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Thesis: “Quality Management Systems in Testing Laboratories which conformed with ISO/IEC 17025:2017 International Standard requirements for accreditation purposes”.

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A DISSERTATION

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Keywords

ACCREDITATION: Third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities. (ISO/IEC 17000:2020).

ACCREDITATION BODY (AB): Authoritative body that performs accreditation (ISO/IEC 17000:2020).

ACCREDITATION CRITERIA: Set of requirements used by an accrediting body which a laboratory must meet in order to be accredited. (ASQ The Measurement Quality Division (2012) The Metrology Handbook, Second Edition, (Jay L. Bucher Ed.), ASQ Quality Press) APAC: Asia Pacific Accreditation Cooperation.

ASSESSMENT: Process undertaken by an accreditation body to determine the competence of a conformity assessment body, based on standard(s) and/or other normative documents and for a defined scope of accreditation (ISO/IEC 17011:2017).

AUTHORIZED REPRESENTATIVE: Individual who is authorized by the laboratory or parent organization to sign the accreditation application and commit the laboratory to fulfill the accreditation criteria. (Based on ISO/IEC 17011:2017)

BIPM: International Bureau of Weights and Measures.

BASE QUANTITY: Quantity in a conventionally chosen subset of a given system of quantities, where no subset quantity can be expressed in terms of the others. (JCGM 200:2012).

CALIBRATION: Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in an second step, uses this information to establish a relation for obtaining a measurement result from an indication. (JCGM 200:2012).

CALIBRATION ACTIVITY OR PROVIDER: A laboratory or facility—including personnel—that perform calibrations in an established location or at customer location(s). It may be external or internal, including subsidiary operations of a larger entity. It may be called a calibration laboratory, shop, or department; a metrology laboratory or department; or an industry-specific name; or any combination or

variation of these. (ASQ The Measurement Quality Division (2012) The Metrology Handbook, Second Edition, (Jay L. Bucher Ed.), ASQ Quality Press).

CALIBRATION AND MEASUREMENT CAPABILITY (CMC): A CMC is a calibration and measurement capability available to customers under normal conditions: (a) as published in the BIPM key comparison database (KCDB) of the CIPM MRA; or (b) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement. (ILAC-P14:09/2020).

CALIBRATION PROGRAM: The set of interrelated or interacting elements necessary to maintain the measurement performance of measuring and test equipment to defined requirements. (ANSI/NCSL Z540.3-2006 (R2013)).

CALIBRATION SEAL: A calibration seal is a device, placard, or label that, when removed or tampered with, and by virtue of its design and material, clearly indicates tampering. The purpose of a calibration seal is to ensure the integrity of the calibration. A calibration seal is usually imprinted with a legend similar to "Calibration Void if Broken or Removed" or "Calibration Seal— Do Not Break or Remove." A calibration seal provides a means of deterring the user from tampering with any adjustment point that can affect the calibration of an instrument and detecting an attempt to access controls that can affect the calibration of an instrument. Note: A calibration seal may also be referred to as a tamper seal. (ASQ The Measurement Quality Division (2012) The Metrology Handbook, Second Edition, (Jay L. Bucher Ed.), ASQ Quality Press) CAR (Corrective Action Request): IAS assessment finding that describes the failure to address, or failure to implement a mandatory requirement of the relevant standard, international requirement or IAS accreditation criteria. (IAS/ADM/052 IAS Guidance on Classification of Findings).

CERTIFIED REFERENCE MATERIAL (CRM): Reference material accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures. (JCGM 200:2012).

CERTIFICATE OF ACCREDITATION: Document issued by IAS to a laboratory that has met the conditions and criteria for accreditation. A current Certificate of Accreditation, accompanied by a Scope of Accreditation, may be used as proof of accredited status. CGPM: General Conference on Weights and Measures

CIPM: International Committee for Weights and Measures

COMBINED STANDARD MEASUREMENT UNCERTAINTY: Standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model. (JCGM 200:2012).

COMPETENCE: For a laboratory, the demonstrated ability to perform the tests or calibrations within the accreditation scope and to meet other criteria established by the accreditation body. For a person, the demonstrated ability to apply knowledge

and skills. Note: The word qualification is sometimes used in the personal sense, since it is a synonym and has more accepted usage in the United States. (ASQ The Measurement Quality Division (2012) The Metrology Handbook, Second Edition, (Jay L. Bucher Ed.), ASQ Quality Press)

CONCERN: Minor nonconformity with the requirements of the relevant standard, international requirement or IAS accreditation criteria (IAS/ADM/052).

CONFORMITY ASSESSMENT BODY (CAB): Body that performs conformity assessment activities, excluding accreditation. (ISO/IEC 17000:2020).

COVERAGE FACTOR: Number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty. (JCGM 200:2012).

COVERAGE INTERVAL: Interval containing the set of true quantity values of a measurand with a stated probability, based on the information available (JCGM 200:2012).

COVERAGE PROBABILITY: Probability that the set of true quantity values of a measurand is contained within a specified coverage interval. (JCGM 200:2012).

DECISION RULE: Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. (ISO/IEC 17025:2017).

DERIVED QUANTITY: Quantity, in a system of quantities, defined in terms of the base quantities of that system. (JCGM 200:2012).

EXPANDED MEASUREMENT UNCERTAINTY: Product of a combined standard measurement uncertainty and a factor larger than the number one. (JCGM 200:2012).

FLEXIBLE SCOPE OF ACCREDITATION: Scope of accreditation expressed to allow laboratories to make changes in methodology and other parameters which fall within the competence of the laboratory as confirmed by the accreditation body (based on ISO/IEC 17011:2017).

IAF: International Accreditation Forum. The world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment. (https://www.iaf.nu).

ILAC: International Laboratory Accreditation Cooperation. The international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189), inspection bodies (using ISO/IEC

17020), proficiency testing providers (using ISO/IEC 17043) and reference material producers (using ISO 17034). (https://ilac.org/about-ilac/).

IMPARTIALITY: Presence of objectivity. (ISO/IEC 17025:2017).

INTERLABORATORY COMPARISON (ILC): Organization, performance, and evaluation of tests or calibrations on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions. (ISO/IEC 17025:2017).

INTERNAL AUDIT: systematic, independent and documented process conducted by, or on behalf of the organization itself, for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. (ISO 19011:2018).

INTERNATIONAL STANDARD: (Standard that is adopted by an international standardizing/standards organization and made available to the public. (ISO/IEC Guide 2:2004).

INTERNATIONAL SYSTEM OF QUANTITIES (ISQ): System of quantities based on the seven base quantities: length, mass, time, electric current, thermodynamic temperature, amount of substance, and luminous intensity. (JCGM 200:2012).

INTERNATIONAL SYSTEM OF UNITS (SI): System of units, based on the International System of Quantities, their names and symbols, including a series of prefixes and their names and symbols, together with rules for their use, adopted by the General Conference of Weights and Measures (CGPM). (JCGM 200:2012).

INTRALABORATORY COMPARISON: organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions. (ISO/IEC 17025:2017).

LABORATORY: Body that performs one or more of the following activities: - testing; - calibration; - sampling, associated with subsequent testing or calibration. (ISO/IEC 17025:2017) LEVEL OF CONFIDENCE: alternate expression used by the GUM for “coverage probability”.

MANAGEMENT REVIEW (MR): Review by laboratory management of its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of the ISO/IEC 17025 standard. (Based on ISO/IEC 17025:2017).

MANAGEMENT SYSTEM (MS): The way in which an organization manages the interrelated parts of its business in order to achieve its objectives. (https://www.iso.org/management-systemstandards.html).

MEASURAND: Quantity intended to be measured (JCGM 200:2012).

MEASUREMENT: Process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity (JCGM 200:2012).

MEASUREMENT ACCURACY: Closeness of agreement between a measured quantity value and a true quantity value of a measurand. (JCGM 200:2012).

MEASUREMENT ERROR: Measured quantity value minus a reference quantity value. (JCGM 200:2012).

MEASUREMENT PRECISION: Closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions. (JCGM 200:2012).

MEASUREMENT PROCEDURE: Detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result. (JCGM 200:2012).

MEASUREMENT UNCERTAINTY: Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. (JCGM 200:2012).

MEASURING INSTRUMENT: Device used for making measurements, alone or in conjunction with supplementary devices. (JCGM 200:2012).

METROLOGY: Science of measurement and its application. (JCGM 200:2012).

METROLOGICAL TRACEABILITY: Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. (JCGM 200:2012).

METROLOGICAL TRACEABILITY CHAIN: Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference. (JCGM 200:2012).

MOBILE OPERATIONS: Operations that are independent of an established calibration laboratory facility. Mobile operations may work from an office space, home, vehicle, or use a virtual office.

MRA: Mutual Recognition Arrangement. For example, through the ILAC MRA, ILAC aims to demonstrate the equivalence of the operation of its Member Accreditation Bodies. As a consequence, the competence (within the accredited scopes) of laboratories, inspection bodies, proficiency testing providers and reference material producers accredited by these accreditation bodies is demonstrated and recognized by all signatory accreditation bodies. (Based on ILACP4:05/2019).

NATIONAL METROLOGY INSTITUTE (NMI): There is only one NMI in each country, and it maintains that country's national standards and provides traceability to the International System of Units (the SI) at stated levels of confidence – often called measurement uncertainty (https://www.npl.co.uk/resources/q-a/what-is-a-national-metrology-institute).

NATURAL CONSTANT: A natural (physical) constant is a fundamental value that is accepted by the scientific community as valid. Natural constants are used in the basic theoretical descriptions of the universe. Examples of natural physical constants important in metrology are the speed of light in a vacuum (c), the triple point of water (273.16 K), the quantum charge ratio (h/e), the gravitational constant (G), the ratio of a circle's circumference to its diameter (p), and the base of natural logarithms (e). (ASQ The Measurement Quality Division (2012) The Metrology Handbook, Second Edition, (Jay L. Bucher Ed.), ASQ Quality Press).

NONCONFORMITY (NCR): non-fulfilment of a requirement (ISO/IEC 17021-1:2015).

OFF-SITE TESTING/CALIBRATION: Any testing or calibration conducted at a facility that is different than the permanent facility assessed and accredited by i.e., IAS. (IAS/TL-CL/026).

PROFICIENCY TESTING (PT): Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons. (ISO/IEC 17025:2017).

QUANTITY VALUE: Number and reference together expressing magnitude of a quantity (JCGM 200:2012).

RANDOM MEASUREMENT ERROR: Component of measurement error that in replicate measurements varies in an unpredictable manner. (JCGM 200:2012).

REFERENCE MATERIAL (RM): Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties. (JCGM 200:2012).

REFERENCE MEASUREMENT STANDARD: Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location. (JCGM 200:2012)

RISK: Effect of uncertainty on objectives (ISO 31000:2018).

REQUIREMENT: Provision that conveys criteria to be fulfilled.

SCOPE OF ACCREDITATION: Specific laboratory activities for which accreditation is sought or has been granted (based on ISO/IEC 17011:2017).

STANDARD PRIMARY: Measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention. ((JCGM 200:2012).

STANDARD SECONDARY: Measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind. (JCGM 200:2012)

STANDARD WORKING: Measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems. (JCGM 200:2012).

STANDARD MEASUREMENT UNCERTAINTY: Measurement uncertainty expressed as a standard deviation. (JCGM 200:2012).

STATEMENTS OF UNCERTAINTY: Statement on the calibration certificate or test report of the value of measurement uncertainty for any specific test or calibration.

SYSTEM OF QUANTITES: Set of quantities together with a set of noncontradictory equations relating those quantities. (JCGM 200:2012).

SYSTEMATIC MEASUREMENT ERROR: Component of measurement error that in replicate measurements remains constant or varies in a predictable manner. (JCGM 200:2012).

TEST UNCERTAINTY RATIO: The ratio of the span of the tolerance of a measurement quantity subject to calibration, to twice the 95% expanded uncertainty of the measurement process used for calibration. (ANSI/NCSL Z540.3-2006 (R2013).

TRACEABILITY: see Metrological Traceability definition.

TYPE A EVALUATION OF MEASUREMENT UNCERTAINTY: Evaluation of a component of measurement uncertainty by a statistical analysis of measured quantity values obtained under defined measurement conditions. (JCGM 200:2012).

TYPE B EVALUATION OF MEASUREMENT UNCERTAINTY: Evaluation of a component of measurement uncertainty determined by means other than a Type A evaluation of measurement uncertainty. (JCGM 200:2012).

UNCERTAINTY BUDGET: Statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination. (JCGM 200:2012).

UNCERTAINTY OF MEASUREMENT (MoU): see measurement uncertainty.

VALIDATION: Confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements have been fulfilled. (ISO/IEC 17000:2020).

VERIFICATION: Confirmation of truthfulness through the provision of objective evidence that specified requirements have been fulfilled. (ISO/IEC 17000:2020).

REFERENCES

ANSI/NCSL Z540.3-2006(R2013): American National Standard for Calibration—Requirements for the Calibration of Measuring and Test Equipment (withdrawn October 2020)

ASQ: The Measurement Quality Division (2012) The Metrology Handbook, Second Edition, (Jay L. Bucher Ed.), ASQ Quality Press

IAS/ADM/052: IAS Guidance on Classification of Findings

IAS/TL-CL/026: IAS Policy on Off-Site Testing/Calibration

ILAC-P14:09/2020: ILAC Policy for Measurement Uncertainty in Calibration

ISO 19011:2018: Guidelines for auditing management systems

ISO 31000:2018: Risk Management - Guidelines

ISO/IEC Guide 2:2004: Standardization and Related Activities – General Vocabulary

ISO/IEC 17000:2020: Conformity assessment – Vocabulary and general principles

ISO/IEC 17011:2017: Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC 17021-1:2015: Conformity assessment — Requirements for bodies providing audit and certification of management systems

ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories

JCGM 100:2008: Evaluation of Measurement Data – Guide to the expression of uncertainty in measurement (GUM)

JCGM 200:2012: International Vocabulary of metrology – Basic and general concepts and associated terms (VIM)

Source IAS/TL-CL/013 February 15, 2022 (https://www.iasonline.org/wp-content/uploads/2022/02/IAS_TL-CL_013-IAS-Calibration-lab-definitions-20220215.pdf)

Abstract

Testing Laboratory accreditation is a procedure by which an authoritative body (accreditation body) gives formal recognition of technical competence for specific tests (physical, chemical, microbiological, mechanical, electrical etc. / measurements), based on third party assessment and following international standards and especially the International Standard ISO/IEC 17025:2017. The accreditation of testing laboratories improves facilitation of accurate and rapid diagnostics, efficiency of treatment and reduction of errors in the laboratory process. With conformance according to International Standard ISO/IEC 17025:2017 laboratories be enabled to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world. Accreditation is important because helps determine if an institution meets or exceeds minimum standards of quality and helps students, individuals, entities etc. to determine acceptable institutions for enrollment and proves that a laboratory has an acceptable quality management system in place, and it has the ability and competence to provide testing and calibration results. We have researched the market and found out what are the accreditation criteria for testing laboratories, from large and globally recognized accreditation bodies, under the auspices of the Global Accredited Laboratories Accreditation Agency (ILAC). In the literature, there was no systematic approach to how compliance of the Management Systems of testing laboratories can be achieved and how the accreditation criteria should be met, the accreditation bodies assume. The methodology used for this work is the research on the requirements of the International Standard concerning the Management System, through the application of the GAP analysis tool, taking into account a specific case study of testing laboratory that perform chemical and microbiological tests. Forms and compliance procedures, drawn from already accredited laboratories are given in the Appendix. The results obtained through the application of the GAP analysis tool ensure the adequacy of the Management System of the testing laboratory, which is the most basic condition for its accreditation. The results will additionally describe the ways for the compliance of the testing

laboratories, regarding the rest of the accreditation criteria, in this particularly case study. Using the results and methodology provided in this thesis, a testing laboratory candidate for accreditation or a laboratory that is accredited but wants to improve its compliance can successfully implement and maintain a successful and fully compliant management system.

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List of Abbreviations

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CERTIFIED REFERENCE MATERIAL (CRM): Reference material accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures. (JCGM 200:2012).

CIPM: International Committee for Weights and Measures IAS/TL-CL/013 February 15, 2022 Page 3 of 8.

IAF: International Accreditation Forum. The world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment. (https://www.iaf.nu).

ILAC: International Laboratory Accreditation Cooperation. The international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO IAS/TL-CL/013 February 15, 2022 Page 4 of 8 15189), inspection bodies (using ISO/IEC 17020), proficiency testing providers (using ISO/IEC 17043) and reference material producers (using ISO 17034). (https://ilac.org/about-ilac/).

INTERLABORATORY COMPARISON (ILC): Organization, performance, and evaluation of tests or calibrations on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions. (ISO/IEC 17025:2017).

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names and symbols, together with rules for their use, adopted by the General Conference of Weights and Measures (CGPM). (JCGM 200:2012).

MANAGEMENT REVIEW (MR): Review by laboratory management of its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of the ISO/IEC 17025 standard. (Based on ISO/IEC 17025:2017).

MANAGEMENT SYSTEM (MS): The way in which an organization manages the interrelated parts of its business in order to achieve its objectives. (https://www.iso.org/management-systemstandards.html).

MRA: Mutual Recognition Arrangement. For example, through the ILAC MRA, ILAC aims to demonstrate the equivalence of the operation of its Member Accreditation Bodies. As a consequence, the competence (within the accredited scopes) of laboratories, inspection bodies, proficiency testing providers and reference material producers accredited by these accreditation bodies is demonstrated and recognized by all signatory accreditation bodies. (Based on ILACP4:05/2019).

NATIONAL METROLOGY INSTITUTE (NMI): There is only one NMI in each country, and it maintains that country's national standards and provides traceability to the International System of Units (the SI) at stated levels of confidence – often called measurement uncertainty (https://www.npl.co.uk/resources/q-a/what-is-a-national-metrology-institute) IAS/TL-CL/013 February 15, 2022 Page 6 of 8.

NONCONFORMITY (NCR): non-fulfilment of a requirement (ISO/IEC 17021-1:2015).

PROFICIENCY TESTING (PT): Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons. (ISO/IEC 17025:2017).

REFERENCE MATERIAL (RM): Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties. (JCGM 200:2012).

UNCERTAINTY OF MEASUREMENT (MoU): see measurement uncertainty.

Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

Signature: _____

Date: _____

Acknowledgements

I would like to thank first of all the Management and Staff of the Laboratory mentioned as an example in this Appendix. It was an honour and a great pleasure to work with them for over 6 months. The result was profitable for the laboratory because it already has accreditation.

I would also like to thank my daughter Alexandra, who is the source of inspiration and life for me, that at an old age I decided to carry out my PhD thesis. I have many times gained courage and strength from her constant interventions.

Finally, a very big thank you to my study supervisor Dr. Salvatore Fava for his patience, his tireless and kind contribution and the absolute support I had during the writing of my thesis.

Chapter 1: Introduction

This chapter outlines the background (section 1.1) and context (section 1.2) of the research, and its purposes (section 1.3). Section 1.4 describes the significance and scope of this research and provides definitions of terms used. Finally, section 1.5 includes an outline of the remaining chapters of the thesis.

Accreditation is the independent evaluation of conformity assessment bodies against recognized standards (mainly ISO/IEC 17025:2017) to carry out specific activities to ensure their impartiality and competence. Through the application of national and international standards, government, procurers and consumers can have confidence in the calibration and test results, inspection reports and certifications provided.

Accreditation bodies are established in many economies with the primary purpose of ensuring that conformity assessment bodies are subject to oversight by an authoritative body. Accreditation bodies, that have been peer evaluated as competent, sign regional and international arrangements to demonstrate their competence. These accreditation bodies then assess and accredit conformity assessment bodies to the relevant standards.

The arrangements support the provision of local or national services, such as providing safe food and clean drinking water, providing energy, delivering health and social care or maintaining an unpolluted environment. In addition, the arrangements enhance the acceptance of products and services across national borders, thereby creating a framework to support international trade through the removal of technical barriers.

The international arrangements are managed by ILAC (International Laboratory Accreditation cooperation, https://ilac.org/) in the fields of calibration, testing, medical testing, inspection, proficiency testing providers and reference material producers accreditation and IAF in the fields of management systems, products, services, personnel and other similar programs of conformity assessment. Both

organizations, ILAC and IAF, work together and coordinate their efforts to enhance the accreditation and the conformity assessment worldwide.

The regional arrangements are managed by the recognized regional co-operation bodies that work in harmony with ILAC and IAF (International Accreditation Forum, https://iaf.nu/en/home/). The recognized regional co-operations are also represented on the ILAC and IAF Executive Committees. ILAC works closely with the regional co-operation bodies involved in accreditation, notably EA (European co-operation in Accreditation, https://european-accreditation.org/) in Europe, APAC (https://www.apac-accreditation.org/) in the Asia-Pacific, IAAC (https://www.iaac.org.mx/index.php/en/) in the Americas, AFRAC (https://www.intra-afrac.com/Pages/Home.aspx) in Africa, SADCA (https://www.sadca.org/Pages/Home.aspx) in Southern Africa and ARAC (https://arab-accreditation.org/) in the Arab region.

ISO (the International Organization for Standardization, https://www.iso.org/home.html) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. In the field of conformity assessment, ISO and the International Electrotechnical Commission (IEC) develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO). ISO/IEC 17025:2017 has been developed with the objective of promoting confidence in the operation of laboratories. ISO/IEC17025:2015 document contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results. Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001.

ISO/IEC 17025:2017 requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving

improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed. The use of this document will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures. The acceptance of results between countries is facilitated if laboratories conform to this document. In ISO/IEC 17025:2017, the following verbal forms are used:

- ✓ "shall" indicates a requirement;
- ✓ "should" indicates a recommendation;
- ✓ "may" indicates a permission;
- ✓ "can" indicates a possibility or a capability.

ISO/IEC 17025:2017 standard specifies the general requirements for the competence, impartiality and consistent operation of laboratories. This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel. Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories. The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- ✓ ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*
- ✓ ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

The methodology used for this work is the research on the requirements of the International Standard concerning the Management System, through the application of the GAP analysis tool, taking into account a specific case study of testing laboratory that perform chemical and microbiological tests. Forms and compliance procedures,

drawn from already accredited laboratories are given in the Appendix. The results obtained through the application of the GAP analysis tool ensure the adequacy of the Management System of the testing laboratory, which is the most basic condition for its accreditation. The results will additionally describe the ways for the compliance of the testing laboratories, regarding the rest of the accreditation criteria, in this particularly case study. Using the results and methodology provided in this thesis, a testing laboratory candidate for accreditation or a laboratory that is accredited but wants to improve its compliance can successfully implement and maintain a successful and fully compliant management system.

1.1 BACKGROUND

Accreditation provides the underlying assurance that organizations are adhering to internationally recognized standards. For calibration and testing laboratories, that standard is ISO/IEC 17025:2017. Laboratory test results impact many areas of our daily lives: assurance of safe drinking water, food safety, health care, environmental monitoring, providing energy, mineral exploration and various production processes. Regulators and others rely on the competence of laboratories to deliver the results on which important decisions are made. Accreditation enhances the public confidence in those test results. Increasingly, regulators and suppliers require laboratory test results to be accredited to the ISO/IEC 17025 standard.

