



Dessei Dalkie,

Minister of Science and Technology

Message from Ministry of Science and Technology

It gives me great pleasure to present this information booklet on the Ethiopian National Accreditation Office (ENAO). ENAO is a key player in the National Quality infrastructure of Ethiopia which forms the basis for comparable measurement, testing, certification and inspection of products and services for both domestic and International trade.

We take great pride in the fact that ENAO has become established and fully operational in such a short space of time from its initial establishment in February 2011 to active accreditation in November 2012. This has been a great achievement for the country and what is even more rewarding is the keen awareness in both government and private sectors of the need and benefits of accreditation.

The non-acceptance of results from Conformity Assessment Bodies (test, inspection and certification bodies or CABs) 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.

The formal recognition of an organization's competence to produce reliable conformity assessment results is generally accepted to be based on the process of accreditation. ENAO was therefore established to provide third-party recognition of CAB's

competence to perform specific tasks. This recognition, or accreditation, provides the assurance to Government, regulators, businesses, manufacturers and to the consumer that the results produced by accredited CABs are reliable. More importantly, it provides the assurance to trading partners that its conformity assessment bodies are competent to test, inspect or certify to its trading partners' requirements, while at the same time overcoming trade barriers by assuring compliance to the WTO TBT agreement.

Consequently, the formation of an internationally recognized accreditation service has been identified as one of the key pillars that will support the establishment of a recognized National Quality Infrastructure (NQI). ENAO is well on the road to achieving that recognition. Having accredited its first laboratories in November 2012, it has now been promoted from Affiliate to Associate Member status as from April 2013.

The next step for ENAO is to become a Full Member of ILAC and a signatory to the Mutual Recognition Arrangement (MRA) managed by the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). This will occur when ENAO has been subjected to a Peer Evaluation by ILAC in order to verify the compliance of its strategic intent, management policies and operational procedures to the requirements of ISO 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies*.

I congratulate and acknowledge the management and staff of ENAO for their achievements to date, particularly for achieving so much in such a short space of time. This is indeed worthy of mention since the usual progression in developing a national accreditation body can take years before the accreditation body starts to accredit conformity assessment bodies. However, there is still a lot for ENAO to do to ensure its smooth path to Full Membership and International recognition and I urge ENAO's stakeholders to participate actively in ENAO's development and to take pride in the establishment of a truly world-class accreditation facility.

Dessei Dalkie,

Minister of Science and Technology



**Mohammed Ahmud Gaes,
State Minister of Science and Technology**

Message from Accreditation Council

From the perspective of my position, as State Minister of Science and Technology and Chairperson of the Accreditation Council I indeed well positioned to witness the rapid development and good performance of the Ethiopian National Accreditation Office (ENAO). From the immediate outset, ENAO's management and operational policies and procedures were structured and aligned to the international requirements for accreditation bodies, ISO/IEC 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies*. It embarked on an ambitious capacity development program which resulted in the:

- Rapid development of awareness of the role of accreditation among stakeholders by the active promotion of ENAO's role, responsibility and services through workshops, conferences and media engagement;
- Establishment of intensive training programs in order to build a pool of ENAO Lead and Technical Assessors;
- Establishment of Accreditation Approval Committees for final decision making on the recommendation from assessment teams;

- Development of specific training courses to enhance assessors technical capabilities;
- Accreditation of 6 laboratories and the more recent receipt of several accreditation applications; and
- Recognition of ENAO as an Associate Member of ILAC.

ENAO's achievement of Associate Membership of ILAC is indeed a noteworthy achievement within just over two years from its official establishment and one which bodes well for its target to achieve Full Membership and international recognition within the next few years.

It is important for local stakeholders such as Government, Regulators, Manufacturers, Business, and Consumers to be aware of the benefits of accreditation and for them to play their role in recognizing the critical part that ENAO fulfills in economic development. It is only through full local or national support will ENAO be able to demand equal support and respect from its international stakeholders once international recognition is achieved in a few years. The key objective here is to have an accreditation body that is recognized worldwide so that trade can be more easily facilitated without duplication of testing, certification and inspection of goods and services.

In the light of this, the Council Members have sensed this challenge and are determined to be part of the solution. Selectively the Council approached the Ministers to influence their Conformity Assessment Bodies implement good quality practices by establishing systems that comply with the requirements of the respective standards so that, ultimately, they can apply for accreditation with ENAO. This not only supports ENAO but strengthens the public services sector in delivering its services to its customers.

Strengthening ENAO is strengthening trade, strengthening quality, strengthening healthy and safety of the society, protecting our environment, strengthening the continuity of our development. Therefore, strengthening ENAO benefits all and I encourage you to play an equally active role in supporting your national accreditation body in achieving its highly commendable objectives.

Finally I congratulate the accredited laboratories and ENAO for your remarkable achievement so far.

Mohammed Ahmud Gaes,
State Minister of Science and Technology



Araya Fesseha, Director General

Forward

The Ethiopian National Accreditation Office (ENAO) is a Federal Government Office that was established by the Council of Ministerial Regulation No. 195/2011 , and later re-established by the Council of Ministerial Regulation No. 279/2012, with the objective of acceptance and appreciation of Ethiopian products and services in domestic and international markets by developing an appropriate infrastructure of a national accreditation system which is compatible with international requirements and which allows locally provided conformity assessment services to be recognized internationally.

To achieve the objectives stated in the Regulation, ENAO has in the last two and half years, developed to the extent that it now provides effective and competent accreditation services that can be recognized both locally and internationally. The main influential factors achieved to date in support of the accreditation service are:

- Established an organizational structure which operates in accordance with the requirements of ISO/IEC 17011 and relevant ILAC requirement;
- Developed a pool of assessors who have successfully been screened and passed a series of training courses and practical evaluations based on

ISO/IEC17025 and ISO15189 and who have been listed on the assessor's database;

- Conducted broad awareness sessions throughout the nation; and
- Accepted as an ILAC Associate Member.

