



ST. MARY'S UNIVERSITY
SCHOOL OF GRADUATE STUDIES
INSTITUTE OF QUALITY AND PRODUCTIVITY MANAGEMENT

CHALLENGES AND IMPACT OF ISO/IEC17025 ACCREDITATION; IN
ETHIOPIAN CONFORMITY ASSESSMENT AND ETHIOPIAN NATIONAL
METROLOGY INSTITUTE

THESIS SUBMITTED TO THE SCHOOL OF GRADUATE STUDIES IN PARTIAL
FULFILMENT OF THE REQUIRMENT FOR THE DEGREE OF MASTERS OF
SCIENCE IN QUALITY AND PRODUCTIVITY MANAGEMENT

BY: WONDALE ANDARGIE

JUNE 2019

Addis Ababa -Ethiopia

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DECLARATION

I, the undersigned, declare that this thesis is my original work, prepared under the guidance of my Advisor Dr.AbduAbagibe. All sources of materials used for the thesis have been duly acknowledged. I further confirm that the thesis has not been submitted either in part or in full to any other higher learning institution for the purpose of earning any degree.

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ENDORSEMENT

This thesis has been submitted to St. Mary's University, School of Graduate Studies for examination with my approval as university advisor.

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June,2019

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ABBREVIATIONS

CABs	Conformity Assessment Bodies
ECAE	Ethiopian Conformity Assessment Enterprise
ENAO	Ethiopian National Accreditation Office
DAKKS	Deutsch AKK/ German accreditation Body
FDG	Focus Group discussion
ILAC	International Laboratory Accreditation Cooperation
ISO/IEC	International Organization for Standardization and the International Electro Technical
LMS	Laboratory Management System
MRAs	Mutual Recognition Arrangements
NMIE	National Metrology Institute of Ethiopia
NQI	National Quality Infrastructure
SANAS	South African National Accreditation System (SANAS)
UNIDO	United Nations Industrial Development Organizations

ABSTRACT

Accreditation is formal recognition that a testing laboratory is competent to carry out the tests identified within the scope of accreditation. Governments in many countries worldwide have increasingly focused on accreditation as an important strategy to improve the quality of products. In Ethiopia, accreditation is still in its initial stage of development. The purpose of this study is to investigate the challenge of institutional accreditation in two government institutions and assess the impact of ISO/IEC 17025 implementation. Both primary and secondary data were used in this research paper. The approach used to gather primary data was both qualitative and quantitative. Secondary data was generated through a literature search on accreditation. Four sections of questionnaires and face to face interview were designed to meet the research objectives. Data was collected from two accredited government laboratories, the Ethiopian Conformity Assessment Enterprise (ECAE) and the Ethiopian National Metrology Institute of (ENMI).

The findings showed that although accreditation was a lengthy process, bureaucratic, as well as involving substantial investment for equipment, supplies, consultant and assessors, all respondents valued accreditation since it helped them to improve their laboratory operations and fulfill their customers' expectations. The study further revealed that accreditation has had a positive impact on laboratory processes and has improved the level of competitive advantage, prevent retesting problems, An effective marketing tool, market share, customer trust. Moreover, the majority agreed that there was a better communication from management and they were satisfied to work in an accredited laboratory. Major obstacles encountered, during implementation and maintenance of accreditation, by the laboratories were lack of suppliers of calibrated equipment, non-existence of enough accredited metrology laboratories for calibration of equipment, and unavailability of proficiency testing and CRM providers, choice of accreditation body and its cost.

Feasible recommendations were made to address the potential barriers to accreditation. The most pressing ones being that calibration laboratories must be accredited to ISO/IEC 17025 at the earliest to boost national awareness on the economic and social benefits of accreditation and there should be an alternative accredited testing and calibration body in the country.

Key words: Accreditation, ISO/IEC 17025, Impact, Customer satisfaction, Metrology

Chapter One

Introduction

This chapter deals with the background of the study, the statement of the problem, objectives of the study, research questions, Significance of the Study and delimitation of the study.

1.1 Background of the study

The last decade has witnessed a growing interest in quality assurance. Governments in most countries worldwide have established QA systems to assure and improve product quality. Quality defined as the ‘degree to which a set of characteristics fulfills requirements’ has been restated in a number of ways. One way to summarize it is to say that “Quality is fitness for purpose”. With the advent of globalization, domestic and export trade have become vital to the development of a country’s economy. There is a need to lower and/or eliminate barriers to trade in order to facilitate trade amongst nations. Barriers to free trade can be in the form of technical regulations and standards, usually referred to as technical barriers, as established by countries. A General Agreement on Tariffs and Trade (GATT) working group, set up to evaluate the impact of non-tariff barriers in international trade in the 1970s, concluded that technical barriers were the largest category of non-tariff measures faced by exporters (WTO, n.d ,(2009).

Accreditation is one of the tools available to lower such barriers. It creates confidence in the work carried out by certification and inspection bodies, as well as testing and calibration laboratories, located anywhere in the world. Without accreditation, tests carried out in the exporting country would have to be repeated by a recognized laboratory in the importing country and an adverse test report could result in the rejection of the finished goods (UNIDO, 2003). Usually there is an increase in cost in producing the required goods. While international trade is fundamentally linked to supply capacity and cost, laboratory accreditation and the recognition of test results is a final determinant as to whether the goods produced by the exporter are acceptable in other countries (UNIDO, 2003).

1.2 Statement of the Problem

Accreditation of laboratories has been a subject of considerable interest because product quality guarantee has become one of the prime factors to be considered in the present time of highly competitive industrial activity. Accreditation is still a new issue for the laboratories in Ethiopia.

To improve on service delivery, government institutions have been adopting accreditation service started since 2007 and 2012 and accredited the NMI and ECA respectively in different accreditation body to standardize the equipment calibration and testing laboratories, therefore public laboratories have been implementing a quality management system in line with the requirements of ISO/IEC 17025 quality improvement which has become a key national and international business strategy. Laboratory accreditation leads to the overall traceability of laboratory work, better knowledge of the methods and equipment, a more systematic and empowering approach to laboratory management, improvement in personnel professionalism and skills, better working instructions, increased level of responsibilities, and fewer errors from employees.

Complaints from the public in Ethiopia show the general dissatisfaction expressed towards the services offered by government institutions (testing and calibration laboratories), rejection of exporting products by importing country laboratory quality assurance, product specification quality and quantity problem , health problem due to poor quality and food safety , cost of transporting for product rejection

The problems are due to lack of the technical competence of testing and calibration report for food and equipment analysis and measurements between technicians to happen different test result in the same product /patient in different testing laboratories due to not proper calibration of measurement devices /equipment's. However, this will not only cause both employee and customer dissatisfaction in the measurement instruments and also will lack competitive advantage on technical skill and equipment competency for the organization.

The first phase of this research deals with the challenges faced in implementing ISO/IEC 17025.

The accreditation process does not merely end with the issuance of testing and calibration reports; when a laboratory is selected to fulfill testing, calibration or measurement needs, this laboratory should be able to make accurate and reliable results.

The impact of unacceptable or poor quality product can be seen from both the exporting firm's suppliers as well as the customers point of view: Danger to enterprise (loss of image; loss of market share; high costs; customer complaints; claims; waste of resource; loss of finance; finally, closing down of business), loss to customer (health problems; safety problems; discomfort; economic losses ...). The impact or tangible and intangible consequences of the issued reports should be assessed against identified baseline items such as:

Risk minimization- accredited products or services are safe and meet the specification and standards, and thus that choosing an accredited laboratory minimizes the risk of producing a faulty product.

Purchasing confidence- accreditation is needed to maintain trading confidence, especially where there is marketing competition because it is difficult to protect the market against high-quality products at low cost.

Marketing advantage: accreditation is also a market access tool for an organization to export product or to submit tenders.

Expensive retesting: Retesting of product incurs extra charges and additional time consumption and the reputation of the testing organization goes down thus laboratory accreditation provides the chance to prevent retesting problems.

The second phase of this research assesses the impact of accreditation against the above baseline items.

1.3: Objectives of the Study

The study aims to identify the challenges in the implementation of ISO/IEC 17025 and the impact of accreditation in ECAE and ENMI.

Five specific purposes of the study are as follows:

1. To identify and investigate the factors that affect the establishment of laboratories' accreditation as gained from the literature review.
2. To identify the extent of benefits obtained by the Testing/Calibration laboratories in implementing ISO/IEC 17025 in ECAE and NMIE
3. To assess the extent of commitment of the management of the Testing/Calibration laboratories in implementing ISO/IEC 17025? in ECAE and NMIE
4. To investigate potential challenges/ barriers faced during implementation of ISO/IEC17025 in testing /calibration laboratories. in ECAE and NMIE
5. To assess the impact of accreditation to ISO/IEC 17025 in testing /calibration laboratories in case of ECAE& ENMI, in Ethiopia.

1.4: Research Questions

- i. What are the extent of benefits obtained by the Testing/Calibration laboratories in implementing ISO/IEC 17025 in ECAE and NMIE?
- ii. What the extent is of the commitment of the management of the Testing/Calibration laboratories in implementing ISO/IEC 17025 in ECAE and NMIE?
- iii. What are the potential challenge/barriers faced during implementation of ISO/IEC17025 in ECAE and NMIE?
- iv. What are the impact of accreditation to ISO/IEC 17025 in testing/Calibration laboratories in case of ENMI and ECAE

1.5. Significance of the Study

This research project will be beneficial to the laboratory community and its customers as this study enhances the importance of accreditation to ISO/IEC17025 for the economic and social development of the country. This study will also be helpful to assess the views of employees involved in the management system based on ISO/IEC 17025. Therefore, the findings are expected to contribute towards improving staff motivation and the management system. However, this research will identify potential obstacles or challenges to the implementation

and maintenance of accreditation to ISO/IEC 17025. Moreover, this infra-structure is new for our country and there is limitation of getting studies around this to see the gap among other researchers. Furthermore, the studies will help for policy maker to see and develop network of the stockholders; suppliers, customers, service giving organizations, employees development and the study will help to develop educational framework in universities. Currently most of stakeholder are found out of the countries and difficult to access easily due to economical and time taking to get certified reference materials (CRM), supplies of materials and equipment's. For proficiency test sample providers and participation recommendations will propose to address these constraints.