Under ISO/IEC 17025:2017, a laboratory's competence is assured via an on-site assessment process and participation in applicable Proficiency Testing programs. The on-site assessment process is a thorough examination of the laboratory's Management System and Quality System. All the quality system elements addressed in ISO 9001 certification are covered. All the technical factors necessary for producing quality data are also examined, including:

- technical competence of staff
- validity and appropriateness of test methods
- suitability, calibration and maintenance of test equipment
- quality assurance of test and calibration data

- records and documents

This on-site assessment process assures that the laboratory is capable of producing accurate, traceable and reproducible data. The process is repeated at regular intervals to ensure the laboratory maintains their capabilities. It is a very intensive process conducted by a team of technical experts from an Accreditation Body.

Accreditation Bodies themselves are also evaluated using internationally recognized standards (ISO/IEC 17011) and are subjected to a similarly rigorous assessment by organizations, such as ILAC. There are recognized accreditation bodies in over 130 countries. While many countries have a single accreditation body, i.e., in Canada, there are two accreditation bodies: Standards Council of Canada (SCC) and the Canadian Association for Laboratory Accreditation (CALA). CALA and SCC work cooperatively to represent Canadian interests on many issues related to international standardization. For example, both organizations have representatives on the ISO committee currently working on updating the 17025 standards. Other countries have another rule.

While the laboratory always had a strong commitment to quality, the first site assessment process for accreditation was a real eye-opener and revealed many shortcomings. Fortunately, the laboratory and laboratory management embraced the accreditation process, especially the commitment to continual improvement, which is an integral part of the ISO standard.

When the extent of accreditation is as large, it becomes embodied within all lab processes. Laboratory staff have a strong awareness of all the various accreditation requirements. It becomes natural to implement these quality requirements in all aspects of laboratory work - even in those processes that are not under the accreditation umbrella. Laboratory clients ultimately benefit from this strong commitment to quality. The unsung laboratory heroes in the accreditation process are the quality assurance (QA) personnel. They devise and implement the systems that make it easier for analysts and others to comply with accreditation requirements. They ensure the necessary records are kept and easily retrievable.

Record-keeping systems have gone from mainly paper records to all manner of electronic record-keeping and everything in-between. While electronic records make some aspects of quality assurance easier, certain other aspects become more difficult. Quality assurance staff ensure that changes to reference methods are incorporated into lab methods and any improvements are appropriately tested and incorporated. In short, they monitor all aspects of change in the lab. It's a process that's never finished.

There are generally no educational programs in universities around the world that teach the subject matter and requirements of accreditation. Accreditation Bodies have commercial departments providing training in various areas of Accreditation, such as Testing Laboratory Accreditation. Only one case of university and Accreditation Body collaboration worldwide was found in the United States of America. Specifically International Accreditation Service (https://www.ias.org) and California State University Dominguez Hills (https://www.csudh.edu/qa-ms/certificates/accreditation-standardization-conformity) has created an educational university program with title “Certificate Program on Accreditation, Standardization and Conformity Assessment”. CSUDH and the IAS have developed a 4-Module Certificate for IAS clients, ICC membership, Assessors, and Subject Matter Experts involved in conformity assessment. The program is for university students/alumni, STEM and technical professionals with practical experience in one or more of the following areas: Quality management, Membership in standards development organizations and Accreditation authorities and the staff of testing and measuring laboratories. This course is delivered via a cohort format consisting of four modules instructed by recognized subject matter experts in their areas of standardization and conformity. Class meetings will take place via Alternate Modality (Zoom) over five weeks and one additional all-day symposium. Delegates must attend all sessions and pass an examination with a score of 70% or better on the final Saturday to receive this certificate. Students must attend all class modules to pass the course. There are no exceptions and there will be no make-up modules.

In this thesis, we will give all the necessary material that one would receive in the specific training program of the Accreditation of Testing Laboratories according

to the requirements of the International Standard ISO/IEC 17025:2017, with a particular focus on the documentation required for the Management System of the Testing Laboratory.

As the signatory of this thesis, I have been professionally involved in accreditation for over 23 years, in the Hellenic Accreditation Body (ESYD-www.esyd.gr) and the American Accreditation Body (IAS) (www.ias.org). Specifically, I am a Lead Assessor in various accreditation schemes (in Management Systems Certification Bodies against the International Standard ISO/IEC 17021-1:2015, in Product and Service Certification Bodies against the International Standard ISO/IEC 17065:2012, in Certification Bodies of Persons against the of International Standard ISO/IEC 17024:2012, in Inspection Bodies against International Standard ISO/IEC 17020:2012, in Clinical Testing Laboratories against International Standard ISO 15189:2022), but with great specialization in Testing and Calibration Laboratories against International Standard ISO/IEC 17025:2017. I have carried out over 1000 assessments of testing laboratories (Chemical, Microbiological and Mechanical Testing) with over 3000 working days in the total of 23 years that I have been working as an «Accreditation Bodies Lead Assessor». In order to obtain the title of "Lead Assessor" I have successfully passed the relevant training programs in the above-mentioned standards, supplementary international standards, supplementary accreditation criteria and accreditation procedures, with successful examinations even in psychometric methods of the assessment process. For this reason, this work is a distillation of knowledge and long-term professional experience.

1.2 CONTEXT

Laboratory accreditation can help laboratories to produce reliable results through implementing the framework of a documented quality system (Beckett and Slay, 2007). Accreditation of the testing and calibration laboratories as per ISO/IEC 17025 standard is the only means to guarantee the reliability of testing laboratories, laboratory management system as per international standard is that the way to give assurance to their customers and also comprising exporters and the business community by providing quality testing and calibrating activities

(Okezue, et al, 2020). Through a laboratory management system, a customer understands that laboratories are showing technical competency for the issuance of authentic, reliable and precise results. Laboratory accreditation enhances the trust and confidence of the customer and they offer the best analytical services to its customers (Memon *et al*., 2020). After the implementation of this international standard, the laboratory will be able to demonstrate that it works with a new framework using modern technology and information technology techniques. Furthermore, the format of this standard has been significantly changed to be more in line with modern ISO formatting guidelines. The standard takes into consideration the newest version of the ISO 9001:2015 standard, to help the implementation of ISO/IEC 17025 in laboratories that have already met the requirements of ISO 9001:2015 (Grochau and Caten, 2012). Laboratories practice ISO/IEC 17025 to implement a high-quality system expected at improving their ability to consistently produce valid results and it's also the premise for accreditation from an accreditation body (Honsa and Mclntye, 2003). Since quality is about competence, accreditation is the official recognition which is an indication of competence. A prerequisite for a laboratory to become accredited is to own a documented quality management system and also the typical contents of the standard operational manuals (SOPs) follow the outline of the ISO/IEC 17025 standard. National Accreditation Bodies are liable for accrediting laboratories to ISO/IEC 17025:2017. Laboratories can use either an area organization or another universally recognized body in cases where the local organization ‘’has either no international recognition or where it lacks recognition in parts of the planet appropriate to the laboratory’s operations’’ Laboratories usually select a variety of common and sometimes used methodologies that might readily advantage and demonstrate a comprehensive quality system that those methodologies run under.

Quality is a comprehensive topic, and it indeed cannot be covered thoroughly within this project, therefore focused on three significant angles that could help the process of implementing quality systems become easier

1.3 PURPOSES

Testing Laboratories shall be conformed against to ISO/IC 17025:2017 standard requirements, with construction of a quality manual, and also the company's readiness for accreditation. The main objectives of this study are to identify and analyze the gaps and also implement the ISO/IEC 17025:2017 quality management system in conformance with the standard. The key data was collected through questionnaires, interviews, observations and study of internal documents. The secondary data was collected from reliable sources of information, including guidebooks and standards linked to the study. As well as this study use gap analysis techniques compare to the existing situations with the expected conditions. It gives a quantitative approach to the research. According to the outcomes, any laboratory should be mostly compliant with the standard, and there was a need for slight modifications or updates in the system to be fully conformed.

The purpose of this work is to provide all the relevant reliable information and guidance, for the necessity of the accreditation of the laboratories, for compliance with the relevant international standards and for proposals to achieve the previous ones.

1.4 SIGNIFICANCE, SCOPE AND DEFINITIONS

The question on what were the key causes for implementing ISO/IEC 17025:2017 solicited the following answer categories; improving the quality of the goods and services, to streamline procedures and simplify work processes, decreasing client complaints and getting access to more work contracts (Shaltout and Gad, 2019). Respondents acknowledged the fact that there is pressure to get ISO/IEC 17025:2017 accreditation because it provides the access to more contracts as some holding organizations prefer using accredited laboratories but improving the quality of the products and services was the key cause stated by respondents. The conclusion from the responses was most of the reasons furnished are somehow interconnected. Better services would lead to fewer client complaints (Cebekhulu and Mugova, 2017).

Reduced client complaints, enhanced testing productivity, enhanced quality

of services and increased efficiency of projects are the key benefits of the implementation of ISO 17025 (Wierzowiecka, 2013). The benefits of applying ISO/IEC 17025:2017 stated by interviewees, survey respondents and what is normally found in literature was more or less the same (Zapata- García *et al*., 2007). The significance of each of those benefits varied from one organization to another. One organization might have product enhancement as their key benefit where another organization might have reduced client complaints as theirs. The possibility of achieving other benefits is an added incentive (Cebekhulu, 2012).

In the literature, there was no systematic approach to how compliance of the Management Systems of testing laboratories can be achieved and how the accreditation criteria should be met, the accreditation bodies assume. The methodology used for this work is the research on the requirements of the International Standard concerning the Management System, through the application of the GAP analysis tool, taking into account a specific case study of testing laboratory that perform chemical and microbiological tests. Forms and compliance procedures, drawn from already accredited laboratories are given in the Appendix. The results obtained through the application of the GAP analysis tool ensure the adequacy of the Management System of the testing laboratory, which is the most basic condition for its accreditation. The results will additionally describe the ways for the compliance of the testing laboratories, regarding the rest of the accreditation criteria, in this particularly case study. Using the results and methodology provided in this thesis, a testing laboratory candidate for accreditation or a laboratory that is accredited but wants to improve its compliance can successfully implement and maintain a successful and fully compliant management system.

1.5 THESIS OUTLINE

In Chapter 2 will see the literature and International Standards review requirement, will demonstrate a thorough knowledge of the area and will provide arguments to support my study focus. In literature review and International Standards chapter, will delineate various theoretical positions and from these to

develop a conceptual framework for generation of hypotheses in my case study (See Appendix) and will be setting up the research question.

In Chapter 3 will outline the design and methodology of the research. Case Study will be the basis for my choice of research method (see in Appendix).

Chapter 4 details all the results of my study. I put some analysis of the results but generally just the results are presented, without interpretation, inference, or evaluation (which will be in Chapter 5). The results will be linked inextricably to the design – describe what happened factually and unemotively.

Chapter 5 will be containing a full discussion, interpretation and evaluation of the results with reference to the literature and International Standards.

And finally, Chapter 6, will be containing conclusions, limitations, and recommendations and discussion of where the study may be extended.

Chapter 2: Literature and International Standards Review

This Chapter is literature and International Standards review chapter, we will demonstrate a thorough knowledge of the area and we will provide arguments to support of this study focus. In this literature review and International Standards chapter, we will delineate various theoretical positions and from these to develop a conceptual framework for generation of hypotheses in the case study (see Appendix) and we will be setting up the research question. In literature review chapter we will do:

- A critical evaluation of the literature rather than merely describes previous literature (i.e., what is good/bad about the body of literature).
- We will show a synthesis and will be integrated rather than being more like an annotated bibliography.
- We will identify the key organizations and the key works in the area, thus acquainting the reader with existing studies relative to what has been found, who has done work, when and where latest research studies were completed and what approaches to research methodology were followed (literature review of methodology sometimes saved for chapter on methodology).
- We will constitute an argument.
- We will clearly identify the gap in the literature that is being addressed by the research question.

The sources for the literature review will be include:

- General integrative reviews cited that relate to the problem situation
- Specific International Standards, books, monographs, bulletins, reports, and research articles – preference shown in most instances for literature of the last 10 years.

- Unpublished materials (e.g., dissertations, theses, papers presented at recent professional meetings not yet in published form, etc.).

This literature review chapter will be arranged in terms of the questions to be considered or objectives/purposes set out in the above Introduction chapter.

We will start with an overview of this chapter by outlining the topics to be discussed.

This chapter will begins with a historical background (section 2.1) and reviews literature and International Standards on the following topics: [topic 1] (section 2.2) [International Standards]; [topic 2] (section 2.3) [Recognized Accreditation Bodies]; and [topic 3] (section 2.4) [Requirements for conformance regarding accreditation of testing laboratories]. And finally, Section 2.5 highlights the implications from the literature and develops the conceptual framework for the study.

2.1 HISTORICAL BACKGROUND

2.2 TOPIC 1 – INTERNATIONAL STANDARDS

As mentioned, the ISO/IEC 17025 standard proposes the enactment of a Quality Management System (QMS) for laboratories which wish to show their competence, thus being adopted by many laboratories around the globe.

Currently, the standard is on its third version as an actual standard, and its origin comes from documents issued as Guides in the last decades of the previous century. The document titled "*ISO Guide 25: Guidelines for assessing the technical competence of testing laboratories*" is considered the first document related to the standard in its current version. This document was issued by ILAC (International Laboratory Accreditation Cooperation) on October 01st 1978.

ILAC is an international cooperation, whose members are accreditation bodies for laboratories according to the current standards, with representatives in more than 70 countries. This cooperation started in October 1977, seeking to develop international cooperations, turning market easier by promoting acceptance of accredited test and calibration results.

The ISO Guide 25 did not address calibration laboratories, only testing laboratories. In the document, there were general guidelines so the laboratories

could prove their technical competences. Still, the Guide allowed the evaluation bodies to ask for other requirements other than the ones already stated in the Guide's text.

The requirements stated in the ISO Guide 25 were: organization, staff, protection, testing and measuring equipment, calibration, test methods and procedures, environment, safety, handling of items to be tested, records and test reports

Such guide was replaced by the "*ISO/IEC Guide 25: General requirements for the technical competence of testing laboratories*", in December 12th 1982. The document presented itself as both an ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission) document.

The ISO is an independent, non-governmental, international organization, made of members from 162 countries. It was created in 1947 to ease international coordination and to unify industrial standardization. Nowadays it has 784 technical committees and subcommittees responsible for the development of international standards.

The IEC, created on 1906, is a worldwide organization that creates and publishes international standards in the electrotechnical area. When plausible, both organizations unite to assure the construction of international standards, which are complementary to each other due to the collaboration between correlated professionals.

The ISO/IEC Guide 25 still used to address only testing laboratories and mentioned, in the "Scope and field of application" topic, that it could be used by accreditation and certification bodies, governmental and non-governmental bodies related to the technical competence of laboratories.

The requirements stated in the previous document were: organization, quality system, staff, testing and measuring equipment, calibration, test methods and procedures, environment, safety, handling of items to be tested, records and test reports. It must be noticed that, when comparing it with ISO Guide 25, the quality system requirement was added.

As mentioned, at the time, international guides only involved testing laboratories until, in 1990, the "*ISO/IEC Guide 25: General requirements for the competence of calibration and testing laboratories*" was published.

This version of the ISO Guide 25 shows the effort from ISO/ CASCO to publish documents that allow laboratory certification to be made based on internationally established documents. The CASCO (Council Committee on Conformity Assessment) is responsible for the documents' issuance, gained by consensus from the Committee itself supported by the ISO and IEC Councils. The purpose of such efforts is to provide support for national systems, thus easing bilateral agreements.

The requirements stated in this version of the ISO Guide 25 were: organization and management, quality system, audit and critical analysis, staff/personnel, facilities and environment, equipment and reference material, measurement and calibration trackabilities', calibration and test methods, handling of the calibration and test items, records and certificates and reports. The Guide also emphasized that by meeting these criteria, the laboratories would meet the criteria of the ISO 9000 standard.

The ISO Guide 25 was the last written version of this document as a Guide, even though, according to Van de Leemput, it had already been written in the standard format by using vocabulary like "shall" and "must" instead of "should" and "may". This document was replaced on 1999 by the standard "*ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories*".

A revision request sent to ISO, on 1993, made by the European Technical Committee on Conformity Assessment after the Guide's failure to replace the prevailing European document on technical competence and laboratory accreditation. On 1994, CASCO decided in favor to revise the Guide after a meeting with the stakeholders. In order to successfully revise the Guide, the main principle was that the new document should allow laboratories to display their competence, whether they were interested in accreditation or not.

Despite the new principle, only the revised Guide's requirements were used as criteria for accreditation.

The revision process took around 6 years, when drafts were written, discussed and voted on. During the process, it was decided that, if IEC approved the document, its prefix would be ISO/IEC. On November 1999, the document got 95% approval rate, being published on December 15th 1999.

Also, during the process, it was agreed that the revised document's relation with ISO 9001 should be clear, with no ambiguity, and its text should cover all aspects of ISO 9001. With this provision, a laboratory which met ISO/IEC 17025 requirements would meet the ISO 9001 requirements too.

It was decided that the new document's requirements would be divided in two categories: management requirements and technical requirements. The ISO/IEC 17025:1999 was divided as follows: 1. Objective; 2. Normative References; 3. Terms and definitions; 4. Management requirements; 5. Technical requirements; Annex A; Annex B; References.

The requirements of item 4, management requirements, addressed the following topics: organization (4.1); quality system (4.2); document control (4.3); review of requests, tenders and contracts (4.4); subcontracting of tests and calibration (4.5); service and supply purchase (4.6); customers' service (4.7); complaints (4.8); non-compliant tests and/or calibration work control (4.9); corrective action (4.10); preventive action (4.11); record control (4.12); internal audits (4.13); review by management (4.14).

The requirements of item 5, technical requirements, addressed the following topics: general (5.1); staff (5.2); facility and environmental conditions (5.3); test and calibration methods and method validation (5.4); equipment (5.5); metrological traceability (5.6); sampling (5.7); handling of test and calibration items (5.8); quality assurance of tests and calibration results (5.9); reporting of results (5.10).

According to Van de Leemput, ISO 9001 norm was also under revision and the publication of its new version was due in 2000. Nevertheless, the ISO/IEC 17025 was issued in 1999 based on the ISO 9001 norm of 1994. Even though the latter norm would be outdated in a short time, the ISO/IEC 17025 was published in 1999 due to

the large demand for it and the illogicality of being based on an unfinished, future norm.

Therefore, on May 2005, the new version of ISO/IEC 17025 was published, and it fit the revision of the ISO 9001 norm, published in 2000. There are no fundamental differences between the 1999 and 2005 version of the norm. Some of the differences are: highlighting of the continuous improvement of the quality management system; more emphasis on establishing effective communication with the customer; use of data to assess the performance of the quality management system and to identify improvement opportunities.

The 2005 version had the following division: 1. Objective; 2. Normative references; 3. Terms and definitions; 4. Management board requirements; 5. Technical requirements; Annex A; Annex B; References.

The requirements of item 4, management board requirements, addressed the following topics: organization (4.1); management system (4.2); document control (4.3); review of requests, tenders and contracts (4.4); subcontracting of tests and calibrations (4.5); service and supply acquisition (4.6); customer service (4.7); complaints (4.8); non-compliant test and/or calibration work control (4.9); improvement (4.10); corrective action (4.11); preventive action (4.12); record control (4.13); internal audits (4.14); review by management board (4.15).

The requirements of item 5, technical requirements, addressed the following topics: general (5.1); personnel (5.2); facility and environmental conditions (5.3); test and calibration methods and method validation (5.4); equipment (5.5); metrological traceability (5.6); sampling (5.7); handling of test and calibration items (5.8); quality assurance of test and calibration results (5.9); reporting of results (5.10).

On the 2005 version of the document, it is possible to notice that the management requirements are assigned to the management board instead to the managers. Due to the focusing of the continuous improvement of the QMS, the topic “Improvement” was added to the management requirements (item 4).

A new and last since today version of the ISO/IEC 17025 was issued on 2017 in order to update and align it to other current norms, including the ISO 9001. To this purpose, the new version included requirements for competency, impartiality, and consistent laboratory operation. The new document has a different structure compared to the older version, and it is not divided into management requirements and technical requirements. The 2017 version is divided as follows: 1. Scope; 2. Normative references; 3. Terms and definitions; 4. General requirements; 5. Structural requirements; 6. Resource requirements; 7. Process requirements; 8. Management system requirements; Annex A; Annex B; References/bibliography.

The newest version is more process-focused instead of the older procedural focus, decreasing the number of required policies and procedures. The Quality Manual is now optional, letting the laboratory decide to establish it or not. The division between technical management and quality management was replaced by the laboratory general responsibility management.

In General requirements, the norm stablishes specific requirements for impartiality and for confidentiality, stressing their importance, in consideration that they are not restricted to the laboratory policies. This version also emphasizes risk management, pointing out the need for risk identification in many of the norm's requirements.

The development of the document in all its version and publications are displayed on Table 1.

Table 1. History of the ISO/IEC 17025 standard

Version	Year	Type	Document name
First	1978	Guide	ISO Guide 25: Guidelines for assessing the technical competence of testing laboratories
Second	1982	Guide	ISO/IEC Guide 25: General requirements for the technical competence of testing laboratories
Third	1990	Guide	ISO/IEC Guide 25: General requirements for the competence of calibration and testing laboratories
Fourth	1999	Norm	ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
Fifth	2005	Norm	ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
Sixth	2017	Norm	ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories

The 2017 version presents a definition for "Laboratory", in which it is defined as a body that performs at least one of the three activities that are presented as "laboratory activity": testing, calibration and sampling followed by testing or

calibration (3.6). It is noticeable that sampling is presented as a laboratory activity.

The concepts of impartiality and independency are differentiated (3.1), and the requirements about impartiality (4.1) and confidentiality (4.2) must be aligned with ISO/CASCO orientation. Furthermore, the risk-based thinking is implemented, in alignment with the ISO 9001 new version (2015). This proposes the monitoring of risks associated with impartiality and laboratories activities. It is suggested classifying the appointed risks according to seriousness and tracking them with the intention of maintaining them under control (8.5). The term "decision rule" is introduced and it states that the laboratory has to define and apply some criteria in order to decide if the obtained result fulfills the requirements, in view to attend the client's demands (7.1.3).

Requirements now focus on the outcome, ensuring quality work and validity of result, which provides more flexibility to laboratories. Besides, the requirements deal with the processes of laboratory activities, looking for a consistent approach on the process and oriented, in the document, by the necessity of documentation of the laboratory's requirements, retention of records and effective communication with people and organizations affected.

This new version has put attention in the technology advance, considering electronic management of data and information (7.11). Lastly, the document was restructured, and the requirements are now organized in different sections: according to the content division of the 2017 norm, the obligatory requirements for laboratories are described in the sections: 4. General requirements; 5. Structural requirements; 6. Resource requirements; 7. Process requirements, and 8. Management system requirements.

The requirements are grouped based on their characteristics. It can be visualized on Figure 1 how they correlate to each other to create a QMS, which has the purpose to meet all proposed requirements. Therefore, Figure 1 is a graphic representation of ISO/ IEC 17025:2017, with the objective of making the norm's requirement groups easier to understand.

The requirements which belong to Section 5, Structural requirements, address the aspects that make the laboratory capable of doing its activities, the latter being considered the base of the QMS. On Figure 1, the laboratory structure is represented in a way that it encompasses all requirements left. The next group to be represented is Section 4, General requirements, which addresses impartiality and confidentiality in the development of the laboratories' activities, setting up the risk to impartiality management in a continuous manner. On Figure 1, this section is located with the structural requirements group.

After the definition of the QMS basic parts, the management processes are represented. They guide and encompass all laboratory activities developed by the laboratory. These processes are represented in lilac, are separated in four blocks, and encircle the remaining requirements. These processes must be executed in the same manner for all tests addressed by the QMS, while other requirements might be specific depending on the laboratory activity. Most of these processes are requirements of Section 8, Management requirements, and include some requirements of Section 7, Process requirements.