The capacity development of ENAO and its marketplace resulted in the accreditation of six testing labs in November 2012 based on the outcome of an independent and impartial review and assessment of their quality management system for compliance to ISO/IEC 17025. In addition, there are now approximately 15 applications currently under review for about 20 laboratories which is a clear indication of the rapid uptake of the benefits of accreditation by ENAO's stakeholders.

ENAO itself undergoes regular self-audit and management review to check its compliance to the requirements of ISO/IEC 17011 and relevant ILAC requirements in preparation for its Peer Evaluation by ILAC in the coming few years.

The successes, so far registered, are results of joint efforts of GIZ Technical Accreditation Director, the Accreditation Council, ENAO's management team, staff and assessors. I trust our joint effort will be strengthened to boost our accreditation service to be accepted internationally.

Finally I call on Regulatory functions in Ethiopia to enforce their mandate of protecting our society in relation to health and safety aspects by using accredited conformity assessment services so that they can rely on credible results; and on the Conformity Assessment Bodies (CABs) to use the golden opportunity where GIZ provides technical consultative support in order to prepare CABs for accreditation.

Araya Fesseha,
Director General

Joint Statement from ILAC and IAF Chairs

World Accreditation Day 2013

Accreditation: Facilitating World Trade

World Accreditation Day is on 9 June 2013 and this year the focus is on the important role accreditation plays in facilitating trade around the world, both within and across national borders.

Nowadays, globalization means that most of us enjoy and rely on a vast number and range of products and services supplied from overseas. International trade represents a significant share of the gross domestic product of most countries—latest figures from the World Trade Organization (for 2011) put the dollar value of world merchandise trade at \$18.2 trillion and the value of world commercial services exports at \$4.1 trillion

At the same time, all countries, and all market sectors, have seen an increase in the number of voluntary and mandatory technical regulations, standards, testing, inspection, and certification procedures. Generally, these are introduced to meet the legitimate requirements of quality and safety that consumers, businesses, regulators and other organizations demand of goods and services, whatever their country of origin.

It is vital, not only for individuals and organizations but 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 these same 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 that prevent access to domestic markets or export opportunities.

Accredited conformity assessment is one tool that is helping businesses not only to comply efficiently and effectively with regulations and standards but also to gain

competitive advantage from doing so and to expand into new markets, including those overseas.

Operating in the public interest across all market sectors, accreditation determines the technical competence, reliability and integrity of conformity assessment bodies, which are organizations that check conformity and compliance with standards and regulations through testing, verification, inspection, and calibration. It does this through a process of transparent and impartial evaluation against internationally recognized standards and other requirements.

Businesses that supply or receive accredited conformity assessment results can show credible evidence of conformance with international standards which can be used to distinguish them from their competitors. Indeed, an increasing number of organizations, in both the public and private sectors are specifying accredited testing, inspection or certification as a precondition to tendering for contracts.

In addition to increasing potential markets, accredited conformity assessment can save businesses time and money in other ways. For example, by providing a basis on which they can make efficient and informed choices about suppliers, allowing them more time to concentrate on business development.

Furthermore, as accreditation is recognized internationally, it can open doors abroad equally as well as those in the domestic market.

The primary purpose of both IAF and ILAC is to establish multilateral arrangements between their member accreditation bodies based on mutual evaluation and acceptance of each other's accreditation systems. These arrangements enhance the acceptance of products and services across national borders by removing the need for them to undergo additional tests, inspections or certification for at each country of entry. This helps to reduce bureaucracy and the costs to businesses and contributes to operational efficiency.

Accreditation therefore acts as catalyst to national economies in two ways--by helping domestic companies pitch for business abroad and by promoting confidence in imports from other countries.

The multilateral arrangements also provide governments and regulators with an internationally recognized stamp of approval to demonstrate compliance with standards and other requirements. With confidence in the conformity assessment process underpinned by accreditation, standards can be used to support a lighter touch approach to regulation, which in turn means that businesses spend less time tied up with bureaucracy.

Concepts and Basis of Accreditation

What is Accreditation?

Accreditation is the process of providing recognition to an organization *for its competence to perform specific tasks. It involves the assessment of technical competence of organizations in providing conformity assessment services, which include testing, calibration, certification and inspection. (ISO/IEC 17000:2004 - Conformity assessment - Vocabulary and general principles)*

What is accreditation certificate?

Accreditation certificate is a document confirming the competence of a conformity assessment body to perform conformity assessment activities in a specified subject or fields of expertise.

Accreditation de facto prerequisite

Accreditation has become a growing part of many countries' overall standards and conformance infrastructure. Such infrastructures have traditionally included a:

1. National standards-writing body;
2. National measurement institute;
3. Legal metrology body;
4. Various conformity assessment bodies such as laboratories, inspection bodies and certification bodies; and more recently
5. National Accreditation Body

Over the past 30-40 years there has been a growing demand for a process to independently evaluate the competence of an economy's conformity assessment bodies. This has led to the establishment of accreditation bodies to fulfill this need in both developed and developing countries

Lack of acceptance of test data and certification results across national borders has been identified by the World Trade Organization (WTO) as a significant technical barrier to trade. Accreditation is viewed as one mechanism which may add confidence to end-recipients of test and certification results, if they are produced by conformity assessment bodies which have been independently evaluated for their competence through an accreditation process. (The potential to use accreditation as a facilitator in acceptance of foreign data has been acknowledged in the WTO's Agreement on Technical Barriers to Trade (TBT) in Article 6.1.1 which states "*...verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence*").

The credibility of individual accreditation bodies themselves is a critical factor in the process of acceptance of foreign conformity assessment data.

