



# ETHIOPIA

## Quality Infrastructure Assessment Report of Ethiopia

April 2020



|     |   |    |
|-----|---|----|
|     | Executive Summary                                     | 3  |
| 1.  | Introduction  | 5  |
| 2.  | Objective and Methodology                             | 6  |
| 3.  | Ethiopian National Accreditation Office               | 7  |
|     | 3.1. Legal Framework                                  | 7  |
|     | 3.2. Administration and Infrastructure                | 9  |
|     | 3.3. Service Delivery and Technical Competency        | 9  |
|     | 3.4. External Relations and International Recognition | 9  |
| 4.  | Ethiopian Standards Agency                            | 12 |
|     | 4.1. Legal Framework                                  | 12 |
|     | 4.2. Administration and Infrastructure                | 13 |
|     | 4.3. Service Delivery and Technical Competency        | 13 |
|     | 4.4. External Relations and International Recognition | 14 |
| 5.  | National Metrology Institute                          | 15 |
|     | 5.1. Legal Framework                                  | 15 |
|     | 5.2. Administration and Infrastructure                | 16 |
|     | 5.3. Service Delivery and Technical Competency        | 16 |
|     | 5.4. External Relations and International Recognition | 16 |
| 6.  | Legal Metrology                                       | 18 |
| 7.  | Technical Regulation                                  | 20 |
| 8.  | Conformity Assessment Activities                      | 21 |
|     | 8.1. Testing  | 21 |
|     | 8.2. Inspection                                       | 23 |
|     | 8.3. Product Certification                            | 24 |
|     | 8.4. System Certification                             | 26 |
| 9.  | General Comments and Recommendations                  | 27 |
|     | 9.1. General Findings                                 | 27 |
|     | 9.2. NQI Strategy and Policy                          | 27 |
|     | 9.3. NQI for Strengthening SMEs                       | 29 |
| 10. | Conclusion  | 30 |
|     | References  | 31 |
|     | Abbreviations   | 32 |
|     | Notes   | 34 |
|     | Imprint   | 36 |

On behalf of



On behalf of the Federal Government of Germany, the Physikalisch-Technische Bundesanstalt promotes the improvement of the framework conditions for economic, social and environmentally friendly action and thus supports the development of quality infrastructure.

The Rapid Diagnostic Tool was jointly developed by the World Bank Group and PTB.

**Disclaimer**

This report has been developed by the author mentioned above, with editing and publishing by PTB. Opinions and recommendations do not necessarily reflect the views of PTB. While effort has been made to verify the information contained in this document, PTB cannot accept any responsibility for any errors that it may contain. This document is strictly an information document and in no way represents the consensus views contained in this and other PTB deliverables.

# Executive Summary

Quality infrastructure (QI) plays an important role in enabling free, fair and safe trade. This is particularly relevant in a world going through rapid globalisation, and with the rise of free trade agreements. This is currently becoming evident as the African Continental Free Trade Area (AfCFTA) is implemented. In order to satisfy the demands of global trade and successfully participate in global value chains, harmonised standards, correct measurements and conformity assessments are essential. The information gained through the implementation of the Rapid Diagnostic Tool developed by the World Bank and PTB provides a useful overview of the strengths and gaps of a national quality infrastructure and can be used to formulate recommendations for its advancement. The toolkit was also used in Ethiopia as part of a worldwide assessment. The necessary information for the toolkit is gathered in face-to-face interviews with experts from each nation.

In 2009, through the development of the Ethiopian national quality infrastructure strategy, major reforms transformed the single Ethiopian quality infrastructure institution into four independent but interlinked authorities. Today, the Ethiopian quality infrastructure is based on four institutions, namely, the Ethiopian Standards Agency (ESA), the National Metrology Institute of Ethiopia (NMIE), the Ethiopian National Accreditation Office (ENAO) and the Ethiopian Conformity Assessment Enterprise (ECAE).

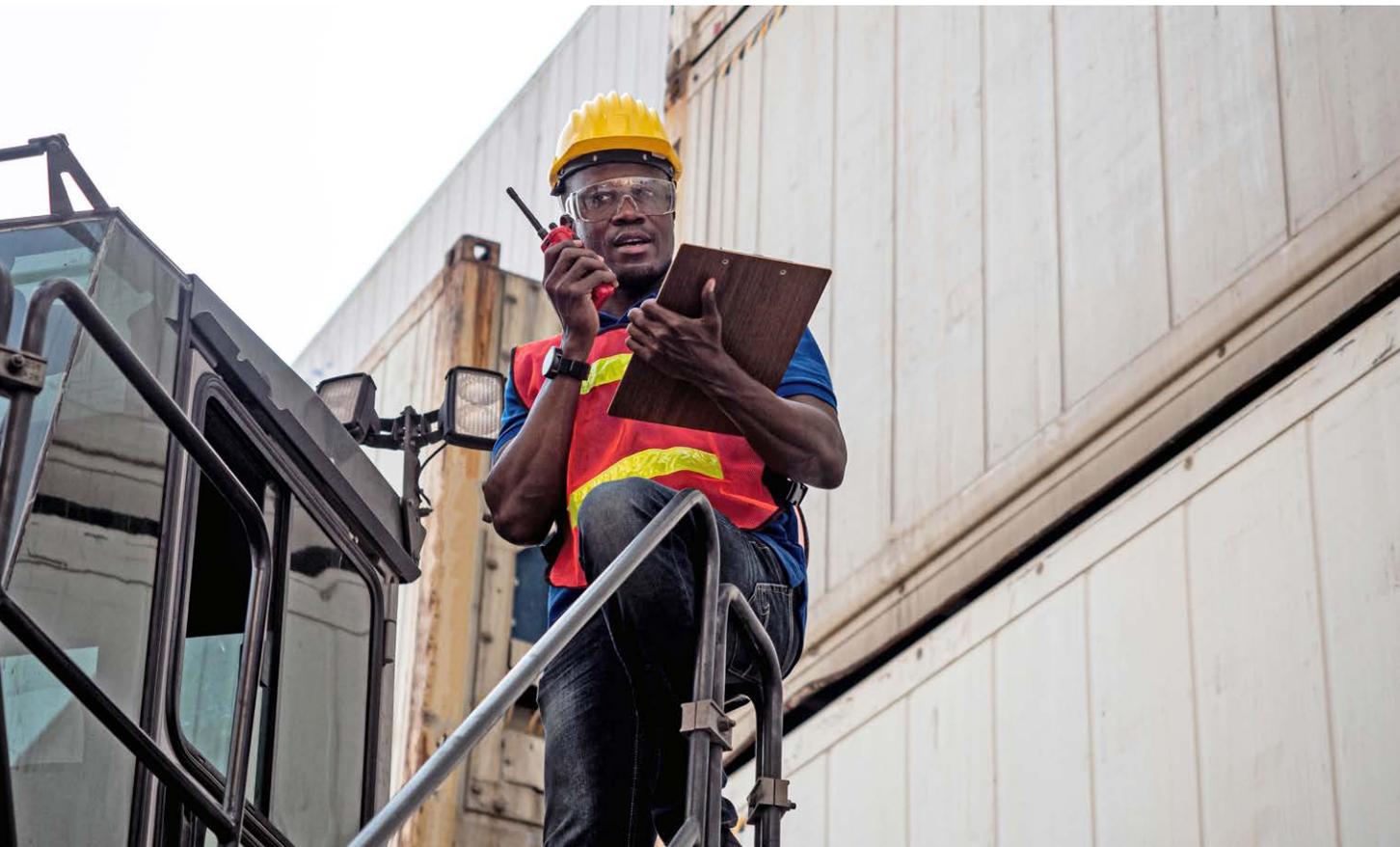
ENAO was re-established two times to meet international demand. ENAO receives support from the World Bank's National Quality Infrastructure Development Project (NQIDP), which focuses on automating the accreditation process and transforming the information technology (IT) service. It has made great strides towards realising its ambition to become visible in the international arena. It became a full member of the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF) and the African Accreditation Cooperation (AFRAC). Other achievements include ENAO's website which provides a vast number of accessible documents which can be consulted by the public. ENAO's main constraint for effective service is

its budget deficits that limit its ability to send experts to regional or international meetings. Another constraint is the challenge of finding suitable technical staff with the expertise required to function effectively.

The Ethiopian Standards Agency, responsible for developing and adopting required standards, is a member of the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and Codex Alimentarius (CODEX). ESA has a fully functioning infrastructure at its disposal to carry out its work. It includes an adequate IT infrastructure which is currently going through an upgrade phase, so that it will be possible to sell standards online in the future. The private sector's lack of involvement in ESA's standard council is a major issue, as it results in an unbalanced representation between public and private stakeholders. Beyond that, ESA's effectiveness is constrained by the fact that positions are filled based on political considerations rather than on merit.

The National Metrology Institute of Ethiopia, established in February 2011, works in the field of scientific measurement and drafts measurement standards based on international recommendations. It is currently facing budget constraints and is supported in training and regional participation by international donors such as PTB and the World Bank. Currently, its physical and digital infrastructures do not meet the organisation's requirements. Its main achievements include becoming a member of the International Bureau of Weights and Measures (BIPM) and AFRIMETS, as well as its cooperation with South Korea in training development. In general, the NMIE is very well positioned in service delivery, and a higher degree of technical competency of the majority of its calibration services has been attested for and certified by the Deutsche Akkreditierungsstelle (DAkkS).

The conformity assessment market in Ethiopia is not yet fully developed. Despite the existence of sector-specific laboratories within research institutions, the market is dominated by the Ethiopian Conformity Assessment Enterprise. ECAE has only accredited a limited number of test items and parameters, and this has created a

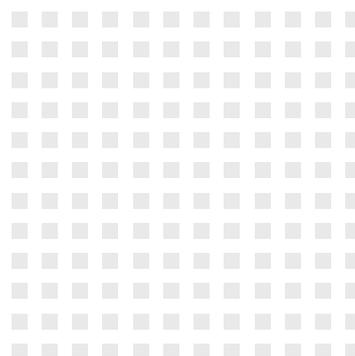


© iStock

situation where many of the parameters of regulated products are tested at high cost outside the country because they are not able to be tested locally. Private laboratories have complained about unfair market conditions. Overall, there is a gap between the required and available levels of competency, transparency and non-discrimination with regard to the designation criteria of testing laboratories.

The Ethiopian quality infrastructure is currently in a development phase and is taking positive steps. But despite taking major steps to develop the national quality infrastructure (NQI), today, the Ethiopian quality infrastructure does not satisfy all the requirements for enterprises to trade with developed markets. This report provides recommendations for filling the gaps in the national quality infrastructure, which include the need to finalise implementing its 2009 national quality infrastructure strategy, as well as its periodic reviewal.

As stated in the NQI strategy, developing a platform to support the exchange and cooperation between QI units is recommended. Further, the quality infrastructure system would benefit from the formulation of a national quality policy (NQP).



# 1. Introduction

This report provides an analysis of the status quo of the Ethiopian quality infrastructure, and aims to provide a full overview by using the Rapid Diagnostic Tool (RDT). The Ethiopia quality infrastructure was founded, designed and implemented in 1968 using a total integrated approach. At that time, all functions related to quality infrastructure were provided by one organisation called the Quality and Standards Authority of Ethiopia (QSAE). These functions included standards development, calibrating metrological measurements, conformity assessment services (testing, inspection and certification), verification of appropriate functionality of measurements, development of technical regulation and regulating implementation. Since the total integrated approach practised by QSAE was susceptible to partiality and conflicts of interest, the Ethiopian national quality infrastructure services could not be accepted at regional and international markets. To achieve this, the national quality infrastructure is required to follow international practices across the value chains so that export firms will be competitive in the global market, all of which ultimately facilitates the economic transformation of the country.

