of balanced representation among government and private sectors, representation of conformity assessment activities (testing, calibration laboratory, medical laboratory, inspection and certification), and also consider the knowledge on the government policy and strategy, the organization he/she represents has to have direct or



Mr. Eshetie Asfaw
Former State Minister of
Trade and Industry, Chairman
of Accreditation council

indirect relation with the accreditation service, volume of conformity assessment activities, the committee-men to serve and contribute in the accreditation council.

The Accreditation council is selected from the organizations: Ministry of Trade and Industry (Chairman), Office of the Prime Minister, Food and Drug Authority (FDA), Ministry of Labor and Social Affairs, Trade competition and Consumer Protection Authority, Ministry of Agriculture, Ministry of Health, Ethiopian Chamber of Commerce and Sectoral Association, Ethiopian Private Health Sector Association (Two participants) Ethiopian Laboratory Association, (Two participants), Inspection Bodies Association, Representative of Certification Bodies and Ethiopian National Accreditation Office (Member & Secretary).



The Council is responsible for:

- Review and approve accreditation strategies developed by ENAO.
- Consider strategic issues of ENAO, collect feedback and promote accreditation
- Ensure the maintenance of good governance in the office by:
- Acting as the last resort for appeals from ENAO clients;
- Protecting the principles of impartiality and non-discrimination by ensuring a balanced representation of interested parties on the council and other committees,
- Where necessary, provide support in attaining resources for fulfillment of ENAO's mandate and to lobby support for accreditation.
- Submit to the government the rate of fees to be charged for the services of the ENAO for approval.
- The Council shall ensure that the membership of an appeals committee does not include those who have been involved in the activity under consideration and ensure that its members have the knowledge on that particular issue under discussion, the council is responsible for the final decision.

The council chairman addressed that better regulation is based on a competent, impartial and effective system where governments, businesses and consumers have a role in maintaining confidence. Regulators rely on national accreditation bodies which verify the com-

petence of Laboratories, Inspection Bodies, Certification Bodies, Validation and Verification Bodies, Proficiency Testing Providers, Reference Material Producers, which offer conformity assessment services to standards/regulatory requirements/scheme criteria for the benefit of government, business and consumer on the market of product of and services that is why that the government has been working to continually improve the quality infrastructures of Ethiopia, NQI institutions laboratory complex and office building are being built at a cost of 1.9 billion birr of which ENAO is one of the beneficiary organization. In addition to this through the National Quality Infrastructure Development Program, World Bank project, the government is building the capacity of the institution at a cost of 50 million dollar.

ETHIOPIA PUBLIC HEALTH INSTITUTE (EPHI)

As a stakeholder, what is your role in promoting quality?

Addisu Kebede: Our Office is duty-bound to control quality via accrediting institutions. One of its missions is to strengthen laboratories' capacity, thereby providing the public with services keeping the required standard in the country. Quality can be well manifested when laboratories get value accreditation. To this end, a number of efforts have been expected, and an institution to give laboratories accreditation is required.

Earlier, there was no such responsible institution, but after the establishment of the Ethiopian National accreditation office, promising activities are being carried out, and we are collaboratively working with them. We as government officials are given the responsibility of building the capacity of laboratories, and provide society with standardized laboratory services. After we have done this, laboratories are ordered to apply to ENAO. After being assessed by this



Addisu Kebede
Director of the National
Laboratories Capacity
Building Directorate in the
Institute.