To address this issue internationally, two bodies, ILAC and IAF, have developed mutual recognition arrangements (MRAs) between accreditation bodies that have demonstrated to their international counterparts that they are competently operating

their accreditation activities in accordance with international best practice (mainly as covered in ISO/IEC 17011).

Developing countries often face difficulties in having their test, inspection and certification data accepted in foreign markets, which may lead to costly delays and duplication of testing for multiple markets. However, accreditation of laboratories or other bodies used to demonstrate compliance of traded goods will facilitate acceptance in overseas markets and reduce the risks to suppliers that they may be producing non-compliant products. However, the availability of local laboratories which are competent to perform the necessary tests, and the ability of those laboratories to achieve accreditation, become key success factors in this process. The availability of a competent accreditation body locally, or access to a credible foreign accreditation body, to undertake any required accreditations, is also a major consideration for exporting countries.

ISO Requirements

To be accredited, a Conformity Assessment Body (CAB) shall comply and implement all the requirements of the relevant standard depending on the type of CAB (testing, calibration, inspection, and certification). These standards are:

- ISO/IEC 17025 for testing and calibration laboratories;
- ISO 15189 for medical laboratories;
- ISO/IEC 17020 for inspection bodies;
- ISO/IEC17021 for management system certification bodies;
- ISO/IEC 17065 for product certification bodies;
- ISO/IEC17043 for proficiency testing bodies; and
- ISO/IEC17024 for personnel certification bodies.

These standards specify requirements for the establishment and maintenance of a documented management system that controls operational and management activities and that provide evidence of the competent performance of specified tasks such as tests, inspections, certifications, etc. The key principle here is that

these standards allow the CAB to prove its competency to perform tasks and that is where the accreditation body, such as ENAO, plays its role.

CAB's that wish to be recognized by third-party accreditation will invite ENAO to assess the system that has been established and maintained within their organization. ENAO will then establish a team of trained and registered assessors to perform an assessment on the organization.

Path to accreditation

The vast majority of CABs in Ethiopia consist of mainly test laboratories and for this reason we will refer to laboratories as a means to explain the accreditation process.

The initial assessment is conducted by the ENAO team of assessors in order to evaluate whether it is competent to undertake certain specified tests and has management policies and practices that are likely to produce reliable test data each time a test is performed. The fundamental document defining the requirements against which a laboratory will be assessed is ISO/IEC 17025, but the accreditation body will have precise requirements specific to the tests being undertaken over and above those that are contained in this standard. For instance, it may have special requirements for the intervals at which equipment must be recalibrated, or periodic checks that must be made, or some particular educational requirements for certain types of laboratory staff.

The assessment consists of preparatory work prior to any visit followed by the assessment itself during which the assessors determine the extent of compliance to the requirements of the relevant standard, in this example ISO/IEC 17025, and to evaluate the effectiveness of the processes and practices that have been implemented in order to prove competence in the performance of tests for which the laboratory seeks accreditation. The assessors are trained to look for objective evidence of compliance and competency. A key principle of accreditation is to ensure that the organization has a system in place continually

produces reliable data. With this in mind the assessors will place a large emphasis on evaluating the technical competency of the system and the staff and, for instance, in testing laboratories the evaluation of quality control systems, competency of personnel, validations of methods, measurement uncertainty, equipment and traceability are key focus areas of the technical assessors. The Lead Assessor will evaluate the management aspects of the system to ensure that it is self-sustainable and regularly audited and reviewed.

Only when the Initial Assessment is completed to the satisfaction of ENAO's Accreditation Approval Committee is accreditation granted. While the accreditation body should not provide a consulting service, the assessment process can also be very instructive to the laboratory. Often there is some legitimate technology transfer from the expert assessment team to the laboratory staff.

Once the laboratory is accredited it is then subject to regular surveillance audits starting 6 months from the date of the accreditation been granted and then yearly after that until 4,5 years has passed when the laboratory is then re-assessed with a new team of assessors. The cycle then repeats itself every four and half years.

Sustainability of Accreditation

ENAO is the mandated government office to supply accreditation services in Ethiopia and is designated as the National Accreditation Office. Its management and operational activities are governed by a management system that has been established in accordance with ISO/IEC 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies*. Until very recently, ENAO was an Affiliate Member of the International Laboratory Accreditation Cooperation (ILAC) Now, having accredited 6 laboratories in Nov 2012, ENAO has now been granted on 24 April an Associate Membership of ILAC and its next level of membership will be Full Membership which will be subject to a Peer Evaluation by an international team of experts whereupon ENAO will be evaluated for compliance to ISO/IEC 17011

whereupon it will be granted full international recognition by Mutual Recognition Arrangement (MRA).

ENAO, being the national accreditation body is fully supported by Government since its services are seen as key to the success of the National Quality Infrastructure and ultimately to the successful reduction of Technical Barriers to Trade (TBT). It is therefore heavily subsidized by Government and consequently its services are priced to be extremely competitive compared to non-Ethiopian accreditation services.

Laboratories that attain foreign accreditation (accreditation from another country's accreditation body) in a developing country scenario have to pay serious attention to sustainability issues to maintain the accreditation status. Amongst the issues that have to be addressed are the financial sustainability of the laboratory as the escalating costs of foreign accreditation have to be met, corporate governance issues and employee motivation. Commercial orientation of the laboratories is of prime importance where the market, customer and competitor analysis and the costing and pricing of services have to be addressed. It is of prime importance to pay attention to the sustainability issues prior to attaining accreditation status.

Basis of accreditation

- 1 Accreditation supports government and regulators work and promotes good regulatory practice.
- 2 Accreditation ensures the movement of goods all over the world; corresponding agreements exist between the various economic areas.
- 3 Accreditation reduces the need for re-inspection, re-testing and re-certification of products in an importing country in doing so save time and money for both exporters and importers.
- 4 Accreditation is a prerequisite for the WTO Agreement on Technical Barriers to Trade (TBT). The TBT agreement states that, "verified compliance, for instance through Accreditation, with relevant guides or recommendations

issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence."

