



Company Name:

QUALITY AND STANDARDS AUTHORITY OF ETHIOPIA

Document No.:

CRD/QD/007

Document Title:

Quality Manual

Issue No.:

1

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Quality Manual



ISSUE HISTORY			
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1. PREFACE

The Quality and Standards Authority of Ethiopia (QSAE) was established in 1970 as an autonomous government body by the Standards Order 64/1970 with the responsibility solely entrusted to promote and expand standardization and quality control activities in the national economy. It was later mandated by Proclamation No. 328/1986 to promote standardization, quality control, quality assurance and certification and metrology as a sole government organ at the national level.

In February 1998, however, the Authority was restructured as the Quality and Standards Authority of Ethiopia mandated by Proclamation 102/1998 to primarily focus on quality promotion in addition to metrological and standardization activities to enhance the country's economic development and technological progress with the following specific objectives:


- to promote and assist the establishment of appropriate quality management practices as an integral and yet distinct management function in the social and economic sectors;
- to assist in the improvement of the quality of products and processes through the promotion and application of Ethiopian Standards;
- to promote and co-ordinate standardization at all levels in the country;
- to establish a sound national metrological system as a basic structure for economic development;
- to strengthen, promote and enhance the reliability of testing laboratories nation-wide.

QSAE, as the national standards body of Ethiopia, is a member of the International organization for Standardization (ISO) and International Organization for Legal Metrology (OIML). Furthermore, it maintains close working relation with the International Electrotechnical Commission (IEC) and Codex Alimentarius Commission (CODEX). It is also a founding member of the African Regional Organization for Standardization (ARSO).

The globalization of the world market and free market economic system gave rise to strong competition among suppliers around the world. The growth and dynamic nature of the customers needs has placed pressure on suppliers, private and government bodies to keep on continuous improvements of their processes, products and services by implementing an appropriate quality management system to the level of confidence required by the customers. In view of this, QSAE has established and implemented a quality management system consistent with ISO 9001:1994, as described in this Quality Manual.

2. RESPONSIBILITY FOR DOCUMENTATION OF THE QUALITY MANUAL

Document Control Center has the responsibility to maintain and control this Quality Manual.

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3. QUALITY POLICY

The Quality and Standards Authority of Ethiopia is committed to continuously and consistently satisfy the needs and expectations of its customers in a process of continuous improvement.

QSAE strives to support the national effort for social and economic development by providing efficient, reliable and impartial services on:

- Formulating Ethiopian standards;
- Product certification;
- Laboratory testing;
- Calibration and verification of measuring equipment; and
- Standards information and training.

COMPETENCE, INTEGRITY and TRANSPARENCY are core values that shall be adhered to when delivering services to our customers.

1999 Nov. 03

Mesai Girma
General Manager

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4. QUALITY OBJECTIVES

The Quality objectives defined in this Manual are consistent with the quality policy. To achieve the objectives a detailed Three-year Quality Plan is prepared.

- 4.1 To be certified to ISO 9001 in all functions of QSAE by December 2000.
- 4.2 To implement ISO/IEC Guide 25 for accreditation in selected fields (See Annex A of this Manual) in Testing and Metrology Laboratories by December 2002.
- 4.3 To be accredited to ISO/IEC Guide 65 in selected products (See Annex A of this Manual) certification by June 2000.
- 4.4 To sensitize one million people on quality, standards, metrology and testing by December 2000.
- 4.5 To train one thousand professionals selected from manufacturing and service providing organizations on quality management system by December 2000.

5. PURPOSE

The purpose of this Quality Manual is to define the quality policy and quality objectives, map of processes, operating procedures and organizational functions within the Quality and Standards Authority of Ethiopia in the framework of ISO 9001 requirements in order to render quality service to its internal and external customers.


6. SCOPE

This Quality Manual shall apply to all functions of the Quality and Standards Authority of Ethiopia.

7. REFERENCES

Proclamation No. 102/1998: Quality and Standards Authority of Ethiopia Establishment Proclamation.

ISO 9001:1994, Quality Systems – Models for quality assurance in design, development, production, installation and servicing.

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8. DEFINITIONS AND ABBREVIATIONS

8.1 Definitions

For the purpose of this manual the definitions given in ISO 8402 apply.

8.2 Abbreviations

CRD:	Criteria Document
DCC:	Document Control Center
DTIS:	Documentation and Technical Information Service
ES:	Ethiopian Standard
FDES:	Final Draft Ethiopian Standard
LD:	Testing and Research Laboratory Department
LS:	Legal Service
MD:	Metrology Department
OP:	Operating Procedure
QD:	Quality Assurance Department
QSAE:	Quality and Standards Authority of Ethiopia
SD:	Standards Specification Department
TD:	Quality Promotion and Training Service
WI:	Work Instruction

Note: When the draft organizational structure of QSAE is approved, the abbreviations and the corresponding descriptions indicated above would be changed accordingly.

9. STRUCTURE OF QUALITY SYSTEM DOCUMENTATION

The structure of the quality system documentation describes the organization (arrangement) of documents within the quality system, and it is in three levels as shown in Figure 1 below.