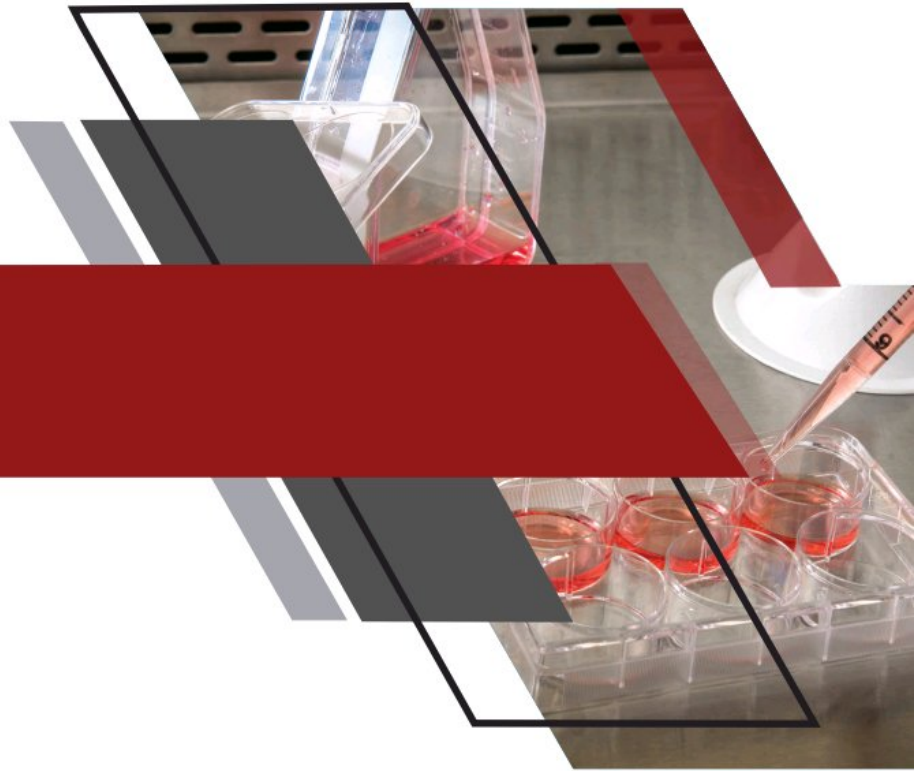
organ, laboratories are given accreditation if they meet the required standards.

So far, over thirty laboratories have been accredited with the help of our effort in Ethiopia – including Ethiopian Public Health Institute (EPHI) and others found in different regional states as well as private ones.

What is your role in building the capacity of institutions?

Addisu Kebede: Our role in this regard has been supporting the service they have been providing. For this, there should be a sufficient service to be given to patients. To come up with a meaningful outcome, institutions need to be provided with input supply, training, different documents, Proficiency testing samples, done at home or abroad, to test the quality of the laboratories. These samples help laboratories know whether the result is correct or not.

This is one of the criteria needed for accreditation; it is



called External Quality Assurance (EQA) a quality testing means. A laboratory that fails to meet this, will not get accreditation, as it is mandatory. The laboratory which does not participate in this quality testing channel will not get any accreditation. Most of the time it is said accreditation is not mandatory, but as far as you are concerned, it is considered mandatory.

How do you respond to that? So far in Ethiopia, many laboratories have not got accreditation. Yes, they are simply working by fulfilling the basic quality requirements. Of the over 4,000 health facilities, those which are accredited are not more than 30 to 40. However, there is a system to test quality—EQA. Institutions are given samples to test at what level they are. There is also quality control

done daily inside laboratories to know the correctness of each and every test. There is training, too, and activities are undertaken by standard operating procedures (SOP) which are read and get people trained. However, accreditation is the system to help us check the fulfillment of all requirements.

What is next?

Addisu Kebede: We are preparing a new strategic plan to be implemented in the coming ten years. In so doing, we are endeavoring to get over 200 laboratories capable of meeting all the requirements of accreditation. We have planned a lot. Yes, the health system in our country requires support. For instance, in developed countries, a laboratory that is not accredited is not allowed to work.

All laboratories apply by fulfilling all the requirements themselves, but in our country, this is not well practiced following lack of skilled manpower, infrastructure and other necessities. These fundamental elements are not yet met as the accreditation process is getting stringent.

In our country, quality has been focused as much as possible, but many laboratories in the country have no accreditation service so far. In the future, there will be an expansion of the health insurance system, and this can be incorporated as a criterion for accreditation. In so doing, they can provide the public with well standardized services.

When a strong regulatory system prevails and health insurance programs expand, laboratories can be competent enough by themselves,

as they are now supported by EPHI or state laboratories. There are not many laboratories that are willing to visit accreditation centers by their own initiation in our country, except some private laboratories. Most of them however are supported by the federal government or other bodies.

As far as our relationship with ENAO is concerned, as we are their stakeholders, we are making laboratories competent through various mechanisms. Since they cannot accredit in the absence of suitable laboratories, we are doing all our level best to make them have competent laboratories. We are providing training, EQA support, prepare documents, and assign professionals to support mentors that we choose annually from 30 to 40 laboratories, etc. When we complete the laboratories that meet the required standard, they are sent to apply for accreditation. We are service providers and supporters and ENAO-accredited laboratories.