Accreditation systems offer potential benefits for conformity assessment bodies

Conformity assessment bodies, including laboratories, have the potential to receive a number of benefits and advantages from achieving accreditation.

For example, accreditation provides the following support:

- As a benchmark for performance

Many conformity assessment bodies operate in isolation from their peers. Assessment by experts for compliance with accreditation criteria brings independent confirmation that they are operating at levels that others have judged to be competent. When deficiencies are identified, they can take corrective action and thus improve their ongoing performance.

- As a recognition of competence

Accreditation provides public recognition of the specific competencies of the accredited conformity assessment bodies. Their outputs will be more easily accepted by suppliers, purchasers, consumers, etc., — both their direct clients and other interested parties, such as regulators.

- As a marketing advantage

Accreditation can give conformity assessment bodies a marketing advantage. Their customers should, have more confidence, knowing that they have been subjected to independent evaluation

- For international recognition

Where conformity assessment bodies are accredited by bodies which are signatories to the Mutual Recognition Arrangements (MRAs) of ILAC and IAF, or their regional Cooperation Bodies (APLAC, EA, IAAC, PAC and AFRAC), they have access to international recognition as competent bodies in multiple foreign markets.

Accreditation benefits government and regulators

Accreditation is beneficial to government and regulators and promotes good regulatory practice (GRP).

Accreditation supports the establishment of a well-structured national technical regulatory framework and could be an important tool for regulators in developing countries. The accreditation process helps provide assurance to regulators that a particular organization / individual is competent to perform a specified conformity assessment activity (scope) based on recognized and transparent criteria and procedures. A properly functioning technical regulation system can benefit the domestic economy by balancing regulatory and trade interests, improving the quality and consistency of technical regulations and supporting compliance with international requirements, which supports good regulatory practice (GPR).

On the international level, accreditation can play an important role in harmonizing technical regulations -through the common reference to international standards and guides for conformity assessment. This supports Article 5.4 of the TBT Agreement by helping to reduce conformity-assessment-related trade obstacles. Harmonized regulations, in conjunction with an accreditation system, can provide importing countries with a cost-efficient basis to be confident in the quality of goods, and an assurance that they satisfy the technical model of trade; this will benefit all participants. An effective technical regulatory system is an important factor for any country that wishes to access international markets, as it should reassure/guarantee the importing country that any exported products or commodities have been fully assessed before export for compliance with the regulatory requirements of the importing country. This reduces the risks of delays and product rejection.

Other ways in which governments benefit from accreditation include:

- As a client of accreditation services

Governments may operate their own laboratories, inspection activities, and certification systems. Accreditation provides the clients (or other affected parties) of government laboratories, certification systems, etc., and the public at large, with reassurance that the Government's own conformity assessment capabilities are independently evaluated and recognized for their technical competence.

- As a user and/or purchaser of services from accredited facilities

Governments are significant users of non-government services, including goods and services requiring conformity assessment. Accreditation by those conformity assessment bodies gives governments the additional confidence of knowing that the competent bodies have confirmed that their purchases comply with their specifications./OR Accreditation reassures governments that their purchases meet their specifications.

- As a body that specifies that conformity assessment services be used.

Government departments, regulatory authorities and agencies will often specify that accredited bodies be used. References to accredited bodies may be found in their public policies, government specifications and regulations. This again provides governments with additional confidence that consumers and society in general have been protected by the use of competent bodies in determining compliance with laws, regulations and specifications.

- For underpinning government-to-government mutual recognition agreements for conformity assessment activities

Some governments have recognized (or designated) their national accreditation bodies as the bodies which will demonstrate the competence of conformity assessment activities in their economy that are relevant to specific regulated sectors covered by government-to-government MRAs.

- For liaison on trade and technical barriers to trade

Some governments work closely with their accreditation bodies, at various levels of formality, in their negotiation of trade and TBT issues with foreign governments. The availability of a well-established accreditation body also means that governments can demonstrate that their economy has access to a process that allows it to gain acceptance of foreign conformity assessment certificates and data as sought in the WTO Agreement on Technical Barriers to Trade.

Accreditation and Political Autonomy

Perhaps the most basic 'value-added' benefit of having a national accreditation system is the economic and political autonomy it can bring. Ownership and control of an accreditation system removes dependence on the accreditation bodies of developed countries; it prevents a developed country from using the threat of withdrawal of accrediting services for political and economic leverage; and, uncertainty about future accreditations are reduced and national pride bolstered.

By developing their own accreditation infrastructure, developing countries can custom-design a system that responds to local needs, and which need not replicate a vast, expensive accreditation system more suited for a developed country.

A country with its own independent accreditation body can directly monitor the work of domestically accredited conformity assessment bodies in that country. In addition to the benefit of greater surveillance access and transparency, having such a system may also eliminate the potential scenario of a 'fly by night' foreign accreditation body which could more readily escape domestic penalties. Domestically controlled accreditation systems will usually be easier to monitor and, where necessary, legally discipline.

The establishment of an accreditation body in any country (developed or developing) needs careful analysis of the costs and benefits. This is particularly so in countries which may have very few potential clients for accreditation.

Operating an accreditation body that meets the requirements for membership of an appropriate MRA, will involve considerable financial and intellectual investment, and the body might never become self-funding. In this case, it will normally be considered an investment in national infrastructure, rather than a commercial enterprise.

Other key considerations in establishing the needs and potential resources for a laboratory accreditation body include:

- Access to a national measurement institute or institutes able to provide calibration and measurement traceability to international standards;
- " Access to technical experts able to undertake assessments of applicant laboratories for the specific tests or measurements sought for accreditation recognition and to serve on any necessary supporting technical committees;
- Access to proficiency testing programs and certified reference materials;
- Availability of accreditation body personnel with appropriate technical and related knowledge on accreditation and related standards;
- Ability to establish an accreditation body within an organizational structure that is free from any conflicts of interest that might impede compliance with the impartiality requirements of international standards such as ISO/IEC 17011.