This is why the Government of Ethiopia is currently in the process of moving the economy from a mixed and transition economy, characterised by a large public sector, towards a market economy. The process includes the privatisation of a large amount of state-owned businesses. The total integrated approach of QI services provided by QSAE was pressurised by the free export market orientation and re-engineered according to international requirements and good practices. This orientation is a result of the double-digit economic growth in the first Growth and Transformation Plan. The second Growth and Transformation Plan (2015/16 to 2019/20) focuses on ensuring rapid, sustainable and broad-based growth by enhancing the productivity of the agriculture and manufacturing sectors, improving the quality of production, stimulating competition within the economy and increasing the competitiveness of export products, as well as enabling emerging sectors to compete at a national, continental and global level using internationally acceptable quality assurance services.

Based on the second GTP, the NQI of Ethiopia was reshaped in order to provide quality service with consistency, impartiality and competency that ultimately enhances the acceptance of services and goods at the international market. To transform the QSAE to meet the requirements of international markets, the Engineering Capacity Building Program (ecbp) was established. It is a national programme aimed at reviewing and improving the competitiveness of local manufacturing industries and the creation of employment opportunities for all Ethiopians, thus improving the standard of living in Ethiopia. The programme was facilitated by the Ministry of Capacity Building of Ethiopia in close collaboration with the Federal Republic of Germany. The German quality infrastructure landscape was taken as an example in the designing phase of the transformative reform of the QSAE which was finalised in 2009. Each unit of the NQI was established as an autonomous organisation, namely, the Ethiopian Standards Agency, the National Metrology Institute of Ethiopia, the Ethiopian National Accreditation Office, the Ethiopian Conformity Assessment Enterprise and the Trade Competition and Consumers Protection Authority. Due to their legal functions, legal metrology and technical regulations were established as departments (or directorates) under the authority of the Ministry of Trade and Industry.

Today, Ethiopian enterprises are still facing a number of challenges in accessing more developed markets, such as those in the United States, the European Union or in Asia, where higher standards and quality practices are required than those applied domestically. Taking these challenges into consideration, the government has devised means to address them, focusing especially on enhancing export potential where the country has a comparative advantage in the international market, for example in the leather, textiles and agro-processing sectors. Support for the implementation is provided by funding from the World Bank in the form of soft loans from the National Quality Infrastructure Development Project programme which aims to further develop the NQI units to support the economy.

## 2. Objective and Methodology

The RDT was used for the first time in Ethiopia in order to assess the status quo of the Ethiopian quality infrastructure and to analyse the current existing capacity on the ground. The outcome of the RDT analysis enables users to learn about the performance and status of the Ethiopian national quality infrastructure by identifying gaps to build upon together with cooperative partners and in collaboration with the government of Ethiopia.

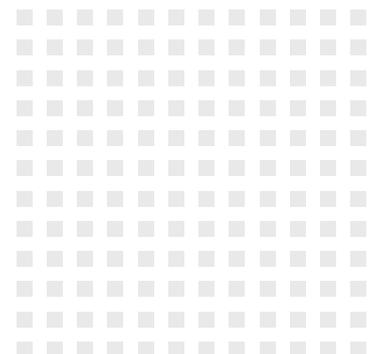
The tool assigns a value from zero to four to each of the following elements to evaluate the status quo of the QI: development, maturity, effectiveness, process status, process at plan and process at conception levels. Each NQI unit is assessed using four main pillars: (1) legal and institutional framework, (2) administration and infrastructure, (3) service delivery and technical competency and (4) external relations and recognition. Each pillar includes different elements, with each element having different activities. Each activity has been given a score value. The aggregated value indicates the position of the overall activity of that particular element.

The score zero indicates that the activity is currently either not started, not planned or is not being used sufficiently. This indicates that the element needs more attention, commitment, budget allocation and exposure to enable the organisation to establish the required system. By contrast, a score of four indicates that the system follows a good practice benchmark, or has a foundation that enables it to extend its service to the level of the good practice benchmark, indicating that the system is able to meet the requirements to the fullest. The aggregated values are given in numbers and in addition in the form of a radar diagram. This allows governments or cooperative partners to easily visualise the position the Ethiopian NQI units are in so they can plan their support.

The RDT questionnaire printout was completed during face-to-face interviews with key individuals from each of the Ethiopian NQI units. The scores were then transferred from hardcopy to softcopy by the RDT interviewer. The following organisations and individuals were interviewed:

- Mr. Endalew Mekonnen, Director General at ESA
- Mr. Yilma Mengistu, Standard Development Director at ESA
- Mr. Mohammed Abdurrahman, Deputy Director General at the NMI
- Mr. Yared Befkadu, Legal Metrology Director at the Ministry of Trade and Industry
- Mr. Eyasu Simeon, Technical Regulation Director at the Ministry of Trade and Industry
- Mr. Teketel Geto, Quality Inspection Director at the Ministry of Trade and Industry
- Mr. Tsegay, Inspection Director at ECAE
- Mr. Abel Anberbir, Director General at ECAE Deputy
- Mr. Futsum Abebe, Team Leader at ECAE Certification
- Mr. Betere Getahun, Director at EFDA Food Regulatory
- Mr. Wondimagegnehu Negera, Chief Executive Officer at ECX
- Mr. Girma Mamo, Quality Manager at Bless Laboratory
- Mr. Wondwosen Fisseha and Mr. Abate Aregaw from the World Bank National Quality Infrastructure Development Project

The assessment was done by interviewing the partners at their respective organisation offices. Additional clarifications were collected by phone. I would like to thank these individuals for their support and provision of the necessary information.



## 3. Ethiopian National Accreditation Office

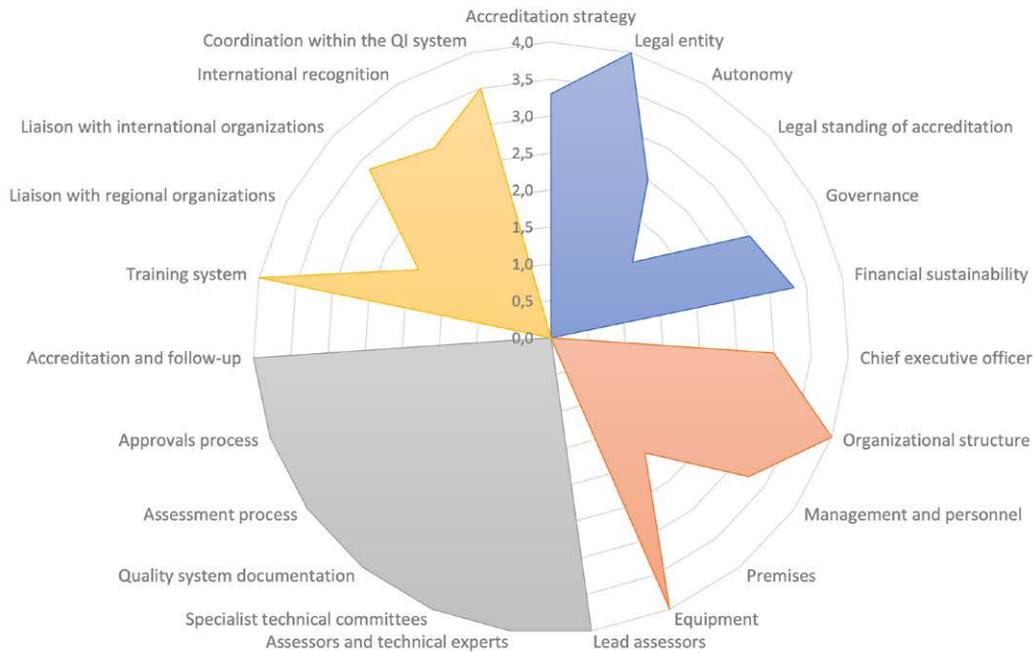


Diagram 1: Accreditation strategy

### 3.1. Legal Framework

The Ethiopian national quality infrastructure comprises four pillars, ENAO being one of them. ENAO was established as the sole third-party accreditation body to verify or attest to the competency of conformity assessment bodies. Despite being established at the end of 2010 by regulation number 195/2010, the regulation was reorganised twice because of inconsistencies with international practice. First, it was re-established by regulation number 279/2012 in 2012, before being reviewed and reorganised for the second time in 2017 by regulation number 410/2017 to incorporate the mandate to provide training on accreditation standards.

ENAO's overall budget deficits limit its functionality. Its financial sustainability is managed by the treasury. However, it is co-financed through the payment of accreditation service fees. Despite being collected by ENAO,

income flows directly back to the government. Because of budget limitations and a shortage of hard currency, the budget does not allow ENAO to contract external experts, nor does it allow ENAO's experts to participate in the international and regional meetings relevant for its operation. By contrast, the treasury budget is able to provide reasonable funding for local operations.

ENAO develops a three-year budget plan in accordance with the regulations of the Ethiopian Ministry of Finance. This is reviewed for adjustments at the beginning of each fiscal year before the annual budget is endorsed by the House of Federation. The results of the physical performance and the financial audit are then reported by the office to the Ministry of Finance. The Federal Audit Department of the Ministry of Finance also audits the financial expenditure and physical performance of ENAO every year, and reports the outcome to the House of Federation.

In accordance with the five-year term of the Ethiopian parliament, the government develops and implements a five-year strategic plan in each legislative period. This national strategy cascades down and is applied at all levels of government, including all NQI units, which then develop corresponding strategic plans.

ENAO's first five-year strategic plan (July 2011 to June 2016) was developed to achieve the following objectives. First, it aimed to develop and implement a management system as per ISO/IEC 17011, ILAC, IAF, AFRAC and national regulatory requirements. Second, it focused on building assessor competency in collaboration with the South African National Accreditation System (SANAS) and with the support of the Deutsche Gesellschaft für Internationale Zusammenarbeit (German Society for International Cooperation, short GIZ). Third, it aimed to market accreditation by providing awareness training to conformity assessment bodies and the public, as well as by providing an accreditation service for testing, medical laboratories and inspections. And lastly, it aimed to be visible in the international accreditation arena by becoming an associate member of ILAC.

The main objective of the second five-year strategic plan (July 2016 to June 2020) was to maintain and improve the established management system by seeking and making use of opportunities for improvement. Other objectives included providing feedback on internal and external audits, as well as conducting management reviews that were used to improve performance. Additionally, it aimed to develop requirements for extending accreditation scope and risk mitigation measures. The number of competent and qualified lead and technical assessors for testing was increased. Collaborations with additional medical laboratories, inspections, quality systems, product and personnel certifications were planned, and measures were taken to ensure there were sufficient trainers in all scopes. In addition, ENAO raised awareness at universities, regional bureaus, hospitals and Ethiopian Parliament Standing Committees to extend the reach of the institution. As another measure for this, the scope of accreditation services on system, product and personnel certifications was extended, and ENAO became a full member of ILAC, IAF and AFRAC. At the time of its creation, ENAO was challenged by external factors. The Ministry of Trade and Industry did not assign accreditation as one of the selection criteria for those conformity assessment bodies

that have been engaging in regulated conformity compliance verification. No regulation for certification has been established. This accounts for the limited market for accreditation of certification, and it prevents ENAO from becoming a full member of IAF.

The upcoming third strategic plan has been extended to a ten-year plan (July 2020 to June 2030). The strategy was developed by considering the challenges, practices and capacities that were explored during the first and second strategic plans. In addition, the third strategic plan provides a forecast for national development during the next 10 years, and takes into consideration the development of the African Continental Free Trade Area, the AFRAC-MRA scopes and the positioning of ENAO to cover all the AFRAC-MRA scopes that have been submitted to the Ministry of Trade and Industry to review for approval.