1.6. Delimitation of the Study

The area of the study focus impact of implementation of ISO/IEC 17025 in testing and calibration laboratories in Ethiopian quality infrastructure based on the two ISO/IEC 17025 implemented organizations, Ethiopian Conformity Assessment and National Metrology Institution due to time constraint and shortage of implemented public organization.

1.7. Limitation of the study

There were some boundaries that had to be set as this research completion was limited to a specified time frame and also there were some obstacles faced during data collection that affected the outcome of the research. Some of them are as below

Getting written related researches paper and journals about those two organizations in Ethiopia and others.

100% response rate could not be obtained as some respondents hesitant to give information and were not willing to dedicate their time to fill in the questionnaires and return.

Lack of Willingness from some respondent to cooperate on questioner data collection

Cannot access to see the data analysis from both organizations due to confidentiality.

1.8 .Definition of Basic Terms used in the Study

Laboratory; body that performs one or more of the following activities: testing; calibration; sampling, associated with subsequent testing or calibration

Impartiality -“freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

Inter-laboratory comparison; organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions Such competence is taken to be assured by the presence of certain features in the laboratory and its organization:

Verification; provision of objective evidence that a given item fulfils specified requirements

Proficiency Testing (PT): exchanging samples and comparing results among laboratories, demonstrates effectiveness of internal reproducibility and accuracy of results.

1.9. Organization to the Study

Chapter one provides a brief introduction of the back ground of the study, problem of the statement, Objective, significance of the study, delimitation of the study and limitation subject matter of the thesis.

Chapter two presents the literature review ; Nature of Quality ,ISO, accreditation, brief History of laboratory accreditation, Reducing Trade Barriers through Conformity Assessment, Benefits and Challenges of Accreditation , benefit and challenge of accreditations, The National Quality Infrastructure (NQI) and conclusion

Chapter three presents Research design and methodology ; the research design, the research methods, source of data , samples and sampling techniques, instruments of data collection , procedures of data collection , methods of data analysis and ethical consideration.

Chapter Four will cover data collection, presentation and analysis of the study. Chapter five will provides conclusions and recommendations of the study.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1. Quality Concept and perspectives

Quality has been a common concept in history, and also has been one of the most controversial concepts. It is because of the variation of human perception in the world, as well as the difference in culture, that make the concept of quality and quality assurances vary from place to place. As there are different ways to understand and interpret the concept of quality, there are also neither way to define quality simply with a single perspective.

In previous study, quality regards mostly to the satisfaction of customers, and it is heavily related to the product (Juran, 1998.). ISO, in their DIS 9000:2000, however, has given a brief definition about quality. It is defined that “Quality is the collection of product/service/system/process to satisfy the needs of customers and all relevant parties.” (ISO, 9000:2000.). Therefore, quality is not just characteristic of a product used daily, but also applied to a process or system.

In modern business context, the concept of quality expands to processes, organization, responsibilities, work instructions and resources to meet normal ISO standards (Hoyle, 2007.). It is an essential approach and a tool for all business looking for sustainable development. This could be simply explained in a way that, when a business implements quality into all the process, improvement of business performance can always be created and renewed. After all, quality has become a necessary factor for a successful business (Schneider-White 2004, 10.)

2.1.1. Role of Quality

Quality is the business process of managing variation around the expectations of our customers. Quality is often measured by business process excellence and product (service) performance as measured against tolerances and specifications. The producer may define Quality, but Quality is ultimately judged by the customer.

2.1.2. Quality in Laboratories

From several definitions that quality could be understood, there is one that more noticeable and suitable in laboratorial work, known as "freedom from defects, imperfections or contamination" (Hoyle, 2007.) In this particular context, Juran's opinion of quality as the "conformance to customer needs" is not completely correct anymore (Juran, 1998.)

Laboratories generally have a slightly different approach towards quality and customers. It has become crucial to determine the validity and to improve the results delivered.

Quality in laboratories can be considered as work to be done in order to conform to requirements and guidelines from standardized and accredited organizations. Under business angle, it is an act to be accepted by the customers.

2.2. International Organization for Standardization (ISO):

ISO is based global consortium in Geneva and has a membership of more than 90 national standardization body, was shortened (ISO) based on the Greek word "ISOS" which means "Equal" (Hahn et al, 2016).

ISO/IEC 17025 was first issued in 1999 by the International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC). It is the single most important standard for calibration and testing laboratories around the world, with more than 50.000 laboratories accredited.

According to International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC), accreditation is defined as "the independent evaluation of conformity assessment bodies against recognized standards to ensure their impartiality and competence."

This standard was developed with the objective of promoting confidence in the operation of laboratories and contains requirements for laboratories to enable them to demonstrate that they operate in a competent and impartial way and that they are able to provide valid results.

During its development phase it has been tried to align the standard with the principles of ISO 9001, although this was not always practically possible. Still it is a fair statement to make that the laboratories complying with the standard will also, in general, comply with the principles of ISO 9001.

The standard can be used for accreditation purposes, for self-assessment of the laboratories and for second party assessments by laboratory customers, regulatory authorities, organizations and schemes using peer-assessment.

Its requirements are applicable to any organization that performs the activities of testing and/or calibration and/or sampling associated with subsequent testing or calibration. Therefore, accreditation to the new standard can be also achieved by organizations offering sampling associated with subsequent testing or calibration. When the standard uses the term "laboratory" is referring to any of the 3 options mentioned above (testing, calibration, and sampling).

Requirements for sampling organizations are similar to testing and calibration laboratories: personnel shall be competent, equipment has to be maintained and calibrated, sampling procedure has to be validated, quality of sampling has to be assured etc. Confirmation of competence of organization to provide sampling can be provided through accreditation against the new ISO/IEC 17025.

The structure of the ISO/IEC 17025 standard has five main sections entitled; General Requirements, Structure Requirements, Resource Requirements, Process Requirements, and Management System Requirements (Euro lab 2017; ISO and IEC 2017; SADCAS 2018) with risk based approach.

2.3. Accreditation

2.3.1. What is accreditation?

It is important that the market has assurance that the conformity assessment bodies (CABs) themselves operate to acceptable standards and this is the purpose of accreditation. The

accreditation process determines, in the public interest, the technical competence and integrity of organizations such as those offering testing, calibration and certification services (commonly referred to as conformity assessment).

2.3.2. Brief History of Laboratory Accreditation

History indicates that testing laboratories emerged in the second half of the nineteenth century (Stanger, 1989). The testing laboratories provided specialized services which included approval and quality assurance programs to specific industries such as the automotive manufacturers and the military.

a) The first accreditation body in Africa is the South African National Accreditation System (SANAS) which has been set up in 1996 (UNIDO, 2003). NATA was the pioneer in the field of laboratory accreditation in the world exhibiting new features as listed below (Garside & Gilmour, 1983): to provide a national testing service for government, industry and commerce,

b) to operate a uniform system throughout Australia, and

c) To use a unique method of assessment of the competence of laboratories by independent experts. The growing interest in laboratory accreditation led to the first ILAC conference in Copenhagen in 1977 (NATA, 2009). ILAC produced a document for laboratory accreditation which was adopted as ISO Guide 25: 1978 (Squirrell, 2008). This standard was revised in 1990 and another revision led to ISO/IEC17025 in 1999. The latest standard published in 2005 incorporates quality management elements of ISO 9001 (Squirrell, 2008). According to ILAC (2009), there are almost 29000 laboratories accredited worldwide in 2007, representing a growth of over 30% since 2004.

2.3.3. Importance of Accreditation

Without accreditation, buyers of commodities or products would solely rely on the seller's assurance about the quality or safety of a product or their own inspections. Assurance from sellers can be unsatisfactory since they have incentives to overstate quality of product and consumers are often deprived of information.

2.3.4. Advantages of Accreditation to ISO/IEC 17025

A study carried out by Hacham and Sheinman (2003) pointed out the benefits of accreditation to ISO/IEC17025 with respect to improved quality customer service and handling customer's complaints, establishing multi-channel communication, enhanced inter-laboratory collaboration and coordination. Another study carried out by Vlachos et al. (2002), on the implementation and the maintenance of the ISO/IEC17025, found that despite drawbacks of developing and maintaining an efficient management system such as time-consuming efforts, increase expenses and bureaucratic procedures, the whole process is quite rewarding and fruitful. Accreditation provides extensive training to both management and laboratory employees. There is evidence of a strong relationship between laboratory accreditation and employee satisfaction (Verstraete et al., 1998). Laboratory accreditation leads to the overall traceability of laboratory work, better knowledge of the methods and equipment, a more systematic and empowering approach to laboratory management, improvement in personnel professionalism and skills, better working instructions, increased level of responsibilities, and fewer errors from employees (Verstraete et al., 1998; Siloaho and Puhakainen,2000). Access to information and data from internal and external sources to perform corrective and preventive activities improves organizational learning (Halevy, 2003). Laboratory accreditation further enhances the performance of the organization through better control of laboratory operations and feedback from customers. This will result in potential increase in business due to enhanced customer satisfaction (NABL, n.d)

According to Wiegiers (2002), accreditation leads to an increase in productivity, morale of staff and ability to stay abreast of developments in requirements for competence and testing. Mukhopadhyay (2004) and ILAC (n.d., 2001, 2008) highlight the following benefits of laboratory accreditation.

2.3.4.1 A recognition of Testing Competence

Laboratory accreditation provides formal recognition of competence to laboratories, thus raising the efficiency and effectiveness of laboratory operation. It allows customers to select appropriate testing services and minimizes the risk of unreliable results.

2.3.4.2 A Marketing Advantage

Accreditation is an effective marketing tool for testing, calibration and measurement organizations, and a passport to submit tenders to contractors that require independently verified laboratories. Users of accredited laboratories will enjoy greater access for their products, in both domestic and international markets.