What does the support of ENAO for you?

Addisu Kebede: When we were working with some international organizations earlier, it was tough, as they requested pay in dollars.

The existence of ENAO helps lessen the burden, as we can pay in Ethiopian currency. Even earlier, we took accessories in dollars, but now we are working with our people who can understand the inside out of our level. This is a great advantage. If there is no ENAO, these 30 or 40 laboratories could not exist. We had tried several times before to be successful, but as they had stringent criteria and require a very costly price in dollars, we had not come up with results as required. So ENAO is greatly benefiting us, as it is a local organization.

What is expected of stakeholders, your institution, and others working in the area to make accreditation successful?

Addisu Kebede: If we want to make accreditation successful, laboratories must be committed. Unless owners of laboratories work day in and day out, our sole support does not have a meaningful benefit, because the issue of accreditation is all about practice. Being given accreditation is equivalent to making an oath to repeat what is suggested during the assessment. So if they do not do it recurrently, it won't have any significance.

Hence, every laboratory is expected to work hard if it wants accreditation, deploying ample and competent professionals, supplying a sufficient budget for quality work, fulfilling any required document requested by ENAO.

To this end, laboratories themselves must exert utmost effort, as other supports including ours have led nowhere. In some circumstances, when laboratories are committed, leadership might not support them. As we assessed somewhere, we have found that when CEOs help laboratories, the latter can go to accreditation soon, but the reverse becomes true in some institutions. Hence, apart from laboratory management, the facility support of CEOs is of paramount importance in making a difference.

Besides, regional health bureaus need to support them, as we simply technically assist. We do not have managerial or administrative power. If a given laboratory for instance says 'I don't want,' we can only report this to the health bureau, no other measure is taken on behalf of us.

Hence, the health bureaus themselves sketch a strategy, and set a plan to support laboratories, and now

ABOUT

how many laboratories must be sent to accreditation annually. We do have annually joint planning with state laboratories like EPHI. There are regional laboratories in every state, but when we go to evaluation annually, we hardly get laboratories fulfilling requirements – except in some places such as in Amhara and Oromia, with a relatively good performance.

Sometimes regional states support and get them competent. Making an annual plan, lack of budget and people consistent reshuffle, The laboratories have to work hard, and facility management or CEO, state health bureaus, and others, need to actively support these institutions. We as a federal institution are committed to helping laboratories fulfill what they need annually.

We have to apply for accreditation, as it is by far better than haphazardly running activities, and we have to make it a culture, since this approach is a quality assurance certificate. If every activity is accredited, we can provide clients or customers with standard service. Even the laboratories themselves can easily build confidence if they are accredited. So, we must focus on accreditation, and get all our institutions accredited.

Stakeholders

ENAO has a stakeholder forum composed of governments and private sectors in which interested parties involved in the accreditation represented, ENAO will consider the balance representation of organizations or persons by considering the scope and volume of their interest/activity towards accreditation, scope of its organizational representation, attachment to accreditation, directly or indirectly use accreditation service, association of conformity assessment bodies, regulatory bodies that links with conformity assessment activities, scheme owners, organizations or institutions engaged on the capacity development of conformity assessment bodies.

The Private Health Sector Association, Ethiopian Laboratory Association, Ethiopian Inspection Association, Representatives from Ethiopian Certification Bodies, Ethiopian National Metrology Institute (ENMI), Food and Drug Authority (FDA), Higher Education Relevance and Quality Agency, Ministry of Agriculture, Ethiopian Institute of Agricultural Research (EIAR), Trade Competition and Consumer Protection Authority of Ethiopia, Ethiopian Commodity Exchange (ECX), Ministry of Trade and Industry, Ministry of Urban Development and Construction, Ministry of Environment, Forest and Climate Change, Ethiopian Chamber of Commerce and Sectoral Association, Ministry of Education, Ministry of Labor and Social Affairs, Ministry of Water, Irrigation and Energy, Ethiopian Energy Authority, Federal General Attorney, Ethiopian Standard Agency and Ethiopian Public Health Institute provide annual input on the accreditation strategic plan in order to ensure the plan accommodates their accreditation needs. The forum will:

- Provide annual input on the accreditation plan in order to ensure the plan accommodates their accreditation needs.
- discuss on the challenges, opportunities and risks on the impartiality in the accreditation activities
- lobby and promote accreditation market
- Initiate new scope of accreditation market
- The forum meets at least once per year to discuss on the risks to impartialities in the accreditation activities.