ENAO's main organ is the Accreditation Council. Its members are drawn from both the government and the private sector following the principle of balanced representation. The council is mandated to:

- review the strategic plan developed by the office
- based on the appeal procedure they receive, analyse and decide whether to appeal against the accreditation decisions made by the director general
- review and recommend service fees and assessor payments that are developed by the office

There are between 13 and 15 Accreditation Council members; out of these representatives, the state minister of Trade and Industry is the chairperson and director general of ENAO. Since the mandate of the council is purely to support the office, the council does not evaluate the performance of the office. The performance of the office is evaluated by the Minister of Trade and Industry, as well as the House of Federation's Trade and Industry Standing Committee.

## 3.2. Administration and Infrastructure

The administration of ENAO is based on two pillars: core focus (accreditation) and supportive services. Each of these pillars is specified in the model of a programme budget. The supportive programme budget comprises the activities of IT, HR, PR, Planning, Finance and Audit departments, whereas the core focus programme budget serves the activities of Quality Managers, Testing, Medical, Inspection and Certification Accreditation departments. The director general is appointed by the Prime Minister's Office. With the support of the deputy director general and the management team, the director general is fully responsible for effectively and efficiently making the office operational. The performance report is submitted to the Ministry of Trade and Industry every month, and to the House of Federation's Trade and Industry Standing Committee every three months.

The ENAO website provides a vast amount of accessible public documents, such as accredited certificates, and the status of accredited CABs. In addition, it has a server and internet access for all its staff members.

ENAO is one of the NQI units that benefits from soft loan funding provided by the World Bank. The World Bank is focused on automating the accreditation process and transforming the ENAO's IT service in a way that allows it to accept online applications, submit clearances and follow up on the accreditation processes. A contract was awarded to a company by the World Bank's NQIDP project to carry out a respective gap analysis. A report has now been submitted, and the material required for the project has been ordered by the project office.

ENAO's office is located near Megegnagna, which makes it convenient for travelling to and from the office, and it has a large parking area. The four NQI units are located in the same compound. The office working area is small, but a G+6 office building is under construction at time of writing, so the difficult circumstances will soon no longer be a factor.

According to its strategy, ENAO requires 60 permanent staff for the full scope of its operations; 45 staff members are currently employed. Of these, 12 are accreditation experts. The office is therefore limited in the accreditation operations it can take part in. The salary of ENAO's ex-

perts corresponds with that of the general civil service scale, which is relatively low compared to that of the private sector and does not come with any other benefits or privileges. Due to these circumstances, ENAO is not able to acquire enough qualified and competent experts. To address the above problems, ENAO has revised its structure and submitted a proposal to the Civil Service Commission for review and approval.

## 3.3. Service Delivery and Technical Competency

The most challenging task ENAO was, and is still, facing is the development of an accreditation market. ENAO is and has been making every possible effort to develop the accreditation service that conformity assessment service providers need. Some of these efforts are:

- In 2012, ENAO proposed, pushed for and streamlined the collaboration between co-operative partners and conformity assessment bodies in order to accredit their services.
- Four accreditation documentary films, each half an hour in length, were developed and aired to the public at prime time to raise awareness.
- Since 2015, for one month out of every year, more than 25 accreditation news reports are aired on television and 10-minute radio programmes are aired, explaining the value of accreditation and accredited CABs to the public.
- So far more than 90 awareness events have been carried out in different parts of the country with relevant stakeholders, such as conformity assessment and regulatory bodies, as well as with the general public.
- Every year since 2011, ENAO has celebrated World Accreditation Day. ENAO holds panel discussions on themes relevant to the motto, and more than 85 stakeholder participants attend each year.

Even though ENAO has expanded its efforts to sell accreditation services, the outcome is underwhelming. The reasons for this disappointing outcome are:

- The regulatory bodies did not use accreditation as an enforcing mechanism for selecting CABs for the delegation to provide conformity services.
- There is no legal framework that foresees the accreditation of CABs by the regulatory body, merely technical competency for performing conformity assessments on regulated products and services.
- The regulatory bodies have a tendency to carry out conformity assessment activities on their own.

These circumstances contribute to the limitations on private conformity assessment bodies' ability to flourish.

ENAO has 95 permanent and part-time assessors, 125 listed experts and three trainers for each accreditation scheme assessor's training. A system has been established which can constitute an ad hoc Technical Advisory Committee, an ad hoc Accreditation Advisory Committee and a permanent Risk Analysers Committee.

The second major act of support by the World Bank's NQIDP project is to improve ENAO's accreditation service for conformity assessment bodies engaged in compliance verification of export items – specifically textile, leather and agro-processing products. The project office has signed a twinning arrangement with the Quality Council of India (QCI) to review ENAO's documents and fill in the identified gaps. The gap analysis is comprised of the production of national standards and technical regulation schemes. The scope of accreditation supported by the twinning programme is:

- accreditation for inspection bodies inspecting leather and leather products, textile and textile products and agro-processed products
- accreditation for product certification for technical regulated products
- accreditation according to management system standards: Quality Management Systems, Environmental Management Systems, Food Safety Management Systems, Information Security Management Systems and Occupational Health and Safety Management Systems

- accreditation for calibration and proficiency testing providers
- development of audio-visual training materials on topics such as accreditation schemes, flexible scope, method validation, verification and uncertainty calculation

At time of writing the gap analysis has been carried out and the remaining activities are expected to be accomplished within the remaining contract period.

### 3.4. External Relations and International Recognition

ENAO is a full member of ILAC and a signatory of ILAC-MRA for Testing (ISO/IEC 17025), Medical Testing (ISO 15189) and Inspection (ISO 17020). In September 2016, ENAO was accepted by IAF and given an accreditation membership. Since the Ethiopian calibration and certification market is underdeveloped and demand for services remains low in Ethiopia, ENAO is finding it difficult to extend its ILAC-MRA for calibration, PT providers and CRM producers. ENAO is not an IAF-MLA signatory because it has not yet demonstrated its competency. However, an application for ENAO to become a signatory of IAF has been submitted and accepted by AFRAC. In the case of the World Bank's NQIDP project providing the necessary consultation support for potential conformity assessment bodies, ENAO developed a plan to apply by the end of 2020 for calibration and QMS MLA scope extension.

In order to build accreditation experience and capacity, ENAO requires international exposure. This will enable it to cooperate and work with regional and international organisations. ILAC, IAF and AFRAC contribute to this process by participating in different Technical Committees.

Due to the shortage of hard currency, there is no support for experts to participate in the international and regional General Assemblies and meetings. This will affect the process of preparing successors with the required knowledge and skills, and this will then result in a lack of preparation once experts are eventually exposed to re-

gional and international meetings – exposure that would ultimately benefit the office because it could then implement the outcomes of these discussions and resolutions.

ENAO is an autonomous body operating its business within the norms of confidentiality, impartiality and competency. Its service is integrated with other NQI units in order to be both complementary to and yet interdependent from one another. ENAO's services cannot be effective or efficient without collaboration and support from the other NQI units.

There is formal communication among ENAO, ESA, ECAE and the NMI led by the State Minister of Trade and Industry. The communication platform is focused on solving problems and on directing the way forward. However, the exchange of communication is not consistent. The efforts being made to improve this are:

- developing documents on cooperation and collaboration between NQI units, research institutions and regulatory bodies
- ESA, ECAE and NMIE representatives participating in ENAO stakeholder meetings
- NMI experts participating in those ENAO advisory technical committees which require metrological expertise
- ENAO employing conformity assessment experts in subject areas in which ENAO is seeking expertise
- ENAO having a platform to engage stakeholders directly in public forum meetings to comment on, discuss and understand new published standards, extension scopes and other relevant documents published by ENAO. Stakeholders also participate via their representatives on risk analysis committees.



© iStock

# 4. Ethiopian Standards Agency

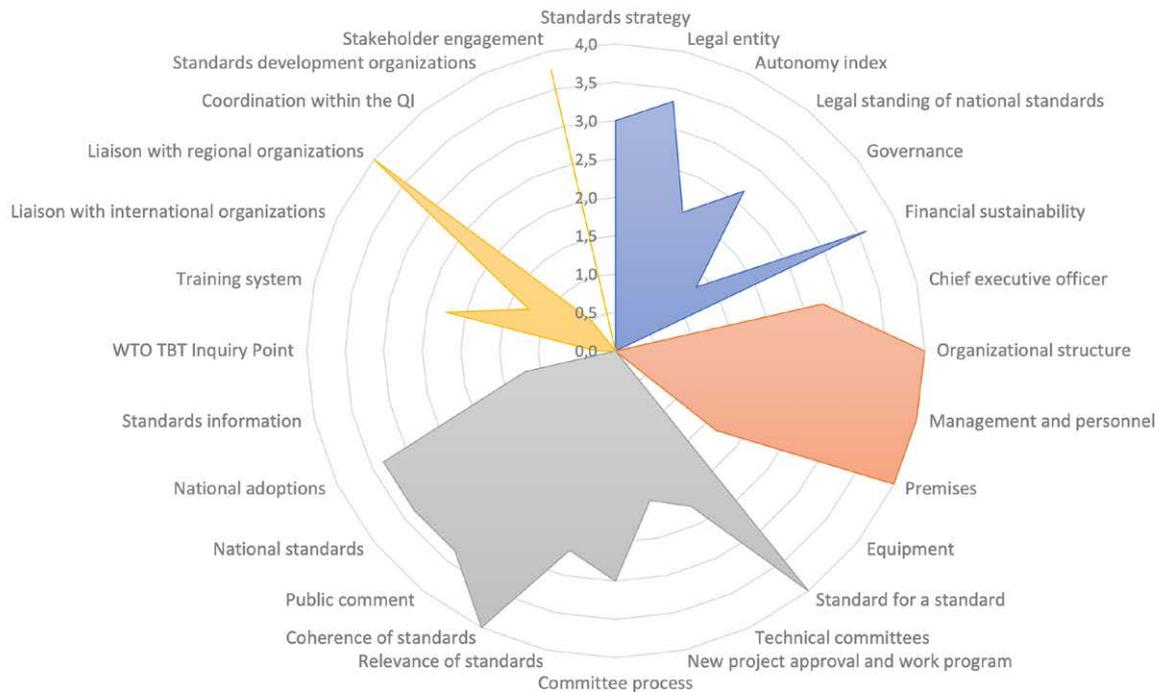


Diagram 2: Standards strategy

## 4.1. Legal Framework

The Ethiopian Standards Agency is the sole standardisation body in the country, and is responsible for developing and issuing national standards. ESA was established by the Council of Ministers (regulation number 193/2010) with the mandate to:

- lead and coordinate national standardisation
- confirm and publish national standards
- promote the implementation of standards
- promote the Ethiopian Standard Mark and authorise its use
- represent Ethiopia in the International Standards Organization, and work in collaboration with other foreign national standard bodies
- establish a National Enquiry Point and deliver services on standardisation, conformity assessment guidelines and technical regulations

- enable Ethiopian industries to benefit from technology transfers by providing technical support, training and consultancy to implement standards

This regulation is currently under revision.

ESA's strategy focuses on the adoption and development of a sufficient number of standards. Strategy limitations stem from the development of a research base on endogenous standards. ESA's first five-year strategic plan (July 2011 to June 2016) was developed and implemented as planned. The second five-year strategic plan (July 2016 to June 2020) has stressed the adoption and development of new standards, the revision of existing standards according to their revision period, participation in regional and international meetings, raising public awareness of standards for the public, automatization of the library, the sale of standards online and the establishment of an enquiry point. Currently, a ten-year strategic plan (July

2020 to June 2030) has been developed and submitted to the Minister of Trade and Industry for review and approval.

ESA created the National Standards Council which is mandated to review and approve standards and the organisation strategy, and to review and recommend service charges to the Ministry of Finance. The members of the council are drawn directly from the government, except for one representative who is drawn from the Federal Chamber of Commerce. The lack of involvement of the private sector in the National Standards Council is in defiance of balanced representation between the private and public sectors.