2.3.4.3. A Benchmark for Performance

Laboratory accreditation ensures that laboratories perform their work correctly and to appropriate standards. It provides them with a benchmark for maintaining that competence. In addition to commercial testing and calibration services manufacturing organizations may use laboratory accreditation to ensure the testing of their products by their own in-house laboratories is being done correctly.

2.3.4.4. Avoid Re-testing

Testing of products and materials can be expensive and time consuming, even when they are done correctly the first time. If not done correctly, then the cost and time involved in re-testing can be even higher if the product has failed to meet specifications or expectations. Not only costs go up, but reputation as a supplier or manufacturer can go down. Thus, a product tested in a particular country by an accredited laboratory minimizes the chances of retesting and reducing chances of additional financial burden and time delays.

2.3.4.5. Enhance Customer Confidence and Satisfaction

Confidence in a product is enhanced if customers know it has been thoroughly evaluated by an independent, competent testing facility, that is, an accredited laboratory. Increasingly, customers are relying on independent evidence, rather than simply accepting a supplier's word that the product is "fit for purpose".

2.3.4.6. International Recognition

Laboratory accreditation ensures international acceptability of test data and facilitates trade among countries. This reduces cost for exporters and duplication of test in the importing countries. Accreditation is gaining due recognition on the international level, the latest being the setting up of a legal framework for accreditation in Europe as it is found that accreditation plays an important role in the European Union's economic infrastructure.

2.3.4.7. Government

Governments are using accreditation through regulations to reduce uncertainties associated with decisions that affect the protection of human health and the environment, and meet their responsibilities and safeguard the public.

2.4 Implementation of ISO/IEC 17025 in Laboratories

Any laboratory willing to be accredited to ISO/IEC 17025 has to work according to the requirements of the standard. For many laboratories the decision to attain accreditation is taken by senior management of the organization and passed down for implementation by the laboratory personnel. The laboratory may apply for as little as one to as many tests, which will be defined under its scope of accreditation. According to Wilson and Weir (1995), the steps involved in establishing a management system for a laboratory are:

1. Choosing an accreditation body. The body will provide the laboratory with relevant guidance documents to implement the system.
2. It is vitally important to involve all staff performing test right from the start. They should be familiar with ISO/IEC 17025 and other relevant documents. All documents in use should be an updated version approved by responsible persons.
3. Establishing laboratory policy with respect to each area of the system. For example, policy with respect to training of staff, dealing with complaints, carrying out audit and handling of test items.
4. Appraise the current system and upgrade it to meet the requirements of the standard.

5. Drafting the Quality Manual which contains policy statements of all clauses of the standard and related procedures.
6. Audit the system
7. Review the system However, there is no one way to implement a management system in a laboratory. Laboratories have the option of hiring the service of an expert in that field (consultant) to implement ISO/IEC 17025, or this can be done in-house.
8. Additional cost will have to be borne by the organization if a consultant is hired. A gap analysis is performed to know the current status of the laboratory. A team is formed to establish relevant documents such as the quality manual, quality procedures, working instructions, forms and other records. The team should ensure that operating equipment manuals are available for ease of reference.

The person in charge of the laboratory prepares a checklist to identify the current calibration status of equipment. Equipment that needs to be calibrated is sent to a metrology laboratory for calibration. The person in charge is required to set a calibration schedule for all equipment used for testing. A conducive environment should be provided to meet the requirements of the tests. For instance, if a test needs to be performed at a temperature of 20C, appropriate measures should be taken to ensure that this condition is maintained throughout the test. Management has to provide training to staff to understand all relevant documents in order to work accordingly. Further training on internal audit, uncertainty of measurement and method validation will have to be conducted by external trainers. The person in charge of the laboratory and all the personnel who participate in carrying out laboratory tests or any other tasks related to accreditation should be qualified and properly trained. The quality management system is run for a period of time as determined by the organization. It is advisable that the laboratory performs an inter-laboratory comparison, Proficiency Test and or Intra- laboratory test comparison for tests that are defined in the scope of accreditation for comparison of test results. Internal audit is then carried out to assess the effectiveness of the system. For any non-compliance with the standard, corrective actions are taken. A management review meeting is conducted to ensure that the laboratory management system is operating as per ISO/IEC 17025. Management decides to submit the application to an accreditation body.

2.5. Benefits and Challenges of Accreditation

Implementing the ISO/IEC 17025 standard within a food testing laboratory provides structure for the laboratory to gain ISO accredited status while also affording many benefits that can be realized by the laboratory. Some of these benefits include: increase in the reliability and trust in the data being generated; minimization of errors in laboratory analyses, sample processing, and reporting of results; reduced costs; improved quality of work being performed; improved training and competency of staff; and provides recognition within the food industry (Martincic(1997); ILAC (2001); Halevy 2003; ISO 2014; ISO 2016; ISO 2017; ISO 2018c).

Even though there are many benefits of obtaining ISO/IEC 17025 accreditation for food testing laboratories, not many or academic laboratories attempt to obtain accreditation because it is very challenging and requires a lot of resources. Implementation of ISO practices involves the development of a quality management system (QMS) and creation of documentation (Zapata-García et al. (2007); Grochau et al. (2010); Grochau and ten Caten(2012), implementation of in-house control programs such as environmental monitoring, training (Honsa and McIntyre (2003), and media qualification programs, and the verification of all in-scope methods used within the laboratory (A2LA 2001; AOAC 2015).

The main challenges associated with implementing all of the requirements to obtain ISO accredited status include the time and difficulty of developing and implementing the quality management system, documents, forms, policies, and programs to meet the requirements, and how well prepared the food testing laboratory is when they begin the accreditation process (Vlachos et al. (2002); Zapata-García et al. (2007); Hullihen et al. 2009; MDT (2016). Obtaining accreditation status is a financially burdensome task that can take several months or even years to accomplish and requires not only management commitment but also the coordination of policies, procedures, and departments within the establishment, all while maintaining and continuing to improve the quality management system (Vlachos et al. (2002); Zapata-García et al. 2007; Hullihen et al. (2009); MDT 2016; DQS et al. 2016; Rahmat et al. 2016). This is not necessarily in the best interests of academic laboratories which are primarily focused on research and teaching activities (Zapata-García et al. (2007);

Grochau et al. (2010) and should be discussed in great detail prior to attempting ISO accreditation. Other challenges that could occur include:

1. Issues developing a QMS and proper organizational structure that meets the needs of the establishment and also the requirements in the standard
2. Developing procedures with risk-based decision making
3. Having appropriate leadership and management commitment to obtaining accreditation
4. Coordinating policies, documentation, processes, and procedures between management and departments and from one department to another
5. Issues meeting all quality requirements in the standards
6. Ensuring the timing of obtaining accreditation fits the business model of the establishment
7. Maintaining the QMS and continuing to improve

2.6. Reducing Trade Barriers through Conformity Assessment

2.6.1. Conformity Assessment

Conformity assessment according to the definition in ISO/IEC 17000 (2004) is the demonstration that specified requirements relating to the product, process, system, person or body are fulfilled. Conformity assessment provides a user or purchaser or regulator with the needed confidence that a product, service, process, system or person meets relevant requirement. There are three types of conformity assessment namely:

1) First Party or Supplier's Declaration of Conformity

This implies that the responsibility rests on the supplier for testing to demonstrate the conformance of a product to its specification, i.e., a self-declaration from the supplier. The declaration may be in the form of a certificate, brochure, manual or product or packaging markings (IEC,(2008).

2) Second Party or Buyer Declaration of Conformity

This implies a person or organization that has a user interest in the product. The purchaser does his/her own testing. For example, a consumer checks an appliance upon purchase to ensure that it conforms to its specification (IEC, 2008).

3) Third Party

This implies a person or an independent body performs the verification that product's specification is being met. Example of third party conformity assessment includes: testing, inspection, certification and accreditation (Unger, (2008)

Third party assessment provides benefits to everyone in the supply chain from the supplier to the consumer. It also involves governmental bodies putting in place conformity assessment infrastructure to ensure that health, safety and environmental conditions are met. Besides providing confidence and trust to consumers and purchasers, conformity assessment also helps to facilitate the free flow of goods and services on the international level.

2.6.2 Conformity Assessment Procedures

According to IEC (2008), technical and regulatory infrastructure of a country must have certain characteristics before one may expect to derive maximum benefit from international standards and conformity assessment:

1. Established metrology infrastructure, both in legal metrology and facilities for traceable calibration of laboratory equipment
2. Competent product test laboratories, whether government or private, with up-to-date equipment
3. Trained personnel, both for laboratories and for government agencies (e.g. regulators)
4. A stable, well-publicized regulatory regime, clearly organized at national level and determining the roles of government agencies and certification bodies. These conformity assessment procedures are technical procedures which confirmed that products fulfill the requirements laid down in regulations and standards.

2.6.3 Technical Barriers to Trade

In 1947, members of the United Nations gathered in Geneva for the first round to discuss international trade. Provisions of GATT only make reference to technical regulations and standards. In the second round of negotiation, the Tokyo round, in the 1970s, it was found that technical barriers to trade were the major problem faced by exporters. In 1995, WTO was set up to continue the work of GATT, WTO's TBT Agreement was established to prohibit the use of technical regulations, product standards and conformity assessment as unnecessary obstacles to international trade (Guasch et al, 2007). The agreement:

- a. Requires national technical regulations to be transparent, justifiable and non-discriminatory based on international standards,
- b. Encourages members to sign mutual recognition agreements on conformity assessment, and
- c. Encourages the development of harmonized international conformity assessment systems.

2.7. The National Quality Infrastructure (NQI) -Ethiopia

The National Quality Infrastructure (NQI) is the institutional framework that establishes and implements the practice of standardization, including conformity assessment services, metrology, and accreditation. This brief outlines the central components of the NQI, discusses measures to develop an effective quality system, and addresses challenges to implementation.