ADDIS ABABA PRIVATE HEALTH INSTITUTIONS

Dawit Moges. Addis Ababa Private Health Institutions Employers Association Board Member. owner of Hema Diagnostics Laboratory .

Dawit said that Hema Diagnostics is the Private accredited medical laboratory, with an ISO 15189 certificate. The duty of the Addis Ababa Private Health Institutions Employers Association is to protect the rights of owners of private health institutions, to be a voice for them, to gather them and help them get what they need and provide them with training etc. The role of ENAO is keeping health quality, supervising others to keep qualities.

GIZ was Supported us in training and Consulting technically in addition to PT support (Thistle) from South Africa .

If you ask me why Hema became accredited private medical laboratory



Dawit Moges.

Addis Ababa Private Health Institutions Employers Association Board Member. owner of Hema Diagnostics Laboratory .

company, it is simple. Quality needs commitment. Since its top management was very eager to change the company, Hema succeeded. An Irish guy trained us, and helped us push our company to the next level of success.

After we had taken the training, we put all theoretical as-

pects into practice, and were assessed. We qualified upon approval. Hence, the training and the commitment of top management matters the most. They came back after six months and carried out auditing; we were deemed fit. ENAO is a stakeholder to well assist us, indeed. The association is participating in the Stakeholder forum. The team identifies loopholes, revises activities, and facilitates conditions for good service. We raise public awareness.

After we had finished being accredited, the accredited institutions were announced for three months through broadcast media free of charge. They said this and that institutions are accredited and awarded. We also labeled ENAO, ISO accreditation to help customers or clients on what things we have been accredited. This



helps companies to be well known by the public and well-preferred; even we are in a position to win public confidence.

Most laboratories are led by non-medical personnel or non-laboratory experts. Anyway, unless laboratories' top management is committed enough to bring about change, accreditation couldn't be secured. If you are ordered to give urine to labs in a given institution, you might find the lab in the vicinity of a latrine. The level of our laboratories is very low in terms of technology, hygiene, and other related aspects. The association is also a member of accreditation council and has been participating in the different meetings which led by the state ministry of trade and industry.

We (Hema and Arsho owners) take part in the assembly of the council, representing the association and raising medication concerns. Laboratories fulfilled all requirements, but finding one which is not available can be difficult, as all things could hardly be found at one place. These compromise ENAO expectations, though this poses no problems quality-wise. All the quality reservation of the public has always been raised in front of the council, and possible mechanisms are devised.

The role of all stakeholders, as the Addis Ababa Private Health Institutions Employers Association, should be motivating the public to be more beneficiaries, adjusting prices that might emanate from quality, working harmoniously with ENAO to settle disagreements if they

arise during auditing, and other related aspects etc. We must advance the system like foreigners do. They browse labs accredited and inform people to get diagnosed using email. Our laboratories should be well standardized, as their outcome is a matter of life and death.

As in the case of Some western countries, accreditation of laboratories has to be mandatory as it helps increase diagnostic/medication quality. To come up with better work with regard to quality, ENAO should well advertise the issue of quality – particularly revolving around medication. Their strength on social media should be repeated on audio-visual and print media, as the public will benefit much more from exploiting accredited laboratories than non-accredited ones.

ETHIOPIAN LABORATORIES ASSOCIATION

Gashaw Tesfaye, Ethiopian Laboratories Association, Secretary and a Council member at the Ethiopian National Accreditation Office (ENAO) for the last two years.

Gashaw Said that The association was set up in 2001 E.C., and has been assisting associations to help them build their capacity and come up with a collective effort. Its main purpose is to work to ensure laboratory patrolling ethics in the country, and to set clear criteria to test products coming out of a laboratory using testing ethics and others. It is difficult to measure and come up with quality laboratories, unless consistent criteria are set. As the combined effort of the accreditation codicil, the government and our laboratory are decisive ones, all are working in a very coordinated manner.