The council meets every three months. The council is chaired by the Minister of Trade and Industry, and the secretary is officiated by ESA's director general. Most of the council members are politicians and therefore not technical experts. The CEO of ESA is not appointed through merit, but rather appointed politically by the Prime Minister's Office. When regulatory bodies request that voluntary standards be made mandatory, namely by establishing a technical regulation, the council reviews the request before approval with regard to consumer health and safety, as well as the extent to which enterprises are economically and technologically ready to comply with the requirements.

There is no practice of referring to standards within the legal system. The national legal instruments do not mandate that regulatory authorities must refer to the national standards. ESA is financed through the national treasury. Its budget does not allow the development of research-based standards for endogenous products.

## 4.2. Administration and Infrastructure

The director general and the deputy are appointed by the Prime Minister, and, together with the management team of ESA, they are fully mandated, responsible and accountable for executing and managing the office's activities. The core functions of the standardisation process cover standard project approval, standard development, editing, the standard information system and the stan-

dard enquiry point. The CEO of ESA reports to the Minister of Trade and Industry and to the House of Federation's Trade and Industry Standing Committee.

The ESA office is located within a convenient distance to public transportation for customers in Addis Ababa's suburb Bole near Megenagna, and in 2019/20 it extended its premises by building a new standard academy building within the existing compound. The site is fully equipped for its purposes, and includes adequate working, training and syndicate premises.

ESA has a satisfactory information technology infrastructure that is currently being upgraded. The IT system provides every staff member with access to the internet and hosts its own website. However, it is unable to allow the technical committee members to work off-site. Once the IT upgrade is complete, ESA will offer the ability to sell standards online.

All team leader, technical expert and other positions have already been filled. It is worth mentioning that most of the positions are staffed using civil service criteria which prioritises years served rather than a person's level of industrial knowledge, skill and practical research experience.

## 4.3. Service Delivery and Technical Competency

ESA has developed a guidance document called the *Standard for a Standard* which technical committees should follow when developing standards. The Standards Development Directorate is responsible for adopting and developing standards, and is a member of the ESA management team. Standard development is not delegated to other organisations. Currently, more than 400 organisations are members of this national technical committee; 30% are from the government and 70% are from industries and associations.

ESA has developed selection criteria for admitting technical committee members engaged in the development of national standards. These criteria entail having sufficient knowledge and understanding of the subject matter, as well as fair representation of interested parties

affected by the particular standard. The latter refers to representation of individuals or collective representation based on the size of the interested parties. The nomination of technical committee members is the sole right of ESA and the right to be a member cannot be claimed or appealed for. Observers may be permitted upon request.

At time of writing, ESA has developed and adopted around 10 871 standards. Out of these, 5200 are requirements and specifications, 5418 are testing methods, procedures and sampling, and the rest are guidelines, codes of practice and terms and definitions. There is no available evidence or data for indicating the implementation status of these technical regulations and standards. Currently, a survey is being carried out to assess the implementation status. Out of the 253 technical regulations, only six use the ISO/IEC 17067 type 5 product scheme. The remaining 247 regulated products do not have schemes, which makes it difficult to know by which scheme they can be classified.

ESA is preparing to open an academy for standards which will serve as the capacity building location of technical committee members, industries and any organisation that is interested in understanding and implementing standards.

#### 4.4. External Relations and International Recognition

An ESA enquiry point has been prepared by assigning trained experts with the appropriate abilities. The activities carried out to make the enquiry point operational are as follows:

- Experts have been trained at the South African Bureau of Standards and by Resident Advisors of ESA contracted by the World Bank's NQIDP project.
- Various standards, requirements, regulatory information and collections of documents are underway. In general, the ESA enquiry point is at a preparatory stage and is expected to start operating in the coming Ethiopian budget year.

ESA is member of ISO, IEC and CODEX, and participates in 104 ISO/IEC TCs (47 as p-member and 57 as o-member). The scope of participation is determined by the country's strategic plan, import and export items and the country's socio-economic policy which predominantly covers agriculture and food, textiles, leather, metal, pharmacy, sugar and mining. The representatives are negotiating capacity gaps. Ethiopian standards are developed by consensus by considering the impact on health, safety and the environment, and are implemented voluntarily.

ESA develops technical regulations at the request of the regulatory bodies, and following good regulatory practices and international experiences. However, regulators do not refer to Ethiopian standards for their regulations, and there is no practice that supports the development, implementation and regulation of voluntary standards when the Ethiopian National Standardization Council changes them into technical regulations. ESA has prepared a document which was approved by the Ethiopian National Standardization Council to reference Ethiopian standards in Ethiopian public policies or/and regulations. However, the implementation will face challenges in the future because the regulatory bodies and policy developers are not accountable to the National Standardization Council.

There is also a gap in the administration of technical regulation quality marks, and action is required to stop fraudulent behaviour with regard to their use of quality marks. Currently, there is no clear regulatory intervention for quality mark administration. Therefore, there should be a system in the policy or in the regulation that supports the development, implementation and regulation of technical regulations, the administration of quality marks and the referencing of standards. There is only one national quality mark for regulated products. With the exception of a certification mark, there is no quality mark for voluntary standard products and services.

# 5. National Metrology Institute

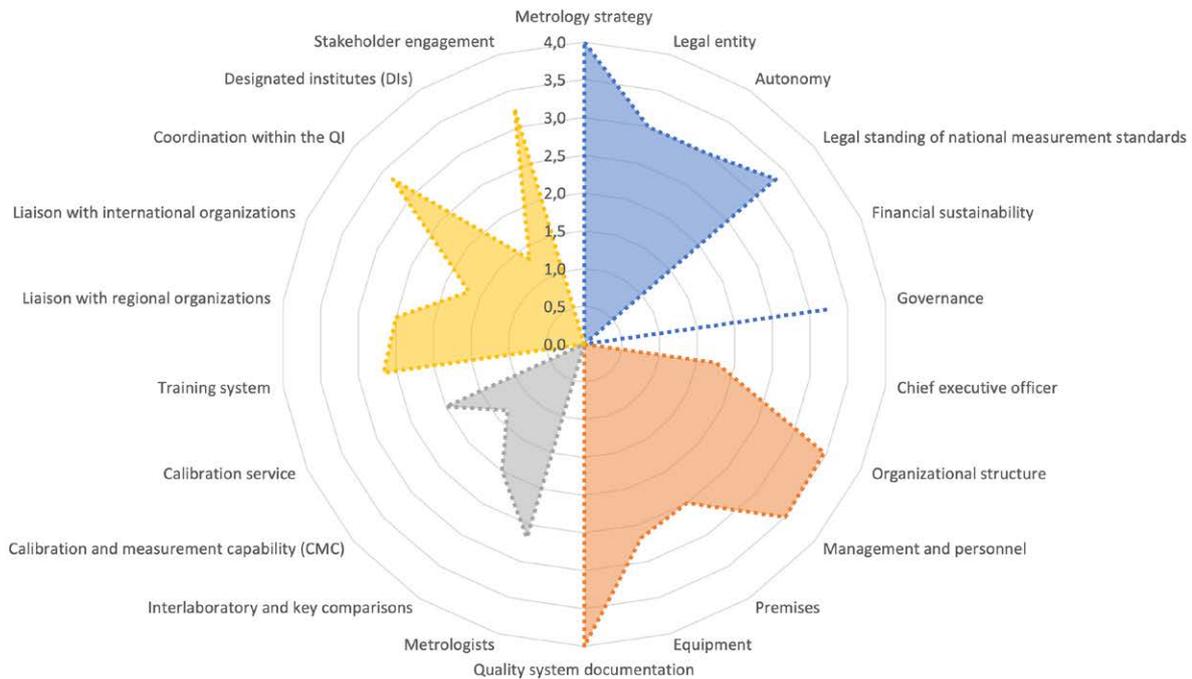


Diagram 3: Metrology strategy

## 5.1. Legal Framework

The National Metrology Institute of Ethiopia was established by the Council of Ministers (regulation number 194/2010) and started operating on 10 February 2011. The institute is responsible for the maintenance of the Ethiopian National Measurement Standards and Certified Reference Materials (CRM). It is also mandated to provide calibration, training and consultancy services in the areas of metrology, scientific equipment maintenance and scientific measuring requirements. The NMIE has neither a board nor a council within its administrative structure.

The first five-year strategic plan (GTP I) was developed and implemented between July 2011 and June 2016. The second five-year strategic plan (GTP II) was developed and implemented between July 2016 and June 2020. The two strategies stressed the maintenance and extension of accreditation scopes that were granted by the national

accreditation body of the Federal Republic of Germany (DAkkS): increasing the number of calibration services, preparations for chemical metrology services, assistance for deliberation of metrological courses at universities and TVET colleges, as well as raising public awareness of metrological measurements, and supporting those private and governmental organisations interested in establishing calibration services. The current ten-year strategic plan (which is in effect from July 2020 to June 2030) was developed and submitted to the Minister of Trade and Industry for review and approval.

The NMIE uses various international recommendations to consider which highest-accuracy standards should become the national measurement standards. For example, for mass, the NMIE currently uses class E1 as the national standard, but is planning to upgrade to the higher accuracy of E0. The NMIE is mandated to establish national measurement standards that are required by industry

and commerce, and yet, it does not address requests for measurement standards coming from commerce and industry.

The NMIE's budget is financed by the treasury budget of the government. It also gets support for training and regional participation from international donors, namely, PTB (Germany) and the World Bank. However, the current budget is not sufficient, as can be seen from its difficulty in upgrading to more highly accurate measuring standards. Because of these hard currency problems, experts were not able to attend much-needed training courses or regional and international meetings where they would have been able to share and gain experience.

## 5.2. Administration and Infrastructure

The NMIE provides calibration services in the following metrological fields: length measuring instruments, standard masses, weighing instruments, temperature measuring instruments, pressure measuring instruments, force measuring instruments, volume measuring instruments, density measuring instruments, electrical measuring instruments and ionising radiation measuring instruments. No particular calibration service provider in Ethiopia has been designated by the NMIE.

The director general and the deputy of the NMIE are appointed by the Prime Minister, and are fully mandated to manage and execute the institute's activities to realise its objectives. The core functions of the NMIE are calibration and scientific measurement, training and consultancy, the development of national measurement standards, maintenance and certifying personnel competency.

The CEO of the NMIE reports to the Minister of Trade and Industry and to the House of Federation's Trade and Industry Standing Committee. The NMIE has two office sites. The main office is located within the ESA compound, and the Scientific Equipment Maintenance Department is located in Kotobei. The main office cannot provide sufficient working space. There are no training and syndicate rooms, nor do the laboratory rooms have controlled access. However, high accuracy measuring equipment is being procured by the World Bank's NQIDP project, and the government has budgeted for laboratory and office

buildings which are currently under construction. The NMIE's IT infrastructure requires an upgrade. The website, for example, is designed to serve the mission of the institute and does not contain information for customers like costs of services, means of payment and how to file a complaint. Now that ESA has built an academic building for standards which will be accessible for all NQI units, the NMIE is able to maintain a degree of independence and impartiality while still using ESA's services.

Even though the NMIE is mandated to provide calibration services for measuring equipment and to verify certified reference materials, the institute has yet to initiate chemical metrology services (the verification of certified reference materials).

## 5.3. Service Delivery and Technical Competency

The NMIE is very well positioned in service delivery and technical competency, as the majority of its calibration services are accredited by DAkkS which certifies a high degree of competency. It has a proper system of documentation, set-up as per ISO/IEC 17025. An important success has been the development and implementation of a documented system for developing competency, which resulted in three metrologists being trained and developing their experience at KRISS (South Korea).