Among four NQI organizations the two ISO 17025 implemented organizations are ECAI & ENMI are covered in this study.

1. National Metrology Institute of Ethiopia (NMIE)

The National Metrology Institute (NMI) of Ethiopia is established by the Council of Ministers regulation No. 194/2010 since 10th February 2011.

The Institute is responsible for the maintenance of Ethiopian National Measurement Standards and Certified Reference Materials (CRM). It also provides calibration, training and consultancy services in the areas of metrology and scientific equipment.

Objectives

The Institute shall have the objectives to:

- a) Develop national metrology system compatible with international metrology system and ensure technology transfer in the sector;
- b) Establish and implement a system that enables to compare Ethiopian National Measurement Standards and Certified Reference Materials (CRM) with international Measurement Standards and to maintain and disseminate them;
- c) Support education and research activities in the field of metrology;
- d) Build National capacity for maintenance of scientific instruments and provide maintenance services;
- e) Provide technical training, consultancy and information services on scientific equipment with a view to supporting users to carry out their duties.

Mission

To make the society beneficiary of the modern measurement system by implementing national measurement system based on the internationally accepted practices.

2. Ethiopian Conformity Assessment Enterprise (ECAE)

ECAE is the acronym for "Ethiopian Conformity Assessment Enterprise". In February 2011, ECAE was established as a federally owned Public Enterprise, governed by the Ministry of Science and Technology. ECAE is at present the major conformity assessment organization in the country providing inspection, laboratory testing and certification services to the public and to industry.

ECAE has about 190 professional and support staff throughout Ethiopia. The headquarters and main laboratory facilities are located in Addis Ababa and an additional eight branch offices are operational in various parts of the country.

Mission

ECAE's mission is to provide internationally accepted and recognized certification, inspection and testing services for exporters, producers, service providers, regulatory bodies, consumers and importers as well as the public through credible, effective, accessible and efficient conformity assessment services that enhances the quality of products and services.

2.8. Cost of Accreditation

There are several factors that affect the cost of accreditation which includes the size of the laboratory, the location of the laboratory, the scope, type and fields of testing, the gap between the status of the laboratory and the requirement for accreditation and the fees required by the selected accreditation body (Wiegers,(2002).Ratliff (2003) stated that there are four categories of quality cost related to laboratory operations:

1. Prevention costs associated with keeping unacceptable data from being generated in the first place such as:
 - a) Quality planning
 - b) Document control and revision
 - c) Quality training
 - d) Quality assurance plans for projects and programmers
 - e) Quality assurance manual
 - f) Preventive maintenance
2. Appraisal costs associated with efforts to maintain measurement system performance such as:
 - 1) System audits
 - 2) Inter-laboratory/Proficiency testing
 - 3) Data validation
 - 4) Statistical analysis of data
 - 5) Calibration
 - 6) Procurement quality control
 - 7) Quality assurance activities associated with pre-test preparation, sample analysis and data reporting

3. Internal-failure costs caused by occurrence of determinations or test results that do not meet acceptance standards such as:
 - a) Scrapping of defective materials
 - b) Cost of re-running tests
 - c) Cost of corrective actions efforts
 - d) Investigation or research efforts
4. External-failure costs caused by unacceptable test or analytical results that have already left the laboratory such as:
 - i. Investigation of complaints from outside sources
 - ii. Cost of corrective action efforts

Cost of re-running test and replacing samples According to Ratliff (2003), the above costs are initially high, but decrease after implementation of accreditation. Furthermore, it has been found that a relatively small increase in prevention expenditures will yield large reductions in appraisal and failure costs. Hence, laboratory management should consider adoption of preventive measures to reduce the total quality control costs

2.9. Conclusion

Quality in laboratories considered as work to be done in order to conform to requirements and guidelines from standardized and accredited organizations. Under business angle, it is an act to be accepted by the customers. Therefore accreditation leads to an increase in productivity, morale of staff and ability to stay abreast of developments in requirements for competence and testing, it helps to build customer confidence, trust and global market share ,without accreditation, buyers of commodities or products would depends on the seller's assurance about the quality or safety of a product or their own inspections. However, lastly would decide by the customers' quality assurance.

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

In this study a detailed descriptions of the essential considerations in designing the research project which encompass the research method, source of samples data and sampling techniques, data gathering instruments, procedure of data collection, methods of data analysis and ethical considerations.

3.1. The Research Design

This study used a mixed type of design. (Creswell, (2007) described that a strong mixed design study should start with a mixed type of research question, to shape the methods and the overall design of a study. Mixed type approach includes both qualitative and quantitative methods. The research was examined in qualitative and quantitative for the fact that the focus of the research had on understanding and interpretation of the data, as well it deals with the effects of variables that affects the ECAE and NMIE Implementations of ISO/IEC 17025.

3.2. The Research Methods

In this study a descriptive survey method was used for investigation which attempts to describe and interpret what exists at present in the form of conditions, practice process, trends, effects, attitudes, beliefs, etc(Crosswell & Piano Clark, 2011). More specifically, descriptive survey method was employed

3.3 Source of Data

In this study both the primary and secondary sources of data was used. Primary source of data was collected from the respondents of NMI & ECAI through questionnaire and interviews. Moreover, secondary data collection was through literature review, journals, and periodicals was referred as secondary sources of data

3.3.1. Questionnaire

Questionnaire was developed on the basis of basic questions of the study, review of literature, and ISO 17025:2017 standards toolkits. The questionnaires were closed-ended and open-ended; respondents have direct involvement in laboratory management system (LMS) application in the organization. The questionnaires help to collect data from large number of respondents in different position from senior to junior level. Further, the questionnaires can be detailed and help to cover many subjects or issues can be easily and quickly analyzed once the field data gathering work is completed. A rating is a measured judgment of some sort. While opened-ended questionnaires were used for respondents to explain their feeling and understanding freely as much as possible based on the question rises.

The respondents were asked to mark their perception about the benefits, management commitment, challenges and impact of accreditation relevance of ISO 17025 certification on a continuous five point Likert scale ranging from “strongly agree (=5)” to “strongly dis agree (=1)”. Likert scale shall mainly be used in structuring the expected responses in the questionnaire. This scale is easy to complete but does have a considerable disadvantage when bold statements are used to bias respondents’ answers. The researcher alleviated this by not using leading questions.

The structured questionnaire consists of four sections (Appendix 1)

1. Personal information - section A
2. Impact of implementation / Benefit ISO 17025 with respect to performance, employees performing test, suppliers, cost and customer satisfaction –Section B
3. Management commitment – Section C
4. Barrier /obstacles to implementation of ISO 17027- section D
5. Impact of laboratory accreditation –section E

3.3.2. Interview

In order to triangulate the data obtained through questionnaire, Most of the interview questions conducted are similar to the questions in the questionnaire. This helped me to cross-check the response given by the respondents on both methods of assessment. The interviewees were senior management and supervisor level similar to that of the survey respondents to collect same and clear data as they are responsible person in purposive

selection. For this, interview guides (a written list of open items) were prepared by the researcher and present face to face interaction. This method was selected because it provides clear and same information, which ensures the comparability of the data (Kumar, (1999). The respondents result of the interview found at (data analysis annex 5 Table.)

3.4 Samples and Sampling Techniques

During designing samples, Copper and Schindler, (2008) suggested that the following should be clearly described: the target population, parameters of interest, sampling frame, appropriate sampling method and the required sample size of the sample. The target population of this study included management member and experts (technicians) from NQI institutions (NMIE & ECAE,). (The sample has been taken from the target population of the study. The senior technical staff of the NMIE & ECAI were selected using purposive sampling techniques. (Croswell, and Clark, (2011), stated that purposive sampling involves identification and selection of individuals that are proficient and well-informed with a phenomenon of interest.

3.4.1. Reliability and Validity of Findings

Questionnaire	No. of Items	Coefficient Alpha
Benefit (section B)	11	<i>0.815</i>
Management commitment (sec. C)	9	<i>0.938</i>
Challenge/Barrier (Sec. D)	10	<i>0.741</i>
Impact of laboratory accreditation	13	<i>0.733</i>

Table 3.4. 1. Reliability Statistics

Cronbach's alpha method was used to test the internal consistency of the questions in the questionnaires.

The results obtained as illustrated in Table 3.4.1 are considered to be valid for interpretation use.

3.5. Procedures of Data Collection

After checking and conducting test for reliability and the pilot test the data gathering instruments has been revised .Then after, data was collected by the researcher. Interviewing and questionnaires are the two main data collection methods in survey research. Questionnaires were developed as per the sample and was distributed for 70 laboratory managements and supervisors for the first three section and 20 different customers respondents (from hotels, airline Catering and Coffee exporters) for the impact assessment , however a face to face interview conducted for ten experts and management group to both the NMI ,ECA and customer representative in Addis Ababa office.

3.6. Methods of Data Analysis

Johnson and Onweugbuzie (2004) state that the most common forms of mixed methods studies entail using different data components to complement or build on what might have been learned from any of those data types independently. The quantitative data first has been organized and put into tables to suit for analysis. Then the data was analyzed using descriptive statistical methods (Mean, Standard deviation, Mode and percentage) that can be done using either Microsoft excel and Minitab .and or statistical package for the social sciences (SPSS) version 20. Other than this, the quantitative data was from Likert scale transcribed and then coded and put into categories with group mean, standard deviation, mode and percentage and discussed. The qualitative data from interview collected and analyzed according to the literature and ISO 17025 standards .

3.7. Ethical Consideration

The respondent were informed in the introductory part of each questionnaire that all information collecting during the survey will treat in confidentiality and will not be used for any other purpose other than this research objective. During data collection a brief explanation was given to the respondents about the benefit obtained from this research activity.

CHAPTER FOUR
ANALYSIS OF FINDINGS & PRESENTATION OF RESULTS

4.1 Introduction

In this chapter, the researcher analyses the various questions posed to respondents and brings out the various shades of opinion from respondents regarding all aspects of the questionnaire.