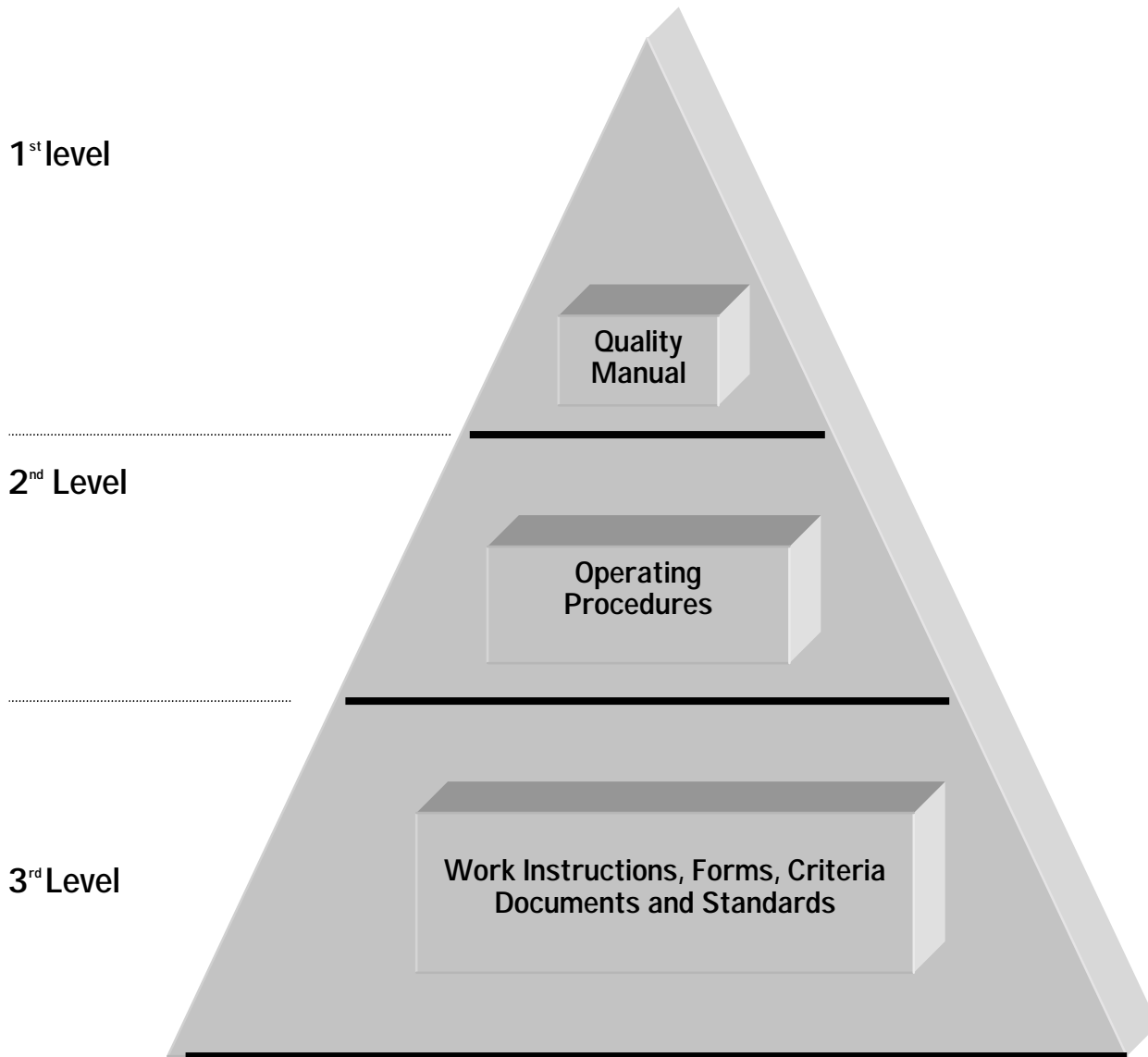



Figure 1- Structure of Quality System Documentation

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10. ORGANIZATIONAL STRUCTURE

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11. DESCRIPTION OF MAIN FUNCTIONS

11.1 Standards Formulation

QSAE formulates, approves, declares and issues Ethiopian Standards for a general and specific application as well as recognizes, any standard established by a national, regional or international standardizing body as an Ethiopian Standard. In addition, it formulates implements and follows up quality promotion and standardization policies and strategies in line with the national development programmes.

11.2 Calibration and Verification

Metrology as the main component of QSAE aims at establishing a sound national metrological system through the maintenance of national physical standards (Etalons) and certified reference materials, and the introduction of the International System of Units (SI) as the sole system of measurement of physical quantities as well as through verification and calibration of measuring instruments. It is the custodian of the national Etalons, and is responsible for their "dissemination" with the aim of ensuring the precision, accuracy and tractability of measurements throughout the country.

The calibration work in different fields are organized in three laboratories:

- 1) Mechanical Measurement Laboratory; 2) Electrical Measurement Laboratory; and
- 3) Physico-chemical Measurement Laboratory.

11.3 Laboratory Testing

QSAE establishes and operates testing laboratories for the purpose of assisting conformance of products certification to relevant requirements, and also assisting industrial and agricultural research and supporting quality promotion and standardization efforts at all levels in the country. Thus, among others, making it possible to protect the welfare and safety of the general consumer.

There are four laboratories primarily classified as: 1) Mechanical Testing Laboratory, 2) Electrical Testing Laboratory, 2) Microbiological Testing Laboratory, and 4) Chemical Testing Laboratory which undertakes testing on materials/products manufactured in accordance with Ethiopian Standards for the grant of licenses under the ES Certification Schemes and/or as per the customers requests.

11.4 Product Certification

QSAE undertakes product certification and Quality Mark licensing based on conformance evaluation on domestic as well as imported products for which Ethiopian standards have been developed.

11.5 Training

QSAE conducts training on Quality, Standardization, Metrology and Testing to help personnel from the economic and social sectors upgrade their knowledge, skill and attitude aimed at improving processes, products and services.

11.6 Standards Information

QSAE provides information related to standardization in the form of standards, codes of practice/guides, reference publications and technical regulations to its internal and external customers.

12. SUMMARY OF QUALITY SYSTEM RESPONSIBILITIES

Table 1 - Summary of Quality System Responsibilities

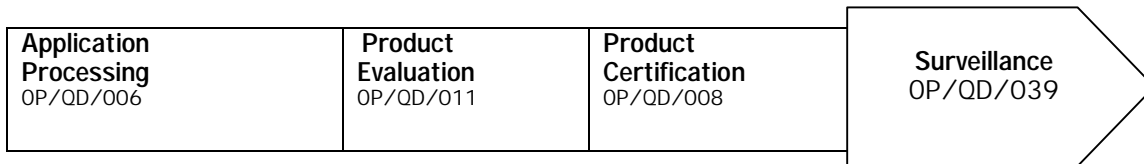
Responsible Person/Body	Responsibility and Authority
Board of Management	<ul style="list-style-type: none"> • Approve and ensure the implementation of policy matters, short- and long-term plans, annual work programmes and budget, annual activity report, • Approve Ethiopian Standards. • Evaluate management review report. • Prescribe Quality Mark fees and other fees for services rendered by QSAE.
General Manager	<ul style="list-style-type: none"> • Define the quality policy and objectives. • Ensure the communication and understanding of the quality policy and objectives through out QSAE. • Review the quality system with Management Committee.
Management Representative (Service Improvement Project Office Head)	<ul style="list-style-type: none"> • Document and maintain the quality policy and objectives. • Ensure that the quality system is established, implemented and maintained. • Reports regularly the suitability and effectiveness of the quality system. • Coordinate improvements to the quality system.
Division, Department, Service and Branch Office Heads	<ul style="list-style-type: none"> • Implement the quality system. • Obtain and communicate customer requirements to appropriate personnel or function. • Ensure that qualified, skilled, and trained personnel and other resources are available to the quality system. • Ensure that the services satisfy customer requirements • Ensure that personnel comply with applicable standards, regulations, specifications, and documented procedures. • Initiate actions to prevent the occurrence of any non-conformity. • Responsible for timely completion of corrective actions in their area of responsibility and verify its effectiveness.
All Personnel	<ul style="list-style-type: none"> • Ensure the quality of their work. • Operate in conformance with the requirements of the quality system. • Stop work in progress or make appropriate notifications when unsafe conditions exist or requirements are not being met.