## 5.4. External Relations and International Recognition

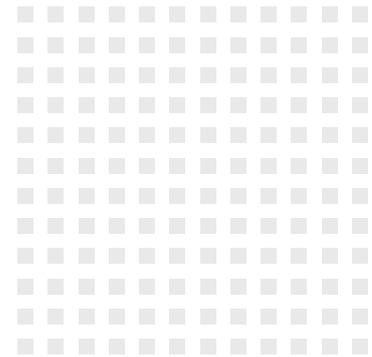
The NMIE's external relations have been actively managed since the foundation of the institute and have resulted in a number of achievements:

- Since January 2018, the NMIE has been an associate member of the International Bureau of Weights and Measures.
- Since September 2006, the NMIE has been a member of AFRIMETS and a member of the sub-regional metrology organisation NEWMET.
- Since the NMIE is not at the required level of technical capacity, it has the privilege of having its BIPM Capacity Building and Knowledge Transfer Programme

capacity building training being funded in collaboration with other NMIs. Recently, the NMIE was nominated to attend a training course at the Turkish NMI Ulusal Meytroloji Enstitüsü (UME), but because of the Covid-19 pandemic, the training has been postponed for now.

- The NMIE is planning to register its calibration and measurement capabilities (CMCs) in the BIPM Key Comparison Database (BIPM-KCDB). This will require approval by AFRIMETS and the other regional metrology organisations (RMOs) from around the world.
- The NMIE's director general participates in AFRIMETS meetings, which is useful for sharing experiences and for amassing contributions and support to strengthen metrology at the regional and international level. Participating in AFRIMETS TC meetings also gives the institute access to inter-comparison platforms and the possibility of sharing technical knowledge among experts.

The NMIE created a stakeholder forum that has an office on the NMIE's premises. The president of the association is commissioned by the NMIE. One of the members of the stakeholder forum is the Ethiopian Laboratory Association (ELA).



© PTB/Fotografie

# 6. Legal Metrology

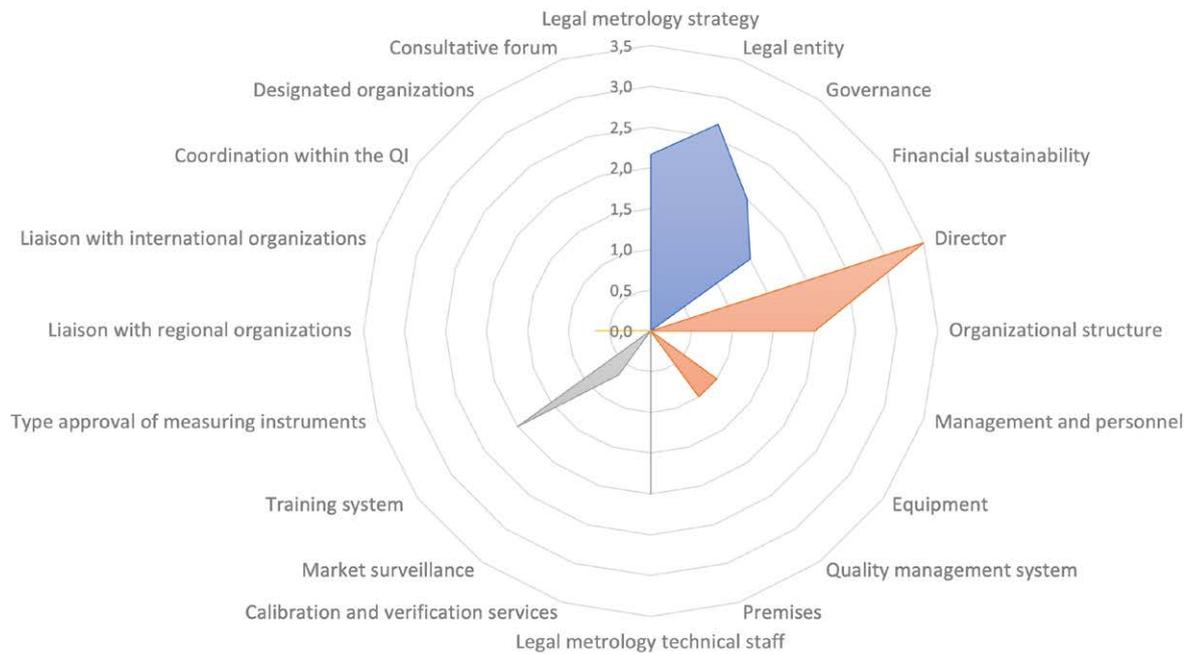


Diagram 4: Legal metrology strategy

Ethiopian legal metrology is directly administered by the Ministry of Trade and Industry, whose director reports to the State Minister of Trade and Industry.

For the past 40 years, all legal metrological operations have been frozen due to the low amount of attention it was given by the Minister of Trade and Industry. In 2019, amendments were made on the way legal metrology is regulated and it was re-established within the Ministry of Trade and Industry. Recently, it started regulating weights, balances, fuel dispensers, consumable items and pre-packaging.

Administering regulatory operations at the ground level and the financial resources that are required for the operation relies on each region's government. In practice, the regulatory performance and level of commitment to regulating varies from region to region. Any political failure is dealt with by the Ministry of Trade and Industry in collaboration with regional bureaus. The Legal Metrology director does not deal with political failures, because it requires responsiveness from superior ranks.

The Ministry of Trade and Industry's Legal Metrology director is legally responsible for corresponding with the International Organization of Legal Metrology (OIML) and participating in international conferences. However, there has been no active engagement so far.

The duties and responsibilities of legal metrology are to:

- regulate the legal metrological system of the country and its enforcement by coordinating the relevant regulatory bodies of each region
- conduct pattern registration of weights and measures of the country and to grant permits
- verify weights and measures used in trade
- organise consultative forums in collaboration with the respective regions on the issue of legal metrology enforcement
- represent the country in seminars, workshops, or conferencing matters related to legal metrology

No separate budget is administered by the Legal Metrology director. The budget is administered by the Ministry of Trade and Industry's Finance Department. The depart-

ment is at a preparatory stage in developing a system that produces working documents, develops strategic plans and recruits its staff.

The Legal Metrology Directorate is managed by a full-time director who is responsible for all aspects of the functions of legal metrology. It is worth mentioning that communications to other ministries are directed through the State Minister or the Minister of Trade and Industry. The role of the Ministry of Trade and Industry's Legal Metrology department is to support regions with capacity development in collaboration with the NMI, as well as to provide reference materials and to represent the country in the regional and international legal metrology arena. The department has standard referencing measuring instruments used to verify the accuracy of measuring equipment in service. However, the department is not currently providing any calibration services, as it is in the process of acquiring enough trained staff for it to operate effectively and efficiently.

A TVET calibration programme is provided by Tegbareed Polytechnic College in Addis Ababa that is not administered by the Legal Metrology authority. The Ministry is housed in a rented office building. In March 2020, the Ministry of Trade and Industry changed its location from Kazanchis to Arat-Kilo, a site which does not have a large enough parking area for the Ministry's purposes.



# 7. Technical Regulation

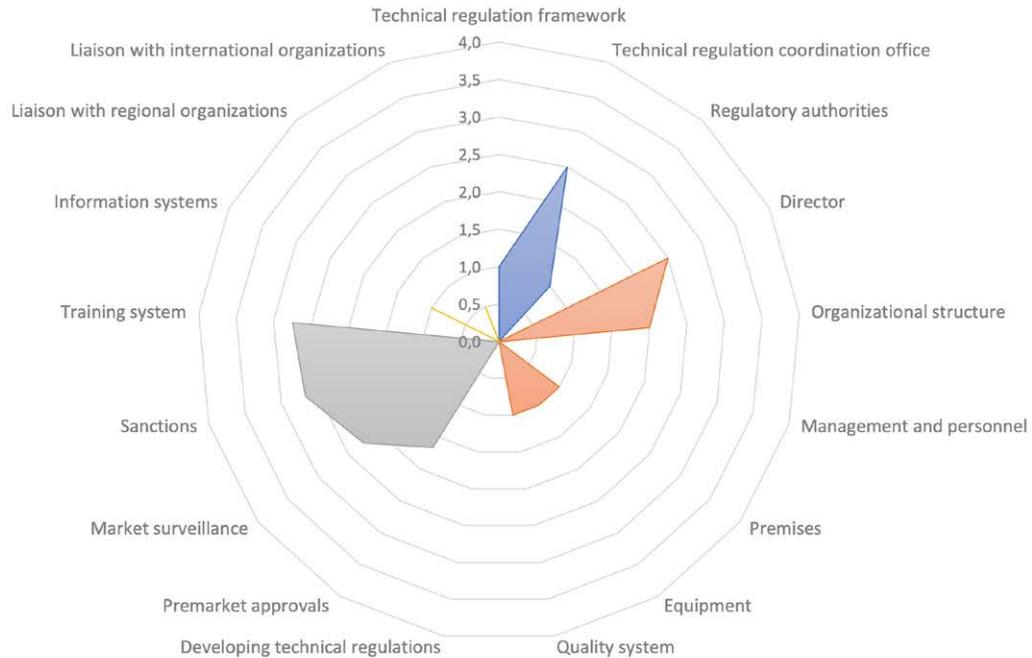


Diagram 5: Technical regulation framework

In the year 2020, a new institution for technical regulation was established as a department (or directorate) within the Ministry of Trade and Industry. The coordination platform, called the NQI Technical Forum, is a forum for NQI units and regulatory bodies and is led by the State Minister of Trade and Industry.

The technical regulation department is currently under development. The director was appointed in January 2020, but does not have sufficient staff to operate the department's services yet. Although it was expected to be operational by now, no technical regulation framework has been developed yet, nor is there a system in place. As a result, the department cannot exercise its responsibilities at the moment.

During the process of restructuring the departments, the Regulatory Inspection Department was renamed as the Department of Trade and Industry. It comprises small teams organised as per the product categories in the functions of premarket approval, market surveillance and imposition of sanctions.

Each region administers its respective technical regulation. Although the presence of the technical authority at the marketplace is within the mandate of each region, the effectiveness of the authority's operation is generally weak across all the regions. The Technical Regulation Department's finances are administered by the Ministry of Trade and Industry's Finance Department. The department has the right to propose its operational budget, and, once approved, it controls it accordingly. In order to operate effectively, the department is expected to employ and train staff according to their mandate. The Technical Regulation Department is not sufficiently equipped for its tasks, as it only has a small amount of inspection equipment, and it is not calibrated regularly. Furthermore, there are no enforcing mechanisms in place to ensure the calibration of the measuring equipment.

Technical regulations are developed similarly to the way a national standard is developed. The regulatory authorities provide training to inspectors on their legal rights and responsibilities. The inspectors have identification cards that identify them as inspectors in case they ever need to be presented. Ethiopia is not yet a member of the WTO, and thus not required to abide by the World Trade Organization's TBT Agreement.

# 8. Conformity Assessment Activities

## 8.1. Testing

The Ethiopian conformity assessment market is not yet developed. Most services are carried out by the national body, namely ECAE. Other conformity assessment bodies such as the Ethiopian Leather Industry Development Institute, the Ethiopian Textile Industry Development Institute (ETIDI), research laboratories, regulatory laboratories, the private laboratory Bless and universities are less dominant in the sector. However, as yet there are no formal selection and delegation criteria for testing laboratories that can serve as a regulatory conformity test. There are three departments within the Ministry of Trade and Industry that require testing services in their regulation process:

- the Department of Technical Regulation
- the Department of Import/Export Quality Control
- the Department of Marketing and Factory Inspection

All of these departments currently use the Ethiopian Conformity Assessment Enterprise's laboratory for quality conformity testing to ensure that regulated products comply with the stipulated requirements.

Despite the fact that there is currently no comprehensive testing service strategy, the World Bank's NQIDP project recently developed a testing strategy for a limited selection of products, namely leather, textiles and food, and this has been approved by the Ministry of Trade and Industry. The regulatory body in the Ministry is currently developing designation criteria that can be used in conformity assessment tests.