If an analysis of the needs for an accreditation body in a country (versus the use of existing accreditation bodies in other countries) is positive, and the resources to develop it can be accessed, then there may be a number of positive benefits, including:

- Independence from the need to access foreign bodies for accreditation services;
- Better awareness of local language and cultural sensitivities;
- Interaction with other standards and conformity infrastructure bodies in the country;
- Development of local awareness of international standards, foreign regulations, etc., amongst industry, government bodies and conformity assessment bodies;
- Opportunities to contribute to the improvement of laboratory and related services in the country.

ENAO is reflection of all of the above in that the Government has invested in the principle of a national accreditation body and has shown its commitment to support this body for the good of the nation.

Accreditation as Market Tool for Developing Countries

The availability of a recognized national laboratory accreditation scheme in a developing country, or the existence of a number of laboratories accredited by a credible foreign accreditation body, can help promote the country's technical capabilities. This may be of even greater significance if the scope of such accreditations cover key export products or commodities, or provide evidence of compliance with key foreign technical regulations.

Accredited facilities in a country might also serve as useful benchmarks for other laboratories and thus encourage broader improvements of laboratory capabilities in the economy.

Individual accredited laboratories should be able to gain additional business within their own economy and beyond, particularly by using the accreditation symbols of their accreditation body on their reports and certificates, especially when competing with those who do not have independent recognition of their competence

Challenge of Accreditation in developing countries

In addition, external forces may also make it difficult for developing countries to implement their own accreditation systems.

- Exporting firms and developing country markets, for example, may prefer accreditation by a body from a developed country with which they are already familiar and confident despite the huge cost deploying for implementation.

- Lack of access to all the information needed to develop an accreditation body. Usually this is facilitated if it can join one of the regional or international accreditation body forums such as ILAC, IAF, APLAC, EA, IAAC, PAC or AFRAC. Normally these organizations have lower fees for developing country members and have classes of membership for bodies which are not yet fully established.
- Lack of access to training for its staff and assessors.
- Not getting fully supported and its functions recognized by its own government. This is a key question for membership of some of the MRAs of bodies such as ILAC.
- Access to competent Metrology Laboratories in order to calibrate equipment for traceability of measurements which is a fundamental requirement for accreditation of conformity assessment bodies.
- Difficulties in prioritizing areas for accreditation or attempting to be cover all types of conformity assessment bodies.
- Lack of access to domestic or international Proficiency Testing (PT) schemes.

ENAO has managed to overcome most of these challenges. Issues such as access to PT schemes will always be challenging but as the accreditation market increases in Ethiopia so will the demand for certain schemes and consequently the cost will reduce either through the establishment of national schemes or by mutual arrangement with scheme providers.

Factors which mitigate the challenges of accreditation

While there are a number of significant hurdles to overcome in implementing an accreditation program in a developing country, there are other factors to be considered when evaluating its feasibility:

A developing country is not developing an accreditation program in a knowledge vacuum. A 'standards heritage' of know-how and resources is available from the international standardization community to assist them. Both the TBT and SPS Agreements encourage WTO members to assist other members in establishing

standardization infrastructures—established accreditation bodies can provide technical assistance to developed countries to set up their own unique 'developing country accreditation systems.

The other major factor to be considered is that an accreditation system is essential if a country is to participate fruitfully in the global economy. With such a system in place, a developing country can take advantage of agreements that give access to developed country markets. An accreditation system is a vital component of the physical and institutional infrastructure which will enable developing countries to provide internationally recognized conformity assessment services to producers and potential exporters and to participate in international standards setting activities and organizations.

Various aid bodies and international accreditation bodies may also provide developmental assistance. For example, UNIDO and other international bodies such as ISO, ILAC and IAF and their associated regional bodies have implemented a number of training and awareness-creation projects on topics of relevance to accreditation.

Other aid agencies have also been active at both a single-country and a regional level to assist development and training in these areas. In the example of the establishment of ENAO, the GIZ has played a major and significant role in the establishment of the national accreditation body by providing managerial and technical support from the very early stages of ENAO's establishment through to its current status. GIZ is not only assisting the organization itself but it is also enhancing the market for ENAO by directly consulting to laboratories that show commitment and resolve in order to attain accreditation status.

Approaches that have been used to satisfy developing country needs for access to accreditation bodies, and the development of these bodies, have included:

- Attachment training abroad of personnel at well-established accreditation bodies;
- Twinning of new or proposed bodies with an established accreditation body;

- Development of a regional solution to a conformity assessment or related service need;
- Selected contracting of foreign assessors to complement the available pool of technical experts within the country;
- Facilitating access to regional or other proficiency testing programs;
- Facilitating membership of regional and international bodies;
- Facilitating access to measurement traceability through the services of foreign metrology institutes (including institutes in other developing countries).

2 Ethiopian National Accreditation Office, ENAO

Vision: Internationally recognized accreditation center by 2012E.C.

Mission: To provide credible accreditation service for conformity assessment bodies

Values:

- **Competence:** world class service through continual improvement
- **Impartiality:** Equal approach and judgment with open mind to all our customers
- **Transparency:** without jeopardizing confidentiality, things are open to all
- **Non-discrimination:** Government and Private Conformity assessment bodies are equally in accreditation.