13. MAP OF PROCESSES

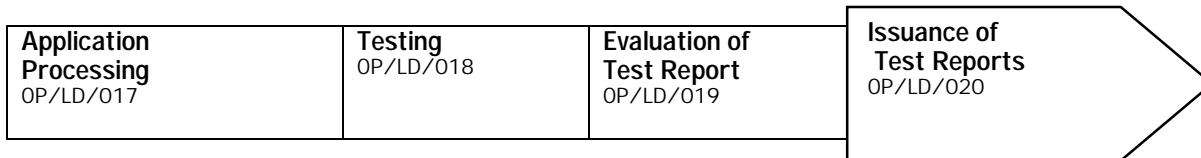
13.1 Main Processes

Main processes which have significant influence on critical success factors towards the achievement of objectives are identified and described as follows.

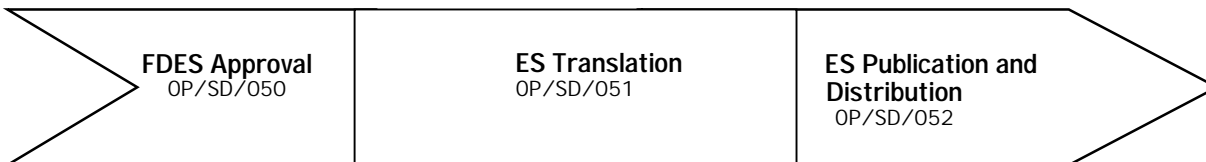
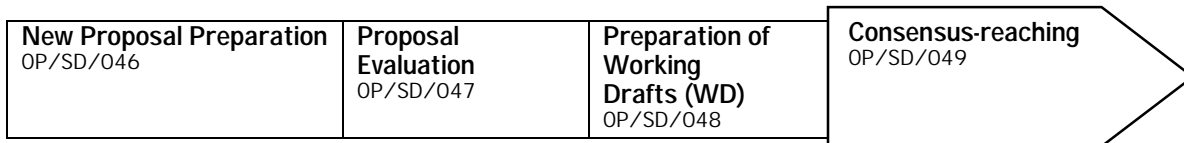
13.1.1 Product Certification



13.1.2 Laboratory Testing

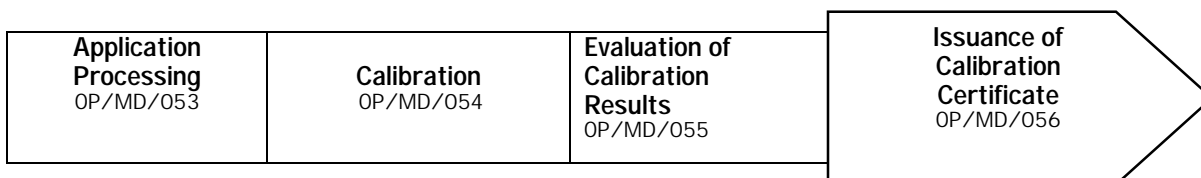


13.1.3 Standardization

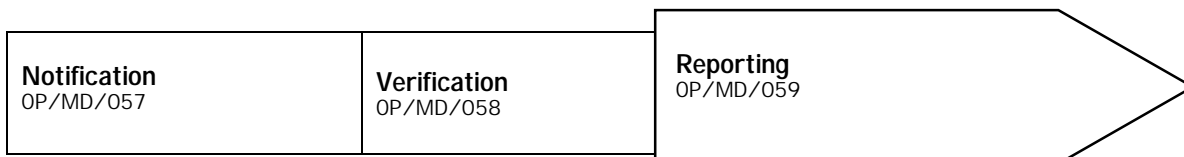


13.1.4 Metrology

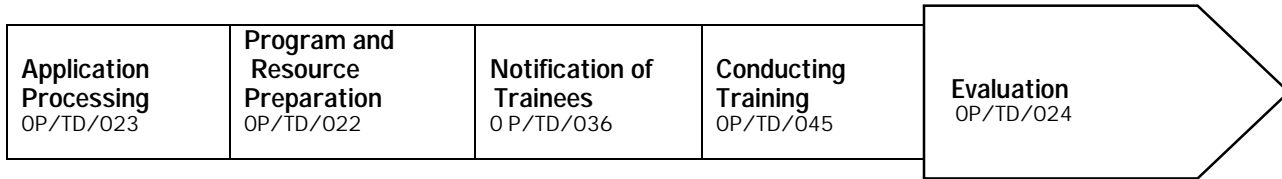
13.1.4.1 Calibration



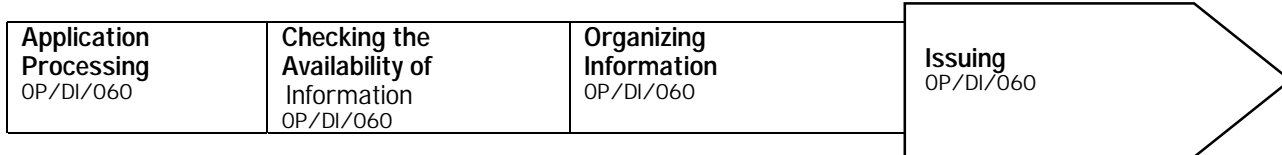
13.1.4.2 Verification



13.1.5 Training



13.1.6 Standards Information



13.2 Support Processes

Support processes, which reinforce the Main Processes and Management Processes, are described as follows.

- a) **Testing and Inspection Equipment Maintenance**
OP/LD/030
- b) **Control of Quality Records**
OP/QD/004
- c) **Documentation and Technical Information Service**
OP/DI/060
- d) **Documents and Data Control**
OP/QD/001, OP/QD/002, OP/QD/003
- e) **Internal Training**
OP/TD/061
- f) **Purchasing**
OP/QD/038
- g) **Storage, Handling and Disposal of Laboratory Samples**
OP/LD/031
- h) **Financial Auditing**
OP/QD/026
- i) **Financial Service**
OP/QD/013, OP/QD/014, OP/QD/016, OP/QD/025
- j) **Recruitment and Induction**
OP/QD/010

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k) Storage and Handling of Laboratory Items

OP/LD/029

l) Customer Complaints Handling

OP/QD/015

m) In-house Calibration

OP/QD/040

n) Legal Service

OP/LD/033, OP/LD/034, OP/LD/035

o) Preventive and Corrective Actions

OP/LD/028

p) Internal Quality Audit

OP/QD/009

q) Customer Service

OP/QD/067

r) Planning and Programming Service

OP/PS/044

13.3 Management Processes

Processes of which the primary responsibility is allocated to the management are described as follows.

a) Resource Management

OP/GM/062

b) Annual Budgeting

OP/GM/063

c) Management Review

OP/GM/064

d) Communication

OP/GM/065

e) Strategic Planning and Investment

OP/GM/066

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14. DESCRIPTION OF PROCESSES

14.1 Main Processes

14.1.1 Standards Formulation

14.1.1.1 NEW PROPOSAL PREPARATION	PROCESS OWNER
Doc. No. OP/SD/046	Standards Engineer/External Body

New standards preparation /periodic review and revision proposals are prepared based on the relevant criteria document(s) and available resources. Standard proposals identifies the objectives, scope, an existing or potential problem(s), necessary resources and detailed activities to be accomplished to finalize the review or preparation of the new Ethiopian standard. When external bodies prepare proposals, OP/SD/041, Proposal Procedure shall apply.