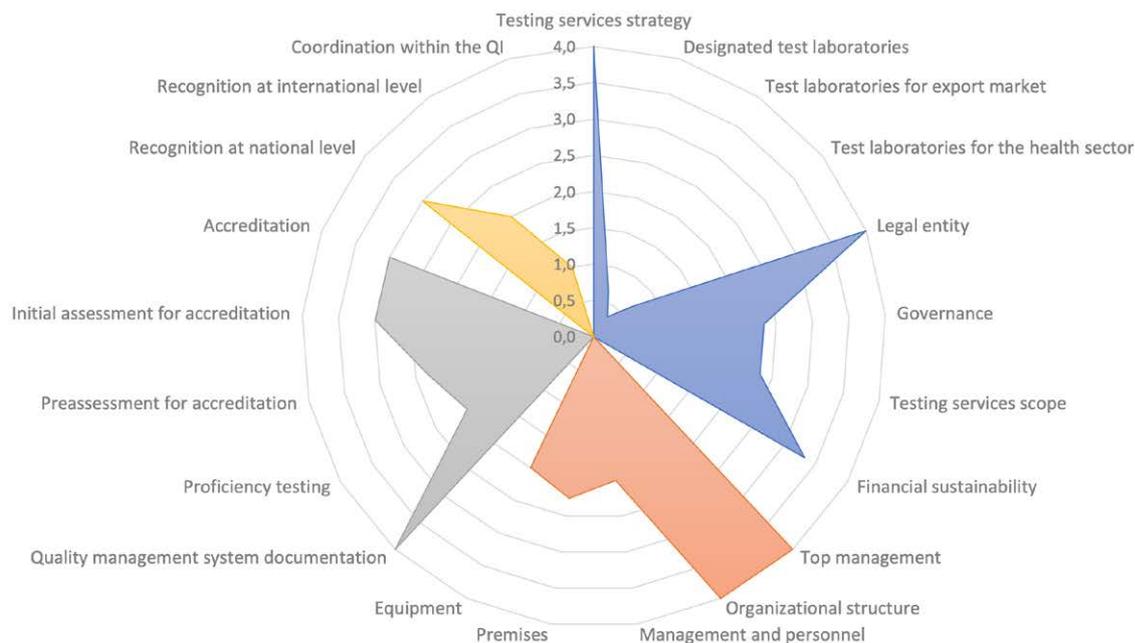


Diagram 6: Testing services strategy

By default, the regulatory bodies considered ECAE a designated testing laboratory, but this created an issue of non-transparency and discrimination by accredited conformity assessment bodies within regulatory bodies. ECAE's board chairman is also the State Minister of Trade and Industry and a majority of the board members are from regulatory bodies, with only one representative from the private sector. This leads to a situation in which other accredited CABs do not have the access required for them to receive information from the delegation of regulators.

There are sector-specific laboratories situated at research institutions and universities with high testing capacities which are able to perform conformity testing but are not used by the regulatory bodies. The private laboratory Bless complained about the unfair competition environment created by regulatory bodies designating ECAE as their testing laboratory. ECAE is established and runs according to market economy principles, but ECAE's market is dependent on the regulatory market. It enjoys market access to regulatory bodies without competency-based competition. It is privileged to have basically no competition from informal regulatory delegation. ECAE's chemical testing laboratory, microbiology testing laboratory, electrical testing laboratory and textile testing laboratory are each accredited for limited test items and parameters. Many of ECAE's testing services at the main office and all testing branches provide non-accredited testing services. Bless has accredited its microbiology laboratory and chemical laboratory testing on limited items and parameters required by regulatory bodies. ECAE is not forced to accredit its testing parameters by regulatory bodies. Many of the parameters of regulated products cannot be tested locally. This includes residual tests which are conducted at high cost outside the country.

The location of the main office of ECAE is on ESA's premises. The main office is conveniently located near public transport, has enough parking space and there are three laboratory blocks whose construction is being supervised by the government. The World Bank's NQIDP project is supporting the provision of equipment necessary for strengthening the testing capacity service for leather and leather products, textiles and textile products and agro-processing products. In comparison with other NQI units, the salary and benefits for ECAE's staff are better

compared to other NQI institutions, resulting in a lower fluctuation rate.

Additionally, conformity testing for non-regulated leather and leather products is conducted at the Ethiopian Leather Industry Development Institute laboratories, and conformity testing for non-regulated textiles and textile products is conducted at the ETIDI laboratory. Both institutions have accredited their testing laboratory for physical testing parameters.

Food and pharmaceutical products are regulated by the Ethiopian Food and Drug Administration (EFDA). This regulatory body has its own laboratories. Its pharmaceutical testing laboratory was accredited by ANAB for drug testing, but the accreditation certificate was withdrawn in 2018. When required, EFDA uses Bless and ECAE laboratories for food testing.

The regulation of animals and animal products is within the mandate of the Ministry of Agriculture and the Ministry of Livestock and Fisheries. Conformity assessments are conducted at the National Animal Health Diagnostic Research and Investigation Center located in Sebeta, in the Oromia Region. This centre has accredited its molecular, serology and bacteriology testing laboratories. There are 15 veterinary testing laboratories throughout the regions that each provide non-accredited testing services.

The Ethiopian National Veterinary Institution produces animal vaccines. The stipulated quality requirements of the produced vaccines are checked and confirmed at its own accredited serology testing laboratory and at the PAN African Veterinary Vaccine Center laboratory in Bishoftu, Oromia Region, which is accredited for veterinary vaccine testing (microbiology testing).

In general, there is a gap between the required and the available competency, transparency, non-discrimination and confidentiality, and the designation criteria of testing laboratories is biased. A further way of taking representative samples by regulatory and product certification bodies is needed. For now, regulatory bodies accept test results that come from outside accredited laboratories accredited by ILAC-MRA signatory bodies in the respective scheme.

## 8.2. Inspection

There are four regulatory departments in the Ministry of Trade and Industry that use inspections in their regulation process:

- The Department of Legal Metrology regulates how appropriate measuring instruments, packaging and food items are by inspecting and/or verifying the extent to which they comply to the stipulated requirements.
- The Department of Import-Export Goods Quality Control ensures that goods comply with the stipulated requirements by using quality assurance inspection tools before the items are exported or imported.
- The Department of Market and Factory Inspection ensures that factory products consistently comply with requirements before they are delivered to clients. Tools used include inspecting the extent to which a factory's processes, inputs and materials comply with

the product certification scheme, as well as inspecting markets to protect customers from any expired, adulterated or counterfeit products.

- The Department of Technical Regulation oversees the implementation of technical regulations.

Even though the need for the existence of these departments is stated in the 2009 strategic plan, it took until the end of 2019 for the departments to be established. The departments are developing systems based on the required policy, procedure, guidance and other relevant working documents. Currently, there is no clear policy or procedure for delegating to accredited inspection bodies. By default, ECAE seems to be the conformity assessment body that gets delegated to for inspecting regulated imported items. ECAE's inspection branches include the Djibouti branch, which is not accredited, and the main office, which has been accredited for inspecting the purity of agricultural products such as oil seed items, cereals, and pulses.

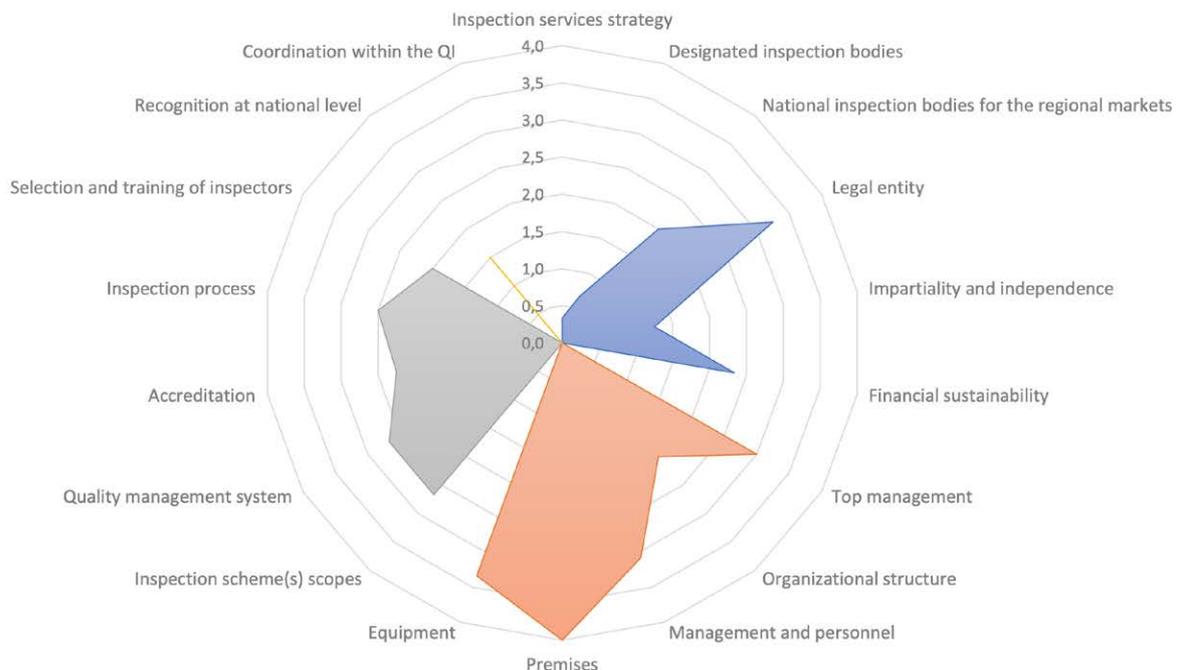


Diagram 7: Inspection services strategy

In addition, the Ministry of Agriculture, the Ministry of Livestock and Fisheries and the Ministry of Health perform inspection activities specific to their sector:

1. The Ministry of Agriculture and the Ministry of Livestock and Fisheries include six quarantine inspection sectors and 16 functional and non-functional slaughtering sectors. Within each of these, inspections are conducted before and after slaughtering. Even though the sector requires competent inspection services or the delegation of inspections to accredited inspection bodies, the inspection is done by the regulatory body – even though their inspection service has yet to be accredited. There is no platform that links the sector with the other NQI units.
2. The Ethiopian Food and Drug Administration has directorates and/or departments for medicine facility inspections, food handling facility inspections and food institution inspections. The departments carry out each inspection despite not having accredited inspection services or being able to delegate tasks to other accredited inspection bodies. Moreover, the sector faces a mandate overlap with the Ministry of Trade and Industry on the issue of regulated food item inspections.
3. The Ethiopian Coffee and Tea Authority's Quality Control and Marketing Department conducts inspections and testing when required. This includes inspections before the coffee is exported as well as certification of the quality of the process of making coffee liquor. Each inspection centre issues a certificate of conformity prepared in accordance with the characteristics of its production area's agro-ecology. If the product meets the required grade, it is sealed and exported. EFDA did not demonstrate its competency by accrediting its service, and at the time of writing this report, there is no enforcing mechanism to accredit the inspection service.
4. The Ethiopian Commodity Exchange Authority inspects and grades items such as coffee, cereals, oils and seeds, for export and local consumption without having accredited their inspection service.

Generally, the country needs to finalise its national quality policy draft document so that inspection policies and strategies can be developed that cascade from the NQP.

