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Contents

1. Introduction

This document set out minimum requirements for the operation of Testing Laboratories. And it is prepared based on International Standard (ISO/IEC 17025).

2. Scope

This criteria document is applicable to any organization performing testing.

3 Terms and definitions

For the purpose of this document, the relevant terms and definitions given in ISO/IEC 17000 apply.

- Testing: - determination of one or more characteristically of an object of conformity assessment, according a procedure.
- Requirement: - expression in the content of a document conveying criteria to be fulfilled if compliance with the document is to be claimed and from which no devotion is permitted.

4. Management and Technical Requirements

4.1 Organization

The laboratory has to be an entity that can be held legally responsible.

4.2 Review of Request and Contracts

- The laboratory shall establish and maintain procedure for the review of requests and contracts.
- Records of review, including any significant changes shall be maintained.

The requirements including the methods to be used are adequately defined.

4.3 External providing services and products

- When a laboratory subcontracts work, this work shall be placed with a competent External providing services and products.
- The laboratory is responsible to the client for the External providing services and products work.
- The laboratory shall maintain a register of all External providing services and products that it uses for testing.

4.4 Complaints

The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties.

4.5 Control of non-conforming work

- The laboratory should have a means of identifying any non-conforming work.
- The laboratory shall have procedure for handling non conforming work.

4.6 Control of Records

- All records must be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provides a suitable environment to prevent damage, deterioration or loss.
- The laboratory shall retain staff records, test data, calibration certificate, and other relevant documents for a defined period of time

4.7 Personnel

- The laboratory shall have qualified personnel for operation of specific equipment, perform tests, evaluate results and sign test reports.
- All technical personnel involved in testing at least need to have collage diploma.
- Current job description should be maintenances for technical and key support personnel.
- Specific personnel should be designated to perform particular type of sampling, test, issue report, and operate equipment.

4.8 Accommodation and Environmental conditions

- The laboratory shall use appropriate facilities for the correct performance of the tests that are specified in the test method.
- There should be a mechanism to control environmental conditions to prevent any effect on the result.
- There should be effective separation between neighboring areas in which there are in compatible activities.
- The laboratory facility needs to have good housekeeping.

4.9 Test and methods

- The laboratory shall use appropriate methods and procedures for all tests including sampling, handling, transport, storage and preparation of the item to be tested.
- There should be instructions on the use and operation of equipment.
- Preference should be given to methods publishes in international, regional or national standards.
- If the lab uses in house method, it should be validated method

4.10 Equipment

- The laboratory shall be equipped with all items of test equipment required for the correct performance of the tests.
- The equipment and software used in the laboratory should be capable of achieving the accuracy required and in compliance with specification.
- All Measuring equipment that can affect the test should be calibrated.
- There should be procedure for safe handling, transport, storage and maintain ace of measuring equipment.
- There should be proof of calibration of the equipment.

4.11 Measurement traceability

- Measurement /equipment/ needs to be traceable to SI units.
- The laboratory should have appropriate reference materials.

4.12 Sampling

- The laboratory shall have sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing.
- The sampling process should address factors to be controlled to ensure validity of results.
- Records relevant to sampling should be maintained.

4.13 Handling of test

- The laboratory shall have procedures for the transport, receipt, handling, protection, storage, retention and disposal of test items.
- The laboratory should have a system to identify the sample throughout its life in the laboratory.
- The laboratory should have appropriate storage facilities for sample.
- There should be a record of the environment conditional of the storage.

4.14 Assuring the quality of test

- The laboratory shall have quality control procedure for monitoring the validity of tests undertaken.

- Whenever possible the laboratory should participate in proficiency.
- The laboratory should demonstrate the use of reference materials/internal control.

4.15 Reporting the results

- The results of each test carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with the test methods.
- The test report issued by the laboratory should include at least the following information.
- Title.
- Name and address of the laboratory
- Unique identification of the test report
- Name and address of the customer
- Identification of the method used.
- Name of the Authorizing person.

5. Impartiality and Confidentiality

- Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.
- The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercially, financially and other pressure to compromise impartiality.
- The laboratory shall be responsible, through legally enforceable commitments for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agree between the laboratory and customer all other information is consider proprietary information and shall be regarded as confidential.
- All personnel , including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf shall be impartial and confidential for all information obtained or created during the performances of laboratory activities except as required by law.

Revision No.	Date approved	Revision History
1	2023-02-07	• Correction done on page 1 that, this document was prepared by Meseret Tessema replaced by Zewdu Ayele (new quality manager). • Former director general was resigned and replaced by Mrs. Meseret Tessema.