14.1.1.2 PROPOSAL EVALUATION	PROCESS OWNER
Doc. No. OP/SD/047	Standards Specification Department Head

Proposals for new standards preparation /periodic review and revision of the existing standards are reviewed and approved by an authorized and competent person. Proposals evaluation ensures that the work of national-level standardization focus on its contribution to the customer needs and the goals of QSAE. When external bodies prepare proposals, OP/SD/041, Proposal Procedure shall apply.

14.1.1.3 PREPARATION OF WORKING DRAFT	PROCESS OWNER
Doc. No. OP/SD/048	Standards Engineers/External Body

The work of new standards preparation /periodic review and revision of the existing standards are carried out based on the objectives and problems identified in the proposal document. During preparation of new standards/revision of the existing standards the national, regional and international conditions are considered to ensure that the standards are harmonized and trade barriers are prevented. When external bodies prepare working drafts, OP/SD/042, Implementation Procedure shall apply.

14.1.1.4 CONSENSUS -REACHING ON DRAFT STANDARDS	PROCESS OWNER
Doc. No. OP/SD/049	Technical Committee/Sub-committee

All concerned parties discuss on the draft standards prepared by the standards engineers until consensus(s) is reached on all provisions of the draft standards. The implementation of consensus principle ensures ownership by all parties, completeness and implementation of the standards. When external bodies prepare draft standards, OP/SD/042, Implementation Procedure shall apply.

14.1.1.5 ES APPROVALS	PROCESS OWNER
Doc. No. OP/SD/050	QSAE Board of Management

Draft Ethiopian Standards are approved as Ethiopian Standard by QSAE to ensure that they are prepared according to the planned arrangements and to give national recognition. When external bodies prepare the working draft(s), OP/SD/043, Acceptance Procedure shall apply.

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14.1.1.6 ES TRANSLATION **PROCESS OWNER**
 Doc. No. OP/SD/051 Translation and Editing Service Head
 As much technical information is available in English Standards are prepared in English and then translated to the Amharic language. The translation is done to facilitate the implementation of Ethiopian Standards, including ESs made compulsory by law, and to handle legal cases when they arise.

E14.1.1.7 ES PUBLICATION AND DISTRIBUTION **PROCESS OWNER**
 Doc. No. OP/SD/052 Documentation and Technical Information Service Head
 All approved Ethiopian Standards are published and made available to users. The standards are available at the Head Office and Branch Offices, and any interested institution or individual has the right to buy and use them.

14.1.2 Products Certification

14.1.2.1 APPLICATION PROCESSING FOR GRANTING OF LICENSE TO USE QUALITY MARK **PROCESS OWNER**
 Doc. No. OP/QD/005 Certification Team Leader
 Before accepting customer requests, the applications are reviewed to ensure that the customer and regulatory requirements are adequately defined and differences or ambiguities in understanding these requirements are resolved.

14.1.2.2 INITIAL INSPECTION **PROCESS OWNER**
 Doc. No. OP/QD/012 Technical Experts Team Leader
 Initial inspection is conducted to ascertain that the manufacturer has the capability to produce products that conforms to the requirements of the relevant scheme of certification continuously and consistently. All processes, which have an impact on the quality of the product, are assessed, representative samples are taken and tested. The results are reviewed against the relevant scheme of certification.

14.1.2.3 CERTIFICATION TO USE QUALITY MARK **PROCESS OWNER**
 Doc. No. OP/QD/007 Certification Team Leader
 The product is evaluated based on the initial and /or surveillance report and the relevant scheme of certification and actions are taken based on the results of the evaluation. Quality Mark license is granted to the applicant if the assessment report reveals complete compliance with the relevant certification scheme. In case of non-compliance, Quality Mark license is denied and the applicant is informed about the reasons for rejection by a formal letter. If the applicant believes that the action taken is unfair/not correct, he/she has the right to appeal as per the Appeals and Complaints Handling Procedure OP/QD/015.

14.1.2.4 SURVEILLANCE ON QUALITY MARK LICENSEES **PROCESS OWNER**
 Doc. No. OP/QD/039 The Respective Inspectors Head
 A periodic processes and product(s) evaluation is conducted on Quality Mark licensees to ensure that they continue to conform to the relevant scheme of certification. The surveillance report is reviewed and actions are taken in accordance with the Certification Procedure for Licensing to Use Quality Mark, OP/QD/007.

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14.1.2.5 APPLICATION PROCESSING FOR BATCH PRODUCT CERTIFICATION **PROCESS OWNER**
The Respective Certification Expert
Doc. No. OP/QD/006

Before accepting customer request, the application is reviewed to ensure that the customer and regulatory requirements are adequately defined and differences or ambiguities in understanding these requirements are resolved.

14.1.2.6 BATCH PRODUCT EVALUATION **PROCESS OWNER**
The Respective Inspectors Head
Doc. No. OP/QD/011

Inspection and testing are conducted to ascertain that the applicant's products conform to the requirements of the relevant scheme of certification. Representative samples are taken from the total consignment and they are inspected and tested. The results are evaluated against the relevant scheme of certification.

14.1.2.7 BATCH PRODUCT CERTIFICATION **PROCESS OWNER**
The Respective Certification Expert
Doc. No. OP/QD/008

The inspection and test report is reviewed against the relevant scheme of certification and actions are taken based on the results of the review. Quality certificate/release note is granted to the applicant if the inspection and test report reveals complete compliance with relevant certification scheme. In case of non-compliance, certificate/release note is denied and the applicant is informed about the reasons for rejection with a registered letter. If the applicant believes that the action taken against him is unfair/not correct, she/he has the right to appeal as per Appeals and Complaints Handling Procedure, OP/QD/015.