### 8.3. Product Certification

Product certification in Ethiopia is mainly run by ESA which uses a product certification scheme policy manual (PCM/ESA/001) based on ISO/IEC 17067 to direct its development scheme requirements and divide products into schemes. The policy manual has 253 technical regulations. Out of those, six items (cable, salt, corn soya blend, beer, bottled drinks, and cement) are classified on the type 5 scheme, while the rest of the regulated products are unclassified. The product certification scheme policy manual, developed by ESA, indicates that the responsibility for establishing and managing product certification schemes lies within ESA's mandate. However, this mandate is not referred to in regulation number 193/2010. As per ESA scheme policy manual, to certify products, processes and services, the certification body must meet the requirements of ISO/IEC 17065. For testing, the conformity assessment body must meet the applicable requirements of ISO/IEC 17025; for inspections, the conformity assessment body must meet the applicable requirements of ISO/IEC 17020; and for management system auditing, the conformity assessment body must meet the applicable requirements of ISO/IEC 17021. Although the product certification scheme promotes accreditation and recommends that all conformity assessment activities should be conducted under accredited conditions, the product certification scheme and policy manual are not implemented accordingly. Up to now, the delegation has not been open to the idea of delegating work to other accredited conformity assessment bodies.

Some awareness-raising programmes on product certification for small and medium sized enterprises (SMEs) have been provided by NQI institutions. However, the topics that were addressed did not enable SMEs to implement the respective standards. Since the training is theoretical, in order to implement the standards in question SMEs will require technical support in the form of consultations.

ESA is not mandated by regulation number 193/2010 to establish and administer product certification. However, outdated product certification practices continue without any formal delegation from either the Technical Regulation Department or the Marketing and Factory Inspection Department.

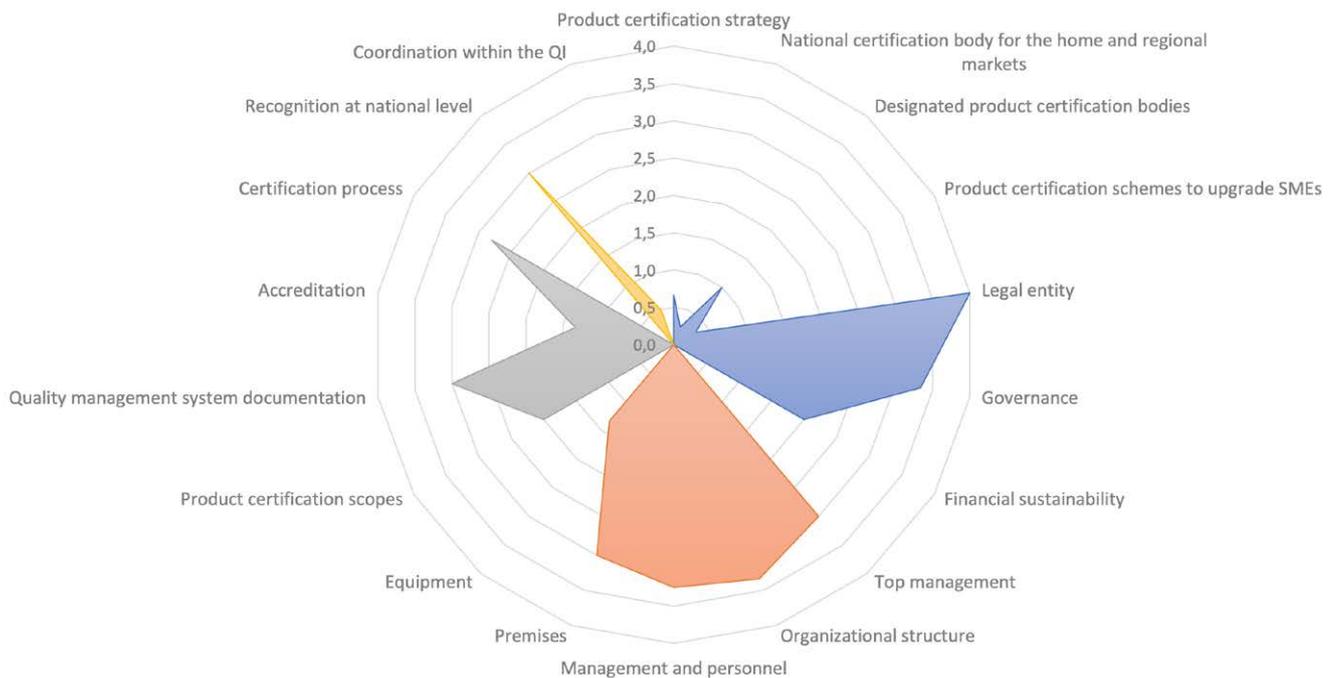


Diagram 8: Product certification strategy

Although the Technical Regulation Department is expected to administer technical regulation, its lack of experience and limited capacity mean that products and services are not regulated and therefore result in failures which can be hazardous to customers' health and safety.

Nowadays, ECAE is considered the sole product certification body to certify regulated factory products by default. Some board members of ECAE are not technical experts, but they are competent enough to evaluate and direct ECAE's strategic plan. It is worth mentioning that ECAE is not accredited for its product certification services and does not face any form of sanctions for not being accredited or failing to maintain its accreditation.

Product certification is administered by an ECAE team leader, and there are currently sufficient staff and part-time auditors for the task. ECAE has made an agreement to work with SGS specifically in order to conduct product conformity verification checks on water pumps and accessories imported to Ethiopia. Sometimes the Ministry of Trade and Industry also accepts product certification provided by SGS.

The Ethiopian Food and Drug Administration does not use ISO/IEC 17065 product certification for drug and food production, but does use the Good Manufacturing Practice (GMP) certificate.



© PTB/Yannick Tylle

## 8.4. System Certification

In Ethiopia, achieving system certification is not mandatory. There is no authority administering the reliability of system certificates.

The Ethiopian Food and Drug Administration accepts GMP certificates for pharmaceutical products despite the fact that in practice GMP certificates are not a method of system certification and instead rely on product certification.

In Ethiopia, ECAE, the accredited certification body ISO-QAR, the German Association for the Certification of Management Systems (DQS) and Bureau Veritas provide voluntary system certification. ECAE provides accredited quality management system certification which it developed and implemented effectively according to all the requirements of ISO/IEC 17021. ISOQAR and DQS have branch offices in Addis Ababa, whereas the branch office of Bureau Veritas is located in Kenya. In general, system certification needs to be used as a supportive tool by regulatory bodies for regulation and facilitating trade.

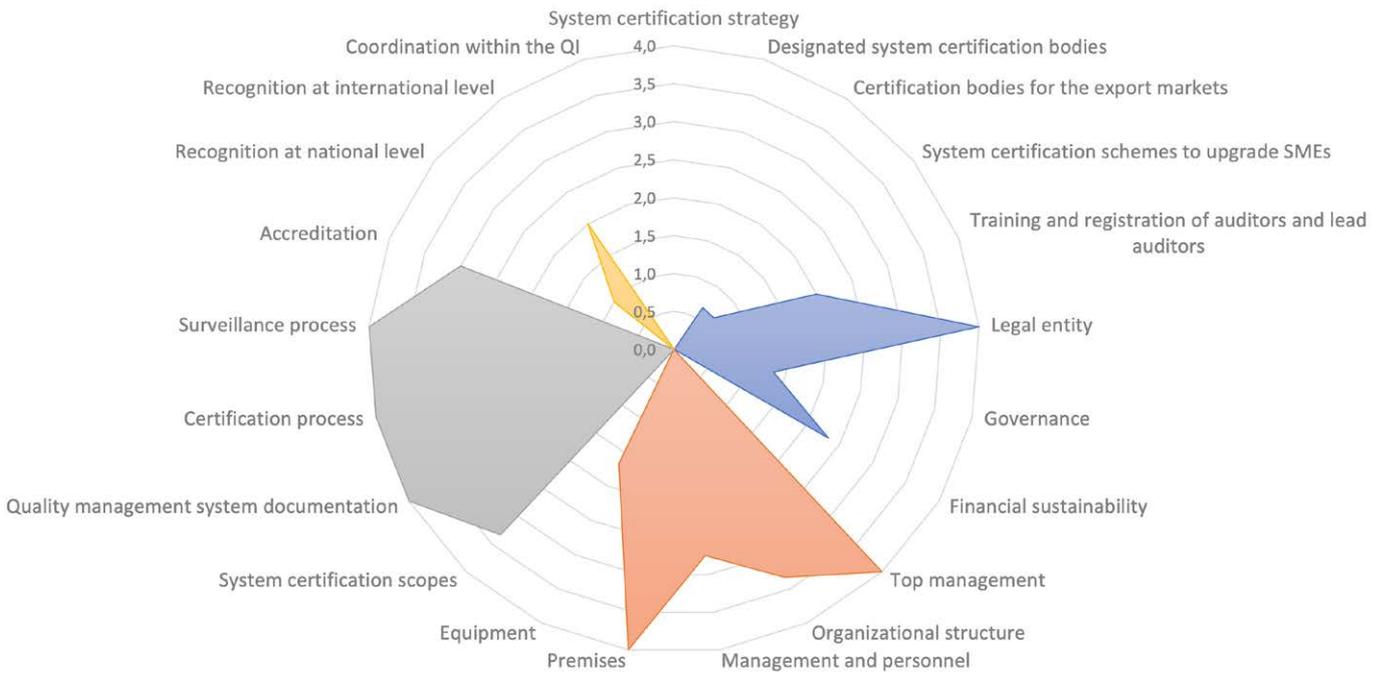


Diagram 9: System certification strategy

# 9. General Comments and Recommendations

## 9.1. General Findings

The Ethiopian National Accreditation office has not been evaluated for IAF-MLA signatory status. Because of this, its certification accreditation service is not internationally accepted. The Ethiopian certification and calibration markets are very limited because of a shortage of hard currency. Because of this, experts do not participate to the required level in international and regional accreditation meetings.

The Ethiopian Standards Agency has developed a sufficient number of standards; however, the status of their implementation is currently unknown. Voluntary standards implementation bodies have yet to use any quality marks as none have been developed for them to use. Voluntary standards are reviewed and approved by the Ethiopian National Standardization Council. However, the members of the council do not have the professional background needed to provide useful consultation to support the implementation of these standards. Most of the technical regulations have no designated scheme which is to be followed and implemented by both conformity assessment bodies and enterprises.

The National Metrology Institution of Ethiopia is not a full member of BIPM which requires members to enumerate scientific keys in order to enter comparison data into the data base. The current scope of measuring equipment traceability does not cover the traceability needs of conformity assessment bodies. The scientific metrology component is not engaged in research activities or chemical metrology services. This makes it difficult to trace and verify the stability of the reference materials that are used. Furthermore, the calibration service is unable to match customer demand. Despite the fact that the demand for these services is high and quickly growing, private calibration services are not flourishing.

So far, there is no established system for regulatory firms, technical regulation, legal metrology, import-export inspections and factory and market inspections. There are currently no clear directives for governing the duties and responsibilities of regional as well as the federal regulatory bodies. Conformity assessment bodies do not use any fair selection criteria to engage in regulation conformity assessment. Additionally, there are no directives for the administration of certifications, nor any clear mandatory inspections to be fulfilled by service providers and enterprises. In general, the regulatory firms are at an infant stage, and still need to build up their capacities, develop systems and produce directive documents.

## 9.2. NQI Strategy and Policy

Ethiopia developed its NQI strategy in 2009 and implemented it by establishing the NMIE, ESA, ENAO, ECAE and the Trade Competition and Consumer Protection Authority. Later, in 2019, the Legal Metrology Directorate, the Technical Regulation Directorate and the NQI Coordinator Directorate were established at the Ministry of Trade and Industry.

The NQI services are highly interlinked. A single NQI unit cannot function properly without the support of the others. For example, ENAO cannot properly function without the NMIE, since conformity assessment body services cannot be accepted or traded without having ENAO's attestation certificate. This example shows that any problem that occurs at ESA automatically affects the efficiency and effectiveness of the other NQI units as well. For instance, problems arising at the NMIE will cramp the accreditation and conformity services. Therefore, a system is required that supports exchanges and cooperation between the NQI units so they can discuss their challenges and plan the way forward together.