Inside the representation of the management processes are the processes directly related to the execution of laboratory activities, that may be specific. The Figure 1 represents a laboratory whose activities are restricted to tests only, excluding sampling activities. The processes represented by blue correspond to the Section 6 requirements, Resource requirements, and the processes in yellow correspond to the Section 7, Process requirements. These processes are placed in order to clarify how both resource and process requirements correlate to each other.

In order to compare the 2017 version with the previous one (2005), it can be stated that the management requirements, previously categorized in section 4, are now reorganized within sections 4, 5 and 8; and the technical requirements, previously categorized in section 5, are now reorganized within sections 6 and 7.

Given all the main changes between the 2005 and 2017 versions mentioned above, it is concluded that the new version of the norm proposes a more efficient

management system, reducing the number of mandatory procedures and not requiring a quality manual, but focuses on consistent processes, with personnel able to perform them and maintain objective evidence of activities duly recorded. This new proposition may help laboratories to create and implement a QMS consistent with its own reality, according to the size of the personnel of each laboratory and the activity it develops (calibration or testing in multiple areas, such as environment, forensics, food and others). Also, the risk management is proposed to help laboratories assure the quality of its activities once the risk to laboratory activities and impartiality are now duly monitored and treated. In addition, this new version highlights the importance of meeting the customer demands through the adoption of a decision rule to report a final result. Focusing on the importance of the measurement provided by the laboratory to the customers' interests, this position reinforces the importance of laboratories to provide reliable and traceable results to support the decision making in different situations. In this way, ISO/IEC 17025 proposes a QMS through the requirements established and mentioned above to prove the technical competence and ensure the quality of the results produced by the laboratory. The use of this document can be presented as a tool to assist the implementation of the Quality concept in testing and calibration laboratories.

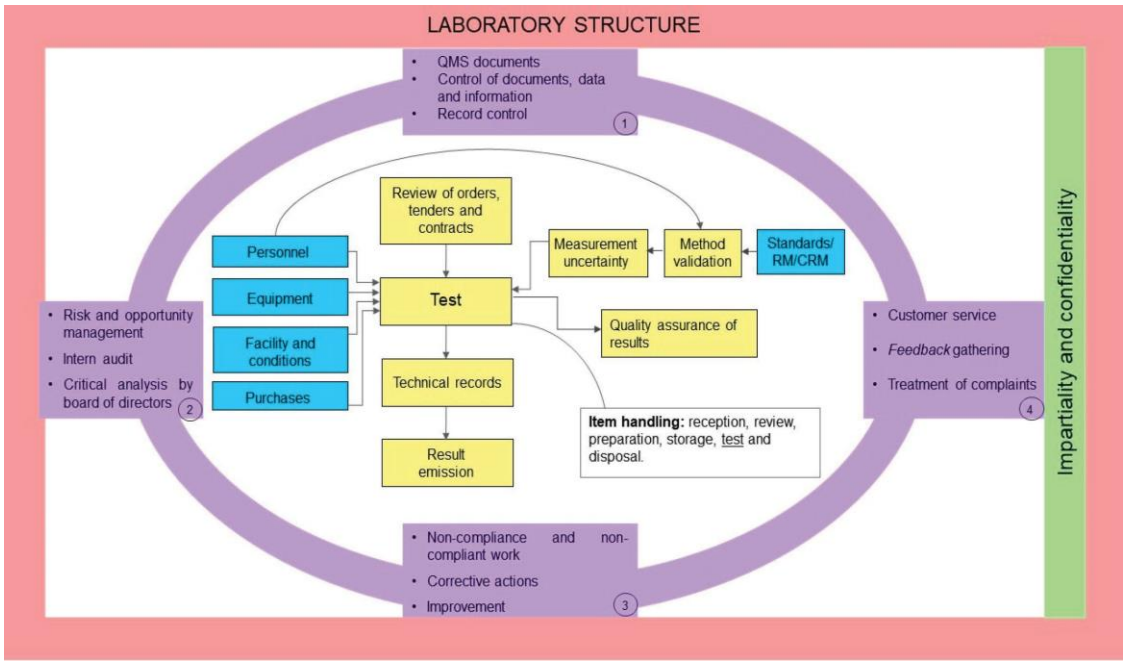

Figure 1. *Graphic representation of ISO/IEC 17025:2017*

2.3 TOPIC 2 – RECOGNIZATED ACCREDIATATION BODIES

Signatories to the ILAC Mutual Recognition Arrangement

No.	Accreditation Body	Economy		Scope	Original Signing Date
1	General Directorate of Accreditation (DPA)	Albania	1	Testing ISO/IEC 17025 Inspection ISO/IEC 17020	16 May 2016 16 Jul 2018
2	Algerian Accreditation Body (ALGERAC)	Algeria	2	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	15 Oct 2017 15 Oct 2017 15 Oct 2017
3	Organismo Argentino de Acreditacion (OAA)	Argentina	3	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	11 Aug 2005 11 Aug 2005 26 Oct 2013
4	National Association of Testing Authorities, Australia (NATA)	Australia	4	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 13 Jan 2016 02 Nov 2000 24 Oct 2012 17 Oct 2019 27 Jul 2020
5	Joint Accreditation System of Australia and New Zealand (JAS-ANZ)	Australia/New Zealand	4	Inspection ISO/IEC 17020	07 Nov 2012

6	Akkreditierung Austria (Akkreditierung)	Austria	5	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	22 Sept 2002 22 Sept 2002 24 Oct 2012

7	Bangladesh Accreditation Board (BAB)	Bangladesh	6	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	09 Mar 2015 09 Jan 2020 29 Jun 2015 09 Jan 2020
8	Belarusian State Centre for Accreditation (BSCA)	Belarus	7	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Testing ISO 15189 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	05 Oct 2018 05 Oct 2018 05 Jun 2020 05 Jun 2020 05 Jun 2020
9	(e) (p)Belgian Accreditation Structure (BELAC)	Belgium	8	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	01 Aug 2006 01 Aug 2006 29 Mar 2013 12 Jun 2019

					23 Mar 2022
10	Institute for Accreditation of Bosnia and Herzegovina (BATA)	Bosnia and Herzegovina	9	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	21 Nov 2012 17 Mar 2022 21 Nov 2012 21 Nov 2012

11	Southern African Development Community Accreditation Service (SADCAS)	BOTSWANA Angola Comoros Congo Lesotho Madagascar Malawi Mozambique Namibia Seychelles Swaziland Tanzania Zambia Zimbabwe	10 11 12 13 14 15 16 17 18 19 20 21 22 23	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	04 Nov 2015 28 Oct 2017 04 Nov 2015 28 Oct 2017
12	[(f)]Coordenação Geral de Acreditação General Coordination for Accreditation (CGCRE)	Brazil	24	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 27 Feb 2013 18 Aug 2020 28 Jul 2021

13	Executive Agency Buldgarina Accreditation Service (EA BAS)	Bulgaria	25	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	04 Oct 2016 04 Oct 2016 04 Oct 2016
14	Cambodian Accreditation National Council- General Department of Accreditation of Cambodia (CANC-GDAC)	Cambodia	26	Testing ISO/IEC 17025	22 Aug 2023
15	(r)Canadian Association for Laboratory Accreditation Inc. (CALA)	Canada	27	Testing ISO/IEC 17025	17 Nov 2005
16	(ee)Accreditation Canada Diagnostics	Canada	27	Testing ISO 15189	05 Dec 2012
17	Standards Council of Canada (SCC)	Canada	27	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	02 Nov 2000 02 Nov 2000
18	Instituto Nacional de Normalización (INN)	Chile	28	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	08 Oct 2010 08 Oct 2010 08 Aug 2016
19	(b) (o)China National Accreditation Service for Conformity Assessment (CNAS)	People's Republic of China	29	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 10 Oct 2019 22 Jul 2020
20	Hong Kong Accreditation Service (HKAS)	China, Hong Kong	30	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 02 Oct 2019 22 Jul 2020
21	Organismo Nacional de Acreditación de Colombia (ONAC)	Colombia	31	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Proficiency Testing Providers ISO/IEC 17043	07 Apr 2014 19 Sep 2019 07 Apr 2014 29 Jun 2020

22	Ente Costarricense de Acreditación (ECA)	Costa Rica	32	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	16 Jan 2007 11 Sep 2017 22 Mar 2010 24 Oct 2012
23	Systéme Ouest Africain d'Accréditation (SOAC WAAS)	COTE D'IVOIRE Benin Burkina Faso Guinea Bissau Mali Niger Senegal Togo	33 34 35 36 37 38 39 40	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	10 May 2022 10 May 2022
24	Croatian Accreditation Agency (HAA)	Croatia	41	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	29 Apr 2010 29 Apr 2010 24 Oct 2012
25	National Accreditation Body of Republica de Cuba (ONARC)	Cuba	42	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	17 Sep 2005 17 Sep 2005 29 Mar 2017
26	Cyprus Organisation for the Promotion of Quality (CYS) Cyprus Accreditation Body (CYSAB)	Cyprus	43	Testing ISO/IEC 17025 & ISO 15189 Inspection ISO/IEC 17020 Calibration ISO/IEC 17025	18 Oct 2011 27 Feb 2013 07 Aug 2014
27	Czech Accreditation Institute (CAI)	Czech Republic	44	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 30 May 2019 21 Apr 2020

28	Danish Accreditation Fund (DANAK)	Denmark	45	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 03 Jun 2019 12 Oct 2021
29	Organismo Dominicano de Acreditación (ODAC)	Dominican Republic	46	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	23 Sep 2020 23 Sep 2020 23 Sep 2020
30	Servicio de Acreditación Ecuatoriano (SAE)	Ecuador	47	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	03 Dec 2011 08 Sep 2023 03 Dec 2011 24 Oct 2012
31	[(x)]Egyptian Accreditation Council (EGAC)	Egypt	48	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	10 Oct 2009 02 Apr 2014 10 Oct 2009 02 Apr 2014 02 Jun 2019
32	Organismo Salvadoreño de Acreditacion (OSA)	El Salvador	49	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	19 Dec 2014 17 Mar 2017 09 Oct 2018
33	Non-Profit Association Estonian Centre for Standardisation and Accreditation (EAK)	Estonia	50	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	18 May 2023 18 May 2023 18 May 2023 18 May 2023
34	[(gg)]Ethiopia Accreditation Service (EAS)	Ethiopia	51	Testing ISO/IEC 17025 & ISO 15189 Inspection ISO/IEC 17020	28 Oct 2017 23 Oct 2019

35	[g]Finnish Accreditation Service (FINAS)	Finland	52	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	02 Nov 2000 02 Nov 2000 24 Oct 2012 28 May 2019
36	Comite Francais d'Accreditation (COFRAC)	France	53	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 20 Jun 2019 10 Aug 2021
37	Georgian Accreditation Center - The Unified National Body of Accreditation (GAC)	Georgia	54	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	13 May 2022 13 May 2022 13 May 2022 28 Jul 2023
38	**(w)** Deutsche Akkreditierungsstelle GmbH (DakkS)	Germany	55	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 07 Jun 2019 22 Apr 2020
39	[j] Hellenic Accreditation System (ESYD)	Greece	56	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	22 May 2004 22 May 2004 30 Nov 2012 04 Jun 2019
40	[jj] Oficina Guatemalteca de Acreditación (OGA)	Guatemala	57	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	26 Jun 2008 14 Mar 2012 02 Apr 2013

41	National Accreditation Authority (NAH)	Hungary	58	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	11 Nov 2016 11 Nov 2016 11 Nov 2016 09 May 2017 24 Jun 2019
42	Federation for Development of Accreditation Services (FDAS)	India	59	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	28 Aug 2023 28 Aug 2023
43	National Accreditation Board for Testing and Calibration Laboratories (NABL)	India	59	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 03 Oct 2019 22 Jul 2020
44	National Accreditation Board for Certification Bodies (NABCB)	India	59	Inspection ISO/IEC 17020	16 Sept 2013
45	Quality and Accreditation Institute, Centre for Laboratory Accreditation (QAI CLA)	India	59	Testing ISO/IEC 17025 Testing ISO 15189	10 Dec 2022 10 Dec 2022
46	National Accreditation Body of Indonesia (KAN)	Indonesia	60	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	20 Jun 2001 14 Mar 2013 30 Dec 2003 24 Oct 2012 03 Oct 2019

47	[(h)]Irish National Accreditation Board (INAB)	Ireland	61	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 17 Apr 2020
48	Israel Laboratory Accreditation Authority (ISRAC)	Israel	62	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	03 Nov 2001 03 Nov 2001 24 Oct 2012
49	[(l)] L'Ente Italiano di Accreditamento (ACCREDIA)	Italy	63	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 07 Oct 2010 07 Nov 2012 03 Jun 2019 20 Apr 2020
50	Jamaica National Agency for Accreditation (JANAAC)	Jamaica	64	Testing ISO/IEC 17025 Testing ISO 15189 Inspection ISO/IEC 17020	31 Aug 2013 18 Sep 2015 25 Mar 2020
51	[(a)]International Accreditation Japan (IAJapan)	Japan	65	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 27 Jul 2020
52	Japan Accreditation Board (JAB)	Japan	65	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 28 Jul 2003 24 Oct 2012 10 Oct 2019 12 Aug 2020
53	Voluntary EMC Laboratory Accreditation Center INC (VLAC)	Japan	65	Testing ISO/IEC 17025	16 Jan 2007
54	Jordan Accreditation & Standardization Systems - Accreditation Unit (JAS-AU)	Jordan	66	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	29 Oct 2017 29 Oct 2017 26 Dec 2021

55	National Center of Accreditation (NCA)	Kazakhstan	67	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025	27 Oct 2010 08 Nov 2018 27 Oct 2010
56	Kenya Accreditation Services (KENAS)	Kenya	68	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	28 Oct 2017 28 Oct 2017 28 Oct 2017
57	Korea Laboratory Accreditation Scheme (KOLAS)	Republic of Korea	69	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 12 Jan 2017 20 Jun 2001 08 Mar 2023 08 Mar 2023
58	[z]The Kyrgyz Center of Accreditation (KCA)	The Kyrgyz Republic	70	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	23 Oct 2013 02 Oct 2018 06 Apr 2022
59	Latvian National Accreditation Bureau (LATAK)	Latvia	71	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	08 Jun 2022 08 Jun 2022 08 Jun 2022
60	Lithuanian National Accreditation Bureau (LA)	Republic of Lithuania	72	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	19 Jan 2018 19 Jan 2018 19 Jan 2018
61	Office Luxembourgeois d'Accréditation et de Surveillance (OLAS)	Luxembourg	73	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	14 Apr 2011 19 Apr 2012 24 Oct 2012
62	Department of Standards Malaysia (Standards Malaysia)	Malaysia	74	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	16 Jan 2003 19 Nov 2003 02 Jul 2015 20 Sep 2021

63	Mauritius Accreditation Service (MAURITAS)	Mauritius	75	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	04 Oct 2018 04 Oct 2018
64	entidad mexicana de acreditación a.c. (ema)	Mexico	76	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	17 Nov 2005 17 Nov 2005 24 Oct 2012 21 Oct 2019 23 Jun 2021
65	National Accreditation Centre from Republic of Moldova (MOLDAC)	Moldova	77	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	11 Oct 2017 11 Oct 2017 11 Oct 2017
66	Mongolian National Authority for Accreditation (MNAS)	Mongolia	78	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	07 Jun 2012 07 Jun 2012 09 Sep 2016
67	Dutch Accreditation Council (RvA)	The Netherlands	79	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 29 May 2019 22 Apr 2020
68	International Accreditation New Zealand (IANZ)	New Zealand	80	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 03 Oct 2019 21 Jul 2020
69	National Accreditation Office (ONA)	Nicaragua	81	Testing ISO/IEC 17025 Inspection ISO/IEC 17020 Calibration ISO/IEC 17025	14 Jan 2015 12 May 2016 16 May 2018

70	[(k)]Norsk Akkreditering (NA)	Norway	82	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	02 Nov 2000 02 Nov 2000 24 Oct 2012 19 Aug 2019
71	Pakistan National Accreditation Council (PNAC)	Pakistan	83	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	21 May 2009 21 May 2009 22 Aug 2019
72	Organismo Nacional de Acreditacion (ONA)	Paraguay	84	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	27 Apr 2012 04 Jul 2022
73	National Institute for Quality (INACAL-DA)	Peru	85	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	15 Apr 2013 15 Apr 2013 15 Apr 2013
74	[(q)]Philippine Accreditation Bureau (PAB)	Philippines	86	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Testing ISO 15189 Inspection ISO/IEC 17020	17 Nov 2005 17 Nov 2005 30 Sep 2019 30 Sep 2019
75	Polish Centre for Accreditation (PCA)	Poland	87	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	19 Jan 2005 19 Jan 2005 24 Oct 2012 29 Jul 2019 28 Dec 2021
76	Instituto Portugues de Acreditacao (IPAC)	Portugal	88	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	10 May 2006 10 May 2006 24 Oct 2012
77	[(dd)]Institute for Accreditation of the Republic of North Macedonia (IARNM)	Republic of North Macedonia	89	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025	19 Apr 2012 06 May 2015 19 Apr 2012

				Inspection ISO/IEC 17020	24 Oct 2012
78	Romanian Accreditation Association (RENAR)	Romania	90	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	22 May 2004 28 May 2009 28 Nov 2013 16 Jul 2019
79	Association of Analytical Centers “Analitica” (AAC “Analitica”)	Russian Federation	91	Testing ISO/IEC 17025 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	21 May 2009 02 Oct 2019 21 Jul 2020
80	Federal Service for Accreditation (RusAccreditation)	Russian Federation	91	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	11 Jul 2017 11 Jul 2017 26 Nov 2021 26 Nov 2021
81	GCC Accreditation Center (GAC)	SAUDI ARABIA Bahrain Kuwait Oman Qatar UAE Yemen	92 93 94 95 96 97 98	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	20 Jun 2016 21 Jul 2021 18 Sep 2018 18 Sep 2018
82	Saudi Accreditation Center (SAAC)	Saudi Arabia	92	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	22 Aug 2021 22 Aug 2021 22 Aug 2021
83	Accreditation Body of Serbia (ATS)	Serbia	99	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	24 May 2012 24 May 2012 24 Oct 2012

84	Singapore Accreditation Council (SAC)	Singapore	100	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	02 Nov 2000 02 Nov 2000 24 Oct 2012 03 Oct 2019
85	Slovak National Accreditation Service (SNAS)	Slovakia	101	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	11 Jun 2001 11 Jun 2001 24 Oct 2012 03 Jun 2019
86	Slovenian Accreditation (SA)	Slovenia	102	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	28 Nov 2003 29 May 2019 28 Nov 2003 24 Oct 2012
87	South African National Accreditation System (SANAS)	South Africa	103	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 11 Dec 2019 17 Apr 2020
88	Entidad Nacional de Acreditacion (ENAC)	Spain	104	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 29 May 2019 17 Apr 2020
89	Sri Lanka Accreditation Board for Conformity Assessment (SLAB)	Sri Lanka	105	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	09 Dec 2009 08 Jun 2012 18 Jan 2016

90	Swedish Board for Accreditation and Conformity Assessment (SWEDAC)	Sweden	106	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043	02 Nov 2000 02 Nov 2000 24 Oct 2012 26 Jun 2019
91	Swiss Accreditation Services (SAS)	Switzerland	107	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 04 Sep 2018
92	[(d)]Taiwan Accreditation Foundation (TAF)	Chinese Taipei	108	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 05 Oct 2019 30 Jul 2020
93	National Bureau of Agricultural Commodity and Food Standards (ACFS)	Thailand	109	Inspection ISO/IEC 17020	03 Jul 2023
94	The Bureau of Laboratory Accreditation, Department of Science Service, Ministry of Higher Education, Science, Research and Innovation (BLA-DSS)	Thailand	109	Testing ISO/IEC 17025 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	23 Aug 2006 07 Oct 2019 21 Jul 2020
95	[(m)]The Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health, Thailand (BLQS-DMSc)	Thailand	109	Testing ISO/IEC 17025 & ISO 15189 Reference Materials Producers ISO 17034	04 Apr 2003 21 Sep 2020
96	[(i) (t) (y) (cc)] National Standardization Council (NSC)	Thailand	109	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	03 Nov 2001 03 Nov 2001 24 Oct 2012

97	Tunisian Accreditation Council (TUNAC)	Tunisia	110	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Apr 2008 02 Feb 2023 02 Apr 2008 06 Oct 2014
98	[(hh)]Turkish Accreditation Agency (TURKAK)	Türkiye	111	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	10 May 2006 10 May 2006 24 Oct 2012 14 Jun 2019 20 Apr 2020
99	[(ff)]National Accreditation Agency of Ukraine (NAAU)	Ukraine	112	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	24 Sep 2014 29 Jan 2021 24 Sep 2014 11 Dec 2014
100	[(bb)] Emirates International Accreditation Centre (EIAC)	United Arab Emirates	97	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	18 Oct 2009 18 Oct 2009 24 Oct 2012
101	[(kk)] Ministry of Industry and Advanced Technology- Emirates National Accreditation System (MoIAT - ENAS)	United Arab Emirates	97	Testing ISO/IEC 17025 Calibrations ISO/IEC 17025	01 Jul 2019 01 Jul 2019
102	United Kingdom Accreditation Service (UKAS)	United Kingdom	113	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 28 May 2019 28 Apr 2020
103	American Association for Laboratory Accreditation (A2LA)	USA	114	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	02 Nov 2000 02 Nov 2000 24 Oct 2012 04 Oct 2019 22 Jul 2020

104	[(s)]ANSI National Accreditation Board (ANAB)	USA	114	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Testing ISO 15189 Proficiency Testing Providers ISO/IEC 17043 Reference Materials Producers ISO 17034	14 Sep 2006 14 Sep 2006 05 Dec 2012 21 May 2019 02 Oct 2019 21 Jul 2020
105	AIHA Laboratory Accreditation Program, LLC (AIHA-LAP, LLC)	USA	114	Testing ISO/IEC 17025	22 Aug 2010
106	[(c)]International Accreditation Service, Inc (IAS)	USA	114	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Testing ISO 15189	02 Nov 2000 09 May 2005 05 Nov 2012 26 Jan 2023
107	National Voluntary Laboratory Accreditation Program (NVLAP)	USA	114	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	02 Nov 2000 02 Nov 2000
108	Perry Johnson Laboratory Accreditation, Inc. (PJLA)	USA	114	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020 Reference Materials Producers ISO 17034 Proficiency Testing Providers ISO/IEC 17043	06 Jun 2008 14 Aug 2019 21 May 2009 18 Jan 2018 15 Oct 2020 24 Jan 2022
109	Organismo Uruguayo De Acreditación (OUA)	Uruguay	115	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	22 Oct 2010 09 Apr 2015
110	Uzbek Center for Accreditation (O'ZAKK)	Uzbekistan	116	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	12 Sep 2022 12 Sep 2022
111	Accreditation Office for Standards Conformity Assessment Capacity (AOSC)	Vietnam	117	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025	11 Sep 2019 13 Sep 2021 11 Sep 2019

112	[(n)]Bureau of Accreditation (BoA)	Vietnam	117	Testing ISO/IEC 17025 Testing ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 05 Dec 2012 02 Nov 2000 24 Oct 2012
113	Vietnam Institute of Accreditation (VACI)	Vietnam	117	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	18 Aug 2023 18 Aug 2023