14.1.3 Laboratory Testing

14.1.3.1 APPLICATION PROCESSING FOR LABORATORY TESTING **PROCESS OWNER**
Testing and Research Laboratory Head
Doc. No. OP/LD/017


Test samples are received identified and delivered to the concerned laboratory after registering, evaluating and recording of test request application. Advance payment is collected when there is no contractual agreement with the customer. Customers are informed immediately if the application is rejected for not fulfilling the requirements set in the procedure. The due date is notified to the customer immediately after the application is approved.

14.1.3.2 TESTING **PROCESS OWNER**
Responsible Team Leader
Doc. No. OP/QD/018

Samples are prepared and tested according to the methods of the Ethiopian Standards, or if national standard is non-existent, the method indicated by the applicant or an approved foreign national, international standard or other professional society standards. Tests are conducted using calibrated equipment and/or certified reagents in ambient environment by qualified personnel (which can be demonstrated from the skill register matrix), to ensure that the results generated are correct.

14.1.3.3 EVALUATION OF TEST RESULT **PROCESS OWNER**
Responsible Team Leader
Doc. No. OP/LD/019

Test results generated by the respective laboratories are inspected, evaluated and approved by authorized personnel. The evaluation ensures that wrong and incomplete results are detected and rectified before reaching customers.

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14.1.3.4 TEST REPORT ISSUANCE **PROCESS OWNER**
 Doc. No. OP/LD/020 Testing and Research Laboratory Head
 The external customers settles the testing fee, test results are organized, approved and issued to the customer.

HANDLING, STORAGE AND DISPOSAL OF LABORATORY SAMPLES **PROCESS OWNER**
 Doc. No. OP/LD/031 Store Keeper
 To prevent the deterioration, damage, mix-up, and loss, samples are identified registered and stored in a separate room organized for the purpose. Counter samples are retained for at least 3 months and disposed as per the procedure.

14.1.3.5 APPLICATION PROCESSING FOR CALIBRATION SERVICE **PROCESS OWNER**
 Doc. No. OP/MD/053 Metrology Department Head
 Before accepting the customer requests, the application is reviewed to ensure that customer requirements are clear, non-ambiguous and within the scope of the calibration facilities. Approved applications are registered and calibration is initiated. Inspection is carried on the measuring equipment to ascertain that the equipment is not broken or non-functional. If the request is out of the scope of the calibration facilities or the measuring equipment is broken or non-functional, the application is rejected and the customer is notified of the reason for rejection.


14.1.4 Calibration and Verification

14.1.4.1 CALIBRATION **PROCESS OWNER**
 Doc. No. OP/MD/054 Responsible Team leader
 Trained and competent personnel do the calibration with traceable Ethalons, and in conditioned environment. Calibrated measuring equipment is properly identified with a conspicuous tag or sticker to enable easy identification of their calibration status.

14.1.4.2 EVALUATION OF CALIBRATION RESULTS **PROCESS OWNER**
 Doc. No. OP/MD/055 Responsible Team Leader
 The reports generated by the calibration expert are inspected and evaluated for completeness by an authorized and competent person. Inspection and evaluation of the calibration reports ensures prevention of non-conformities from reaching customers.

14.1.4.3 ISSUANCE OF CALIBRATION CERTIFICATES **PROCESS OWNER**
 Doc. No. OP/MD/056 Metrology Department Head
 Customers settle the calibration fees, and the calibration certificate is issued identifying the information affixed on the calibrated measuring equipment, including the next calibration period.

14.1.4.4 NOTIFICATION OF THE MEASURING DEVICES' (COVERED UNDER THE LEGAL METROLOGY) OWNERS **PROCESS OWNER**
 Doc. No. OP/MD/057 Metrology Department Head
 An announcement is made (including types of measuring equipment or devices, dates and place where the verification is to be carried out) by suitable means to notify the owners of measuring devices (equipment) being used in commercial transactions.

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14.1.4.5 VERIFICATION OF MEASURING DEVICES' (THE LEGAL METROLOGY) PROCESS OWNER
The Responsible Inspector
Doc. No. OP/MD/058

Trained and competent personnel verify the registered measuring equipment and devices. Any false measuring equipment or device is registered and identified as defective and excluded from use by suitable means until the defect is rectified and verified again.

14.1.4.6 EVALUATION OF THE VERIFICATION REPORTS PROCESS OWNER
Metrology Department Head
Doc. No. OP/MD/059

The verification reports are inspected and evaluated for completeness and the status of measuring equipment and devices as a whole and the magnitude of false measurement occurring in the market.

14.1.5 Training

14.1.5.1 TRAINING NEED ASSESSMENT PROCESS OWNER
Quality Promotion and Training
Service Head
Doc. No. OP/TD/021

Training need assessment on quality, standards, metrology and testing are conducted and the outputs are used for planning. It is performed by distributing need assessment questionnaire on quality, standards, and metrology and testing to government and private organizations.

14.1.5.2 TRAINING PROGRAM AND RESOURCE PREPARATION PROCESS OWNER
Quality Promotion and Training
Service Head
Doc. No. OP/TD/022

Based on the assessed needs adequate resources and programs are prepared to ensure that the training is conducted effectively.

14.1.5.3 TRAINING NOTIFICATION PROCESS OWNER
Quality Promotion and Training
Service Head
Doc. No. OP/TD/036


Notification of training is done based on registered, reviewed and approved lists of organizations that have been selected.

14.1.5.4 TRAINING APPLICATION PROCESSING PROCESS OWNER
Quality Promotion and Training
Service Head
Doc. No. OP/TD/023

Training applications are received, registered evaluated to ensure that adequate resources are available.

14.1.5.5 CONDUCTING TRAINING PROCESS OWNER
Quality Promotion and Training
Service Head
Doc. No. OP/TD/045

Trainees are registered; the necessary training materials are issued and the locations of the facilities are introduced. The training process is designed to be interactive among the trainees and the facilitators to ensure that good practices are discussed and shared among participants.

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14.1.5.2 TRAINING PROCESS EVALUATION
Doc. No. OP/TD/024

PROCESS OWNER
Quality Promotion and Training
Service Head

Evaluation of training process on quality, standards, metrology and testing are performed by distributing evaluation questionnaire to the participant, and finally the filled questionnaire are collected, evaluated and documented so that it is used as an information source for future improvement.

14.1.6 Standards Information

STANDARDS INFORMATION ISSUANCE
Doc. No. OP/TD/60

PROCESS OWNER
Document and Information
service Head

Standards and related information is organized and issued to the customers up on request. Organizing of the information may include interpretation, photocopying, binding as per the request of the customer.

14.2 Support Processes

**14.2.1 DOCUMENT AND DATA CONTROL:
PROCEDURES AND WORK INSTRUCTIONS WRITING**
Doc. No. OP/QD/001

PROCESS OWNER
Document Control Center

Quality system documents are created reviewed and approved by an authorized person for adequacy, clarity and completeness prior to distribution and use. Master list of all documents is maintained by Document Control Center. Documents are available to all personnel in the location where they are needed.