Power and Duties of ENAO

Ethiopian National Accreditation Office is a national Accreditation body established to:

- ➔ Provide accreditation service to conformity assessment bodies based on national and international requirements;
- ➔ Determine the shape and other features of the national accreditation symbol and authorize its use;
- ➔ Conduct surveillance audits on those bodies that have been accredited;

- Keep a register and publicize the list of accredited bodies and those whose accreditations have been suspended and withdrawn, and forward same to the concerned regulatory bodies;
- Issue and implement directives governing the accreditation process, in particular, the assessment of applicants and the granting, suspending and withdrawing of accreditation and handling of grievances relating thereto;
- Organize consultative meetings of stakeholders, as may be necessary;
- Work in cooperation with the relevant stakeholders to ensure the existence of an integrated support for strengthening the national quality infrastructure;
- Represent the country's interest in international forums regarding accreditation and to follow up the implementation of treaties to which Ethiopia is a party;
- Charge fees for the services it renders in accordance with the rate approved by the government;
- Own property, enter into contract, sue and be sued in its own name;
- Carry out other related activities necessary for attainment of its objectives.

Organizational structure: The organization is structured in the way that can facilitate to deliver effective and efficient accreditation services which meet the mission and objective of the office.

The core business focus is the Accreditation function which comprises the Accreditation Directorate under which there are testing, inspection and certification groups. The supporting services consist of human resource and development, public and human relation, information communication technology, finance and supply, planning, reform officer and audit. In addition there is also the Accreditation Approval Committee which receives the recommendations from Assessment Teams and which makes the final decision on granting accreditation

and the Appeals Committee which arbitrates on appeals from stakeholders on grievances.

ORGANISATIONAL STRUCTURE



Accreditation Directorate



Kidist Hailu

A/ Accreditation Director

Since its establishment, ENAO has been actively working to the fulfillment of ISO/IEC17011, ILAC and national regulatory requirements that enable to be internationally recognized Accreditation Body. The following are brief descriptions of many of the core activities completed so far:

Quality Management Documents: More than 80 documents which enable us to provide the accreditation service have been prepared and are under continual review and revision. These documents are backbones of our Quality Management System which has been developed based on ISO/IEC17011 and ILAC requirements. The documents are categorized as Policy, Procedure, Requirement, Guidance, Advisory, Job Description and Forms. Those documents which are relevant and essential to our customers are uploaded on our website to make the procedure of accreditation easy.

Assessors Training: Conformity Assessment Bodies seeking accreditation are assessed on site for compliance with specified accreditation criteria; such assessments are carried out either by ENAO assessors directly employed or, more commonly, by par

time assessors appointed by ENAO to act on its behalf. In either case the assessors play vital role in determining the credibility of the scheme. Therefore, curiosity on assessor's selection and training is imperatively important. Because of these ENAO gives assessors training a priority active since it established by Council of Ministers Regulation 195/2011. As ENAO potential assessor he/she has to fulfill the requirements stated on JD10 for technical assessor and JD09 for lead assessor. So far, three rounds of trainings on ISO/IEC17025, two rounds of trainings on ISO15189 and one round of training on ISO/IEC17020 have been conducted.

The trainees were selected from different fields of profession came from Government and private organizations with a background of Chemistry, Biology, Engineering, medical laboratory technology, agriculture, pharmacy, food and other relevant fields having a four year relevant (testing, calibration, inspection) experience. For the first round Invitations were widely distributed to organizations throughout Ethiopia for suitably qualified candidates to apply for the assessor-training program. A total of 350 applications were received out of which the top 40 candidates twenty from medical laboratories and twenty from testing and calibration laboratories were selected.

For convenience of the trainer to monitor the trainee participation and to recognize their potential, around 20 trainees are attaining in a class.

The schemes which assessors trained so far are on:

- ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories,*
- ISO 15189, *Medical laboratories – Particular requirements for quality and competence,* and
- ISO/IEC 17020: *Conformity assessment -- Requirements for the operation of various types of bodies performing inspection.*

The ENAO assessor-training program is intensive, demanding and stringent with only 60% of the candidates making it through to the final stages of evaluation and possible registration as ENAO assessors. The training programs will be continual till ENAO

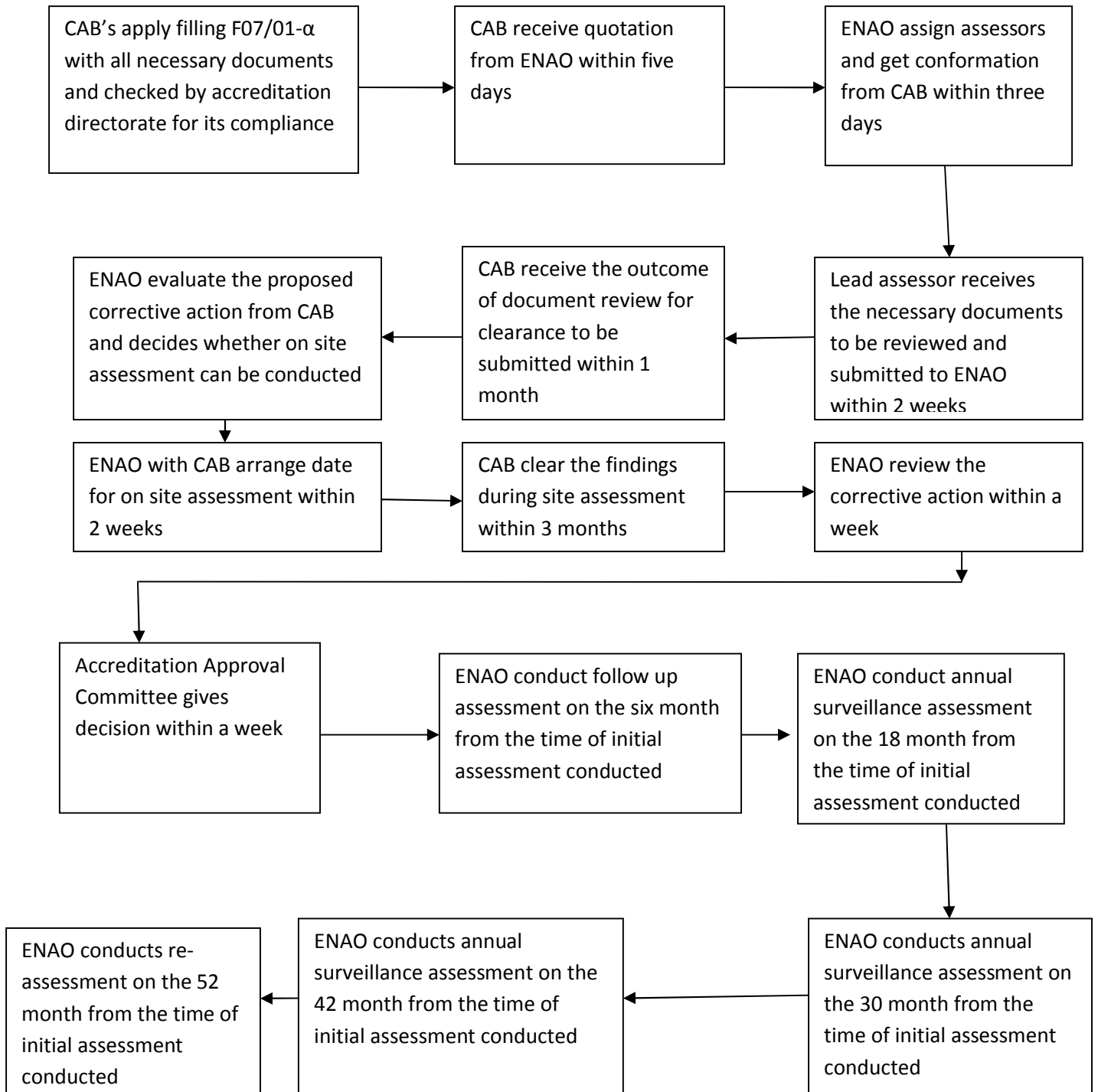
accommodates sufficient number of qualified assessors; in the future ENAO will expand assessors training on certification bodies.