(a) IAJapan was formed from a restructure of JCSS and JNLA on 1 April 2002.
(b) CNAL was formed from a restructure of CCIBLAC and CNACL on 20 Feb 2003
(c) IAS was formed from a restructure of ICBO on 1 Dec 2002
(d) TAF was formed from a restructure of CNLA on 16 April 2005
(e) BELTEST and BKO/OBE originally signed the MRA
(f) Diretoria de Credenciamento e Qualidade/Instituto Nacional de Metrologia, Normalizacao e Qualidade Industrial (INMETRO) originally signed the MRA
(g) FINAS, Finnish Accreditation Service Centre for Metrology and Accreditation originally signed the MRA. Their name changed to Finnish Accreditation Service (FINAS)
(h) The Irish National Accreditation Board (NAB) originally signed the MRA. NAB changed their name to Irish National Accreditation Board (INAB)
(i) Thai Laboratory Accreditation Scheme (TLAS) originally signed the MRA. TLAS changed their name to TISI
(j) Hellenic Accreditation Council originally signed the MRA. Hellenic Accreditation Council changed their name to Hellenic Accreditation System S.A. (ESYD)
(k) Norwegian Accreditation originally signed the MRA. Norwegian Accreditation changed their name to Norsk Akkreditering (NA)
(l) Sistema Nazionale per l'Accreditamento originally signed the MRA. Sistema Nazionale per l'Accreditamneto changed their name to Sistema Nazionale per l'Accreditamneto di Laboratori (SINAL). ACCREDIA was formed as a result of the incorporation of SINAL and SINCERT and was accepted as signatory to the EA MLA on 29 May 2009 for testing only.
(m) SIT (original signing date – 9 April 2003 for calibration only) was incorporated into COPA. EA MLA signatory status was transferred to COPA on 4 November 2009. Signatory status of COPA to the ILAC MRA was withdrawn effective 21 May 2010 as a result of the termination of COPA's membership in EA as per EA Resolution 2010 (25) 3.
(n) ACCREDIA assumed the responsibilities for the accreditation of calibration laboratories in Italy from July 2010 as COPA was no longer operational. ACCREDIA was accepted as a signatory to the EA MLA for calibration on 7 October 2010.
(o) Bureau of Laboratory Quality Standards (BLQS) Department of Medical Sciences (DMSc) originally signed the MRA. Their name changed to The Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health, Thailand (BLQS-DMSc)
(p) Vietnam Laboratory Accreditation Scheme (VILAS/STAMEQ) originally signed the MRA. Their name changed to Bureau of Accreditation (BoA)
(q) CNAS was formed from the merger of CNAL and CNAB
(r) BELTEST and BKO/OBE ceased to exist on 1 August 2006
(s) PAO was reinstated as a signatory by the APLAC MRA Council for testing and calibration on 10 December 2008. This follows the suspension as a result of the Resolution of the APLAC MRA Council on 5 June 2008 whereby the signatory status for calibration and testing for PAO was suspended.
(t) Canadian Association for Environmental Analytical Laboratories (CAEAL) originally signed the MRA. CAEAL changed its name to Canadian Association for Laboratory Accreditation Inc. (CALA) on 23 June 2008
(u) Assured Calibration and Laboratory Accreditation Select Services was acquired by ANSI-ASQ National Accreditation Board and are now know as ANSI-ASQ National Accreditation Board *doing business as* ACLASS as of 18 September 08. As of 1 January 2012, ANSI-ASQ National Accreditation Board acquired Forensic Quality Services (FQS) a signatory to the ILAC MRA for testing since 10 December 2010 and are now known as ANSI-ASQ National Accreditation Board doing business as FQS. As of 30.01.15, ACLASS/FQS moved to the single branding of ANAB.

(v) TLAS changed their name to National Standardization Council of Thailand – Office of the National Accreditation Council on 29 January 2009.
(w) DakkS was formed from a merger of DGA and DKD in December 2009.
(x) DGA was formed from a merger of Deutsches Akkreditierungssytem Prufwesen (DAP), Deutsche Akkreditierungsstelle (DACH), and Deutsche Akkreditierungsstelle Technik in Trägergemeinschaft für Akkreditierung German Association for Accreditation GmbH (DATech in TGA GmbH).
(y) National Laboratories Accreditation Bureau (NLAB) merged into EGAC as of 28 December 2009.
(z) National Standardization Council of Thailand - Office of the National Accreditation Council (NSC-ONAC) changed their name to National Standardization Council of Thailand - Office of the National Standardization Council (NSC-ONSC) on 27 March 2014.
(aa) The signatory status of KCA to the ILAC MRA for testing (ISO/IEC 17025) was re-instated by Arrangement Council ballot on 2 October 2018.
(ff) The signatory status of NAAU for inspection body accreditation using ISO/IEC 17020 was suspended on 24 March 2021 and re-instated on 6 October 2021 in accordance with IAF/ILAC A2 Annex 7, Clause 1.3 and the decisions of EA.
(gg) Ethiopian National Accreditation Office (ENAO) changed their name to Ethiopia Accreditation Service (EAS).
(hh) Turkey has officially changed its economy name to Türkiye.
(jj) The signatory status of OGA was suspended on 16 March 2023 and re-instated on 30 May 2023 in accordance with IAF/ILAC A2 Annex 7, Clause 1.3 and the decisions of IAAC.
(kk) Emirates National Accreditation System (ENAS) changed their name to Ministry of Industry and Advanced Technology- Emirates National Accreditation System (MoIAT - ENAS) in April 2023

Note: The activities and signatory status of Hungarian Accreditation Board (NAT) were terminated on 31st December 2015.

2.4 TOPIC 3- REQUIREMENTS FOR CONFORMANCE REGARDING ACCREDITATION OF TESTING LABORATORIES

In this topic we will see in detail all the compliance requirements of a testing laboratory regarding the requirements of the International Standard ISO/IEC 17025:2017. We have kept the paragraphs as listed in the International Standard:

General requirements for the competence of testing and calibration laboratories according to ISO/IEC 17025:2017

1 Scope

This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel.

Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide

99 and ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1 Impartiality: presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the *laboratory* (3.6).
Note 2 to entry: Other terms that are useful in conveying the element of impartiality include "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even- handedness", "detachment", "balance".

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words "the certification body" have been replaced by "the laboratory" in Note 1 to entry, and the word "independence" has been deleted from the list in Note 2 to entry.]

3.2 complaint: expression of dissatisfaction by any person or organization to a *laboratory* (3.6), relating to the activities or results of that laboratory, where a response is expected

[SOURCE: ISO/IEC 17000:2004, 6.5, modified — The words "other than appeal" have been deleted, and the words "a conformity assessment body or accreditation body, relating to the activities of that body" have been replaced by "a laboratory, relating to the activities or results of that laboratory".]

3.3 interlaboratory 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

[SOURCE: ISO/IEC 17043:2010, 3.4]

3.4 intralaboratory comparison: organization, performance and evaluation of measurements or tests on the same or similar items within the same *laboratory* (3.6) in accordance with predetermined conditions

3.5 proficiency testing: evaluation of participant performance against pre-established criteria by means of *interlaboratory comparisons* (3.3)

[SOURCE: ISO/IEC 17043:2010, 3.7, modified — Notes to entry have been deleted.]

3.6 laboratory: body that performs one or more of the following activities:

— testing;

— calibration;

— sampling, associated with subsequent testing or calibration

Note 1 to entry: In the context of this document, "laboratory activities" refer to the three above-mentioned activities.

3.7 decision rule: rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

3.8 verification: provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: When applicable, measurement uncertainty should be taken into consideration.

Note 2 to entry: The item may be, for example, a process, measurement procedure, material, compound, or measuring system.

Note 3 to entry: The specified requirements may be, for example, that a manufacturer's specifications are met.

Note 4 to entry: Verification in legal metrology, as defined in VIML, and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.

Note 5 to entry: Verification should not be confused with calibration. Not every verification is a *validation* (3.9).

Note 6 to entry: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

[SOURCE: ISO/IEC Guide 99:2007, 2.44]

3.9 validation: *verification* (3.8), where the specified requirements are adequate for an intended use

EXAMPLE A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum.

[SOURCE: ISO/IEC Guide 99:2007, 2.45]

4 General requirements

4.1 IMPARTIALITY

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management shall be committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This

shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

4.2 CONFIDENTIALITY

4.2.1 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 agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

5 Structural requirements

5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2 The laboratory shall identify management that has overall responsibility for the laboratory.

5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

5.4 Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5.5 The laboratory shall:

a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;

b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;

c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to laboratory management on the performance of the management system and any need for improvement;

e) ensuring the effectiveness of laboratory activities.

5.7 Laboratory management shall ensure that:

a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;

b) the integrity of the management system is maintained when changes to the management system are planned and implemented.

6 Resource requirements

6.1 GENERAL

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

6.2 PERSONNEL

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

6.2.3 The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

6.2.5 The laboratory shall have procedure(s) and retain records for:

a) determining the competence requirements;

b) selection of personnel;

c) training of personnel;

d) supervision of personnel;

e) authorization of personnel;

f) monitoring competence of personnel.

6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a) development, modification, verification and validation of methods;

b) analysis of results, including statements of conformity or opinions and interpretations;

c) report, review and authorization of results.

6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS

6.3.1 The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.

NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.

6.3.3 The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:

a) access to and use of areas affecting laboratory activities;

b) prevention of contamination, interference or adverse influences on laboratory activities;

c) effective separation between areas with incompatible laboratory activities.

6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

6.4 EQUIPMENT

6.4.1 The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the

correct performance of laboratory activities and that can influence the results.

NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.

NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.

6.4.2 When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.

6.4.3 The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.

6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6 Measuring equipment shall be calibrated when:

— the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or

— calibration of the equipment is required to establish the metrological traceability of the reported results.

NOTE Types of equipment having an effect on the validity of the reported results can include:

— those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;

— those used to make corrections to the measured value, e.g. temperature measurements;

— those used to obtain a measurement result calculated from multiple quantities.

6.4.7 The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.

6.4.11 When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.

6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:

a) the identity of equipment, including software and firmware version;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) evidence of verification that equipment conforms with specified requirements;

d) the current location;

e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;

f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;

g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;

h) details of any damage, malfunction, modification to, or repair of, the equipment.

6.5 METROLOGICAL TRACEABILITY

6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the “property of a measurement result whereby the result can be related to a reference through a

documented unbroken chain of calibrations, each contributing to the measurement uncertainty".

NOTE 2 See Annex A for additional information on metrological traceability.

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or

NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or

NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.

6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:

a) certified values of certified reference materials provided by a competent producer;

b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.6 EXTERNALLY PROVIDED PRODUCTS AND SERVICES

6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

a) are intended for incorporation into the laboratory's own activities;

b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;

c) are used to support the operation of the laboratory.

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

6.6.2 The laboratory shall have a procedure and retain records for:

a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;

b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;

d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3 The laboratory shall communicate its requirements to external providers for:

a) the products and services to be provided;

b) the acceptance criteria;

c) competence, including any required qualification of personnel;

d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

7 Process requirements

7.1 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:

a) the requirements are adequately defined, documented and understood;

b) the laboratory has the capability and resources to meet the requirements;

c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;

NOTE 1 It is recognized that externally provided laboratory activities can occur when:

— the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;

— the laboratory does not have the resources or competence to perform the activities.

d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

NOTE 2For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.

7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.

7.1.5 The customer shall be informed of any deviation from the contract.

7.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

7.1.7 The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

NOTE Such cooperation can include:

a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;

b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.

7.1.8 Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

7.2 SELECTION, VERIFICATION AND VALIDATION OF METHODS

7.2.1 Selection and verification of methods

7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

NOTE "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).

7.2.1.3 The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.

7.2.1.4 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.

7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.

7.2.1.7 Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

NOTE Customer acceptance of deviations can be agreed in advance in the contract.

7.2.2 Validation of methods

7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items. NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:

a) calibration or evaluation of bias and precision using reference standards or reference materials;

b) systematic assessment of the factors influencing the result;

c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;

d) comparison of results achieved with other validated methods;

e) interlaboratory comparisons;

f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

7.2.2.4 The laboratory shall retain the following records of validation:

a) the validation procedure used;

b) specification of the requirements;

c) determination of the performance characteristics of the method;

d) results obtained;

e) a statement on the validity of the method, detailing its fitness for the intended use.

7.3 SAMPLING

7.3.1 The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration.

The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

7.3.2 The sampling method shall describe:

a) the selection of samples or sites;

b) the sampling plan;

c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.

NOTE When received into the laboratory, further handling can be required as specified in 7.4.

7.3.3 The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:

a) reference to the sampling method used;

b) date and time of sampling;

c) data to identify and describe the sample (e.g. number, amount, name);

d) identification of the personnel performing sampling;

e) identification of the equipment used;

f) environmental or transport conditions;

g) diagrams or other equivalent means to identify the sampling location, when appropriate;

h) deviations, additions to or exclusions from the sampling method and sampling plan.

7.4 HANDLING OF TEST OR CALIBRATION ITEMS

7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.

7.4.2 The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.

7.4.4 When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

7.5 TECHNICAL RECORDS

7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible,

identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

7.5.2 The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.6 EVALUATION OF MEASUREMENT UNCERTAINTY

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

7.6.3 A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.

7.7 ENSURING THE VALIDITY OF RESULTS

7.7.1 The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;

b) use of alternative instrumentation that has been calibrated to provide traceable results;

c) functional check(s) of measuring and testing equipment;

d) use of check or working standards with control charts, where applicable;

e) intermediate checks on measuring equipment;

f) replicate tests or calibrations using the same or different methods;

g) retesting or recalibration of retained items;

h) correlation of results for different characteristics of an item;

i) review of reported results;

j) intralaboratory comparisons;

k) testing of blind sample(s).

7.7.2 The laboratory shall monitor its performance by comparison with results of

other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;

NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing.

7.7.3 Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

7.8 REPORTING OF RESULTS

7.8.1 General

7.8.1.1 The results shall be reviewed and authorized prior to release.

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.

NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

a) a title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”);

b) the name and address of the laboratory;

c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities;

d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;

e) the name and contact information of the customer;

f) identification of the method used;

g) a description, unambiguous identification, and, when necessary, the condition of the item;

h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;

i) the date(s) of performance of the laboratory activity;

j) the date of issue of the report;

k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;

l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;

m) the results with, where appropriate, the units of measurement;

n) additions to, deviations, or exclusions from the method;

o) identification of the person(s) authorizing the report;

p) clear identification when results are from external providers.

NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.

7.8.2.2 The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a) information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:

— it is relevant to the validity or application of the test results;

— a customer's instruction so requires, or

— the measurement uncertainty affects conformity to a specification limit;

d) where appropriate, opinions and interpretations (see 7.8.7);

e) additional information that may be required by specific methods, authorities, customers or groups of customers.

7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:

a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.

b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

c) a statement identifying how the measurements are metrologically traceable (see Annex A);

d) the results before and after any adjustment or repair, if available;

e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

f) where appropriate, opinions and interpretations (see 7.8.7).

7.8.4.2 Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

7.8.4.3 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with

the customer.

7.8.5 Reporting sampling – specific requirements

Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:

a) the date of sampling;

b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);

c) the location of sampling, including any diagrams, sketches or photographs;

d) a reference to the sampling plan and sampling method;

e) details of any environmental conditions during sampling that affect the interpretation of the results;

f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2 The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

a) to which results the statement of conformity applies;

b) which specifications, standards or parts thereof are met or not met;

c) the decision rule applied (unless it is inherent in the requested specification or standard).

NOTE For further information, see ISO/IEC Guide 98-4.

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.

NOTE It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.

7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

7.8.8 Amendments to reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number… [or as otherwise identified]”, or an equivalent form of wording. Such amendments shall meet all the requirements of this document.

7.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

7.9 COMPLAINTS

7.9.1 The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.

7.9.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken.

7.9.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

NOTE This can be performed by external personnel.

7.9.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

7.10 NONCONFORMING WORK

7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are defined;

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

7.10.2 The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

7.11 CONTROL OF DATA AND INFORMATION MANAGEMENT

7.11.1 The laboratory shall have access to the data and information needed to perform laboratory activities.

7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for

functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

NOTE 1 In this document "laboratory information management system(s)" includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.

NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

7.11.3 The laboratory information management system(s) shall:

a) be protected from unauthorized access;

b) be safeguarded against tampering and loss;

c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

d) be maintained in a manner that ensures the integrity of the data and information;

e) include recording system failures and the appropriate immediate and corrective actions.

7.11.4 When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 The laboratory shall ensure that instructions, manuals and reference data

relevant to the laboratory information management system(s) are made readily available to personnel.

7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

8 Management system requirements

8.1 OPTIONS

8.1.1 General

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B.

NOTE See Annex B for more information.

8.1.2 Option A

As a minimum, the management system of the laboratory shall address the following:

— management system documentation (see 8.2);

— control of management system documents (see 8.3);

— control of records (see 8.4);

— actions to address risks and opportunities (see 8.5);

— improvement (see 8.6);

— corrective actions (see 8.7);

— internal audits (see 8.8);

— management reviews (see 8.9).

8.1.3 Option B

A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.

8.2 MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)

8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.

8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS (OPTION A)

8.3.1 The laboratory shall control the documents (internal and external) that

relate to the fulfilment of this document.

NOTE In this context, “documents” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

8.3.2 The laboratory shall ensure that:

a) documents are approved for adequacy prior to issue by authorized personnel;

b) documents are periodically reviewed, and updated as necessary;

c) changes and the current revision status of documents are identified;

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) documents are uniquely identified;

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

8.4 CONTROL OF RECORDS (OPTION A)

8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.

8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.

NOTE Additional requirements regarding technical records are given in 7.5.

8.5 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES (OPTION A)

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) give assurance that the management system achieves its intended results;

b) enhance opportunities to achieve the purpose and objectives of the laboratory;

c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;

d) achieve improvement.

8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities;

b) how to:

— integrate and implement these actions into its management system;

— evaluate the effectiveness of these actions.

NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

8.6 IMPROVEMENT (OPTION A)

8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

8.6.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities and customer service.

NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

8.7 CORRECTIVE ACTIONS (OPTION A)

8.7.1 When a nonconformity occurs, the laboratory shall:

a) react to the nonconformity and, as applicable:

— take action to control and correct it;

— address the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

— reviewing and analysing the nonconformity;

— determining the causes of the nonconformity;

— determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the management system, if necessary.

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The laboratory shall retain records as evidence of:

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

8.8 INTERNAL AUDITS (OPTION A)

8.8.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:

a) conforms to:

— the laboratory's own requirements for its management system, including the laboratory activities;

— the requirements of this document;

b) is effectively implemented and maintained.

8.8.2 The laboratory shall:

a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) ensure that the results of the audits are reported to relevant management;

d) implement appropriate correction and corrective actions without undue delay;

e) retain records as evidence of the implementation of the audit programme and the audit results.

NOTE ISO 19011 provides guidance for internal audits.

8.9 MANAGEMENT REVIEWS (OPTION A)

8.9.1 The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;

b) fulfilment of objectives;

c) suitability of policies and procedures;

d) status of actions from previous management reviews;

e) outcome of recent internal audits;

f) corrective actions;

g) assessments by external bodies;

h) changes in the volume and type of the work or in the range of laboratory activities;

i) customer and personnel feedback;

j) complaints;

k) effectiveness of any implemented improvements;

l) adequacy of resources;

m) results of risk identification;

n) outcomes of the assurance of the validity of results; and

o) other relevant factors, such as monitoring activities and training.

8.9.3 The outputs from the management review shall record all decisions and actions related to at least:

a) the effectiveness of the management system and its processes;

b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;

c) provision of required resources;

d) any need for change.

2.5 SUMMARY AND IMPLICATIONS

ISO/IEC 17025:2017 accreditation is a more thorough process than ISO 9001:2015 registration. This is because ISO/IEC 17025:2017 accreditation is recognition of a laboratory's competence to produce technically valid results, while ISO 9001:2015 registration of a laboratory is limited to QMS conformance.

ISO/IEC 17025:2017 QMS and technical requirements serve as criteria for on-site assessments similar to ISO 9001:2015 audits. These assessments are performed by a third-party accreditation body, which is primarily interested in the laboratory's ability to perform specific tests or calibrations.

Accreditation can be a valuable tool, demonstrating that a laboratory operates an efficient QMS and is competent to perform calibration or testing, leading to improved credibility, fewer customer complaints and a strong competitive edge.

An ISO/IEC 17025:2017 accreditation certificate is valid for two years, with a surveillance assessment conducted after one year. When a laboratory is part of a larger facility, ISO/IEC 17025:2017 accreditation can occur at the same time as ISO 9001:2015 registration if the auditor is working for both an accreditation body and a registrar. In these circumstances, the laboratory must have an independent QMS from the rest of the facility. Before a calibration or testing laboratory can be considered for accreditation, several preliminary steps must be taken:

1) The first step is to implement a management system that meets ISO/IEC 17025:2017 management and technical requirements.

2) A Quality Manual or equivalent document must be created which stipulates the laboratory's quality-related policies, procedures and technical practices. In particular, it must contain a quality policy statement describing overall quality objectives. This document plays a vital role in the accreditation process. Because the manual is the principal document used during an assessment, it must be a true reflection of the laboratory's management system. The manual must also address, point by point, all ISO/IEC 17025:2017 requirements.

3) The laboratory's management system must be in operation for a minimum of three to six months so that employees are familiar with the system and an evidentiary trail of documents have been created for auditors to review.

After successfully completing the preliminary steps, a relationship must be established with a recognized accreditation body. The accreditation body's job is to verify whether a laboratory's management system has been properly implemented and conforms to ISO/IEC 17025:2017 requirements, and if the laboratory is technically competent to perform calibrations or tests within its scope.

The scope of accreditation for testing laboratories is normally identified in terms of standard test methods. The scope of accreditation for calibration laboratories is in terms of measurement parameter, range of measurement and best attainable uncertainties.

Once the services of a recognized accreditation body have been obtained, a formal application must be filed. When all of the paperwork has been submitted, the accreditation body audits the laboratory's quality manual and related documentation. If the accreditation body's auditors find documentation gaps, they may ask the laboratory to implement corrective action before scheduling the assessment. The laboratory may request a preassessment to improve the chances of a successful assessment.

After the accreditation body has verified that the manual and other documentation is a satisfactory reflection of the laboratory's management system and meets all ISO/IEC 17025:2017 requirements, and has determined the tests to possibly witness, an on-site assessment of the laboratory is scheduled.

During the assessment, the accreditation body conducts an entry briefing with laboratory management; audits the management system to verify that it is fully operational and conforms to all ISO/IEC 17025:2017 elements, including documentation; interviews technical staff; witnesses selected tests and/or calibrations; and examines equipment and calibration records.

The purpose of the assessment is to ensure that the laboratory conforms to all ISO/IEC 17025:2017 requirements and can competently perform the types of tests or calibrations within its scope. Auditors may also provide advice, based on observations or in response to questions, to help the laboratory improve its performance.

Afterward, the accreditation body reports its findings in an assessment report. If any major or minor nonconformities were found, the laboratory must take corrective action to remedy the cause of the nonconformity.

Major nonconformities directly affect the integrity of calibration or test results, can be several related minor nonconformities, or are repeat nonconformities from previous assessments. Examples include a laboratory's inability to perform a test or type of test for which it seeks accreditation; and a laboratory's management system which does not conform to a clause or section of ISO/IEC 17025:2017, is not adequately documented or is not completely operational. Minor nonconformities do not directly affect the integrity of calibration or test results.

At the end of the assessment, the Lead Auditor prepares a report of findings, identifying nonconformities which the laboratory must resolve in order to achieve ISO/IEC 17025:2017 accreditation.