**14.2.2 DOCUMENT AND DATA CONTROL:
CONTROL OF DOCUMENT CHANGE**
Doc. No. OP/QD/002

PROCESS OWNER
Document Control Center

Changing or modification of any controlled document is reviewed and approved for adequacy, clarity and completeness prior to issue by the same person that performed the original review and approval. Changes to documents are identified and maintained by Document Control Center. The revised versions are registered and distributed to all locations where they are needed.

**14.2.3 DOCUMENT AND DATA CONTROL:
CONTROL OF DOCUMENT DISPOSAL**
Doc. No. OP/QD/003

PROCESS OWNER
Document Control Center

Obsolete documents are removed from all locations based on the distribution list. Obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified and kept separately.

14.2.4 CONTROL OF QUALITY RECORDS
Doc. No. OP/QD/004

PROCESS OWNER
The respective Department/Service/Branch Office
Head and the Central Archive

The quality records are collected, identified and stored properly to ensure that they are protected from damage and loss and are retrievable. The long and short term retention periods are defined for each category of record. Confidential records are retained in the location where they are created and are access controlled.

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14.2.5 INTERNAL QUALITY AUDIT

PROCESS OWNER

Doc. No. OP/QD/009

Management Representative

The suitability and effectiveness of the quality system is verified by conducting an internal quality audits on a regular basis by trained personnel who are independent of the process to be audited. The management, to assess the status of the quality system reviews the results of the audit and initiates corrective actions for non-conformities identified during the audit process.

Department/Service/Branch Office Heads from which the non-conformities are identified have the responsibility to implement corrective actions.

14.2.6 PREVENTIVE AND CORRECTIVE ACTION

PROCESS OWNER

Doc. No. OP/LD/028

Management Representative

Preventive and corrective actions are taken to assure that potential and actual causes of non-conformities are resolved and permanent solutions are implemented in order to maintain continuous improvement. Department/Service/Branch Office Heads from which the non-conformities are identified have the responsibility to implement and monitor the effectiveness of preventive and corrective actions.

14.2.7 PERSONNEL RECRUITMENT

PROCESS OWNER

Doc. No. OP/QD/010

Administration and Finance Service Head

The recruitment of personnel on both permanent and contract bass is done in a planned and controlled manner to ensure that personnel are recruited on the bass of organizational goals and personnel's merit.

14.2.8 PURCHASING

PROCESS OWNER

Doc. No. OP/QD/038

Administration and Finance Service Head

The purchasing procedure describes that all purchase orders shall define the detail specifications of the material/service to be purchased. The suppliers are evaluated and short-listed based on their ability to supply a quality product or service consistently and continuously. To avoid bought-in problems inspection is conducted on the in-coming materials and any non-conforming products identified during inspection are rejected.

14.2.9 HANDLING AND STORAGE OF LABORATORY ITEMS & EQUIPMENT

PROCESS OWNER

Doc. No. OP/LD/029

Store Keeper

To prevent from damage and deterioration, all laboratory items like glassware, chemicals, instruments, spare parts, etc. are, received, identified, handled and stored properly. Requisition of materials for laboratory use is evaluated and approved by authorized personnel before delivery. In order to prevent shortage of consumable items, purchase order is raised when the level of the stock reaches the minimum amount. For the purpose of controlling the level of the sock, bin cards and electronic database are employed.


14.2.10 MAINTENANCE OF LABORATORY EQUIPMENT

PROCESS OWNER

Doc. No. OP/LD/029

Maintenance Head

All test equipment are registered identified and planned for preventive and corrective maintenance to ensure that only non-defective test equipment are used for testing. If the magnitude of the problem is beyond the capability of the maintenance personnel, it is sub-contracted to sub - contractors. To keep the history of the equipment, parts changed and/or fixed shall be recorded.

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14.2.11 APPEALS AND COMPLAINTS HANDLING **PROCESS OWNER**
General Manager
Doc. No. OP/QD/015

Customers' appeals and complaints are registered on a prescribed form and analyzed by a panel, which comprises a group of people independent of the process against which the appeal or complaint is raised. If appeals and complaints are justified as true, corrective actions are taken as per the procedure OP/QD/028.

14.2.12 FINANCIAL AUDITING **PROCESS OWNER**
Audit Service Head
Doc. No. OP/QD/026

Pre- and post financial audits are made to verify the correctness of transaction documents and financial status reports generated every month.

14.2.13 INVENTORY **PROCESS OWNER**
Audit Service Head
Doc. No. OP/QD/027

Periodic inventory is conducted on properties by a team, which is assigned by the General Manager to ensure that the status and conditions of properties are according to the planned arrangements. The status (conditions) of properties are recorded and reported to the General Manager. Actions are taken based on the results of the evaluation on the inventory report.

14.2.14 PAYMENT **PROCESS OWNER**
Finance Division Head
Doc. No. OP/QD/013

Payment requests are registered and checked for correctness and availability of budget and authorized. Authorized payments are effected and records are maintained.

14.2.15 FEE COLLECTING **PROCESS OWNER**
Finance Division Head
Doc. No. OP/QD/013

Fees are collected from the customers for the service delivered to them. The collected fees are deposited in the bank, audited and the deposit slips are retained.

14.2.16 FINANCIAL STATEMENT PREPARATION **PROCESS OWNER**
Finance Division Head
Doc. No. OP/QD/016

Transaction documents are collected, journalized, posted and trial balances are extracted. Financial statements are generated and verified and documented every month. External Auditors are subcontracted to verify annual financial statement.

14.2.17 BANK RECONCILIATION **PROCESS OWNER**
Finance Division Head
Doc. No. OP/QD/025

Deposit/advance slips are collected, journalized and posted. The recording book is checked against bank statement and bank reconciliation report is generated.

14.2.18 ISSUANCE OF LEGAL OPINION **PROCESS OWNER**
Legal Service Head
Doc. No. OP/LD/034

Legal opinion is handled by giving explanation or answer to the requester after studying and understanding the facts against the concerned laws as a result opinion is given clearly.

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14.2.19 LAWS AND REGULATION PREPARATION

Doc. No. OP/LD/035

PROCESS OWNER

Legal Service Head

Laws and regulations are prepared based on the Business Plan and the identified problems. The approved and published laws and regulations are communicated to the employees through training. Evaluation is conducted to ascertain effective implementation of the laws and regulations.

14.2.20 CLAIMS HANDLING

Doc. No. OP/LD/040

PROCESS OWNER

Legal Service Head

Claims both as plaintiff or defendant is handled by presenting or producing oral and written explanation and evidence to courts.