The data provided by the respondents were statistically analyzed by the researcher using Minitab, excel and the results reported in the following sections of this chapter. The quantitative technique employed for this research was based on frequencies, percentages and Standard deviation.

4.2 Section A- Background Information.

The table below represents the demographic of respondents involved in this study. The demographic of respondents are categorized into two areas which are: Highest level of education and field of study. As mentioned in Chapter 3, the respondents comprise of two public organization who have laboratory accredited.

4. 2.1 Employee Profile

Table 4.2. 1. Educational back ground and expected service in the organization.

Organizati on	Educational back ground		Field of studies	Years of service		Percentage
				0-4	≥5	
ECA	Masters	1	Biology, Chemistry,	9	1	2%
	Degree	17	Electrical, Engineer, etc		8	34%
	Diploma	2			2	4%
NMI	Masters	1	Physics, Chemistry,	17	1	2%
	Degree	29	Engineering		12	58%

Source : Data collected from researchers questioner ;2019

The above table 4.2.1 data shows that out of 50 respondents, 30 employees representing 60%, are from NMI and other 20, which is 40% from ECA. Out of 50 respondents surveyed, 26 have less than 4 years of service as shown in Table 4.2.2 and other 24 have five years and above years of service.

Out of a total of 70 questionnaires distributed, 50 completed questionnaires were returned (average response rate found 72%)

Table 4.2. 2 Respondent rate as per the organization

S N	Respondent company	Location	Number of population involved in scientific measurement and Testing laboratory	Number of questionnaire distribution	Number of respondents	Respondents rats %
1	ECA	Addis Ababa	55	30	20	29%
2	NMIE	Addis Ababa	70	40	30	43%
					Total	72%

Source : Data collected from researchers questioner ;2019

This section gives a description of respondents' profile of both surveys carried out.

Out of 50 respondents ; Masters and above 2 employees (4%), Degree 46 employees (92%) and Diploma 2 employees (4%), It is the policy of the government to recruit technical officers who possess as a minimum a diploma qualification in scientific field.

Mann and Kehoe (1995) listed employees' skill levels, employees' length of employment (experience) and employees' educational levels as some of the factors that affect total quality management implementation. Highly educated and highly skilled employees are usually more receptive to change than their less educated and less skilled counterparts. The highly skilled personnel also feel less threatened by proposals of implementing changes and understand why there is a need for change. It was based on this background that the

respondents' skills and education levels were solicited. All of the interviewees had a QA/QC qualification. All of the respondents had two or more years' experience with ISO 17025 in varying roles. The knowledge, education and skills of the interview respondents was also critical in ensuring the validity of the study

Table 4.2. 3 Profile of laboratories

Respondent	Nature of Organization	Field of Testing	Years in Operation	Last Accredited on	Accreditation Body
Lab (ECA)	Public	Chemical & Environment, microbiological, electrical etc..	Feb.2011	2019	ENAO /Ethiopia
Lab2(NMIE)	Public	Textile , scale mass, pressure, Volume Temperature,& Garment	Feb.2011	2017	DAKKS /Germany

Source of data: from researcher interview and website publication of the organization; 2019

SECTION B – Descriptive statistics.

Table 4.3. 1 This section describes the findings of benefits of accreditation with respect to performance, employees performing test, suppliers, cost and customer satisfaction.

Benefits of accreditation	Mean	SD	mode	5	4	3	2	1
				St Agree	Agee	Neutra	Dis Agree	St.Dis Agree
B1. Improves Lab. service quality and Remains competitive	4.78	0.65	5	84%	14%	0%	0%	2%
B2. Increase in profitability / productivity, Enhances the organization's image	4.24	0.87	5	46%	38%	10%	6%	0%
B3. An effective marketing tool for your organization	4.48	0.81	4	60%	32%	2%	6%	0%
B4. Guarantees that the laboratory performs the work correctly and Feedback from customer for improvement	3.84	0.58	4	4%	82%	8%	6%	0%
B5 . Increase in personnel confidence performing tests	3.92	0.49	5	4%	88%	4%	4%	0%
B6. Proud to work in an accredited laboratory using internationally recognized test method	4.62	0.64	5	68%	28%	2%	2%	0%
B7. Gain more financial benefits	2.34	0.52	2	0%	0%	36%	62%	2%
B8. More dedication in performing your work and More responsibilities and Better job satisfaction	4.3	0.93	5	54%	30%	8%	8%	0%
B9. Accreditation provides a conducive environment	4.12	0.66	4	28%	54%	16%	0%	2%
B10. Sufficient opportunities to	4.3	1.07	5	60%	24%	4%	10%	2%

receive training to improve skills								
B11. Helps to measure customer satisfaction and Reduction in your service delivery time	4.02	1.08	4	38%	42%	8%	10%	2%

Survey Scale: 5=Strongly Agree 4=Agree 3=Neutral 4=Disagree 5=Strongly Dis agree

Source: Data collected by the researcher through questionnaire ,2019

Table 4.3.0 descriptive statistics generated from Survey and illustrates the following:

B1 : The benefit of accreditation increasing laboratory service and remains competitive respondent rate of mean found nearly to strongly agree and the standard deviation found less than one and this is closer to the mean that accreditation is an effective tool for marketing .According to the literature review and majority responded agreed it gives quality service and remain competitive.

B2: Here the respondent rate of mean value closer to agree and the standard deviation found less than one which is closer to the mean for that accreditation guarantees the laboratory performs work correctly and get Feedback from customer for improvement, increase in profitability / productivity, enhances the organization’s image.

B3 ; The respondents mean of rate closer to strongly agreed and the standard deviation found less than one which is closer to the mean and that shows that accreditation is a strong marketing tool for the laboratories.

B4 ; Here the respondent mean rate found nearly to agreed and the standard deviation also found less the one which is closer to the mean for accreditation guarantees that the laboratory performs the work correctly and Feedback from customer for improvement

B5: Here the respondent mean rate found nearly to agreed and the standard deviation also found less the one which is closer to the mean and shows that accreditation increase the laboratory personnel confidence working with international standards ;

B6: The respondents mean of rate closer to strongly agreed and the standard deviation found less than one which is closer to the mean that the respondent proud to work in an accredited laboratory using internationally recognized test method;

B7:Here the respondent mean rate found nearly to neutral and the standard deviation also

found less than one which is closer to the mean and this shows that accreditation do not gain more in financial benefits for laboratory personnel. It was expected that most respondents would agree to this statement. According to Siloaho and Puhakainen (2000), the first benefit of the laboratory quality system evaluated by the personnel was purely financial.

B8: The respondent rate mean nearly to strongly agreed and the standard deviation below one and this shows the deviation closer to the mean that shows accreditation helps dedication in performing work and more responsibilities and better job satisfaction.

B9: 28% strongly agree and 56% agreed that accreditation provides a conducive working environment, according to literature review accreditation helps to create a conducive environment ;

B10: The respondents rate of mean and standard deviation closer to the mean and which shows agreed that accreditation may create sufficient opportunities to receive training to improve skills ,

B11: The respondents rate of mean and standard deviation closer to the mean and which shows agreed that accreditation helps to measure customer satisfaction and reduction in employee service delivery time

On the Benefits of implementing ISO 17025 from the survey questionnaire, interview and literatures view the major benefits of accreditation are; (1) reduced customer complaints, (2) Improved process efficiency, (3) Improved quality of performance and services and (4) Increased productivity , profit and create competitive observed after the implementation of ISO 17025. In general the benefits of implementing ISO 17025 stated by interviewees, questionnaire respondents and what is generally found in literature was more or less the same. Of course, the importance of each of those benefits differed from one organization to another. The ECA testing and NMI calibration laboratory's main focus is on improving process quality and the potential of securing new clients.

Table 4.3. 2 Respondents data from closed Questionnaires

		ECA		NMI		Total		% total	
		yes	No	Yes	No	Yes	No	Yes	No
12	Do your customers require accredited tests results?	18	2	26	4	44	6	92%	8%
13	Do accreditation improve the employee satisfaction?	20	0	27	3	47	3	94%	6%

Source : 4.3.1 qualitative data collected from research questioner ;2019

In the above table 4.3.1 92% of respondents said customers require accredited test results reason it build their confident and increase the market share, however 8% of the respondent agreed as the customer not require or request accredited test results and no need to cost for it, according to the literature review the customers need independent testing facility results , independent evidence rather than suppliers word.

94 % of the respondent agree with the accreditation improves the employees satisfaction according to respondents the result is error free and reliable test and or calibration report to customers have been helped for the international recognition with the scope of standards, however 6 % of the respondent said being accredited did not have satisfaction in employee, according to the litterateurs review there is evidence of a strong relationship between laboratory accreditation and employee satisfaction (Verstraete et al.,(1998)

SECTION C. MANAGEMENT COMMITMENT

Table 4.3. 3 respondents rate in the management commencement questionnaire

Management commitment	Mean	SD	Mode	5	4	3	2	1
				St Agree	Agreed	Neutral	Dis agreed	St.Dis – Agreed
C1. Control of management system documents	4.36	0.63	4	44%	48%	8%	0%	0%
C2. Create , achieve and review the quality objective	4.36	0.68	5	54%	40%	4%	2%	0%
C3. Better control of records and retain according to filing period	4.16	0.82	4	38%	44%	14%	4%	0%
C4. Initiate actions to address risks and opportunities	4.14	1.02	5	44%	34%	10%	12%	0%
C5.Plane and follow up improvement	4.3	0.91	5	52%	34%	6%	8%	0%
C6. Initiate and follow up corrective actions for non - conformity	4.26	0.97	5	48%	42%	6%	4%	0%
C7.plan and conduct periodical internal audits	4.32	0.71	4	44%	46%	8%	2%	0%
C8.Conduct periodical management reviews and committed for corrective action	4.22	0.86	5	44%	40%	10%	6%	0%
C9.Better flow of communication from management	3.96	1.01	5	34%	42%	10%	14%	0%

Survey Scale: 5=Strongly Agree 4=Agree 3=Neutral 2=Disagree 1=Strongly Dis agree

Source :Data collected by the researcher through questionnaire ;2019

In the table 4.3.2: The management commitment C1, Here the respondent mean rate found nearly to strongly agree (mean value above 4) and the standard deviation found also less than one which is closer to the mean value for that it control of management system documents. According to ISO 17025 standard shows that one of the management responsibility is document system control therefore, accumulative of 92% respond agreed according to the standards ;

C2, Here the respondent mean rate found nearly to strongly agree (mean value above 4) and the standard deviation found also less than one which is closer to the mean value for that the management commitment helps to Create, achieve and review the quality objective,

C3, Here the respondent mean rate found nearly to agree and the standard deviation found also less than one which is closer to the mean value for that the management commitments helps for better control of records and retain according to filing period for accreditation.