The accreditation body auditors hold an exit briefing with the laboratory's top management, going over findings and presenting a deficiency report which lists nonconformities. The laboratory's authorized representative or designee is asked to sign the deficiency report to attest that it has been reviewed. This does not indicate concurrence with any deficiency findings.

The laboratory is requested to respond within one month after the exit briefing with either corrective action or why it does not believe a deficiency exists. The corrective action response must include a copy of the objective evidence, such as calibration certificates, laboratory procedures, paid invoices, packaging slips and training records, to indicate that corrective actions have been implemented and completed.

If the laboratory disagrees with deficiency findings, it is requested to explain the reasons for this disagreement. A laboratory that fails to respond in writing within four months after the exit briefing is treated as a new accreditation applicant.

Accreditation is for two years. After the first year, each laboratory must undergo a one-day surveillance assessment, which is performed to confirm that the laboratory's management system and technical capabilities remain in conformity to ISO/IEC 17025:2017.

A full on-site reaudit of all ISO/IEC 17025:2017 accredited laboratories is conducted at least every two years. Reaudits may also be conducted if the laboratory or its customers indicate that significant technical changes in the laboratory have occurred.

Each accredited laboratory is sent a renewal questionnaire, well in advance of its anniversary date, to allow sufficient time to complete the renewal process. A successful on-site reaudit must be completed before accreditation is extended for another two years, with all deficiencies resolved.

A laboratory may request an expansion of its accreditation scope at any time, with each request handled on a case-by-case basis. Unless the previous auditor can verify the competence of the laboratory to perform the additional tests or calibrations, another on-site assessment is normally required. If the additional tests or calibrations require a new technology, another assessment is definitely required.

Accreditation to ISO/IEC 17025:2017 is almost impossible to fake, as the standard focuses on performance, documentation, objective/audit evidence and technical competence.

Chapter 3: Research Design

In this chapter will outline the design and methodology of research. Case Study will be the basis for choice of research method (see in Appendix). This chapter will describe the design adopted by this research to achieve the aims and objectives stated in section 1.3 of Chapter 1.

Section 3.1 Will discusses the methodology which will be Case Study, the stages by which the methodology was be implemented, and the research design; section

Errore. L'origine riferimento non è stata trovata. Details of the Case Study; section

Errore. L'origine riferimento non è stata trovata. Lists all the documents be used in the Case study and justifies their use; section

3.2 Outlines the procedure be used and the timeline for completion of each stage of the study; section

3.3 Discusses how the data was be analysed; finally, section

3.4 Discusses the ethical considerations of the research and its potential problems and limitations.

3.1 METHODOLOGY AND RESEARCH DESIGN

3.1.1 Methodology of Case Study and Research

This research was conducted using a quantitative method supported by qualitative data. The quantitative method in this study objectives to measure how far the laboratory readiness in applying ISO/IEC 17025:2017 standard. Though the qualitative data method generating a broad picture of the readiness of the laboratory in implementing ISO/IEC 17025:2017 (Aqidawathi *et al.*, 2019).

This study uses the gap analysis method (Gap Analysis) for assessing the readiness of laboratory in case study of the Appendix to applying ISO/IEC 17025:2017.

The concept of a gap analysis is fairly straight-forward. A gap analysis is a useful technique that can use you to identify the gap between current management system and the revised management system. Part of conducting the gap analysis is determining the tasks that need to be done to close the gap.

3.1.2 Research Design

The first step in any gap analysis is to identify the 'future state.' In other words, what does management system need to include to conform to the new requirements. In order to determine this, will need to become familiar with the revised ISO/IEC 17025 standard.

When doing the gap analysis, should also consider whether the future state of management system includes other changes not necessarily related to the meeting the requirements of the standard. Are there any deficiencies in current management system that want to address at this time? For example, changing how policies are written, or putting quality manual or other management system documents online. If this work is going to be done as part of the update of management system, then include these details in the description of the future state of management system.

The next step in the gap analysis is to analyze the current situation. What is currently included in management system documents? May need to consult other people in laboratory to get an accurate picture of what is included in the management system documents and if there are any additional changes required. Make note of what information need and who will be getting this from.

The third step in the gap analysis is to compare the future state of management system to the current state and develop an action plan to make the changes. The typical format used for a gap analysis should work well for this step.

3.2 PROCEDURE AND TIMELINE

Once gap analysis is complete, can use it to develop your plan for updating management system. Is also important to develop a communication strategy so everyone in laboratory understands the changes being put in place, and they have an opportunity for input, where applicable.

Documenting your ISO IEC 17025 compliant quality system is not just a matter of 'writing' a quality manual. A well-structured quality system will support your laboratory operations, not be a burden.

Step 1: Familiarize with ISO IEC 17025. Conduct a gap analysis of your company's practices and existing documentation against ISO IEC 17025. Could use an Assessment Worksheet as a template (see below Table 2). ISO/IEC 17025:2017 Gap Analysis is useful for clauses that are new to the standard following its revision. It also contains some guidance comments which may be helpful. It is highly likely there will be current practices in your laboratory that already meet the requirements of clauses in ISO/IEC 17025. The way to get staff to engage with efforts to gain accreditation is to show them they are already halfway there and then get them involved in filling the gaps.

Step 2: Once the gaps in current system have been identified, determine how these gaps will be addressed. Where possible, design any new processes in such a way that they complement current practices as this will make implementation simpler (and get the relevant staff involved as they likely know what will work and what won't! Document new processes where necessary and determine what records will be (or should be!) generated, bearing in mind the principle of traceability. Keep documents simple and easy to follow - remember that you want people to read them!!

Step 3: Draw all elements from the above steps into a formal 'system', traditionally this has been a "Quality Manual" ('QM'). Although a formal QM is no longer a requirement of ISO IEC 17025, most laboratories find it helpful to document their processes this way. The QM is the skeleton that all other documentation hangs on. May have a brief QM that refers to supporting stand-alone procedures and/or work instructions or may include the procedures in the QM itself or have a combination of both. All documentation must be referenced in some way in the QM. Reference to required records must also be included.

Step 4: Quality Manuals come in all shapes and sizes. There is no 'right' or 'wrong' as far as structure is concerned. It is not a requirement that your QM reflect

the numbered clauses of the standard. Keep your overall goal in mind. Needed QM/procedures to be read by staff and for them to actively engage with the processes. With this in mind, structure QM in a way that is clear and staff can easily find what they are looking for.

Step 5a: Pros and cons of a Quality Manual structure that is determined by clause numbers in the standard: Pro- easy for auditors and easy to make sure have addressed all the relevant clauses. Con- usually not particularly user friendly nor do they necessarily reflect the flow of activities in laboratory. Easy to fall into the trap of including meaningless clauses just to match the standard. Risk- staff might not read it.

Step 5b: Pros and cons of a Quality Manual structure that is determined by processes: Pro- encourages staff engagement and ownership. Con- requires a more careful document review to ensure that all clauses of the standard are met. Risk- auditor might not like it (but it's not a problem).

Step 6: Make sure audit your practices against the Quality Manual. Ideally it should be someone different from the person who wrote the Manual. Don't just audit but also take action on all of the findings to ensure that keep improving.

Table 2: Gap Analysis and Self – Assessment Check-list

ISO/IEC 17025:2017 Clause No.	Element	Compliance with requirements			Reference to laboratory system documents / explanation on how the laboratory fulfils the requirements
		Y	N	NA	
4	**General Requirements**				
4.1	**Impartiality**				
4.1.1	Has the laboratory activities undertaken impartially and structured and managed so as to safeguard impartiality?				
4.1.2	Does the laboratory management commit to impartiality?				
4.1.3	Does the laboratory responsible for the impartiality of its laboratory activities and not to allow commercial, financial or other pressures to compromise impartiality?				
4.1.4	Has the laboratory identified risks to its impartiality on an on-going basis? (*This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality*)				
4.1.5	If a risk to impartiality is identified, does the laboratory able to demonstrate how it eliminates or minimizes such risk?				
4.2	**Confidentiality**				

4.2.1	Does the laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities? Is it informed 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 agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential)				
4.2.2	When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is customer or individual concerned, unless prohibited by law, notified of the information provided?				
4.2.3	Are information about the customer obtained from sources other than the customer (e.g. complainant, regulators) confidential between the customer and the laboratory? (The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source)				
4.2.4	Are personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities?				
5	**Structural Requirements**				
5.1	Is the laboratory legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities?				
5.2	Does the laboratory shall identify management that has overall responsibility for the laboratory?				
5.3	Is it defined and documented the range of laboratory activities for which it conforms with this document (The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis)				
5.4	Do the laboratory activities carry out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition? Are laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.				
5.5	Does the laboratory, a. define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services; b. specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities; c. document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.				
5.6	Does the laboratory have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: a. implementation, maintenance and improvement of the management system; b. identification of deviations from the management system or from the procedures for performing laboratory activities; c. initiation of actions to prevent or minimize such deviations; d. reporting to laboratory management on the performance of the management system and any need for improvement; e. ensuring the effectiveness of laboratory activities.				

5.7	Does the laboratory management ensured that: a. communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements; b. the integrity of the management system is maintained when changes to the management system are planned and implemented.				
6	**Resource Requirements**				
6.1	**General** Does the laboratory have available personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities?				
6.2	**Personnel**				
6.2.1	Are all personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially, be competent and work in accordance with the laboratory's management system?				
6.2.2	Does the laboratory document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience?				
6.2.3	Is it ensured that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations?				
6.2.4	Does the management of the laboratory communicate to personnel their duties, responsibilities and authorities?				
6.2.5	Does the laboratory have procedure(s) and retain records for: a. determining the competence requirements; b. selection of personnel; c. training of personnel; d. supervision of personnel; e. authorization of personnel; f. monitoring of competence of personnel.				
6.2.6	Is it authorized personnel to perform specific laboratory activities, including but not limited to, the following: a. development, modification, verification and validation of methods; b. analysis of results, including statements of conformity or opinions and interpretations; c. report, review and authorization of results.				
6.3	**Facilities and environmental conditions**				
6.3.1	Are facilities and environmental conditions suitable for the laboratory activities and shall not adversely affect the validity of results?				
6.3.2	Is it documented that the requirements for facilities and environmental conditions necessary for the performance of the laboratory activities?				
6.3.3	Does the laboratory monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results?				
6.3.4	Are there measures to control facilities implemented, monitored and periodically reviewed and shall include, but not be limited to: a. access to and use of areas affecting laboratory activities; b. prevention of contamination, interference or adverse influences on laboratory activities; c. effective separation between areas with incompatible laboratory activities.				
6.3.5	When the laboratory performs laboratory activities at sites or facilities outside its permanent control, is it ensured that the requirements related to facilities and environmental conditions of this document are met?				

6.4	**Equipment**				
6.4.1	Does the laboratory have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus which is required for the correct performance of laboratory activities and which can influence the result?				
6.4.2	In those cases where the laboratory uses equipment outside its permanent control, is it ensured that the requirements for equipment of this document are met?				
6.4.3	Does the laboratory have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration?				
6.4.4	Are they verify that equipment conforms to specified requirements before being placed or returned into service?				
6.4.5	Are equipment used for measurement capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result?				
6.4.6	Does the measuring equipment calibrated when: — the measurement accuracy or measurement uncertainty affects the validity of the reported results, — or calibration of the equipment is required to establish the metrological traceability of the reported result. — those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; — those used to make corrections to the measured value, e.g. temperature measurements				
6.4.7	Are calibration programme established, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration?				
6.4.8	Are all equipment requiring calibration or which has a defined period of validity labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity?				
6.4.9	Are equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, taken out of service? Is it isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly? Is it examined the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure?				
6.4.10	When intermediate checks are necessary to maintain confidence in the performance of the equipment, are these checks carried out according to a procedure?				
6.4.11	When calibration and reference material data include reference values or correction factors, is it ensured that the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements?				
6.4.12	Does the laboratory take practicable measures to prevent unintended adjustments of equipment from invalidating results?				
6.4.13	Are records retained for equipment which can influence laboratory activities. The records shall include the following, where applicable: a. the identity of equipment, including software and firmware version; b. the manufacturer's name, type identification, and serial number or other unique identification; c. evidence of verification that equipment conforms with specified requirements; d. the current location;				

	e. calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval; f. documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity; g. the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; h. details of any damage, malfunction, modification to, or repair of, the equipment				
6.5	**Metrological Traceability**				
6.5.1	Does the laboratory establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference?				
6.5.2	Is it ensured that measurement results are traceable to the International System of Units (SI) through one of the following: a. calibration provided by a competent laboratory; b. certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; c. direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.				
6.5.3	When metrological traceability to the SI units is not technically possible, is it demonstrates metrological traceability to an appropriate reference, e.g. a. certified values of certified reference materials provided by a competent producer; b. results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.				
6.6	**Externally provided products and services**				
6.6.1	Is it ensured that only suitable externally provided products and services that affect laboratory activities are used, when such products and services: a. are intended for incorporation into the laboratory's own activities; b. are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; c. are used to support the operation of the laboratory.				
6.6.2	Are there procedure and retain records for: a. defining, reviewing and approving the laboratory's requirements for externally provided products and services; b. defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers; c. ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer; d. taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.				
6.6.3	Does the laboratory communicate its requirements to external providers for: a. the products and services to be provided; b. the acceptance criteria; c. competence, including any required qualification of personnel; d. activities that the laboratory, or its customer, intends to perform at the external provider's premises				
7	**Process requirements**				
7.1	**Review of requests, tenders and contracts**				

7.1.1	Does the laboratory have a procedure for the review of requests, tenders and contracts? The procedure shall ensure that: a. the requirements are adequately defined, documented and understood; b. the laboratory has the capability and resources to meet the requirements; c. where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval; d. the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.				
7.1.2	Does the laboratory inform the customer when the method requested by the customer is considered to be inappropriate or out of date?				
7.1.3	When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) the specification or standard, and the decision rule are clearly defined? Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.				
7.1.4	Are any differences between the request or tender and the contract resolved before laboratory activities commence? (Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results)				
7.1.5	Are customers informed of any deviation from the contract?				
7.1.6	Does the contract review repeated and any amendments are communicated to all affected personnel, if a contract is amended after work has commenced?				
7.1.7	Does the laboratory cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed. a. providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities; b. preparation, packaging, and dispatch of items needed by the customer for verification purposes.				
7.1.8	Does the laboratory retain records of reviews, including any significant changes? Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.				
7.2	**Selection, verification and validation of methods**				
7.2.1	**Selection and verification of methods**				
7.2.1.1	Does the laboratory use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data?				
7.2.1.2	All Does the laboratory keep all methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, up to date and made readily available to personnel?				
7.2.1.3	Does the laboratory ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application?				
7.2.1.4	When the customer does not specify the method to be used, does the laboratory select an appropriate method and inform the customer of the method chosen?				

	Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.				
7.2.1.5	Does the laboratory verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance? Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.				
7.2.1.6	When method development is required, is this planned activity and assigned to competent personnel equipped with adequate resources? As method development proceeds, are periodic review carried out to confirm that the needs of the customer are still being fulfilled? Are any modifications to the development plan approved and authorized?				
7.2.1.7	Are deviations from methods for all laboratory activities occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer?				
7.2.2	**Validation of methods**				
7.2.2.1	Does the laboratory validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified? The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.				
7.2.2.2	When changes are made to a validated method, are the influence of such changes determined and where they are found to affect the original validation, a new method validation is performed?				
7.2.2.3	The performance characteristics of validated methods as assessed for the intended use, is it relevant to the customers' needs and consistent with specified requirements?				
7.2.2.4	Does the laboratory retain the following records of validation? a. the validation procedure used; b. specification of the requirements; c. determination of the performance characteristics of the method; d. results obtained; e. a statement on the validity of the method, detailing its fitness for the intended use.				
7.3	**Sampling**				
7.3.1	Does the laboratory have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration? Does the sampling method address the factors to be controlled to ensure the validity of subsequent testing or calibration results? Are sampling plan and method available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.				
7.3.2	Does the sampling method describe: a. the selection of samples or sites; b. the sampling plan; c. preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.				
7.3.3	Does the laboratory retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant: a. reference to the sampling method used; b. date and time of sampling;				

	c. data to identify and describe the sample (e.g. number, amount, name); d. identification of the personnel performing sampling; e. identification of the equipment used; f. environmental or transport conditions; g. diagrams or other equivalent means to identify the sampling location when appropriate; h. deviations, additions to or exclusions from the sampling method and sampling plan.				
7.4	**Handling of test or calibration items**				
7.4.1	Does the laboratory have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer? Are precautions taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for, testing or calibration. Are handling instructions provided with the item followed?				
7.4.2	Does the laboratory have a system for the unambiguous identification of test or calibration items? Is identification retained while the item is under the responsibility of the laboratory? Does the system ensure that items will not be confused physically or when referred to in records or other documents? The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.				
7.4.3	Upon receipt of the test or calibration item, deviations from specified conditions are recorded? When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, does the laboratory consult the customer for further instructions before proceeding and record the results of this consultation? When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, does the laboratory include a disclaimer in the report indicating which results may be affected by the deviation?				
7.4.4	When items need to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded?				
7.5	**Technical records**				
7.5.1	Does the laboratory ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original? Are technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results? Are original observations, data and calculations recorded at the time they are made and identifiable with the specific task?				
7.5.2	Does the laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations? Are both the original and amended data and files kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations?				

7.6	**Evaluation of measurement uncertainty**				
7.6.1	Does the laboratory identify the contributions to measurement uncertainty? When evaluating measurement uncertainty, all contributions which are of significance, including those arising from sampling, have been taken into account using appropriate methods of analysis?				
7.6.2	A laboratory performing calibrations, including of its own equipment, are they evaluate the measurement uncertainty for all calibrations?				
7.6.3	Does the laboratory performing testing evaluate measurement uncertainty? Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation are made based on an understanding of the theoretical principles or practical experience of the performance of the method?				
7.7	**Ensuring the validity of results**				
7.7.1	Does the laboratory have a procedure for monitoring the validity of results? Are resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques applied to review the results? Does this monitoring planned and reviewed and include, where appropriate, but not be limited to: a. use of reference materials or quality control materials; b. use of alternative instrumentation that has been calibrated to provide traceable results; c. functional check(s) of measuring and testing equipment; d. use of check or working standards with control charts, where applicable; e. intermediate checks on measuring equipment; f. replicate tests or calibrations using the same or different methods; g. retesting or recalibration of retained items; h. correlation of results for different characteristics of an item; i. review of reported results; j. intralaboratory comparisons; k. testing of blind sample(s).				
7.7.2	Does the laboratory monitor its performance by comparison with results of other laboratories, where available and appropriate? Is this monitoring planned and reviewed and include, but not be limited to, either or both of the following? a. participation in proficiency testing; b. participation in interlaboratory comparisons other than proficiency testing.				
7.7.3	Are data from monitoring activities analysed, used to control and, if applicable, improve the laboratory's activities? If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, are appropriate action taken to prevent incorrect results from being reported?				
7.8	**Reporting of results**				
7.8.1	**General**				
7.8.1.1	Are results reviewed and authorized prior to release? The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling) and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.				

7.8.1.2	When agreed with the customer, are results reported in a simplified way? Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.				
7.8.2	**Common requirements for reports (test, calibration or sampling)**				
7.8.2.1	Does each report include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse? a. a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling"); b. the name and address of the laboratory; c. the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities; d. unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; e. the name and contact information of the customer; f. identification of the method used; g. a description, unambiguous identification, and, when necessary, the condition of the item ; h. the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results; i. the date(s) of performance of the laboratory activity; j. the date of issue of the report; k. reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results; l. a statement to the effect that the results relate only to the items tested, calibrated or sampled; m. the results with, where appropriate, the units of measurement; n. additions to, deviations, or exclusions from the method; o. identification of the person(s) authorizing the report; p. clear identification when results are from external providers.				
7.8.2.2	Does the laboratory responsible for all the information provided in the report, except when information is provided by the customer? Are data provided by a customer clearly identified? In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.				
7.8.3	**Specific requirements for test reports**				
7.8.3.1	In addition to the requirements listed in 7.8.2, are test reports, where necessary for the interpretation of the test results, included the following: a. information on specific test conditions, such as environmental conditions; b. where relevant, a statement of conformity with requirements or specifications (see 7.8.6); c. where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when: — it is relevant to the validity or application of the test results; — a customer's instruction so requires, or — the measurement uncertainty affects conformity to a specification limit; d. where appropriate, opinions and interpretations (see 7.8.7);				

	e. additional information which may be required by specific methods, authorities, customers or groups of customers.				
7.8.3.2	Where the laboratory is responsible for the sampling activity, are test reports meet the requirements listed in 7.8.5 where necessary for the interpretation of test results?				
7.8.4	**Specific requirements for calibration certificates**				
7.8.4.1	In addition to the requirements listed in 7.8.2, does the calibration certificates include the following? a. the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent); NOTE According to JCGM 200:2012, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty. b. the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results; c. a statement identifying how the measurements are metrologically traceable; d. the results before and after any adjustment or repair, if available; e. where relevant, a statement of conformity with requirements or specifications (see 7.8.6); f. where appropriate, opinions and interpretations (see 7.8.7).				
7.8.4.2	Where the laboratory is responsible for the sampling activity, does the calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of test results?				
7.8.4.3	A calibration certificate or calibration label shall not contain any recommendation on the calibration interval except where this has been agreed with the customer.				
7.8.5	**Reporting sampling–specific requirements** Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, does reports include the following, where necessary for the interpretation of results: a. the date of sampling; b. unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate); c. the location of sampling, including any diagrams, sketches or photographs; d. a reference to the sampling plan and sampling method; e. details of any environmental conditions during sampling that affect the interpretation of the test results; f. Information required to evaluate measurement uncertainty for subsequent testing or calibration.				
7.8.6	**Reporting statements of conformity**				
7.8.6.1	When a statement of conformity to a specification or standard is provided, does the laboratory document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule?				
7.8.6.2	Does the laboratory report on the statement of conformity? such that the statement clearly identifies: a. to which results the statement of conformity applies; b. which specifications, standards or parts thereof are met or not met; c. the decision rule applied (unless it is inherent in the requested specification or standard).				
7.8.7	**Reporting opinions and interpretations**				