The 2009 Ethiopian NQI strategy proposed two such platforms, and yet those platforms have yet to be effectively established. The suggested platforms are:

- the NQI Technical Committee, that comprises members from different regulatory bodies as well as of the director generals of each of the Ethiopian NQI units
- the National Quality Forum, consisting of one representative from each region, one state minister representative from every existing ministry, the director generals of each of the Ethiopian NQI units and one representative from each relevant association

The strategy was developed in 2009 when the four NQI units were accountable to the Ministry of Science and Technology. In October 2018, the Ministry of Science and Technology was re-structured and renamed the Ministry of Technology and Innovation. In that process, four NQI units (ESA, ENAO, ECAE and the NMIE) were structured to report to the Ministry of Trade and Industry. In addition, the strategy was not able to consider and analyse the comparative advantage of the African Continental Free Trade Area that came into force after the formulation of the strategy. Additionally, the strategy was developed without the formulation of a national quality policy. Since the strategy was developed a considerable time ago, it should be revised to correct any previous imperfections, failures of implementation or environmental changes.

The appointment of NQI staff depends on the civil service commission that, in turn, relies on academic qualifications. However, the requirement for academic qualifications does not in and of itself result in adequate staff that fulfil their duties. Before commencing their duties independently, they need to develop the required technical competency through short-term training, sharing experiences from other similar institutions and being mentored and monitored by experienced colleagues during their daily activities. This demonstrates that the process for the development of the technical competency of NQI experts consumes large amounts of time and financial resources. Therefore, a strategic approach is required when employing competent staff for a reasonable period of time and within the institutions they are competent in and have contractually agreed to serve in for a fixed period of time (or alternatively, when making arrangements for them to serve as external experts once they leave the institutions). The NQI units need an easily

accessible database with a pool of experts which allows institutions to easily identify and employ experts for specific disciplines.

The NQI units should also establish a system to update their experts on revised or newly developed documents and procedures so that experts are able to maintain their level of competency. The institutions should perform periodical monitoring so that they can implement a procedure to fill any gaps they identify.

In practice, the rate of turnover in the NQI institutions is high, which causes the institutions to:

- struggle with long-term objectives
- fail to conduct activities beyond simple and easily managed
- execute the same, basic level capacity building activities

The government should reconsider the seriousness of these problems and strive to alleviate them. The career structures of the organisations should consider and reward the value of knowledge, the skills gained from experience and any short-term training.

The Ethiopian government's market economy policy is export-oriented free market competition and the economic policy is Agricultural-Development-Led-Industrialization (ADLI). There are seven priority economic sectors under this umbrella: leather and leather products, textiles and textile products, agro-processing, metal, mining, pharmacy and sugar. However, the NQI units are not directed to prepare and provide internationally accepted NQI services for these priority areas. There is no platform that connects enterprises that demand these services with NQI service providers. This is because demand-based plans are not developed in a way that will perfectly extend the scopes of NQI services.

It takes between two to five years to prepare internationally acceptable NQI services depending on the availability of resources and how committed the leadership is. Therefore, to predict the future demands for NQI services there should be a task force responsible for drafting and analysing a survey so that every organisation can start its preparations in good time for future international service provision.

The fact that each of the NQI director generals are politically appointed, rather than based on merit, will hinder the development of the national quality infrastructure. This is because the appointed persons often do not have the required professional background in directing and supporting an NQI. Currently, there is no fixed service term for the position – it is open until retirement. This kind of practice does not provide opportunities for potential aspiring leaders. The evaluation of CEOs is currently based less in terms of achievements and more on political criteria.

### 9.3. NQI for Strengthening SMEs

Since the manufacturing sector of Ethiopia is at an infant stage, the government is committed to strengthening the sector by developing SMEs in various fields and to providing the necessary support, such as by providing market linkages with other manufacturing industries or capacity development via the following:

- intra-firm learning which is where internal experts share their technological knowledge, skills and practices of doing research to identify cost-incurring processes, learning from each other about the development of new products, acquainting new employees with the current QM system and mentoring their progress by competent experts
- inter-firm relationships via interaction between experts, technological alliances, joint R&D, and cooperative management of traceability and quality standards
- consultation for system development and the utilisation of NQI services that enable partners to compete in regional and international markets

The support could be:

- adopting, adapting and developing quality requirements and/or standards to be used by SMEs
- calibrating their measuring equipment for legal metrological traceability
- encouraging SMEs to offer conformity assessment services, teaching them how their service can comply with the stipulated requirements and accrediting their activities for regional and international recognition

In May 2018, the Addis Ababa city administration's Bureau of SME Enterprise and Development attempted to create a communication platform with ENAO and ESA, and requested training from both organisations. Each organisation provided a week of training for SMEs from various economic sectors. However, the cooperation ended after the implementation of the training due to the absence of a system for continual collaboration.

In order to support SMEs, ECAE also provides conformity assessment services, for which it charges service fees. However, the majority of SMEs are too financially weak to pay for these services. Moreover, a TVET calibration programme has been established, but has yet to be embedded into a strategy to engage the programme's graduates in providing services in the areas of calibration, maintenance and verification of measuring equipment. In general, there is a lack of interaction between SMEs and NQI services which is neither addressed in the NQI policy nor in the NQI strategy. Cooperative partners such as donors could also be involved to make up for this deficit.



© iStock

# 10. Conclusion

The Ethiopian NQI is currently still at a developmental stage. Positive steps have been taken by the government to support the sector by allocating more than two billion ETB for NQI office buildings and infrastructure, and by providing support for the National Quality Infrastructure Development Project, meaning they have been able to upgrade their institutional capacity building programmes by providing scientific laboratory equipment, upgrading their systems and building the capacity of experts.

On the other hand, there are issues that need additional attention and intervention:

1. Since the NQI strategy is not periodically reviewed, it should be reviewed against the needs of national services and international and regional technological development. Therefore, NQI should draft policy needs which must subsequently be finalised. The strategy should be reviewed by considering:
  - the economic policy of the government
  - national economy priority sectors
  - the national comparative advantage of marketing goods and services within the African Continental Free Trade Area
  - the regulatory requirements of potential recipient countries or regions
  - WTO requirements
  - accessibility to the higher national body for better resource allocation and for fundamental support
  - the NQI policy guideline developed by UNIDO, and other relevant documents
2. There is no endorsed policy or strategy at the national level to direct conformity assessment testing, inspections, product certification, system certification results or reports and certificates for acceptance. Therefore, a responsible body must be developed and implemented with a system that supports regulatory bodies, and provides criteria to delegate conformity for system certification and sanctions for any fraudulent behaviour.
3. Delegation practices should be implemented for the development of sector-specific standards.
4. A quality mark for voluntary standards and a technical regulation mark should be developed and administered by the Technical Regulation Department, or the technical regulator should formally authorise ESA to administer the mark.
5. Most ECAE board members are from regulatory bodies. This level of representation cannot create fair and equitable access for all conformity assessment bodies to participate in the regulatory conformity market and henceforth needs to be revised.
6. There should be a platform that creates a communication environment among SMEs and NQI units so that NQI units can provide continual support to SMEs.

# References

Ethiopia Growth and Transformation Plan I of 2010

Ethiopia Growth and Transformation Plan II of 2015

ENAO Transformation Plan of 2011

ENAO Transformation Plan of 2016

ENAO Transformation Plan of 2020

Ethiopian National Quality Infrastructure Strategy of 2009

Regulation N° 193/2010

Regulation N° 194/2010

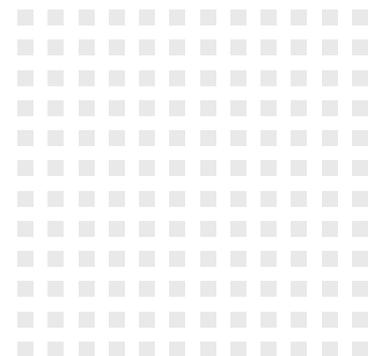
Regulation N° 195/2010

Regulation N° 279/2012

Regulation N° 410/2017

World Bank / PTB Rapid Diagnostic Tool

<http://www.ethiopia.gov.et/economy>



# Abbreviations

|          |   |
|----------|---|
| AfCFTA   | African Continental Free Trade Area                     |
| AFRAC    | African Accreditation Cooperation                       |
| AFRIMETS | Intra-Africa Metrology System                           |
| ANAB     | ANSI National Accreditation Board                       |
| ANSI     | American National Standards Institute                   |
| BIPM     | International Bureau of Weights and Measures            |
| CAB      | Conformity Assessment Body                              |
| CMC      | Calibration Measurement Capability                      |
| CODEX    | Codex Alimentarius                                      |
| CRM      | Certified Reference Materials                           |
| DAkKS    | Deutsche Akkreditierungsstelle                          |
| DG       | Director General  |
| ECAE     | Ethiopian Conformity Assessment Enterprise              |
| ecbp     | Engineering Capacity Building Program                   |
| EFDA     | Ethiopian Food and Drug Administration                  |
| ELA      | Ethiopian Laboratory Association                        |
| ENAO     | Ethiopian National Accreditation Office                 |
| ESA      | Ethiopian Standards Agency                              |
| ETIDI    | Ethiopian Textile Industry Development Institute        |
| GIZ      | Deutsche Gesellschaft für Internationale Zusammenarbeit |
| GMP      | Good Manufacturing Practice                             |
| GTP      | Growth and Transformation Plan                          |
| IAF      | International Accreditation Forum                       |
| IEC      | International Electrotechnical Commission               |
| ILAC     | International Laboratory Accreditation Cooperation      |
| ISO      | International Organization for Standardization          |
| IT       | Information Technology                                  |
| KCDB     | Key Comparison Database                                 |
| KRISS    | Korea Research Institute of Standards and Science       |
| MLA      | Multilateral Recognition Arrangement                    |
| MRA      | Mutual Recognition Arrangement                          |
| NAB      | National Accreditation Body                             |
| NMI      | National Metrology Institute                            |
| NMIE     | National Metrology Institute of Ethiopia                |
| NQI      | National Quality Infrastructure                         |
| NQIDP    | National Quality Infrastructure Development Project     |
| NQP      | National Quality Policy                                 |
| NSB      | National Standards Body                                 |
| OIML     | International Organization of Legal Metrology           |
| PT       | Proficiency Tests                                       |

|       |   |
|-------|---|
| QCI   | Quality Council of India                        |
| QI    | Quality Infrastructure                          |
| QSAE  | Quality and Standards Authority of Ethiopia     |
| RDT   | Rapid Diagnostic Tool                           |
| SANAS | South African National Accreditation System     |
| SGS   | Société Générale de Surveillance                |
| SME   | Small and Medium Sized Enterprises              |
| SPS   | Sanitary and Phytosanitary Measures             |
| TBT   | Technical Barriers to Trade                     |
| TC    | Technical Committee                             |
| TVET  | Technical and Vocational Education and Training |
| WTO   | World Trade Organization                        |









# Imprint

**Published by**

Physikalisch-Technische Bundesanstalt  
Bundesallee 100  
38116 Braunschweig  
Germany

**Responsible**

Susanne Wendt  
+49 531 592-9030  
[susanne.wendt@ptb.de](mailto:susanne.wendt@ptb.de)  
[www.ptb.de/9.3/en](http://www.ptb.de/9.3/en)

**Text**

Araya Fesseha

**Title image**

© iStock

As of April 2020





## Contact

Physikalisch-Technische Bundesanstalt

International Cooperation

Susanne Wendt

Phone +49 531 592-9030

Fax +49 531 592-8225

[susanne.wendt@ptb.de](mailto:susanne.wendt@ptb.de)

[www.ptb.de/9.3/en](http://www.ptb.de/9.3/en)