14.2.21 LABORATORY SAFETY

Doc. No. OP/LD/035

PROCESS OWNER

Testing and Research Laboratory Head

To ensure that the laboratory testing personnel are safe from any life hazards during carrying out the tests or any activity in relation to testing and inspection, the necessary safety facilities are provided. Employees are trained on the safety rules, and safety instructions are posted at the appropriate locations where employees can read them easily.

14.2.22 STANDARDS INFORMATION ISSUANCE

Doc. No. OP/TD/60

PROCESS OWNER

DTIS Head

Standards and related information is organized and issued to the customers up on request. Organizing of the may include interpretation, photocopying, binding as per the request of the customer.

14.2.23 INTERNAL TRAINING

Doc. No. OP/TD/061

PROCESS OWNER

Training Department Head

To ensure effectiveness, efficiency and continuous improvement, all personnel who perform an activity, which has an effect on quality, are trained and retrained on the basis of a yearly plan. Department/service/branch office head identifies training needs and retains training records to demonstrate that a competent person or group of persons does to an activity, which has an impact on quality.

14.2.24 IN-HOUSE EQUIPMENT CALIBRATION

Doc. No. OP/TD/040

PROCESS OWNER

The Respective Team Leaders

All measuring equipment and devices are registered, identified and planned for periodic calibration. A minimum calibration period is set for each category of measuring equipment and device and the calibration is done based on the plan. Tag or stickers properly identify calibrated measuring equipment and devices. Non calibrated and measuring equipment and devices are properly identified (marked and/or physically excluded) to ensure that they are not in use unintentionally.


14.2.25 PLANNING AND PROGRAMMING SERICE

Doc. No. OP/PS/044

PROCESS OWNER

Planning and Program Service Head

The annual budgets prepared at the Department/Service/Branch Office level are organized and compiled as organizational yearly plan and submitted to the management and Board of Management for discussion and approval. The approved plan is distributed to the respective addressees. The monthly, quarterly, six months and yearly performance reports collected from each

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Department/Service/Branch Office are organized and submitted to the management for review against the plan.

14.2.26 CUSTOMER SERVICE
 Doc. No. OP/QD/067

PROCESS OWNER
 General Manager

Customer service is organized in such a manner that customers are handled and their requests (needs) are processed properly. At the Head Office, the customer service personnel receive all customer requests. The Customer Service Personnel are competent to deliver adequate information to the customers about the services they requested. The outputs of the departments and services are delivered to the customers through the Customer Service.

14.3 Management Processes

14.3.1 RESOURCE MANAGEMENT
 Doc. No. OP/MG/062

PROCESS OWNER
 General Manager

The management ensures adequate resources, including trained manpower, are allocated to all processes that affects quality. A periodic review is conducted on resources to ascertain that they are properly and efficiently utilized. All resources are identified and maintained to ensure that no resource is in shortage, mishandled or misused.

14.3.2 ANNUAL BUDGETING
 Doc. No. OP/MG/063

PROCESS OWNER
 General Manager

Annual budgets are prepared by each Department/Service/Branch Office and submitted to Planning and Programming Service for organization and compilation. The budgets are discussed and approved by the management based on the available resources, strategic plan and assumptions. The Board of Management finally approves the budgets. The approved budgets are notified to the Departments, Services, and Branch Offices for implementation.

14.3.3 MANAGEMENT REVIEW
 Doc. No. OP/MG/064


PROCESS OWNER
 General Manager

The Management Representative periodically reports the status of the quality system to the management. The management review meetings are conducted at least twice a year on the status of the quality system. The management reviews the quality audit report, customer complaints, resources required, and opportunities for further improvement. If existing or potential non-conformities are identified, the review report initiates corrective and preventive actions,

14.3.4 COMMUNICATION
 Doc. No. OP/MG/065

PROCESS OWNER
 General Manager

Policies, objectives, strategic plans, standard information are communicated to the employees at all levels through newsletters, pamphlets, brochures, posting, discussions and training. Employees discuss on the non-conformities identified in their area of responsibilities and propose corrective and preventive actions. Employees participate in annual budget preparation and evaluate the performance reports against the plan.

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14.3.1 STRATEGIC PLANNING AND INVESTMENT

PROCESS OWNER

Doc. No. OP/MG/066

General Manager

The strategic plans are prepared based on the strategic objectives of the Organization. The plans are prepared by the management and discussed among the employees. The Board of Management finally approves the strategic plans.

15 CONFORMANCE TO ISO 9001 REQUIREMENTS

Conformance of the quality system documentation to the requirements of ISO 9001 is as indicated in the matrix in Table 2 below.

TABLE 2- Conformance of the quality system documentation to ISO 9001

S.N.	ISO 9001 Requirements Procedures	4.1 Management Responsibility	4.2 Quality System	4.3 Contract Review	4.4 Design Control	4.5 Documents and Data Control	4.6 Purchasing	4.7 Control of Customer Supplied Products	4.8 Identification and Traceability	4.9 Process Control	4.10 Inspection and Testing	4.11 Control of Inspection, Measuring, and Test Equipment	4.12 Inspection and Test Status	4.13 Control of Non-conforming Products	4.14 Corrective and preventive Action	4.15 Handling, Storage, Packaging, Preservation and delivery	4.16 Control of Quality Records	4.17 Internal Quality Audit	4.18 Training	4.19 Servicing	20. Statistical Techniques
		Ethiopian Standards Formulation																			
1	New Proposals Preparation Procedure OP/SD/041 , OP/SD/042 ,OP/SD/043 and OP/SD/046				✓					✓	✓			✓	✓						
2	Proposal Evaluation Procedure OP/SD/047									✓	✓			✓							
3	Working Draft Standards Preparation Procedure OP/SD/048				✓					✓											✓
4	Procedure for Consensus-reaching on Draft ES OP/SD/049									✓	✓			✓	✓						
5	ES Approvals Procedure OP/SD/050									✓	✓			✓	✓						
6	ES Translation Procedure OP/SD/051									✓	✓			✓							
7	ES Publication and Distribution Procedure OP/SD/052									✓						✓					
	Product Certification																				
8	Procedure for Application Processing for Granting of License to Use Quality mark OP/QD /005				✓					✓											
9	Initial Inspection Procedure OP/QD/012									✓											
10	Certification Procedure for Licensing to Use Quality Mark OP/QD/007									✓	✓			✓							
11	Surveillance Procedure OP/QD/039									✓	✓										
12	Application Processing Procedure for Batch Product Certification OP/QD/006				✓					✓											
13	Batch Product Evaluation Procedure OP/QD/011									✓				✓							
14	Batch Product Certification Procedure OP/QD/008									✓	✓										

Table 2- Cont.