7.8.7.1	When opinions and interpretations are expressed, does the laboratory ensure that only personnel authorized for the expression of opinions and interpretations releases the respective statement? Does the laboratory document the basis upon which the opinions and interpretations have been made?				
7.8.7.2	The opinions and interpretations expressed in reports is it based on the results obtained from the tested or calibrated item and shall be clearly identified as such?				
7.8.7.3	When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue are retained?				
7.8.8	**Amendments to reports**				
7.8.8.1	When an issued report needs to be changed, amended or re-issued, any change of information are clearly identified and, where appropriate, the reason for the change included in the report?				
7.8.8.2	Are amendments to a report after issue made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number... [or as otherwise identified]", or an equivalent form of wording? Such amendments shall meet all the requirements of this document.				
7.8.8.3	When it is necessary to issue a complete new report, is it uniquely identified and contain a reference to the original that it replaces?				
7.9	**Complaints**				
7.9.1	Does the laboratory have a documented process to receive, evaluate and make decisions on complaints?				
7.9.2	Is description of the handling process for complaints available to any interested party on request? Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it? Does the laboratory responsible for all decisions at all levels of the handling process for complaints?				
7.9.3	Does the process for handling complaints include at least the following elements and methods: a. description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; b. tracking and recording complaints, including actions undertaken to resolve them; c. ensuring that any appropriate action is taken.				
7.9.4	When laboratory receiving the complaint is it responsible for gathering and verifying all necessary information to validate the complaint?				
7.9.5	Whenever possible, does the laboratory acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome?				
7.9.6	The outcomes to be communicated to the complainant are made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question?				
7.9.7	Whenever possible, does the laboratory give formal notice of the end of the complaint handling to the complainant?				
7.10	**Nonconforming work**				
7.10.1	Does the laboratory have a procedure that implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer? (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that: a. the responsibilities and authorities for the management of nonconforming work are defined;				

	b. actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory; c. an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results; d. a decision is taken on the acceptability of the nonconforming work; e. where necessary, the customer is notified and work is recalled; f. the responsibility for authorizing the resumption of work is defined.				
7.10.2	Does the laboratory retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f)?				
7.10.3	Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, does the laboratory implement corrective action?				
7.11	**Control of data and information management**				
7.11.1	Does the laboratory have access to the data and information needed to perform laboratory activities?				
7.11.2	The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data are validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction? Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, are they authorized, documented and validated before implementation?				
7.11.3	Does the laboratory information management system(s): a. be protected from unauthorized access; b. be safeguarded against tampering and loss; c. be operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; d. be maintained in a manner that ensures the integrity of the data and information; e. include recording system failures and the appropriate immediate and corrective actions.				
7.11.4	When a laboratory information management system is managed and maintained off-site or through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of this document?				
7.11.5	Does the laboratory ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel?				
7.11.6	Are calculations and data transfers checked in an appropriate and systematic manner?				
8	**Management system requirements**				
8.1	**Options**				
8.1.1	**General** Does the laboratory establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results? In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B.				
8.1.2	**Option A**				

	As a minimum, does the management system of the laboratory address the following? - management system documentation (see 8.2) - control of management system documentation (see 8.3) - control of records (see 8.4) - actions to address risks and opportunities (see 8.5) - improvement (see 8.6) - corrective actions (see 8.7) - internal audits (see 8.8) - management reviews (see 8.9)				
8.1.3	**Option B** A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.				
8.2	**Management system documentation (Option A)**				
8.2.1	Does the laboratory management establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization?				
8.2.2	Are policies and objectives address the competence, impartiality and consistent operation of the laboratory?				
8.2.3	Does the laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?				
8.2.4	Are all documentation, processes, systems, records, related to the fulfilment of the requirements of this document included in, referenced from, or linked to the management system?				
8.2.5	Are all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities?				
8.3	**Control of management system documents (Option A)**				
8.3.1	Does the laboratory control the documents (internal and external) that relate to the fulfillment of this document?				
8.3.2	Does the laboratory ensure that: a. documents are approved for adequacy prior to issue by authorized personnel; b. documents are periodically reviewed, and updated as necessary; c. changes and the current revision status of documents are identified; d. relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; e. documents are uniquely identified; f. the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.				
8.4	**Control of records (Option A)**				
8.4.1	Does the laboratory establish and retain legible records to demonstrate fulfillment of the requirements in this document?				
8.4.2	Does the laboratory implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records? Does the laboratory retain records for a period consistent with its contractual obligations? Are access to these records consistent with the confidentiality commitments and records readily available?				
8.5	**Actions to address risks and opportunities (Option A)**				

8.5.1	Does the laboratory consider the risks and opportunities associated with the laboratory activities? in order to: a. give assurance that the management system achieves its intended results; b. enhance opportunities to achieve the purpose and objectives of the laboratory; c. prevent, or reduce, undesired impacts and potential failures in the laboratory activities; d. achieve improvement.				
8.5.2	Does the laboratory plan: a. actions to address these risks and opportunities; b. how to: - integrate and implement these actions into its management system - evaluate the effectiveness of these actions				
8.5.3	Are actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results?				
8.6	**Improvement (Option A)**				
8.6.1	Does the laboratory identify and select opportunities for improvement and implement any necessary actions?				
8.6.2	Does the laboratory seek feedback, both positive and negative, from its customers? Are feedbacks analyzed and used to improve the management system, laboratory activities and customer service?				
8.7	**Corrective action (Option A)**				
8.7.1	When a nonconformity occurs, does the laboratory: a. react to the nonconformity and, as applicable: — take action to control and correct it; — address the consequences; b. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: — reviewing and analysing the nonconformity; — determining the causes of the nonconformity; — determining if similar nonconformities exist, or could potentially occur; c. implement any action needed; d. review the effectiveness of any corrective action taken; e. update risks and opportunities determined during planning, if necessary; f. make changes to the management system, if necessary.				
8.7.2	Are corrective actions appropriate to the effects of the nonconformities encountered?				
8.7.3	Does the laboratory retain records as evidence of: a) the nature of the nonconformities, cause(s) and any subsequent actions taken; b) the results of any corrective action.				
8.8	**Internal audits (Option A)**				
8.8.1	Does the laboratory conduct internal audits at planned intervals to provide information on whether the management system: a. conforms to: — the laboratory's own requirements for its management system, including the laboratory activities; — the requirements of this document; b. is effectively implemented and maintained.				
8.8.2	Does the laboratory: a. plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration				

	the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits; b. define the audit criteria and scope for each audit; c. ensure that the results of the audits are reported to relevant management; d. implement appropriate correction and corrective actions without undue delay; e. retain records as evidence of the implementation of the audit programme and the audit results.				
8.9	**Management reviews (Option A)**				
8.9.1	Does the laboratory management review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document?				
8.9.2	Are inputs to management review recorded and included information related to the following? changes in internal and external issues that are relevant to the laboratory; fulfilment of objectives; suitability of policies and procedures; status of actions from previous management reviews; outcome of recent internal audits; corrective actions; assessments by external bodies; changes in the volume and type of the work or in the range of laboratory activities; customer and personnel feedback; complaints; effectiveness of any implemented improvements; adequacy of resources; results of risk identification; outcomes of the assurance of the validity of results; and other relevant factors, such as monitoring activities and training.				
8.9.3	Are outputs from the management review recorded all decisions and actions related to? at least: the effectiveness of the management system and its processes; improvement of the laboratory activities related to the fulfillment of the requirements of this document; provision of required resources; any need for change.				

Note 1: Y – Comply N – Not Comply NA- Not Applicable
Note 2: Please attach evidence for laboratory system documents

3.3 ANALYSIS

For the gap analysis process data collection was done by conducting an internal audit by distributing questionnaires and in-depth interviews to main informants (General Manager, Assistant General Manager, Quality Assurance Manager, Quality Assurance Executive,) at the laboratory of the Appendix. Figure 1 shows the framework questionnaires,

The primary step of this tool is developing a gap analysis checklist that purposes to recognize gaps among written requirements, resources, and the actual process carried out (Putri *et al.*, 2019). This checklist was made based on the requirements of ISO/IEC 17025 (like the above checklists). To facilitate the analysis of each clause, scoring for assessment was given in Table 03 below.

The designing of the questionnaire was carried out by determining the variables that are influencing the readiness of the Appendix laboratory. Determining the variables was done by deriving the clause contained in ISO/IEC 17025 and identifying the documents and resources required in ISO/IEC 17025. Furthermore, the level of fulfillment was measured.

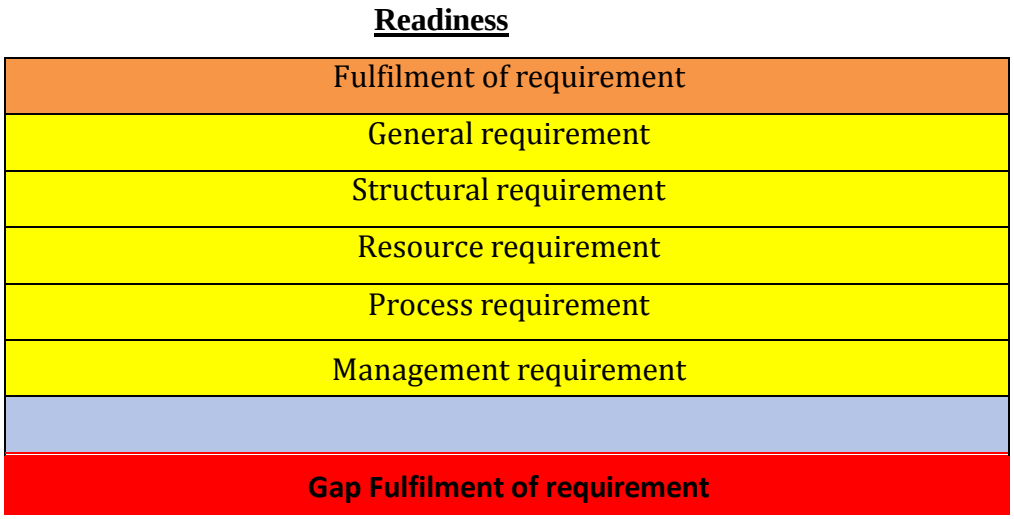

Figure 02: Framework questionnaires

Table 03: Scoring Benchmarks

Score	Criteria
0	The requirement is implemented consistently and having the essential document and resource
1	The requirement is implemented inconsistently and having the essential document and resource
2	The requirement is not implemented, but having the essential document and resource
3	The requirement is implemented, but don't have the all-essential document and resource
4	Comprehend with the requirement, but not implementing the requirement and don't have the essential document and resource
5	Don't comprehend the requirement, not implementing the requirement and don't have the essential document and resource

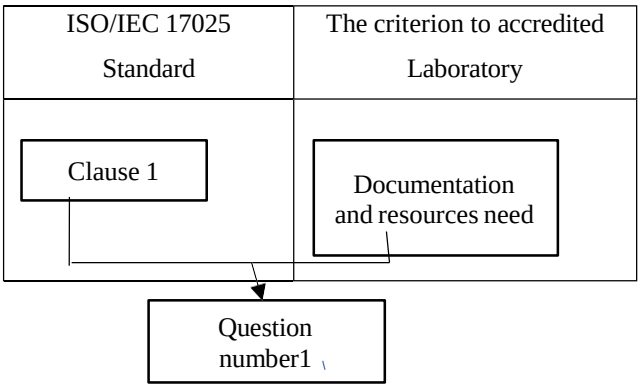

Figure 03: Questionnaire Design

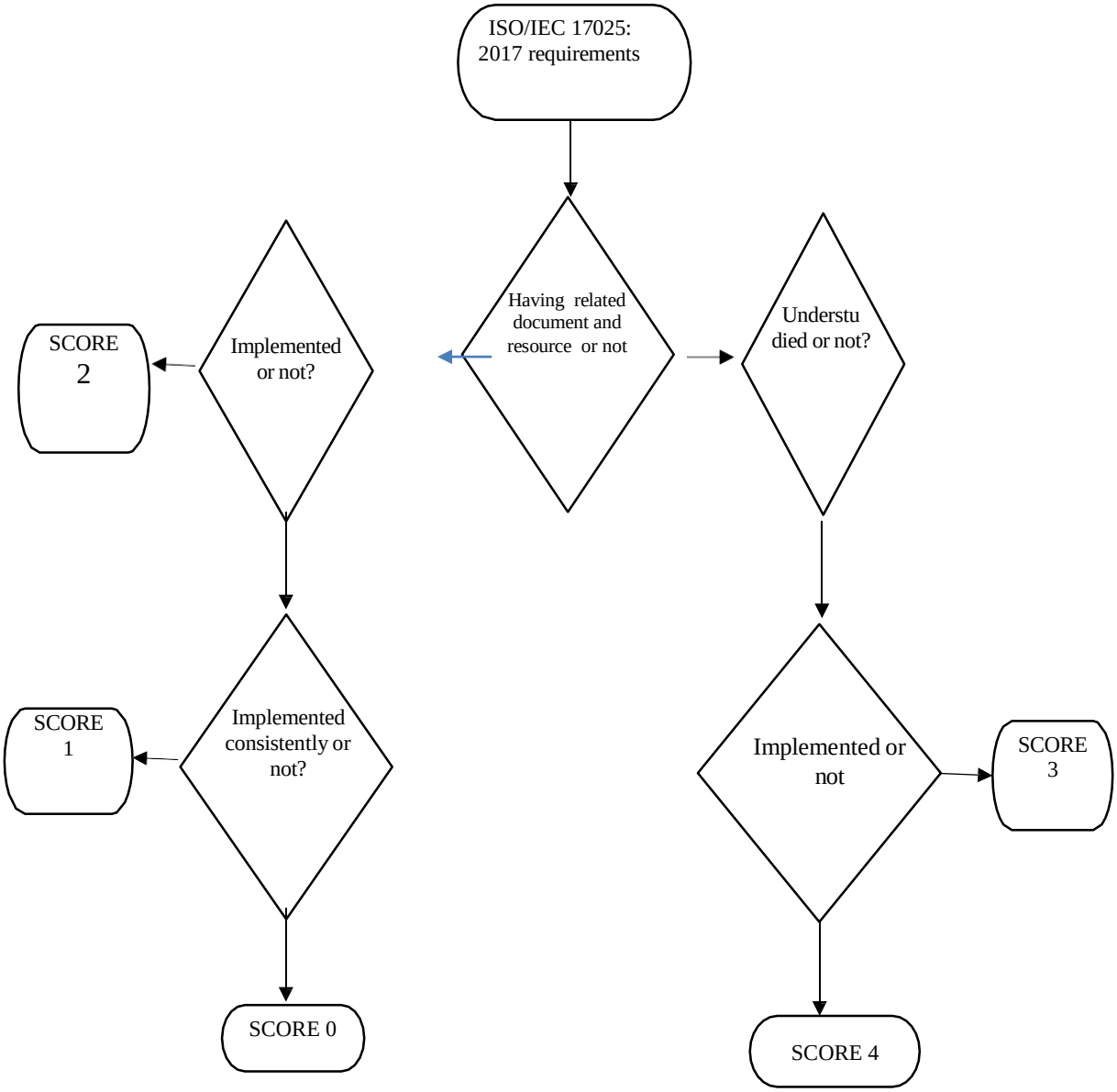

Figure 04: Flow Chart for scoring

Implementation process

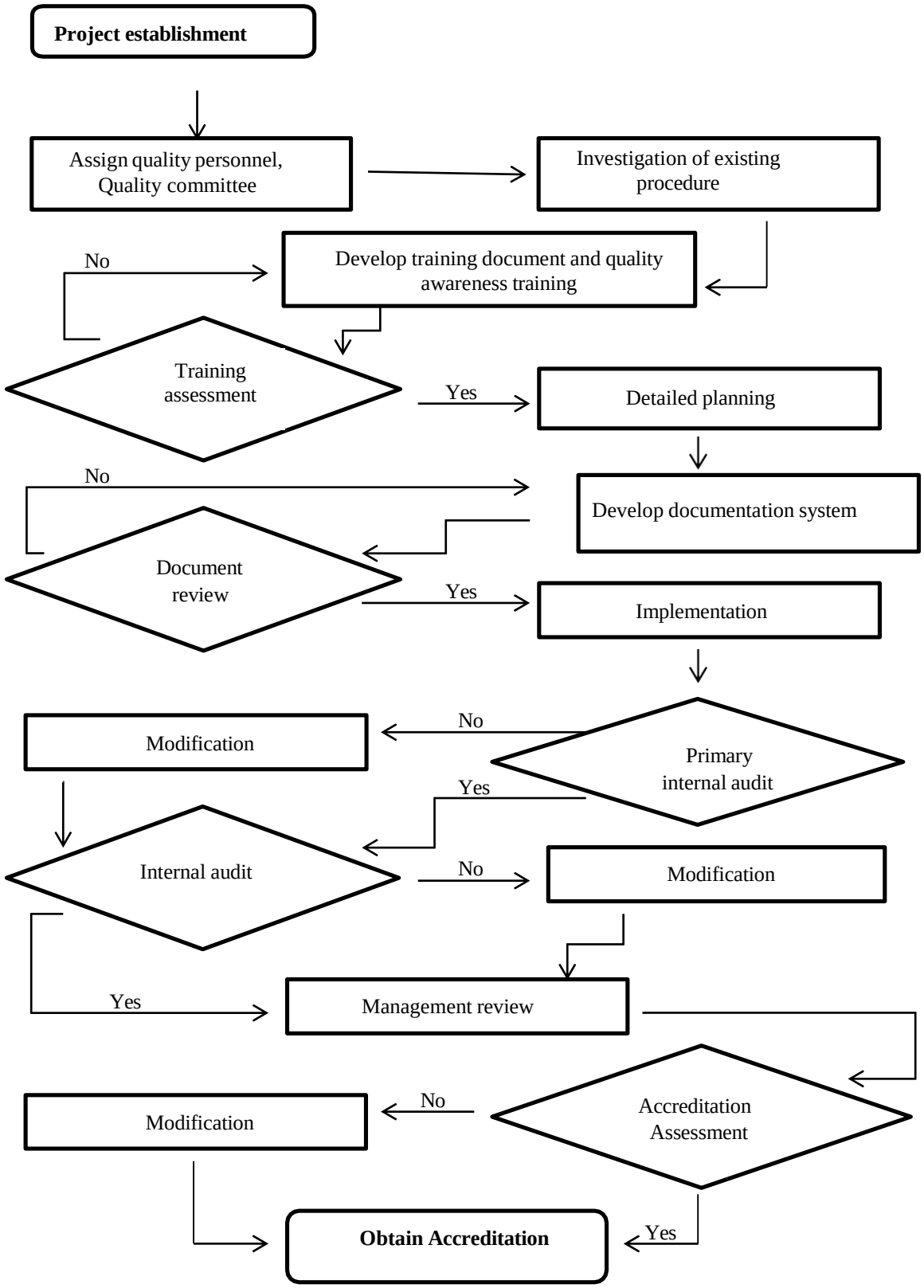

Figure 05: Flow chart for the Implementation Process

According to the above methodology in the formation of questionnaires and questions to determine whether or not there is compliance with the requirements of ISO/IEC 17025:2017, let the following approach:

3.4 ETHICS AND LIMITATIONS

The methodology we used in this qualitative study was a mixture of two methodologies: this Case Study Methodology and this Data Collection Methodology. There is clearly a degree of uncertainty because we do not have rigorous numerical data of multiple cases. But the correct search of the bibliography, combined with the work experience of the person signing the study, significantly reduces this degree of uncertainty.

In this study we had to manage issues of confidentiality, reluctant IRB, privacy and anonymity. Obviously, we do not disclose the name of the laboratory and personnel that we give as an example in the Appendix. This is what we were asked by the lab and its staff and this is what we did. There was a willingness to collaborate and an efficient exchange of views at all stages of the internal inspections and with a clear intention to improve on the part of the laboratory.

In this study there were no issues regarding inappropriate relationships because I am personally bound by an impartiality and confidentiality agreement with the accreditation body I work for. No personal friendship or any relationship can get in the way of the conformity assessment work, as this will create a conflict of interest.

In this study there was informed consent from the Laboratory Management which we exemplify in the Appendix and informed consent from the staff we interviewed.

Chapter 4: Results

Chapter 4 details all the results of the study. In the results containing the Management System Documentation that presented in Appendix.

ISO/IEC 17025:2017 accreditation is a more thorough process than ISO 9001:2015 registration. This is because ISO/IEC 17025:2017 accreditation is recognition of a laboratory's competence to produce technically valid results, while ISO 9001:2015 registration of a laboratory is limited to QMS conformance.

ISO/IEC 17025:2017 QMS and technical requirements serve as criteria for on-site assessments similar to ISO 9001:2015 audits. These assessments are performed by a third-party accreditation body, which is primarily interested in the laboratory's ability to perform specific tests or calibrations.

Accreditation can be a valuable tool, demonstrating that a laboratory operates an efficient QMS and is competent to perform calibration or testing, leading to improved credibility, fewer customer complaints and a strong competitive edge.

An ISO/IEC 17025:2017 accreditation certificate is valid for two years, with a surveillance assessment conducted after one year. When a laboratory is part of a larger facility, ISO/IEC 17025:2017 accreditation can occur at the same time as ISO 9001:2015 or IATF 16949 registration if the Assessor is working for both an accreditation body and a registrar. In these circumstances, the laboratory must have an independent QMS from the rest of the facility.

Key Steps to Achieving Accreditation

Before a calibration or testing laboratory can be considered for accreditation, several preliminary steps must be taken:

- The first step is to implement a management system that meets ISO/IEC 17025:2017 management and technical requirements.

- A Quality Manual or equivalent document must be created which stipulates the laboratory's quality-related policies, procedures and technical practices. In particular, it must contain a quality policy statement describing overall quality objectives. This document plays a vital role in the accreditation process. Because the manual is the principal document used during an assessment, it must be a true reflection of the laboratory's management system. The manual must also address, point by point, all ISO/IEC 17025:2017 requirements.

- The laboratory's management system must be in operation for a minimum of three to six months so that employees are familiar with the system and an evidentiary trail of documents have been created for Assessors to review.

After successfully completing the preliminary steps, a relationship must be established with a recognized accreditation body. The accreditation body's job is to verify whether a laboratory's management system has been properly implemented and conforms to ISO/IEC 17025:2017 requirements, and if the laboratory is technically competent to perform calibrations or tests within its scope.

The scope of accreditation for testing laboratories is normally identified in terms of standard test methods. The scope of accreditation for calibration laboratories is in terms of measurement parameter, range of measurement and best attainable uncertainties.

Once the services of a recognized accreditation body have been obtained, a formal application must be filed. When all of the paperwork has been submitted, the accreditation body audits the laboratory's quality manual and related documentation. If the accreditation body's Assessors find documentation gaps, they may ask the laboratory to implement corrective action before scheduling the assessment. The laboratory may request a preassessment to improve the chances of a successful assessment.

After the accreditation body has verified that the manual and other documentation is a satisfactory reflection of the laboratory's management system and

meets all ISO/IEC 17025:2017 requirements, and has determined the tests to possibly witness, an on-site assessment of the laboratory is scheduled.

During the assessment, the accreditation body conducts an entry briefing with laboratory management; audits the management system to verify that it is fully operational and conforms to all ISO/IEC 17025:2017 elements, including documentation; interviews technical staff; witnesses selected tests and/or calibrations; and examines equipment and calibration records.

The purpose of the assessment is to ensure that the laboratory conforms to all ISO/IEC 17025:2017 requirements and can competently perform the types of tests or calibrations within its scope. Assessors may also provide advice, based on observations or in response to questions, to help the laboratory improve its performance.

Afterward, the accreditation body reports its findings in an assessment report. If any major or minor nonconformities were found, the laboratory must take corrective action to remedy the cause of the nonconformity.

Major nonconformities directly affect the integrity of calibration or test results, can be several related minor nonconformities, or are repeat nonconformities from previous assessments. Examples include a laboratory's inability to perform a test or type of test for which it seeks accreditation; and a laboratory's management system which does not conform to a clause or section of ISO/IEC 17025:2017, is not adequately documented or is not completely operational. Minor nonconformities do not directly affect the integrity of calibration or test results.

At the end of the assessment, the Lead Assessor prepares a report of findings, identifying nonconformities which the laboratory must resolve in order to achieve ISO/IEC 17025:2017 accreditation. The accreditation body Assessors hold an exit briefing with the laboratory's top management, going over findings and presenting a deficiency report which lists nonconformities. The laboratory's authorized representative or designee is asked to sign the deficiency report to attest that it has been reviewed. This does not indicate concurrence with any deficiency findings.

The laboratory is requested to respond within one month after the exit briefing with either corrective action or why it does not believe a deficiency exists. The corrective action response must include a copy of the objective evidence, such as calibration certificates, laboratory procedures, paid invoices, packaging slips and training records, to indicate that corrective actions have been implemented and completed.