C4, Here the respondent mean rate found nearly to agree and the standard deviation found one which is closer to the mean value for that the management commitment initiate actions to address risks and opportunities, however 12 % of the respondent dis agreed, according to ISO 17025:2017 risk and opportunity consider in laboratory accreditation in management with the management responsibility ;

C5 , Here the respondent mean rate found nearly to strongly agree (above 4) and the standard deviation found also less than one which is closer to the mean value for that the management commitment helps to plane and follow up improvement.

C6, Here the respondent mean rate found agreed (above 4) and the standard deviation found also less than one which is closer to the mean value for that the management commitment initiate and follow up corrective actions for non-conformity , however 6% of the respondent dis agreed, as per ISO 17025 standard the clause for management activities to initiate and follow up corrective action for non-conformity;

C7, The respondent mean rate found nearly to strongly agree (above 4) and the standard deviation found also less than one which is closer to the mean value for that the management commitment plan and conduct periodical internal audits.

C8, The respondent mean rate found nearly to strongly agree (above 4) and the standard deviation found also less than one which is closer to the mean value for that the management commitment helps to conduct periodical management reviews and committed for corrective action, however ,6% of the respondents disagreed , according to ISO 17025 periodical internal audit and management review meeting conducted to assess the effectiveness of the system;

C9 The respondent mean rate found nearly to agreed and the standard deviation found also less than one which is closer to the mean value for that the management commitment helps for better flow of communication from management, however ,14 % of the respondent disagreed, according to literature review ISO/IEC17025 clearly states that top management must ensure that appropriate communication processes should be established within the laboratory.

In general, From the above table 4.3.2 all the respondent points mean score, and mode value found above 4 strongly agree and agreed by the listed points concerning management commitment and activities and the Standard deviation showed less than one .

Identification and investigation of the factors that affect the establishment of laboratories' accreditation as gained from the literature review summary states the following;

Lack of management commitment , Training need and consultant in availability , Getting accredited laboratories locally for inter laboratory comparison , difficult to get Proficiency testing provider and its costs, Conducting supplier assessment according to the standards procedure, in availability of calibrated equipment supplier, laboratory media /chemical supplier as per the scope of standard method and high cost locally ,getting Certified reference material, unavailability of equipment calibration body as per the specification , preparation of quality manual, procedures, policies, forms with risk based decision making, lack of commitments from the employees, or lack of management involvement in the system, timing of obtaining accreditation fits the business model of the establishment, expensive to expand the scope to serve the needs to the manufacturer and exporter and specific skill requirement

SECTION D- Barriers of laboratory accreditation

Table 4.3. 4 Organization respondents rate for Barriers /obstacles of accreditation

Barriers	Mean	SD	Mode	5	4	3	2	1
				St.Ag reed	Agre ed	Neutr al	Dis Agree	Str. Dis
D1.Choice of accreditation body	4.34	0.48	4	34%	66%	0%	0%	0%
D2.Unavailability of consultancy services	4.22	0.71	4	36%	52%	10%	2%	0%
D3. Lack of qualified staff	4.12	0.75	4	32%	50%	16%	2%	0%
D4. Unavailability of training facilities/needs	4.16	0.79	4	36%	48%	12%	4%	0%
D5. Unavailability of suppliers of calibrated instruments , equipment ,consumable materials	4.18	0.87	5	42%	40%	12%	6%	0%
D6. Lack of accredited metrology laboratories for calibration of equipment	4.46	0.54	4	48%	50%	2%	0%	0%
D7. Unavailability of proficiency testing providers/ Ease of finding another laboratory for inter-laboratory comparison	4.26	0.88	5	48%	36%	10%	6%	0%
D8 .Cost associated with consultancy services , with training	3.82	0.87	3	26%	34%	36%	4%	0%
D9 . Cost associated with calibrated equipment, Laboratory consumable materials problem	3.88	0.92	4	28%	40%	24%	8%	0%
D10. Increase in paperwork and workload	3.4	1.02	4	22%	24%	22%	28%	4%

Survey Scale: 5=Strongly Agree 4=Agree 3=Neutral 4=Disagree 5=Strongly Dis agree

Source : Respondents data from questionnaire; 2019

The researcher observed from Table 4.3.4 all the points found above the mean score observed above 3.0 (neutral score) , all lists in the above table considered as obstacles of laboratories accreditation and the literature review re- enforces that those are the factors that affects implementation of ISO 17025

D2: Here the respondent mean rate found nearly to agree (above 4) and the standard deviation found also less than one which is closer to the mean value that unavailability of consultancy services have been obstacle for laboratory accreditation,

D3: The respondent mean rate found nearly to agree and the standard deviation found also less than one which is closer to the mean value for that lack of qualified staff have been obstacle to accreditation.

D4: The respondent mean rate found nearly to agree and the standard deviation found also less than one which is closer to the mean value for that unavailability of training facilities/needs have been obstacle to accreditation of laboratory, however 4% dis agreed ;according to the ISO 17025 standard laboratory accreditation need high training need and development as per the change in scope and new method development

D5: The respondent mean rate found nearly to strongly agree (mean value above 4) and the standard deviation found also less than one which is closer to the mean value for that unavailability of suppliers of calibrated instruments, equipment ,consumable materials have been the obstacle of accreditation of laboratory, however 6% respondent dis agreed; but this also addressed by the interview as the main obstacle to implement laboratory accreditation in ECA and NMI according to the respondent.

D6 : The respondent mean rate found nearly to strongly agree (mean value above 4) and the standard deviation found also less than one which is closer to the mean value for that lack of accredited metrology laboratories for calibration of equipment have been the obstacle of laboratory accreditation ,according to the survey and interview in availability of accreditation body locally challenges both ECA and NMI and cost to get from other countries .

D7: 48% strongly agreed and 36% agreed The respondent mean rate found nearly to strongly agree (mean value above 4) and the standard deviation found also less than one which is closer to the mean value for that unavailability of proficiency testing providers/ Ease of finding another laboratory for inter- laboratory comparison is the obstacle of laboratory accreditation, however 6% percent respondent found dis agreed but this are the main factor of affecting implementation of laboratory accreditation both in interview respondents replies difficult to get locally and have high cost to participate once in a year for all scope from outside of the country .

D8: The respondent mean rate found nearly to agree and the standard deviation found also less than one which is closer to the mean value for that cost associated with consultancy services , with training are obstacle for laboratory accreditation,

D9: The respondent mean rate found nearly to agree and the standard deviation found also less than one which is closer to the mean value for that cost associated with calibrated equipment is considered as appraisal cost, may consider as barrier to accreditation, however 8% respondent disagreed as the barrier, As per the ISO 17025 costs associated to calibration in the literature review consider as appraisal cost but it may has impact on foreign currency and area of calibration out of national , Ethiopia.

D10 : The mean rate found nearly to agree and the standard deviation found also less than one which is closer to the mean value for that accreditation leads to an increase in workload and paperwork. As per ISO/IEC 17025, laboratories should have a proper way of maintaining records to show evidence of traceability of work during internal audits, surveillances and assessments. Records may be on paper and electronic media. All laboratories surveyed kept paper records, hence an increase in paperwork and workload.

Only 32% of responses, either strongly disagreed or disagreed accreditation increase in paperwork and workload. This can be explained by the fact that they already have proper records keeping and are working in accordance to in-house developed procedures prior to accreditation. The literature review showed the record helps for trace ability check and preventive and corrective action follow up and in addition to the mean, mode value analysis the overall standards devotion showed that all points closer to the mean and it strengthen that

as there no deviation rather nearer to central point.

The researcher summarizes the analysis the questionnaire and interview the main reasons for implementing ISO 17025 and concludes by summarizing the benefits of accreditation such as : (1) Improving the quality of the process and services (2) To reduce customer complains (3) To get access to more work contracts and so on . Respondents acknowledged the fact that there is pressure to get ISO 17025 accreditation because it gives you access to more contracts as some holding organizations prefer using accredited laboratories but improving the quality of the process and services was the main reason stated by respondents. Improved services would lead to less customer complains.

Challenges faced when implementing ISO 17025: both survey and interview respondents stated the following as the main challenges faced during ISO 17025implementation summarizes :(1) Burdensome documentation (2) Time constraints (3) Financial constraints (4) Lack of support/staff participation (5)PT participation , getting accredited laboratories for both Testing and calibration laboratories. there was a minor disparity between what the questionnaire respondents regarded as the major disadvantage and what the interviewees stated as the researcher finding from survey and interview response.