Accreditation service: The reason why ENAO has such a large assessor pool is that in its strategic plan ENAO has committed to accredit 60 conformity assessment bodies seeking accreditation. In this regard the office has to be in a position to address the target given in the GTP preparing the quality manuals, training and storing potential assessors as per to the ISO/IEC 17011 and ILAC requirements and ENAO with great endeavor had done these all. However, to achieve the 60 target is a daunting task since ENAO can only market the benefits of accreditation and cannot consult CABs to assist them, to achieve the level of conformity and competence in order to apply for accreditation since this would be a conflict of interest acting as both player and referee in the marketplace, so to speak.

Thankfully, GIZ has stepped in to assist by providing consultancy services to CABs that are committed to achieve accreditation. To date, GIZ have assisted approximately 30 laboratories, 6 of which have already been accredited, more than five have applied and the remainders are on track for applying for accreditation in the very near future.

The six laboratories that are already accredited are from the Ethiopian Conformity Assessment Enterprise (ECAE) and EZANA Mineral Development PLC. Their scopes of accreditation can be accessed on ENAO's website (www.ena-eth.org).

The details of accreditation process and accreditation time rule are already uploaded on our website; the summary is highlighted as follows:



Testing Assessor Group



Getnet Tsigemelak
Medical Laboratory Accreditation
Technical Assessor



Getie Birhanu
Laboratory Accreditation
Technical Assessor

Potential customer assessment: To extend ENAO's scope of accreditation services it is necessary to rely on the availability of real data. For the time being data of 60 laboratories, 3 inspections and 3 certification bodies have been listed with all the necessary information of company name, methods used, products tested, testing parameters, major equipment and physical address. We will consolidate the list including more data in the near future which is solely used for the office and for customers wishing to participate in PT schemes.

We are competent to provide accreditation service on the scope of ISO/IEC17025 and ISO 15189. Please use us!

Inspection Accreditation Team



Asfa Leta
Inspection Team Leader



Gebrekrstos Gebreamlak
Inspection Assessor

Inspection assessors are on the final stage of onsite training. After a couple of months potential assessors will be registered which enables us to commence inspection accreditation service on our own assessors.

Communication and Public Relation service

The PR of the office adheres to the responsibilities:

- Develop and maintain a valid and usable database of all CABs in Ethiopia which will be used as a marketing database of potential and existing clients.
Prepare annual plan and performance report or the work programs and budgets of the service.



Nigussie Kibru, Head



**Girma Nigussie
Camera Man**

- Planning, developing and implementing communication and public relation strategies.
- Organizing events including press conferences, press briefings, open day and press tours.
- Writing and editing house magazines case studies speeches, articles and annual reports.
- Confer with production and support personnel to produce or coordinate production of advertisements and promotions.
- Arranging public appearances, lectures, contests, or exhibits for clients to increase product and service awareness and promote good will.
- Respond to request for information from the media or designate another appropriate spoken person or information source.
- Confirm and follow up production of newsletter, brochures, office profile, calendar and agenda.
- Maintaining and updating information on the organization.
- Collating and analyzing media coverage.

The marketing of ENAO has started from awareness creation session in collaboration with the Ethiopian Health and Nutrition Research Institution, EHNRI on the selected topics:

- Ethiopian National Quality infrastructure
- Accreditation and WTO requirements
- Steps towards Accreditation
- WHO-AFRO/ASLM/SLIPTA approach
- Status of ENAO.

To six targeted regions which are Addis Ababa, Amara, Tigray, Oromia, South Nations and Nationalities, and Dredawa.

Ethiopian Television, FM and Radio Fana were very instrumental for advocacy of ENAO service. Government and Non Government newsletters played a great role in connecting and introduced readers with ENAO. Massive numbers of brochures and quarterly ENAO newsletter are also introducing ENAO's service to customers.

ENAO holds press conferences with journalists on different events of ENAO activities such as the scopes of accreditation started, World Accreditation days, and accreditation certificate award to CABs.