If the laboratory disagrees with deficiency findings, it is requested to explain the reasons for this disagreement. A laboratory that fails to respond in writing within four months after the exit briefing is treated as a new accreditation applicant.

Accreditation is for two years. After the first year, each laboratory must undergo a one-day surveillance assessment, which is performed to confirm that the laboratory's management system and technical capabilities remain in conformity to ISO/IEC 17025:2017.

A full on-site reaudit of all ISO/IEC 17025:2017 accredited laboratories is conducted at least every two years. Reaudits may also be conducted if the laboratory or its customers indicate that significant technical changes in the laboratory have occurred.

Each accredited laboratory is sent a renewal questionnaire, well in advance of its anniversary date, to allow sufficient time to complete the renewal process. A successful on-site reaudit must be completed before accreditation is extended for another two years, with all deficiencies resolved.

A laboratory may request an expansion of its accreditation scope at any time, with each request handled on a case-by-case basis. Unless the previous Assessor can verify the competence of the laboratory to perform the additional tests or calibrations, another on-site assessment is normally required. If the additional tests or calibrations require a new technology, another assessment is definitely required.

Remember: Accreditation to ISO/IEC 17025:2017 is almost impossible to fake, as the standard focuses on performance, documentation, objective/audit evidence and technical competence.

What to Look for in an Accreditation Body

In selecting an accreditation body, it is extremely important for every laboratory to be aware of the relevant qualifications. An accreditation body must:

- Be recognized by an international, regional or national recognition body such as the National Cooperation for Laboratory Accreditation (NACLA), the International Laboratory Accreditation Cooperation (ILAC), the Asia-Pacific Laboratory Accreditation Cooperation (APLAC) or the European Cooperation for Accreditation (EA).
- Maintain a listing of its ISO/IEC 17025:2017 qualified Assessors.
- Have personnel on its executive (accreditation) committee or governing board with experience and expertise in the appropriate testing or calibration scope.
- Conform to ISO/IEC 17011, *General Requirements for accreditation bodies accrediting conformity assessment bodies.*

What to Look for in an Assessor

Requirements have been established for the Assessors working for ISO/IEC 17025:2017 recognized accreditation bodies. Before an Assessor can evaluate a laboratory to verify whether its management system and technical competence conform to ISO/IEC 17025:2017 requirements, the Assessor must satisfy the following conditions:

- Assessors must have satisfactorily completed ISO/IEC 17025:2017 training courses and demonstrate their knowledge of ISO/IEC 17025:2017 by passing an exam. A certificate is awarded to those Assessors who have successfully completed this training.

- Assessors must comply with ISO 19011:2018, *Guidelines for quality and/or environmental management systems auditing*, regarding their qualifications.

- They must be recognized and qualified as ISO/IEC 17025:2017 Assessors under the accreditation body's criteria.

- At least one member of an audit team must have relevant industry experience in the appropriate testing or calibration scope, as determined by the accreditation body's qualification process, for each customer.

Before hiring the services of an accreditation body, it's a good idea to make sure the accreditation body and its Assessors have met the above qualifications.

Results of the first audit

The score value was gained from the outcomes of the questionnaire assessment. The maximum score is the maximum gap value where if it reaches that value, it means that the laboratory has not comprehended yet and the laboratory system does not potentially apply ISO / IEC 17025 (Khodabocus and Balgobin, 2011). Then the calculation of the score divided by a maximum score will show the gap value. From the results of the gap, it can be seen the percentage of fulfillment of requirements from ISO / IEC 17025. The first internal audit was conducted to measure the existing situation of the laboratory. In the next Chapter 5, can see the relative questions per ISO/IEC 17021:2017 standard paragraph.

Question code 1-9 for general requirements comprising of impartiality and confidentiality. In this laboratory, a total score of 0 was created. This shows that a gap value of 0% was created because the laboratory system fulfilled the document, resource requirements and the level of accomplishment of 100% was created because the laboratory has been understood and implementing impartiality and also confidentiality requirements as well as already documented the requirements.

Question code 10-16 for structural requirements. In this laboratory, a total score of 15 was created. This shows that a gap value of 43% was created because the laboratory does not have a technical manager accountable for the testing process

and also there was no documented organizational structure. Then a fulfillment percentage of 57% was created because the laboratory has already defined the laboratory as a legal entity and it was legally responsible for its laboratory activities and also, they identified and documented the overall responsibility of the laboratory.

Question code 17-47 for resource requirements. In this laboratory, a total score of 83 was created. This displays that 37% is created because the laboratory doesn't have complete documentation and resources even though has been understood the requirements. The reasons for the gaps were, Laboratory did not possess all personnel, facilities, equipment, systems and support services. As well as they had not documented monitoring records of facilities and environmental conditions. The duties and responsibilities of laboratory employees are properly communicated, the laboratory was established and maintained metrological traceability of its measurement results, and also it has ensured measurement results are traceable to the international system of the unit. Therefore, with these requirements, the laboratory creates 63% compliance.

Question code 48-114 for process requirements. In this laboratory, a total score of 112 was created. This displays that the gap value is 33%. The main reason for this gap value is the laboratory does not have complete documentation, as well as laboratory does not keep all methods, procedures and supporting documentation. There are, instructions, standards, manuals, and reference data related to the laboratory activities, laboratory have implemented a proper sampling plan and methods but it hasn't documented well, the laboratory doesn't have a written procedure for transportation, receiving, handling, protection, storage, retention and calibration or disposal item. Most of the requirements were implemented but without any proper documentation. Hence the fulfillment rate was 67% achieved because the laboratory has understood the requirements of ISO / IEC 17025 and carried out some of these requirements. Therefore, the laboratory has a procedure for the review of the request, tenders, and contracts, laboratory use appropriate test methods, laboratory properly validates test methods and also retain a document of validation. The laboratory has documented procedures to receive, evaluate and make decisions on complaints.

Question code 115-137 for management requirements. In this lab, the total score was 71 created. This displays that the resulting gap value is 62% and the fulfillment percentage is 38% because the laboratory staff understood the requirements of the management system but have not compiled yet the document recording procedure.

Question code 115-137 for management requirements. In this lab, the total score was 71 created. This displays that the resulting gap value is 62% and the fulfillment percentage is 38% because the laboratory staff understood the requirements of the management system but have not compiled yet the document recording procedure. Figure 5 shows the readiness level of implementing ISO 17025, Based on the first internal audit results laboratory have more gaps to fulfill to achieve ISO 17025:2017. The main reason did not have proper documentation. Most of the requirements were already comprehended and implemented but the problem is they were not documented well.

Results of the second audit

After the implementation process, the quality committee was conducted a second internal audit to measure the readiness of the laboratory to achieve ISO 17025:2017. The general requirements were fully completed there were no gaps and also have proper documentation.

The structural requirement, before implementation the gap value was 43% but after the implementation process, the gap value decreases to 26%. The compliance level increases 57% to 74%. Because the laboratory was documented the organizational structure of the laboratory and the management of the laboratory were identified and documented overall responsibility of the laboratory. But there was a remaining 26% of gaps to fill. The reason was some of the documents were not documented yet.

In the resource requirement before implementation, the gap value was 37% but after the implementation process, the gap value decreases to 16%. The compliance level increase to 63%-84%. Because the laboratory fulfills the necessary

equipment, personnel, systems, and support services. Before the implementation process, the laboratory there is a shortage of laboratory equipment. Hence increase in the compliance level but there was still a 16% gap is remaining because of some documentation problems of facilities and environmental procedures. In the process requirement, before implementation, the gap value was 33% but after the implementation process, the gap value has decreased to 9%. The reason for that was the laboratory was kept all methods, procedures and supporting documentation relevant to the laboratory activities. As well as they were prepared a quality manual and standard operating procedures for all equipment and laboratory tests. Because of that, the compliance level was increased to 67-91%. In the management requirement, the first audit gap value was 38% but after the implementation process, it was decreased to 13%. The compliance level was increased from 62% to 87%.

Based on the above results most of the requirements of ISO 17025: 2017 standard were reached a 75% compliance level because of that the laboratory is suitable for applying to get ISO 17025:2017 to the laboratory. This analysis was done by the quality department internal audit team but needs to confirm exactly by Internal audit results to verify the company has succeeded in meeting these standard's requirements

As the key objective of this project was to support the company to implement the ISO/IEC 17025:2017 into a quality management system. The company reached a better point of view of its stance in quality management. Now it has a clear framework of steps to walk up the accreditation process. As well as the readiness analysis supports the top management and also staff to comprehend the requirements from the standard. The establishment of a quality manual achieves the main requirement from the manager. A set of Standard Operation procedures (SOP) works as guidance documents for staff to follow. The learning of standard requirement clauses can also serve as a tool and reference for staff in case they want additional explanation or guidelines from the requirements. At the end of the project, the top management team and staff have a clear sight about what are the requirements of the quality management system and how to obtain accreditation. The company has reached quite a satisfactory level of implementing the standard,

but the research, also proves that there is still have for enhancement. A few of the greatest significant parts that the company misses from the quality management system are the work and records of annual reviews and audits, management reviews, and staff training. Even though it is adequate to prove that the company has started those activities from the date the accreditation application being sent, earlier records during the whole business time will increase the image of the company in compliant standard and quality. Besides, the documentation system might want preparation and rearrangement. Because of the nature of business, a large quantity of documents stored in the internal electronic documentation system is in not proper state. Those can still be improved with the implementation of other document management systems. This restriction can seriously affect the audit result as well as the accreditation outcome. But, one of the simple methods to fix the problem is to attach an appendix to each document and the other method is manually note down what has been changed as proof of record. Each single quality management system needs a different set of documentation, organization and also work procedures.

Chapter 5: Analysis

This Chapter 5 will be containing a full discussion by paragraph of ISO/IEC 17025:2017, interpretation and evaluation of the results and how we have created the Appendix result, with reference to the literature and International Standards.

As with the previous chapters, will be include a paragraph at the beginning summarising the structure of the chapter. We have organised the chapter in terms of the objectives of the study and/or the theoretical framework.

Thus, this research outcomes will be tied together in relation to the theory, review of the literature and International Standards, and rationale. As outcome of this analysis, we have created the documentation of the Appendix "Laboratory "X".

4 (General requirements)

This paragraph of the Standard it is imperative that laboratories complying with ISO/IEC 17025:2017 adhere to two fundamental concepts: (a) impartiality and (b) confidentiality. Not unlike a person's relationship with their family doctor or that inopportune time when a person ends up in traffic court, the expectation is that regardless of outcome, impartiality and confidentiality are appropriately maintained. Laboratories are required to adhere with those same principles. Because of the brevity of clause 4.1 (Impartiality) and clause 4.2 (Confidentiality) of ISO/IEC 17025:2017, both clauses will be reviewed in this initial chapter. Clause 4.1 and clause 4.2 are essentially cornerstones for laboratories wishing to achieve compliance with ISO/IEC 17025:2017 requirements. Impartiality is rooted in a laboratory's ability to prioritize a customer's needs above those of the laboratory. It starts with the management making difficult decisions that may not be in the best interest of the laboratory but supports a customer's need for impartiality in the obtaining of accurate calibration or test results, regardless of the outcome. This becomes an extremely important task when supporting highly regulated industries such as aerospace and defense or med tech. Regardless, impartiality is a top-down

driven concept that is routed in laboratory integrity. Tools for complying with clause 4.2 are less abstract as contracts and nondisclosure agreements (NDAs) can be scripted to ensure information is appropriately protected. Additionally, for med tech clients, there is always the possibility for patient information to potentially be involved in failure investigations. As a result, there may be a need to address Health Insurance Portability and Accountability Act (HIPAA) requirements in support of protesting patient related information. Regardless, a well written contract and a signed NDA are a laboratory's best friend when addressing confidentiality concerns. Questions placed at the end of this and subsequent chapters are relevant to the subject matter discussed in each chapter. However, the questions are intended to be an all-inclusive list. They can be used to populate a conformity assessment checklist or supplier questionnaire and used as part of the supplier assessment process:

- Could the fiscal health of the laboratory impact the laboratory's ability to remain impartial?
- Has someone reviewed a recent Dun & Bradstreet report that provides a general financial picture of the laboratory?
- Is there ongoing litigation or other regulatory action potentially influencing the impartiality of the laboratory?
- Are contracts required to be in place with all laboratory clients?
- Are NDAs required to be signed for all clients?

For this initial chapter, maintaining impartiality and protecting the confidentiality of information is not rocket science. It is easy to pursue common-sense approaches that result in laboratories being able to provide accurate and impartial calibration or test results, while protecting the confidentiality of the information handled. It starts with management's commitment to these basic fundamentals—maintaining impartiality and confidentiality—at all costs. Customers demand it, ISO/IEC 17025:2017 requires it, and laboratories shall

comply with it; all are requirements associated with maintaining impartiality and confidentiality.

Paragraph 5 Structural Requirements

Similar to other ISO standards, identifying the salient requirements needed for establishing the foundation for an effective organization are delineated within clause 5 of ISO/IEC 17025:2017. If an organization is seeking accreditation to 17025, and an approved ISO 9001:2015 Quality Management System (QMS) has already been certified by a recognized registrar, then the chances are good an acceptable organizational infrastructure has already been established. It is imperative that the identification of the legal entity of the laboratory and its relationship to a parent organization or subsidiaries be clearly defined. Additionally, the laboratory's management system, policies, procedures, organizational structure, responsibilities of personnel, the interrelationships of laboratory personnel, identification of key management personnel, the handling of deviations from the QMS, methods of communication, and the reporting of the laboratory performance to management must be defined and developed in the context of complying with 17025. Further, the primary task of a laboratory is to perform testing and calibration activities in accordance with ISO/IEC 17025:2017. Finally, and arguably the most important point for a laboratory, is the ability to meet and hopefully exceed the expectation of their customers, including meeting all applicable regulatory and statutory requirements. This initial chapter will examine the requirements and the steps necessary for a laboratory to comply with clause 5 of ISO/IEC 17025:2017—Structural Requirements. Clause 5 is essentially an overview of elements required from laboratory management to maintain an effective management system. For example, the laboratory is required to retain adequate and properly trained resources to ensure the management system always remains in compliance with ISO/IEC 17025:2017. When deviations from the management system have been identified, management is tasked with correcting the deviation in accordance with clause 5.6(b) of ISO/IEC 17025:2017. For starters, the creation of an organizational chart is a fundamental requirement for laboratories considering accreditation. A well-constructed organization chart clearly delineates the functional structure of the laboratory. It is

imperative that the roles of the laboratory's quality manager and technical manager are clearly depicted on the chart. The fundamental requirement is to ensure the roles, responsibilities, and the authority established within the laboratory is adequate and in compliance with 17025. The importance of having a job description will be discussed in greater detail later in this book; however, it is strongly recommended that the job description contain the reporting structure for each job. For example, the calibration technicians report directly to the test and calibration supervisor. Additionally, it is also imperative that every laboratory employee is trained to understand the influence their functional duties have on the over- all effectiveness of the laboratory's management system. Most organizations accomplish this task through initial employee orientation and training. Regardless of the approach pursued, make sure the training is documented in accordance with clause 5.6 of ISO/IEC 17025:2017. Further, it is important that the laboratory appoint a quality manager and a technical manager and delineate the specific roles and responsibilities for each of these positions. Once again, the job description will play a key role in definition of duties and responsibilities. For small organizations (e.g., less than ten individuals and in some cases one or two employees), team members will be tasked with wearing many hats. However, organizational size does not result in diminished levels of compliance with the standard. Finally, laboratories must ensure the confidential nature of customer data. ISO/IEC requires that laboratories script a policy and procedure that defines the protection of confidentiality process. The procedure should be prescriptive when it comes to defining the security of confidential data. Questions to consider during a conformity assessment:

- Is the laboratory a stand-alone entity or part of a larger organization?
- Is the laboratory currently accredited to ISO/IEC 17025:2017?
- Is the certificate of accreditation current?
- Does the laboratory have a documented management system that delineates all policies, procedures, and work instructions employed during testing and calibration?

- Has the laboratory created an organizational chart?
- Has a policy and procedure been established that protects the confidentiality of customer information?
- Have the responsibility and authority level for each employee been established?
- Does the laboratory have a designated quality manager?
- Does the laboratory have a designated technical manager?

For this chapter, there are four fundamental requirements needed to achieve compliance with clause 5 of ISO/IEC 17025:2017: First, the laboratory should identify roles, responsibilities, and levels of authority for employees. The organizational chart is the perfect tool to accomplish this requirement. Second, ensure that job descriptions are clear and concise in regard to reporting relationships. Third, ensure that a procedure is scripted that delineates the laboratory's approach for protecting and securing the confidential nature of a client's data. Finally, make sure the laboratory appoints a quality manager and technical manager. An expectation of all accredited laboratories is maintaining the effectiveness of the management system and employing corrective action and preventive action (CAPA) to correct deviations. It will become a daunting challenge to meet customer expectations without a deployed management system along with all the supporting policies and procedures to ensure ongoing effectiveness of the management system. Remember, meeting customer expectations is a fundamental requirement of ISO/IEC 17025:2017.

6.1. Resources Requirements: General

Clause 6.1 of ISO/IEC 17025:2017 is nothing more than a direct statement requiring laboratories to obtain and implement the resources necessary to successfully carry out their day-to-day activities. In accordance with IOO/ IEC 17025:2017, laboratories are required to have:

- Personnel

- Appropriate facilities and associated infrastructure
- Necessary equipment
- Systems
- Laboratory support

These elements are necessary to drive the overall success of the laboratory. Although clause 6.1 does not require an established procedure, it is recommended that a simple procedure be created that acknowledges the requirement. A procedure containing pointers that explain where each of the elements influencing measurement uncertainty can be found will suffice. For example, the following elements should be referenced in a high-level procedure:

- Personnel (6.2 of ISO/IEC 17025:2017);
- Facilities and environmental conditions (6.3 of ISO/IEC 17025:2017);
- Equipment (6.4 of ISO/IEC 17025:2017);
- Metrological traceability (6.5 of ISO/IEC 17025:2017); and
- Externally provided products and services (6.6 of ISO/IEC 17025:2017).

Getting down into the proverbial weeds with sufficient granularity can occur with the scripting of the individual procedures. Questions to consider during a conformity assessment:

- Has the laboratory implemented the appropriate infrastructure necessary to be successful?
- Has an organizational chart been created, and does the chart reflect an appropriate level of resources necessary to sustain labo- ratory operations?
- Has the equipment been appropriately identified and calibrated?
- Have environmental conditions been appropriately identified?

- Are environmental conditions being monitored?

- If certain environmental conditions (e.g., particulate counts) do not influence laboratory activities, has rationale explaining that these conditions do not impact test or calibration results been scripted?

6.2. Personnel

At the core of any successful organization are the people that support the day-to-day operations. Experience, skill, education, and training are important elements that need to be considered when working toward compliance with ISO/IEC 17025:2017's personnel (6.2) requirements. It is imperative that appropriate levels of competency are established for each function within the organization. Additionally, adequate supervision must be provided during the initial training of personnel until required competency levels for each employee are achieved. As a laboratory continues to grow, effective training programs and supervisory personnel must expand to ensure that employees keep pace with the ongoing evolution of technology. It is incumbent on laboratories wishing to achieve or retain ISO/IEC 17025:2017 accreditation to sustain continuous improvement opportunities that will be driven by a highly skilled and well-trained employee base. A basic requirement for laboratories working toward accreditation or sustaining accreditation is the establishment of a documented policy/procedure that delineates the training requirements for all laboratory personnel. Employee training and competence drives the overall quality and performance of the laboratory. Laboratories are expected to ensure all personnel have the appropriate levels of skill, experience, education, and training in support of executing testing and calibration activities. In some instances, specific technical training may be required (e.g., operating a scanning electron microscope). This additional certification could be premised on an industry standard or a regulatory/statutory certification requirement. Additionally, laboratory personnel tasked with the interpretation of test results or the authoring of test reports must possess:

- Relevant industry or technical knowledge as it pertains to the mate- rials tested or the actual performance of a specific test

- An appropriate level of knowledge of applicable standards and regulatory/statutory requirements
- A thorough understanding of noted deviations associated with the materials tested and the overall testing process

One tool that should be employed in support of meeting the training requirement is a training matrix. The training matrix will assist laboratory management in the defining and management of training requirements for all laboratory personnel, including contract labor. It is recommended the training matrix include: (a) training to validated test methods; (b) training to industry standards, such as ASTM International; (c) training to quality system procedures; (d) training to applicable sections of ISO/IEC 17025:2017; and (e) training to applicable regulatory and statutory requirements. Please keep in mind that the training record is a viable tool for managing the big picture of the laboratory's training; however, additional detail is required. Documented training is also required for all laboratory personnel. It is recommended that an individual training file be opened and maintained for each laboratory employee, regardless of their job function. The individual employee training records should contain documented evidence of previous (relevant) training, current training, certifications, applicable education, and evidence of competency testing (if deemed appropriate). Additionally, best in class training records for laboratory personnel will contain a resume and a job description. A well-written job description will support the overall training requirement for laboratory personnel. Unlike ISO 9001:2015, which does not specify a requirement for a job description, clause 6.2.4 of ISO/IEC 17025:2017 requires laboratories to write and maintain job descriptions for laboratory personnel. There is some latitude granted regarding job description content; however, there are minimum requirements for defining responsibilities for management, technical personnel, and key support personnel. For example, each job description should define the responsibilities:

- As they pertain to performing tests and calibrations
- As they pertain to planning tests and calibration

- As they pertain to evaluating test results
- As they pertain to the generation of reports that state opinions and interpretations of the test and calibration results
- As they pertain to test method validation (TMV) activities

Additionally, the job description needs to include expertise and experience required, qualifications, training programs, and managerial specific duties. Questions to consider during a conformity assessment:

- Does the laboratory have a documented program for training?
- Does the training procedure address the goals and requirements for specific levels of education, training, experience, and demon-strated skills
- Who is responsible for identifying the training needs for the laboratory?
- Is there a requirement for verifying if the training performed is effective?
- Does the training procedure address the requirement for supervision of employees in training?
- Does the laboratory have training records, and do they maintain them for all employees?
- Who is responsible for managing employee training records?
- Is there an annual review process for training?
- Does the laboratory have written job descriptions for all employees?
- Are the job descriptions current?

6.3. Facilities and Environmental Conditions

Similar to the infrastructure and work environment clauses delineated within ISO 9001:2015, ISO/IEC 17025:2017 has specific requirements nestled within clause 6.3 that relate to maintaining a proper laboratory environment. It is imperative that

laboratories establish and maintain environmental conditions appropriate for the testing and calibration work being performed. Laboratories must ensure that environmental conditions never have an adverse effect on the results of testing and calibration. Not only is the establishment of a suitable laboratory environment required, but the laboratory is required to monitor, control, and record environmental conditions relevant to the performance of the test method and calibration methods. Specific requirements needing to be considered by laboratories are: (a) biological factors (sterility), (b) dust, (c) electromagnetic interference, (d) radiation, (e) temperature, (f) relative humidity, (g) source of electrical supply, (h) sound levels, and (i) vibration. Other factors needing to be considered to support compliance with ISO/IEC 17025:2017 are housekeeping practices, contamination control, and restricted access to work areas. In this chapter, industry standards for environmental control and monitoring, housekeeping practices, effective contamination control, and subsidiary practices necessary for establishing good laboratory practices (GLP) will be discussed. In support of obtaining accurate test and calibration results, laboratories are required to maintain adequate facilities, environmental controls, and good housekeeping. For example, temperature has a measurable effect on the accuracy of gage block calibration, so it is important that temperatures be controlled. The temperature associated with the dimensional calibration is typically 20°C +/− 2.0°C, so the laboratory would have to control and monitor the temperature for 20°C. The same would hold true for relative humidity (RH) if RH is a factor influencing test or calibration accuracy. The laboratory will need to establish a procedure for environmental controls. At a minimum, it is recommended that the procedure contain requirements for:

- Temperature (note that temperature ranges could vary dependent upon area utilization)
- Relative humidity
- Particulate count (for cleanroom environment)
- Positive pressure (required for cleanroom environment)

- Barometric pressure (if appropriate)
- Contamination control needed to meet sterility requirements (for cleanroom environment)

Additionally, (a) control limits, (b) action limits, (c) methods for sample collection, (d) environmental monitoring, and (e) environmental testing (including equipment) will need to be included into the procedure. For example, Magnehelic gages, needed to monitor the positive pressure of a clean- room, will need to be included into the laboratory's calibration program.