SECTION E: Laboratory Accreditation Impact Analysis

Table 4.3. 5 impact of testing /Calibration laboratories ISO/IEC 17925 accreditation

Impacts laboratory accreditation	Mean	Mode	SD	Str. Agree	Agree	Neutra	Dis agree	Dis agree
				5	4	3	2	1
E1. Maintain trading confidence	4.95	5	0.22	95%	5%	0%	0%	0%
E2. Improves the organization's image	4.25	4	0.64	35%	55%	10%	0%	0%
E3. An effective marketing tool to export product or to submit tender	4.75	5	0.44	75%	25%	0%	0%	0%
E4. Laboratory minimizes the risk of producing a faulty product.	4.3	4	0.47	30%	70%	0%	0%	0%
E5. Helps Products or services are safe and meet the specification and standards	4.25	4	0.44	25%	75%	0%	0%	0%
E6. Increase competitive advantage for trade	4.7	5	0.47	70%	30%	0%	0%	0%
E7. Provides the chance to prevent retesting problems	4.9	5	0.31	90%	10%	0%	0%	0%
E8. Facilitates trade among countries	4.45	4	0.51	45%	55%	0%	0%	0%
E9. Support benchmark for maintaining that competence	4.1	4	0.55	20%	70%	10%	0%	0%
E10. Provides formal recognition of competence to laboratories	4.75	5	0.44	75%	25%	0%	0%	0%
E11. Help for government regulations to reduce uncertainties	4.55	5	0.51	55%	45%	0%	0%	0%
E12. Build confidence of the firm and customer	4.75	5	0.44	75%	25%	0%	0%	0%
E13. Provides formal recognition of competence to laboratories.	4.45	4	0.51	45%	55%	0%	0%	0%

Source : Respondents data from questionnaire; 2019

From table 4.3.4 ; Most of the points found above three which have highly agreed the respondents that these are the impact of testing /calibration laboratories of ISO/IEC accreditation. The most leading impact of laboratory accreditation which are strongly agreed by the respondent for laboratory accreditation; Maintain trading confidence (95%) and provides the chance to prevent retesting problems (90%) respectively , however , most of the statement respondent rate found above the neutral scale the standard deviation closer to the

mean as observed in the table all most all not deviate each other and these are less than one , therefore the researcher understands that all are positive impacts of laboratory accreditation, moreover, survey data and interview response most likely the same response, which are the respondent found same conceptual understanding.

In conclusion the survey questioner (table 4.3.4) and interview (Appendix6;Table:4.3.6 interview response data) response the researcher triangulates survey questionnaire and interview about the impact of laboratory accreditation found ; Maintain trading confidence, provides the chance to prevent retesting problems , increase competitive advantage for trade , an effective marketing tool to export product and build confidence of the firm and customer

CHAPTER 5

SUMMARY OF MAJOR FINDINGS, CONCLUSION AND RECOMMENDATION

Introduction

This chapter summarizes the conclusion of the survey findings from the two laboratories investigated and proposes recommendations. It also discusses the extent to which this study has achieved its objectives and areas of further research.

5.1 Summary of major findings

This part presents the summarized result and finding based on the objectives established at the beginning of the study.

Findings showed that although accreditation was a lengthy process, bureaucratic, as well as involving substantial investment, all respondents valued accreditation since it helped them to improve their laboratory operations and fulfil their customers' expectations. Major obstacles encountered, during implementation and maintenance of accreditation, by the laboratories were: lack of suppliers of calibrated equipment, non-existence of accredited metrology laboratories for calibration of equipment, and unavailability of proficiency testing providers. Moreover, despite more responsibilities, employees claimed that accreditation did not benefit them financially in different benefit package as internationally recognized activities .

The first research objective of the study was to identify the extent of benefits obtained by the Testing/Calibration laboratories in implementing ISO/IEC 17025 in ECAE and NMIE Majority of the result found that the mean scores of all confirmed that accreditation to ISO/IEC 17025 has benefit on laboratories. The performance of laboratories has improved through better control of operations and staff working diligently and efficiently, leading to enhanced customer satisfaction.

Looking to perceived benefits derived from ISO 17025 implementation, the researcher found out that all the benefits were scored average percentage of most the items listed (80%) agreed and interview response summary that of implementation ISO 17025 triangulate and was advantageous on the highlighted areas of increase foreign market share, documentation, high

quality awareness in employees, increase preventive action, increase laboratory traceability, increase customers satisfaction and confidence and decrease rework test.

The second objective was to assess the extent of commitment ISO/IEC 17025 of the management of the Testing/Calibration laboratories in implementing in ECAE and NMIE. Result revealed that the overall summary of the respondent rate strongly agree and agree around 80% and found high extent of commitment, however, the ECA testing laboratory did not conducted renew the accreditation on time and it was suspended for almost two year, for this reason pointed out from the researchers observation and questioned why it was happen and verbally response that there were very few industries that they need the accreditation test certification due to lack of customer awareness and the cost for laboratory accreditation was high ,however the cannot cover the expense of accreditation and other reason it took time from the process plan. However, laboratories are encouraged to implement ISO/IEC 17025 to improve customer satisfaction and to support the country's economic initiatives to WTO and nation policy developer.

The third objective of the study was to investigate potential challenges /barriers during implementation of ISO/IEC 17025 in testing laboratories. Findings showed that problems faced by laboratories were specific to Ethiopian Conformity Assessment and National Metrology Institute as a national problem, such as unavailability of proficiency testing scheme in their field of testing, lack of accredited calibration services and lack of suppliers of calibrated equipment, lack of CRM and consumable items supplier. However, it is worth noting that staff was willing to work according to ISO/IEC 17025, otherwise this would have been the major obstacle on implementing the laboratory management system (LMS). Accreditation involves a cost of quality borne by the laboratories.

The final objective for Impact of laboratory accreditation in ECA and NMI in Ethiopian, researcher survey and interview response triangulates and conclude somehow similar , however, from FDG point this(impact) was not assess and studied by the organization and recorded and not well known by the experts but they keep performing the procedures and policies of ISO 17025 standards system. Moreover, some exporting companies and international service organizations such as hotels, airl line catering , coffee exporters, leather

manufacturing and 'Selet' (Sesame) processing and export benefits to broken the trade barrier and join the world market share.

5.2 Conclusion

In General the researcher respondents data summaries both from the survey questionnaire and from face to face interview and triangulate as follow;

The first research objective of the study was to identify and investigate the factors that affect the establishment of laboratories' accreditation as gained from the literature review.

The second research objective of the study was to identify the extent of benefits obtained by the Testing/Calibration laboratories in implementing ISO/IEC 17025 in ECAE and NMIE most of survey question found that the mean scores of all in section 4.3.0 confirms that accreditation to ISO/IEC 17025 has categorized as benefits on laboratories. Only statement B7 mean score found less than three with the mode value of the respondent, which found 24% dis agree and respondent claimed that they didn't gain more financial benefits. It was expected that most respondents would agree to this statement .The performance of laboratories has improved through better control of operations and staff working diligently and efficiently, leading to enhanced customer satisfaction. However the face to face interview also shows most likely same reply.

The third objective was to assess the extent of commitment ISO/IEC 17025 of the management of the Testing/Calibration laboratories in implementing in ECAE and NMIE .Results revealed that accreditation organized better management commitment for continue laboratory change. Thus, laboratories are encouraged to implement ISO/IEC 17025 to improve customer satisfaction and to support the Countries economic initiatives to WTO and nation policy developer and from the interview response also emphasizes the importance of management commitment for the continuous change.

The fourth objective of the study was to investigate potential barriers during implementation of ISO/IEC 17025 in testing laboratories. Findings showed that problems faced by laboratories were specific to Ethiopian Conformity Assessment and National Metrology Institute of Ethiopia, such as unavailability of proficiency testing scheme in their field of

testing, lack of accredited calibration services and lack of suppliers of calibrated equipment, lack of CRM and consumable items supplier. However, it is worth noting that staff was willing to work according to ISO/IEC 17025, otherwise this would have been the major obstacle on implementing the management system. Accreditation involves a cost of quality borne by the laboratories. However the face to face interview also shows most likely same reply

The final objective of the study was to assess the impact of accreditation to ISO/IEC 17025 in testing /calibration laboratories in case of ECAE, ENMI and customer the researcher found and conclude a positive impact for both the laboratory and customers as per the survey and interview finding .Finding showed that it has impact on customer/purchasing confidence, global market share, error free testing /calibration result, market share , global acceptance of the laboratory report and customer , risk minimization .

5.3 Recommendations

The majority of respondents complained that no other local providers of calibration services. It will be in the interest of the laboratory community for the calibration laboratories to be accredited at the earliest and need. Subsequently, this will be beneficial to both accredited laboratories and those seeking accreditation.

Respondents also pointed out that not all equipment could be calibrated locally. The metrology laboratory could invest in acquiring new technology and capability for calibration of a wide range of instruments based on ISO17025 laboratory requirements and should support other to be accredited. This will lead in reduction of cost calibration of equipment for laboratories.

Another major difficulty faced by respondents was the non-existence of proficiency testing and CRM providers for traceability and validation. It would be advisable that NQI of Ethiopia in particular ECA and NMI to acts as a coordinating unit grouping the needs at the local level and acting as a focal point for directing and assisting laboratories in their search of accredited proficiency testing facilities at a lower cost plus encouraging other laboratories to invest and developing PT and CRM providing.

A strong majority of employee's survey showed their disappointment with regard to financial gain. In literature review shows Implementing ISO/IEC 17025 is not an easy task, and laboratory personnel are actively involved. Recognition to employees 'contribution towards achieving accreditation and appropriate reward, for instance revision in the salary structure, would motivate further the staff.

In the public sector, head of departments could appeal to the Ministry of Civil Service and /or other concern for additional salary increment or benefit package to technical staff on successful and continual implementation of ISO/IEC 17025 in laboratories. In private companies, different remuneration package could be proposed on quality-based performance.

The current policy of ENAO/ILAC requests accredited laboratories to perform proficiency testing once every year. Increment this time period at least to two years will be in the advantage of local accredited laboratories to benchmark their technical competence economically and socially due to currency and skilled manpower problem, Supporting the public and or private organization to provide PT nationally, organizing CRM providers locally and calibration traceability and validation in national and international capacity to maintain the accuracy of instrument measurements.

There is a lack of awareness on the benefits of using an accredited laboratory. To promote laboratory accreditation on a national level, Ethiopia, in collaboration with NQI and the Ministry of science and technology MOST in particular developing ECA and NMI with a competitive capacity, could create awareness campaigns to stress on the importance and the benefits of accreditation both to the public and the industry.

5.4 Future Work

Further research would be necessary to assess the views of laboratories 'customers on the value of accreditation. An analysis of customer satisfaction(both internal and external) could demonstrate the success of accredited laboratories, investigation of employee satisfaction working in accredited laboratories and financial benefit to employee being accreditation.