ENAO is celebrating World Accreditation Day every 9 June and we celebrate this year, 2013 for the third time. We started celebrating in 2011 at Addis Ababa, Hilton hotel on the theme "Accreditation support the work of regulatory". Keynote speaker was his Excellency Mr. Dessie Dalkie, Minister of Science and Technology. The message of his Excellency stressed the Government commitment to strengthen and support the quality infrastructure which is a very influential instrument to sustain and to continue the economic development of the nation by making products and service of the nation competitive in the global market.

The second celebration on 9 June 2012 was carried out on the same place where the first celebration was conducted on the theme “Accreditation Supporting Safe Food and Clean Drinking Water”. Keynote speaker was his Excellency Mr. Mohammed Ahmud Gaes, State Minister of Science and Technology. His Excellency emphasized the importance of accreditation to human life and its supporting role for the ongoing process in the five year growth and transformation plan of the country in which agriculture as leading economic sector will be surpassed by the industrial sector as the leading contributor to the economy. The motto of this year, 2013 is “Accreditation Facilitating World Trade”

Being a member of AFRAC and ILAC, ENAO is participating in the General Assemblies. Mr. Araya Fesseha, Deputy Director General of ENAO attended the second and third General Assembly (GA) meetings of AFRAC held in Mauritius and South Africa respectively. The Deputy Director General also attended the 16th GA meeting of ILAC held in Rio-de-Janeiro that benefitted ENAO in terms of exposure to international and regional practices.

Finance and Supply Service



We work with team spirit to overwhelm our responsibilities:

- Planning, Organizing, coordinating and leading the financial activities of the organization.
- Analyze financial budget and prepare financial statements.
- Controlling and supervising the financial system of the organization

Mesyt Asemamawu, Head

- Preparing the working capital and salary budgets in coordination with departments.
- Develop financial formats , receipts and evaluate the applications
- Preparing and distributing the income statements and expense to other departments
- Prepare Cash flow and bank statements, investigating the gaps and take corrective actions.
- Approved cash collection, controlling the financial obligations of the organization on the due date
- Making good financial relationships with other organizations
- Cooperate with the external auditors to investigate the financial activities of the organizations and response accordingly to the recommended issues.
- Organizing, Coordinating, controlling and reporting the inventory at the end of the budget year.
- Developing and implementing the modern accounting systems
- Purchase supplies according to the Identified demand of the departments
- Identifying the procurement opportunities of the organization with government procedures during purchasing

Finance is very instrumental to address the objective of the office, applying the budget to the desired purpose effectively and efficiently.

Store Personnel



Tesfaye Worku
Store Clark



Girma W/Gorgise
Store Keeper

By ensuring the safe transaction of materials from suppliers to users, we support the service of accreditation to be efficient and effective

Human Resource Development and Management Service

Human resource and development supports the accreditation service addressing its responsibilities in terms of:



Fikerte Abebe, Acting Head,

- Perform recruitment and selecting activities based on rules and regulations of civil servants proclamation.
- Data collection and analysis for human resource planning, job analysis, recruitment and selection activities,
- Supervise Human resource training, occupation of health and safety of the employees.

- Planning, organizing, leading, coordinating, controlling and evaluating of administrative, tasks under his supervision,

- Develop organization policy, rules and regulations and submit for approval,
- Prepare short term, medium and long-term human resource or for the purpose of promotion and transfer activities.
- Monitor employee salary increment and other incentives,
- Evaluate the records and archives management system of the organizations,
- Facilitate the retirement formalities of the employees are among the major activities carried out daily in a budgeted, planned and monitored manner.

Human Resource works towards internal capacity building which enhances ENAO's ability to supply effective and efficient accreditation services.

Office Archive



Fanaye Desta, Head

We are committed to value confidentiality of records and related information conducting the business relationship obediently and ensuring discretion for all our customers delivering fast transaction of letters which connects the office and customers

Transport Service (Drivers)



Punctuality is the loyalty that we shall display in our office to satisfy our customers waiting us beyond, we are aware of assessor's delay during assessment which hammers ENAO acceptance. Therefore, we strictly handle and maintain to the availability of transport with precaution care which inevitably affects ENAO punctuality

Kassahun Tadesse & Eyob Seteargachw
Driver Driver Mechanic

Office Keepers



We care the office rooms and corridors to give a pleasant environment that make you to stay and work effectively despite of walkout from unpleasant smell. We always keep clean for a better accreditation service

Emebet Fekermariam and Tigest Tshome

Information Documentation Service

RESPONSIBILITIES

- Ensure integrity and protection of company information processes and of the overall ICT system operating in ENAO.



- Updates software, protect computers and servers of the organizations,
- Computer and related properties specifications during purchasing
- Recommend new and up dated software's and technologies

Desta Kenenissa, Head

- Communicate and share experience with other related organizations to upgrade information technology systems of the organization.
- Standardize the information technology documents and the organization information system.
- Develop office application software
- Prepare Annual plan of the service
- Submitting reports periodically

It was during 9 June 2011 World Accreditation day that the website of ENAO was officially launched which enables ENAO to make all the necessary information and documentation, including accreditation news and updates, freely available to the public. In addition, all staff of ENAO are connected internally among themselves to make exchange of information and reporting easy and cost effective.

Software programs that facilitate the office work are selectively uploaded and minor maintenances are also conducted. Staff capacitating on IT utilization is also one of the tasks carried on to the target of Bsc automation implementation

“There are three kinds of death in this world. There's heart death, there's brain death, and there's being off the network.” ~Guy Almes

Therefore, ensure your alive keeping in touch with ENAO website.

Cross Sector Issue

ENAO is not ignoring the cross sector issues, rather appointed a desk that can follow the issue of women, child and youth, HIV/AIDS and Environment in planned and budgeted way which can be evaluated and audited as of the other accreditation supporting activities.