Gashaw Tesfaye,
Ethiopian Laboratories
Association Secretary

The association is working hard to minimize maintenance costs. We must build our capacity, knowledge and systems, as some machinery stopped functioning due to minor defects. We train our members, and accreditation training collectively, as it is costly otherwise. We have provided our members with over 20 trainings. Our members are now 17 from 30, such as ELA, Meteorology Institute, Bless Agriculture PLC, Ethiopian Public Health Institute (EPHI), Addis Ababa University, Haramaya University, Sebeta Agro-Industry, Environmental protection Authority etc. Some 13 were reduced due to the bureaucratic red tape of licensing and other factors – the very reason to come together in overcoming the common problem revolving around maintenance, for instance.



What is your relationship with the Ethiopian National Accreditation Office (ENAO)? And the benefit you gained?

Gashaw Tesfaye:- Our relations with them are meeting the basic things that require policy, as they need to be dealt with together with them. There are plans to enable us to easily meet accreditation with their help. They train our members with no pay, as the main thing is capitalizing on human power. They need us to recruit members and we are working on that, though a lot remains to be done on our side. They share our problems and provide us with inputs for policy instruments. Above all, they have made the playing field conducive for us.

In terms of helping them in due course of producing competent laboratories, we are lagging behind.

What are the challenges in relation to this industry?

Gashaw Tesfaye:- An encouraging system pushing institutions forward must be established. Besides, providing a fair playing field and encouraging incentives must be practiced. Motivations – especially for accredited laboratories – need to be made a culture. Of all our members, some are not accredited. For instance, food and beverages do have a good lab, but are not our members. Institutions do have awareness, but want to avoid hurdles and pressing scenarios. However, if incentives are provided, this would make it more attractive for them. Equipment must be calibrated. Many labs should be available to test water, flour, seeds, among others, as combined efforts help in coming up with a real difference. It is costly to individually move to run effective and competent services.

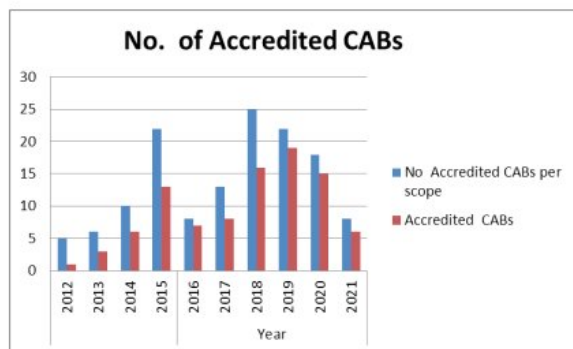
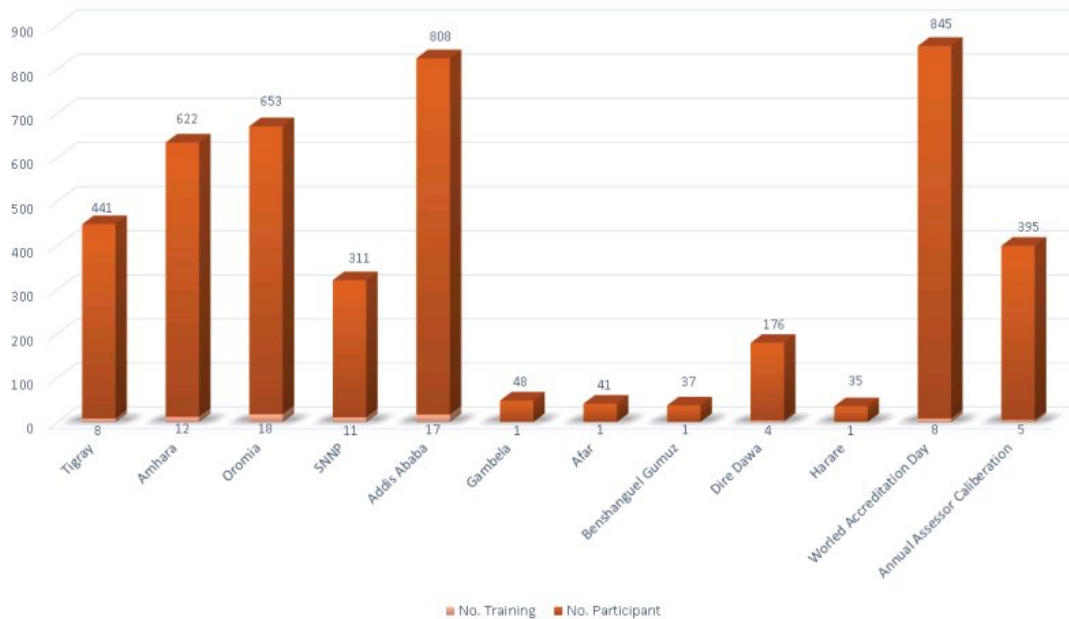
What is expected of stakeholders to consolidate accreditation?