This study examined the effects of institutional accreditation as perceived by staff members in two government institutions. The primary aim of accreditation is to stimulate changes and improvements in the institutions; however, to date, little is known about the actual impact of accreditation in the users' context. Therefore, with limited evidence of the impact of accreditation, the researcher faces difficulties in its efforts to enhance the accreditation system. The study also focused on the impact of accreditation to ISO/IEC 17025 on testing/calibration laboratories in Addis Ababa larger sample population could be surveyed in the future for an in-depth analysis of the associated impact and cost of accreditation.

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Appendix 1- Clauses of ISO/IEC 17025 :2017

Main Requirements;

Clause 4 - General requirements

Clause 5 - Structural requirements

Clause 6 - Resource requirements

Clause 4 - Process requirements

Clause 8 - Management system requirements

Appendix 2- Clauses of ISO/IEC 17025 Process requirements

Review of requests, tenders and contracts

Selection, verification and validation of methods

Sampling

Handling of test or calibration items

Technical records

Evaluation of measurement uncertainty

Complaints

Nonconforming work

Control of data – Information management

Management System requirements

Appendix 3 Survey(1,2,3)

Dear Sir/Madam, As part of my MSc programme with the University of St Mary, I am currently conducting a research project on the Impact of Implementation of ISO/IEC 17025 in testing /Calibration laboratories in the case of Ethiopian Conformity Assessment /National Metrology Institute of Ethiopia”

I would be grateful if you kindly fill in the questionnaire below. Please rest assured that all information gathered during the survey will be treated in confidence.

Thanking you for your valuable participation.

Wondale Andargie (Mr.)

SECTION A- ACCREDITATION

A1. In which year is your laboratory accredited to ISO/IEC 17025 ? _____

accredited by (organization) _____

A2. In which field of testing are your laboratory accredited? (More than one answer allowed)

A3. Personal characteristics:

(a) Highest qualification held:

- Diploma
- Degree
- Master’s Degree & above

(b) Area of qualification _____

(c) How long have you been working for your organization? _____

Appendix 3- Survey 1

SECTION B- IMPACT OF ACCREDITATION TO ISO/IEC 17025 ON YOUR LABORATORY

To what extent do you agree that being an accredited laboratory brings the following changes to your organization? (Tick as appropriate)

Table A-3. 1 Appendix 3 survey 1

Benefits of accreditation	Strongly Agree (5)	Agree (4)	(3)	Dis agree (2)	Dis agree (1)
1. Improves laboratory service quality and Remains competitive					
2. Increase in profitability / productivity, Enhances the organization's image					
3. An effective marketing tool for your organization					
4. Guarantees that the laboratory performs the work correctly and Feedback from customer for improvement					
5. Increase in personnel confidence performing tests					
6. Proud to work in an accredited laboratory using internationally recognized test method					
7. Helps to gain financial benefits					
8. Create more responsibilities and Better job satisfaction					
9. Accreditation provides a conducive environment					
10.. Sufficient opportunities to receive training to improve skills					
11. Helps to measure customer satisfaction and					

Reduction in your service delivery time					
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12. Do your customers require accredited tests results?

Yes

No

If Yes, Why _____

If No, why? _____

13. Do accreditation improve the employee satisfaction?

Yes

No

How _____

Appendix 3 - Survey 2

SECTION C. MANAGEMENT COMMITMENT

Accreditation has brought changes to your way of work. To what extent of management commitment do you agree to the following? (Tick as appropriate)

Table A-3. 2 Appendix 3 survey 2

Management commitment	Strongly Agree (5)	Agree (4)	Neutral (3)	Dis agree (2)	Strongly Dis agree (1)
1. Control of management system documents					
2. Create , achieve and review the quality objective					
3. Better control of records and retain according to filing period					
4. Initiate actions to address risks and opportunities					
5.Plane and follow up improvement					
6. Initiate and follow up corrective actions for non - conformity					
7.plan and conduct periodical internal audits					
8 .Conduct periodical management reviews and committed for corrective action					
9.Better flow of communication from management					

9. Any comments /suggestions/improvement regarding the management system in your laboratory?

Appendix 3 - Survey 3

SECTION D- POTENTIAL OBSTACLE /BARRIERS DURING IMPLEMENTATION OF ISO/IEC 17025

To what extent do you agree to the following difficulties faced during the implementation of ISO/IEC 17025 in your laboratory? (Tick as appropriate)

Table A-3. 3 Appendix 3 survey 3

Barriers	Strongly Agree (5)	Agree (4)	Neutral (3)	Dis agree (2)	Strongly Dis agree (1)
1. Choice of accreditation body					
2. Unavailability of consultancy services					
3 .Lack of qualified staff					
4 .Unavailability of training facilities/needs					
5 .Unavailability of suppliers of calibrated instruments , equipment ,consumable materials					
6 .Lack of accredited metrology laboratories for calibration of equipment					
7 .Unavailability of proficiency testing providers/ Ease of finding another laboratory for inter- laboratory comparison					
8 .Cost associated with consultancy services , with training					
9 .Cost associated with calibrated equipment, Laboratory consumable materials problem					
10. Increase in paperwork and workload					

10. Any other problem encountered during implementation of ISO/IEC 17025 which is not mentioned above?

Appendix 3 - Survey Section 4

SECTION E- impact of accreditation to ISO/IEC 17025 on testing/calibration laboratory

To what extent do you agree that it is an impact of the laboratory accreditation?

(Tick as appropriate)

Table A-3. 4 Appendix 3 survey 4

Survey Scale: 5=Strongly Agree 4=Agree 3=Neutral 2=Disagree 1= Strongly dis agree

Impacts laboratory accreditation	Strongly	Agree	Neutral	Disagree	Strongly disagree
	5	4	3	2	1
1. Maintain trading confidence					
2. Improves the organization's image					
3. An effective marketing tool to export product or to submit tender					
4. Laboratory minimizes the risk of producing a faulty product.					
5. Helps Products or services are safe and meet the specification and standards					
6. Increase competitive advantage for trade					
7. Provides the chance to prevent retesting problems					
8. Facilitates trade among countries					
9. Support benchmark for maintaining that competence					
10. Provides formal recognition of competence to laboratories					
11. Help for government regulations to reduce uncertainties					
12. Build confidence of the firm and customer					

13. Provides formal recognition of competence to laboratories.					
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End of Questionnaire

Thanking you for your precious time in completing the questionnaire

Appendix 4- Reliability and Validity of Findings

Table A-3. 5 Table Reliability and Validity of Findings

Questionnaire	No. of Items	Coefficient <u>Alpha</u>
Benefit (section B)	11	<i>0.815</i>
Management commitment (sec.	9	<i>0.938</i>
Challenge/Barrier (Sec. D)	10	<i>0.741</i>
Impact of laboratory accreditation	13	<i>0.733</i>

Table 3.2.2: Reliability Statistics

Cronbach's alpha method was used to test the internal consistency of the questions in the questionnaires.

The results obtained as illustrated in Table 3.2.2 are considered to be valid for interpretation use.

Appendix 6: Interview questions and respondents.

Table A-3. 6 Interview questions and respondents

Interview questions	Summary of responses
<p>Q1. What is the benefits/ reason behind your laboratory being accredited to ISO/IEC17025?</p>	<p>The reason to be accreditation have many benefits Such as ; To be Competent and Credible to specific tests and Results are: Accurate, Reproducible and Traceable Improving the quality of the products and services , reduce customer complains , get access to more work contracts ,It helps to employee knowledge and competitive advantage ,Revenue generation ,Confidence building for Technical staff , Improvement in performance and test result , Cost minimization and helps to waste reduction</p>
<p>Q2. How do you evaluate the impact of testing/calibration before and after accreditation in terms of ;</p> <ul style="list-style-type: none"> i. Product/ test/ calibration result realization ii. Economic and trade value iii. Coffee testing for trade iv. For Leather product testing 	<ul style="list-style-type: none"> i. Before laboratory accreditation the test/calibration result was no traceability check with CRM and there was no trust in consumers. After the laboratory accreditation the result can be traceable and trust worth in customer’s side, It has International acceptance due to following international standards of checking. It have been assessed by third party assessor for approval of the accreditation system . ii. There was no detail analysis about the economic and trade value for the impact of accreditation before and after accreditation as the researcher observation from both in NMI and ECA staffs FGD with technical staffs and no indication of impact analysis from NQI 6th newsletter publication report. iii. Built Trade confident and create market share to European Market and have been developed customer confident for coffee user as it is an organic product in test report. iv. It create leather market share in the Africa

<p>Q3. What are the extents of the management commitment for improvement in laboratory accreditation</p>	<p>Committed for staff training , to fulfil laboratory infrastructure, to plan and follow up improvement, corrective action , create and review the procedure and policy and control the documentation .</p>
<p>Q4. To what extent does your company have a policy to ensure customer satisfaction?</p>	<p>The laboratory has established quality policy and quality objectives cover the contents of:</p> <ul style="list-style-type: none"> Commitment to good professional practice, Statement of the laboratory’s standard of service , Purpose of the management system related to quality , Personnel familiarization with the system , Commitment to ISO/IEC 17025:2005 and continual improvement , Statement to comply with stated methods and customer requirements ,
<p>Q5. What are major challenges you have to laboratory accreditation</p>	<p>Access and frequency of PT participation every year</p> <p>Getting CRM and inter-laboratory participation with accredited laboratory locally</p> <p>Load of paper work and documentation</p> <p>Lack of Media/ Chemical according to standards in local market and supplier selection problem.</p>
<p>Q6. What is the procedure if there is any defective result?</p>	<p>The laboratory manager after reviewing the non-conformance decides halting of work if the outcome potentially affects the quality of the test results, authorizes resumption, if found to cause no negative impact and after correction.</p> <p>Non- conforming works that has serious impact on the quality of test result corrected immediately.</p>

Source: Data collected from interview of selected employee experts and managers