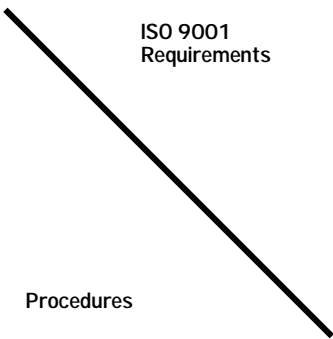

S.N.	<div style="text-align: center;">  <p>ISO 9001 Requirements</p> <p>Procedures</p> </div>	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19	20.
		Management Responsibility	Quality System	Contract Review	Design Control	Documents and Data Control	Purchasing	Control of Customer Supplied Products	Identification and Traceability	Process Control	Inspection and Testing	Control of Inspection, Measuring, and Test Equipment	Inspection and Test Status	Control of Non-conforming Products	Corrective and preventive Action	Handling, Storage, Packaging, Preservation and delivery	Control of Quality Records	Internal Quality Audit	Training	Servicing	Statistical Techniques
	Laboratory Testing																				
15	Application Processing Procedure for Laboratory Testing OP/LD/017			✓				✓		✓	✓		✓								
16	Testing Procedure OP/LD/018									✓	✓		✓								
17	Test Results Evaluation Procedure OP/LD/019									✓	✓		✓	✓							
18	Test Report Issuance Procedure OP/LD/020									✓						✓					
19	Handling, Storage and Disposal of Laboratory Samples OP/LD/031							✓	✓	✓	✓		✓	✓							
	Calibration																				
20	Application Processing Procedure for Calibration Service OP/MD/053			✓				✓	✓	✓											
21	Calibration Procedure OP/MD/054							✓		✓			✓								
22	Calibration Results Evaluation Procedure OP/MD/055							✓		✓	✓		✓	✓							
23	Calibration Results Issuance Procedure OP/MD/056									✓						✓					
	Verification																				
24	Notification Procedure for Verification of Measuring Equipment OP/MD/057									✓											
25	Verification Procedure OP/MD/058							✓		✓			✓								
26	Evaluation Procedure for Verification Results OP/MD/059									✓	✓		✓	✓							
	Training																				
27	Training Needs Assessment Procedure OP/TD/021				✓					✓											
28	Training Program and Resources Preparation Procedure OP/TD/022				✓					✓	✓		✓								
29	Training Program Notification Procedure OP/TD/036									✓											
30	Training Application Processing Procedure OP/TD/023			✓						✓											
31	Training Procedure OP/TD/045									✓											

Table 2- Cont.

S.N.	ISO 9001 Requirements Procedures	4.1 Management Responsibility	4.2 Quality System	4.3 Contract Review	4.4 Design Control	4.5 Documents and Data Control	4.6 Purchasing	4.7 Control of Customer Supplied	4.8 Identification and Traceability	4.9 Process Control	4.10 Inspection and Testing	4.11 Control of Inspection, Measuring, and Test Equipment	4.12 Inspection and Test Status	4.13 Control of Non-conforming	4.14 Corrective and preventive Action	4.15 Handling, Storage, Packaging ,	4.16 Control of Quality Records	4.17 Internal Quality Audit	4.18 Training	4.19 Servicing	20. Statistical Techniques	
32	Training Process Evaluation Procedure OP/TD/024									✓	✓			✓								
	Standards Information																					
33	Standards Information Issuance Procedure OP/LD/060			✓						✓	✓			✓								
	Support Processes																					
34	Documents and Data Control: Procedures and Work Instructions Writing Procedure OP/QD/001					✓				✓												
35	Documents and Data Control: Documents Change Procedure OP/QD/002					✓				✓												
36	Documents and Data Control: Documents Disposal Procedure OP/QD/003					✓				✓												
37	Quality Records Control Procedure OP/QD/004									✓							✓					
38	Internal Quality Audit Procedure OP/QD/009									✓								✓				
39	Preventive and Corrective Actions Procedure OP/LD/028									✓				✓								
40	Personnel Recruitment Procedure OP/QD/010									✓												
41	Purchasing Procedure OP/QD/038						✓			✓												
42	Materials and Equipment Handling Procedure OP/LD/029									✓												
43	Laboratory Equipment Maintenance Procedure OP/LD/030									✓				✓								
44	Appeals and Complaints Handling Procedure OP/QD/015									✓				✓								
45	Financial Auditing Procedure OP/QD/026									✓	✓		✓	✓								
46	Inventory Procedure OP/QD/027									✓	✓		✓	✓								
47	Payment Procedure OP/QD/013									✓												
48	Fee Collecting Procedure OP/QD/014									✓												
49	Financial Statement Preparation Procedure OP/QD/016									✓												
50	Bank Reconciliation Procedure OP/QD/025									✓												
51	Legal Opinion Issuance Procedure OP/LD/034									✓												

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Annex A: Quality System Implementation and Accreditation Areas /Fields

As the area/fields indicated in the annex are broad, the specific materials, testing and measurement methods are specified in the Quality Plan.

1. AREAS OF ISO/IEC GUIDE 25 : 1990 IMPLEMENTATION IN TESTING LABORATORIES

1.1 Agricultural Products

- a) Cereals and pulses
- b) Oil seeds
- c) Spices and condiments
- d) Coffee
- e) Fruits and vegetables
- f) Chemical fertilizers

1.2 Textile and Leather


- a) Raw cotton
- b) Cotton fibers
- c) Semi finished and finished leather products (goat and sheep skins)

1.3 Mechanical and Construction Materials

- a) Cement
- b) Reinforcement steel bars
- c) Steel sheets, plain and corrugated

1.4 Food Products

- a) Mycotoxins (Ochratoxins, Aflatoxins, and others).
- b) Microbiological (Salmonella, Shigella Staphylococcus, Brucella, Vibrio).
- c) Pesticides, herbicides, fungicides, antibiotics and fertilizer residues

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2. AREAS OF ISO/IEC GUIDE 25 : 1990 IMPLEMENTATION IN METROLOGY LABORATORIES

- 2.1 Mass measurement
- 2.2 Volume measurement
- 2.3 Length measurement
- 2.4 Force measurement
- 2.5 Electrical measurement

3. FIELDS OF PRODUCT CERTIFICATION FOR ISO/IEC GUIDE 65 : 1996 ACCREDITATION

- 3.1 Oil seeds
- 3.2 Pulses and cereals
- 3.3 Coffee
- 3.4 Spices and condiments
- 3.5 Fruits and vegetables
- 3.6 Raw hides and skins
- 3.7 Cotton and cotton yarn
- 3.8 Fertilizers
- 3.9 Cement and cement products
- 3.10 Reinforcement steel bars