Gashaw Tesfaye:- Organizations working on conformity assessment need to devise mechanisms to choose institutions to work upon. It would also be the best option if they send it to an accredited institution to test. Public awareness should be raised to make them well aware of requesting institutions to be accredited.

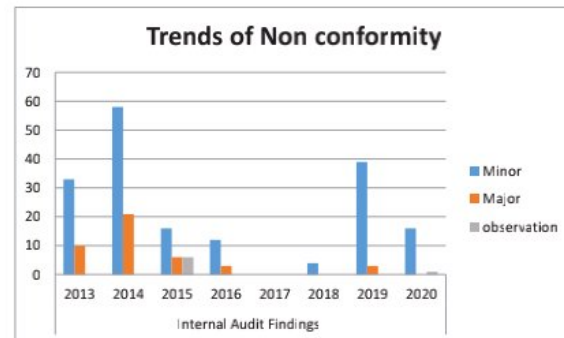
We must work from dawn to dusk to help the nation enjoy quality in all aspects. Stakeholders have to be alert enough in this regard. Moreover, the public should want services from accredited institutions. If this is demanded, institutions must be willing to provide them.

ENAO FACTS

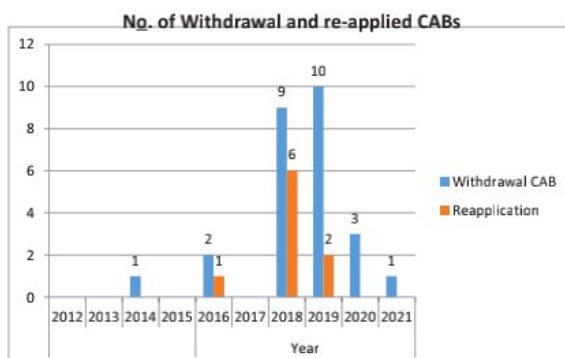
Awareness training



94 Accredited CABs in 137 Scopes



Trends of Internal Audit Findings since 2013



Total withdrawal CABs



Quality Service Survey Analysis Report

Regional and International Accreditation Organizations



PUBLIC SECTOR ASSURANCE

<https://puplicsectorassurance.org>



BUSINESS BENEFITS
Evidence. Impact. Value.

<https://business-benefits.org>

ENAO STRATEGY Road Map

Establishment of ENAO
Feb 2011
Council appointment
June 2011

ENAO QMS development
Oct. 2011
Mock assessment
Nov. 2011
ILAC affiliate membership
August 2011

**Ready to provide
accreditation service**
March 2012
**Provide awareness on five
themes to stakeholders**
Jan 2012

1 Accredited CABs	June 2012
3 Accredited CABs	June 2013
6 Accredited CABs	June 2014
13 Accredited CABs	June 2015
7 Accredited CABs	June 2016
8 Accredited CABs	June 2017
16 Accredited CABs	June 2018
19 Accredited CABs	June 2019
15 Accredited CABs	June 2020
6 Accredited CABs	June 2021

Affiliate member of ILAC -2011
Associate member of ILAC -2013
Full membership of AFRAC -2013
Peer Evaluation by AFRAC/ILAC -2015
Membership of IAF -2016
AFRAC/ILAC MRA signatory -2017
AFRAC/ILAC MRA signatory on Inspection-2019
Certification Peer Evaluation (AFRAC)-2021



Tip

Ethiopian National Accreditation Office/ENAO/ has changed its name to Ethiopian Accreditation Service /EAS/ as of October 2021. And a new logo has been developed.

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