If the laboratory employs cleanroom environments for testing, the clean- room will need to be properly validated. It is strongly recommended that ISO 14644 (Cleanrooms and Associated Controlled Environments) be employed for the validation process, as a reference. There are many organizations that specialize in the generation and execution of validation protocols needed to certify a cleanroom. For further clarification needed for cleanroom classification, it is recommended that Table 1 of ISO 14644–1 be referenced. Remember, it is important to retain the validation protocols and reports and have copies available, upon request, for review by laboratory clients and regulatory bodies.

If the laboratory employs a controlled environment such as a cleanroom, a procedure for gowning will also be required. The gowning procedure, depending on the cleanroom classification, may require a lab coat, a full gown, a hair cover, a beard cover, booties, hand washing, makeup removal, and/or jewelry removal. Access into the controlled environment will also need to be regulated. One final note: the high efficiency particulate air (HEPA) filtration system, needed to support cleanroom operations, must be included into the laboratory's preventive maintenance (PM) program. Good housekeeping is essential for maintaining a clean environment capable of performing accurate testing and calibration. Housekeeping is another area of the laboratory where having an established procedure is essential. Housekeeping is much more than emptying trash bins, sweeping laboratory floors, and cleaning restrooms. Work benches, shelves, storage areas, desk- tops, chairs, benches, walls, and everything else within the laboratory must be kept clean and in good working

order. For housekeeping requirements inside the cleanroom, the task becomes even more challenging, as contamination prevention and control are extremely important. It is important to create log sheets to document all the cleaning activities as a part of the housekeeping procedure. If a janitorial service is employed for the housekeeping, it is imperative that the janitorial staff be instructed in accordance with the laboratory's housekeeping procedure and that the training is documented. The laboratory is required to have a facility that is adequate to support test and calibration operations. For example, the source of facility power is expected to be stable. If power interruptions are frequent, then a backup generator would be a reasonable capital asset. If they can potentially influence test and calibration accuracy, then other facility requirements, such as (a) adequate lighting, (b) controlled access to restricted areas, (c) special shielding of laboratory areas from EMI, (d) radiation protection, or (e) use of lasers, will need to be considered. It is important to maintain records for all facility maintenance activities, including the inclusion of facility related equipment into the laboratory's PM program, if appropriate (e.g., HEPA filtration system). Questions to consider during a conformity assessment:

- Are the environmental conditions for the laboratory being adequately controlled?
- Does the laboratory have an established procedure for the monitoring and control of the laboratory environment?
- What environmental elements are being monitored?
- Are records of environmental monitoring being maintained?
- Does the laboratory have an established procedure for housekeeping?
- Does the laboratory employ a janitorial service for housekeeping? If so, are the service's employees trained in the laboratory's housekeeping procedure?

6.4. Equipment

ISO/IEC 17025:2017 requires laboratories to be properly equipped to support performance testing and calibration activities. The equipment and software selected for use by the laboratory must be capable of obtaining accurate measurements when employed in a testing and calibration environment. Additionally, laboratory equipment must always be calibrated against a defined specification or standard prior to its use. If a laboratory has the need to lease a piece of equipment for a specific purpose, the leased equipment must meet all the laboratory requirements and the ISO standard's requirements. Laboratories are also required to maintain records for their equipment. ISO/IEC 17025:2017 delineates specific requirements that laboratories must comply with regarding the record-keeping process. Record keeping, because of its overall impact to the performance of a laboratory, will be discussed in detail in this chapter. Further, ISO/IEC 17025:2017 incorporates requirements that are similar to ISO 9001:2015. For example, calibration labels that reflect calibration status and equipment that is being safeguarded from adjustments are mandatory requirements of clause 6.4.13 of ISO/IEC 17025:2017. Finally, the proper handling of equipment is necessary to ensure that improper handling does not influence the accuracy of the measurement results obtained. When there is evidence that equipment has been mishandled or failed to perform within the instrument's stated specifications, the laboratory must pursue appropriate action, including the immediate removal of suspect equipment from service. Practical guidance for complying with clause 6.4 will be the premise for the material provided in this chapter. It is expected that laboratories be fully equipped with the appropriate pieces of tools and equipment needed for the collection of samples and the execution of testing and calibration. The selected equipment and software (as applicable) must be capable of obtaining accurate and repeatable test and calibration results. Equipment range, accuracy, resolution, and measurement uncertainty are factors that laboratories need to consider when selecting lab- oratory equipment. All laboratory equipment, as applicable, is required to be calibrated prior to its use. In fact, it is extremely important that a laboratory have an effective calibration and PM program; this includes a requirement for measurement traceability of calibrated equipment to be traceable to the National Institute of Standards and Technology (NIST) or to the equivalent standard outside of the United States. Training is extremely important

when it comes to the operation of equipment employed for testing and calibration. It is imperative that each engineer, operator, and technician be properly trained in the use of laboratory equipment. In some cases, it may be necessary for the equipment manufacturer to pro- vide the training because of equipment complexity. Regardless, the training should be documented within the training folders for all laboratory personnel. Best practice would be to place the requirement to operate specific pieces of equipment into the laboratory's job descriptions. It is recommended that the operation manual for each piece of equipment be made available at their point of use. A practice that works extremely well is to build a kiosk in the laboratory that houses all the appropriate work instructions, procedures, and manuals relevant to the work being performed in the laboratory area. It is imperative that all equipment used in the pursuit of testing and calibration be properly identified. A common practice employed in many industries is to affix a label to each piece of equipment that contains: (a) an equipment identification number, (b) a calibration date, and (c) a calibration due date. For standards sent to a metrology for calibration, this is already a readily accepted practice.

When scripting the procedure for calibration and PM (Control of Monitoring and Measuring Devices), ISO/IEC 17025:2017 requires specific pieces of information to be collected and retained in each equipment file. At a minimum, the following pieces of information need to be included as part of each piece of equipment's master file (the following pieces of data can easily be managed through the use of state-of-the-art software solutions):

- The identification of equipment (including software, if applicable)
- The name of the manufacturer
- The equipment's serial number
- Verification and validation activities, including functional performance
- Equipment owner/location
- Manufacturer's operating instructions or manual or a pointer to the location of

the manuals (e.g., a kiosk)

- Calibration records (reports, certificates, adjustments, acceptance criteria, and calibration due date)
- PM schedule (if applicable)
- History of equipment problems (damage, out-of-tolerance reports, malfunctions, modifications, and repairs)

There are software solutions available that can assist with the management of calibration and PM records. For example, SIMCO Electronics has developed CERDAAC's Compliance Solution—a Title 21 Code of Federal Regulations (CFR) § 11 (the FDA's digital signature requirement) compliance tool for the management of calibration records. Other options on the market include GAGEtrak, Blue Mountain, and CATSWeb. These software solutions have the capability of managing all aspects of record management. A section is needed to address the handling, storage, and transportation of laboratory equipment as part of the laboratory's procedure for calibration and PM. When not in use and when practical, laboratory equipment should be adequately protected in a suitable environment. Whenever possible, best practice is to store and transport laboratory equipment in its original carrying case. When equipment is in place on the laboratory floor, it is important to place the equipment in a manner where it cannot be accidentally dropped or damaged due to its location. When equipment has been identified as being mishandled or providing erroneous results or when it has been determined to be functioning outside of its specification limits, the equipment must be taken out of service. If laboratory equipment is moved outside of the laboratory's direct control, then the functional performance and calibration status must be verified prior to the return of the equipment to service. In a perfect world, metrology facilities never make mistakes and equipment is never damaged during routine transportation; however, the world is far from perfect. Upon receipt, the equipment should be checked to verify: (1) that a new calibration label has been affixed, (2) that the equipment is functional (it turns on), and (3) that the calibration certificate is accurate. Calibration results should be routinely compared to previous results to ensure that equipment performance

remains consistent. If a piece of equipment was determined to be out of tolerance when received by the metrology lab, an adjustment to the calibration interval (in this case, shortening) is in order. In some cases, correction factors may be needed to equipment or soft- ware. Again, the requirement should be documented in the calibration procedure. Correction factors should reside in the equipment file and be updated as required. It is not unusual for some pieces of laboratory equipment to be dedicated to a specific test or calibration. This is particularly true when the setup of a test or calibration is time consuming. Most equipment has a feature or capability to lock potentiometers into place to prevent measurement adjustments. In these cases, it is often beneficial to lock adjustments into place through the use of lock-out tape or the application of an epoxy adhesive. If software is loaded into laboratory equipment prior to its use, the software must be controlled. Only the most current version of software and firmware should be available at its point of use. According to Rick Hogan: Test Uncertainty Ratio or TUR is a common term used in calibration. It is the ratio of the tolerance or specification of the test measurement in relation to the uncertainty in measurement results. It is used to evaluate measurement risk and validate the suitability of calibration methods. The most common requirement for many calibrations is a 4:1 TUR. However, not all calibrations meet a 4:1 TUR. A correction factor is any mathematical adjustment made to a calculation to account for deviations in either the sample or the method of measurement. Additionally, the application of correction factors will vary depending upon the test, instrument, or process being analyzed or calibrated. For example, correction factors used to calibrate an oscilloscope, waveform analyzer, or digital multimeter will vary considerably versus the determination used for assessing insulin sensitivity in a patient who is managing their blood sugar. Simply stated, the correction factors that are calculated will be specific to the task at hand. Questions to consider during a conformity assessment:

- Does the laboratory have adequate measurement equipment to sup- port testing and calibration?
- Is equipment and supporting software capable of supporting the necessary accuracy needed for testing and calibration?

- How is equipment capability determined (Test Uncertainty Ratio/ Test Accuracy Ratio 10:1)?
- Are instructions for the proper operation of equipment available for operatory use?
- Is equipment being operated by trained operators?
- Are training records available for the operators and are those records current?
- Are records being maintained for each piece of equipment?
- How are these records being maintained (e.g., GAGEtrak)?
- What type of information do the equipment records contain?
- Does the laboratory have an established procedure for addressing nonconforming equipment?
- Does the laboratory permit use of its equipment outside of the laboratory environment?
- How is equipment that is used outside the laboratory identified?
- Is equipment that is used outside the laboratory environment evaluated prior to returning it to use inside the laboratory?
- Is the laboratory employing correction factors in support of calibration?
- Is test equipment being safeguarded from unauthorized adjustments that can influence measurement accuracy?

6.5. Metrological Traceability

The accuracy of the measurements obtained during testing or the performance of calibration can be directly attributed to the equipment employed as part of the measuring process. The cornerstone for measurement traceability is

calibration. As mentioned in the previous chapter, all monitoring and measuring equipment must be properly calibrated. ISO/IEC 17025:2017 specifically requires laboratories to establish a program and procedure for calibration. Another requirement of the calibration process is to maintain traceability to a recognized standard. There are several nuances associated with the use of primary measurement standards, national standards, and international standards associated with calibration and specific to ISO/IEC 17025. The fundamental question to ask should be: "When is each standard appropriate for use?" Another challenge for laboratories is the traceability of calibrations and measurements to the International System of Units (SI) or the linking to SI units through the use of a reference made to a national standard. In some cases, the use of SI units is just not practical. Finally, the calibration, use, and management of reference standards are also a requirement of ISO/IEC 17025 requiring an established procedure. In this chapter, a proactive approach for ensuring laboratories can achieve and sustain compliance to clause 5.6 will be discussed, including examples of different approaches for managing calibration and reference standards. Laboratories are required to calibrate their equipment prior to its use. As stated in previous Chapter 6.4 (Equipment), laboratories are required to establish a calibration program that is documented by a written procedure. Besides calibration, the program created by the laboratory must also include the laboratory's processes for:

- Checking equipment
- Controlling measurement standards
- Maintaining measurement standards
- Reference materials employed as measurement standards

For laboratories dedicated to the execution of calibration work, equipment used must be capable of obtaining accurate measurement and calibration results while being traceable to the SI (System International Units). SI units, premised on the metric system, have been universally adopted by most countries. However, the United States *has not* adopted the SI unit system. According to the ISO, "calibration" is the set of

operations that establish, under specified conditions, the relationship between values as indicated by a measuring instrument or a measuring system or as indicated by values represented by a material measure and the corresponding known values of a measurand (a quantity intended to be measured). Note: traceability is also a critical component of the calibration process. According to a working paper developed by the United Nations Indus- trial Development Organization (UNIDO 2006), "*traceability" is the concept of establishing valid calibration of a measuring standard or instrument by step-by-step comparison with better standards up to an accepted national or international standard.* Collectively, calibration and traceability are two terms that define a laboratory's calibration program. Basically, all equipment employed in the calibration process must eventually be traceable back to a national standard such as NIST through the use of primary and secondary (reference) standards. It is imperative that when a laboratory employs a metrology lab for the performance of equipment calibration, the metrology laboratory selected should be accredited to ISO/IEC 17025:2017. Compliance with ISO/IEC 17025:2017, although not a complete guarantee, reflects the organization's status of demonstrating technical competence, measurement capability, and measurement traceability. As previously stated, when employing an independent metrology laboratory, it is imperative that the laboratory selected should be accredited to ISO/IEC 17025:2017. Prior to their addition onto the approved supplier's list (ASL), the laboratory should be evaluated by employing the tools mentioned in Chapter 5 (Subcontracting Tests and Calibrations) and Chapter 6 (Purchasing Services and Supplies). Make sure the metrology laboratory provides actual values associated with each calibration as part of the Certificate of Calibration. Besides the mandatory content requirements specified in Chapter 6.4 (Equipment), best practice is to incorporate the requirements delineated within ISO 9001:2015 or ISO 13485:2016. As a minimum, the following requirements will need to be included and addressed within the laboratory's established calibration procedure:

- Laboratory equipment must be calibrated at predefined intervals against standards that are traceable to a national standard (e.g., NIST). Make sure the calibration intervals are placed into a table within the procedure.

- Laboratory equipment (if applicable) must be able to be adjusted or readjusted as necessary.

- Laboratory equipment will be properly identified in regards to calibration status.

- Laboratory equipment must be safeguarded against adjustments that would invalidate the results of obtained measurements.

- Laboratory equipment must be protected from damage and deterioration during handling, maintenance, and storage.

- Laboratories will need to perform a comparative analysis of calibration data versus the previous calibration data obtained. This is why it is extremely important to have metrology labs provide the actual calibration data.

- Laboratories must take action when nonconforming equipment has been identified.

- Laboratories need to maintain records of all calibration activities.

Testing within the laboratory still requires the employment of calibrated measuring equipment and includes the requirement for traceability. When equipment is employed for testing, the equipment must be capable of supporting the need for addressing measurement uncertainty. Additionally, testing must be performed within an adequate laboratory environment. For example, if the testing is being performed on biologics, then the expectation is that the laboratory performs these tests in a controlled environment (cleanroom).

Laboratories are required to establish procedures for all of their reference standards. Reference standards should be considered restricted use standards as they should only be used for calibration. The metrology lab tasked with the calibration of reference standards must ensure the calibration is performed using equipment traceable directly to a national standard (e.g., NIST).

As part of the calibration procedure, the laboratory needs to define the requirements for the control of reference materials. Whenever possible, reference materials will need to be traceable to SI units (except in the United States). It is always a best practice to employ certified reference materials; however, if certification is not possible, the laboratory will need to establish a procedure for validating the use of reference materials. Questions to consider during a conformity assessment:

- Is all laboratory measurement equipment employed in testing and calibration calibrated?
- Does the laboratory have an established procedure documenting its calibration program?
- Are measurements that are obtained by laboratories traceable to International System of Units (SI)?
- If the laboratory is not employing traceability to SI units, has traceability to an appropriate measurement standard been established?
- Does the laboratory employ reference materials in support of calibration?
- Does the laboratory have an established procedure for the calibration of reference standards?
- Does the laboratory have an established procedure for the handling, transportation, and storage of reference materials and standards?

6.6. Externally Provided Products and Services

Laboratories are required to retain only qualified sources for externally provided products and services. Due to the changing needs of a dynamic business environment that may influence laboratories, the use of a subcontracting laboratory facility may become necessary. ISO/IEC 17025:2017 recognizes the inevitable and has identified a few requirements associated with the subcontracting of work to other laboratories. It is incumbent upon the laboratory to ensure that all off-loaded work

is sent to a competent sub- contractor (e.g., compliant with 17025:2017). A point to keep in mind is that all work done at the subcontractor's location must be performed in accordance with the requirements delineated within 17025:2017. In fact, the facility or organization subcontracting the work is responsible for the accuracy and quality of the work. However, if the use of a specific subcontractor is delineated within a customer's contract, then the customer retains the responsibility for subcontractor performance and general oversight. However, best practice is to take some ownership in the work activities per- formed at the subcontractor's location, even if the selection process is made by someone else. In this chapter, the identification, selection, and use of qualified subcontractors will be discussed.

When a laboratory needs to outsource work to another laboratory, the preferred path is to select a laboratory that is already accredited to ISO/ IEC 17025:2017. For example, if the laboratory has a valid accreditation certificate from a recognized accreditation body (e.g., The American Association for Laboratory Accreditation, or A2LA, as it is now known), then the laboratory should have the appropriate certificate and should have completed a brief questionnaire. However, if the laboratory selected for outsourcing is not accredited, an on-site evaluation is probably warranted to determine the overall level of compliance to ISO/ IEC 17025:2017. The NIST website has a complete supplier survey form that can be employed for the performance of a detailed laboratory assessment.

Another important point to remember pertains to responsibilities and customer notification. The laboratory is ultimately responsible for the performance of all outsourced work. It is also important to ensure the laboratory's customer is informed in writing about any work being outsourced. Hopefully, this will be captured during the initial contact review process. Finally, there is a need to ensure that a laboratory's supplier base is appropriately qualified. From a QMS perspective, supplier qualification should be premised on risk. For example, a supplier selected to perform janitorial services will probably be considered low risk. Conversely, a sup- plier that is providing components to repair damaged equipment or that is selected to actually perform the repair work may be considered a medium or high- risk supplier. Questions to consider during a conformity assessment:

- Does the laboratory subcontract to external supplier's test and/or calibration work?

- Are the external suppliers employed for the performance of sub- contracted work in compliance with and/or accredited in accordance with ISO/IEC 17025:2017?

- Does the laboratory notify customers, in writing, when all or part of their work is outsourced?

- Does the laboratory maintain an ASL containing the names of their qualified subcontractors?

- Does the laboratory have documented evidence that their subcon- tractors are either in compliance with or accredited to ISO/IEC 17025:2017?

- Are suppliers being appropriately assessed premised on risk?

7.1. Review of Requests, Tenders, and Contracts

In attempting to break down the concept of "review of requests, tenders, and contracts," this chapter can easily be aligned with clause 8.2 of ISO 9001:2015 (Requirements for Products and Services). Similar to ISO 9001:2015, ISO/IEC 17025:2017 requires laboratories to establish policies and procedures delineating processes associated with the review of customer requests, the identification of laboratory resources, and the selection of an appropriate test method or calibration method to be used for meeting customer requirements. Documented contract reviews are also a salient requirement of 17025:2017. It is not enough for laboratories to review customer and contractual requirements. These critical reviews, including the decision to accept or request a modification or to reject a customer order, must be documented. The use of a contractor must be incorporated into the review process and disclosed to the customer should the laboratory plan to subcontract activities in accordance with ISO/IEC 17025:2017, clause 7.1.1(c). It is inevitable that contract deviations are going to occur. It is imperative to recognize that 17025:2017 requires laboratories to notify their customers when deviations occur or when a

decision is made to outsource work to another laboratory. Finally, ISO/ IEC 17025:2017 recognizes a contract as being oral or written; however, it is always best to have a written contract that clearly defines customer requirements and expectations. This chapter will expand upon the importance of the review of requests, tenders, and contracts. Having an established procedure for contract review is a mandatory requirement for laboratories. The expectation is that the written procedure be prescriptive enough to support an effective contract review process. One tool that can be implemented quickly is a contract review checklist. The elements noted in Figure 7.1.1 should be considered when construction the checklist. Remember, it is requirement of the standard to retain all records associated with the contract review process. Additionally, when deviations are noted, it is imperative that the customer be notified and their approval of the deviation approved. Finally, contract changes received after work has commenced require the same level of scrutiny as the original contract/purchase order review. Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure for the review of requests, tenders, and contracts?
- Does the review process entail a review of test methods required, an alignment of laboratory capabilities, and a determination regarding whether the customer requirement can be met?
- Are records of the reviews of requests, tenders, and contracts retained by the laboratory?
- Does the review entail an assessment for the need to outsource testing or calibration work?
- Are customers notified of deviations from the contract?
- Are contracts reviewed when amendments to the contract are made?

Understanding customer requirements is a fundamental requirement of

7.2. Selection, Verification, and Validation of Method

It is not enough for laboratories to perform testing and calibration services in an appropriate environment. ISO/IEC 17025:2017 requires substantial granularity in regards to procedures employed for testing and calibration. For example, established procedures are required to address: (a) sampling requirements, (b) handling, (c) transport, (d) storage, (e) the preparation of items to be tested or calibrated, and (f) the test methodologies employed. Measurement uncertainty and statistical techniques are also salient factors required to be considered as part of the analysis of test and calibration results. Another important tool driving the accuracy, reproducibility, and repeat- ability of measurement results is the TMV. Standard methods, laboratory- developed methods, and nonstandard methods that are used by a laboratory are required to be validated. The primary focus of the procedures and vali- dated test methods is to support the obtainment of accurate measurement data using a stable measurement platform. Measurement range, accuracy, measurement uncertainty, detection limit, linearity, repeatability, reproducibility, industry accepted practices for addressing measurement uncertainty, and measurement error will be explored as part of the discussion on compliance in clause 7.2. Laboratories are required to employ documented procedures and test methods for all test and calibration activities. The test methods employed are required to be validated unless they are a recognized standard developed by Procedure Content. ISO/IEC 17025:2017 does require that each new procedure generated for test or calibration contain specific content. At a minimum, procedures scripted for testing or calibration should contain (as appropriate):

- Procedure identification
- Scope
- Description of test or calibration
- Test or calibration parameters
- List of necessary equipment to execute the test or calibration

- List of reference standards
- List of reference materials
- Detailed procedural steps
- Test or calibration acceptance or rejection criteria
- Data collection sheets and the data recording process
- Measurement uncertainty
- Process for documenting test or calibration deviations

Laboratories must validate all laboratory developed methods, nonstandard test methods, and standard methods that have been modified for use, regard- less of application. According to 21 CFR § 820 (the FDA's Quality System Regulation), validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. Additionally, validation is establishing documented evidence that provides a high degree of assurance a specific process will consistently produce a product that meets its predetermined specifications and quality attributes. Although not specifically required by the standard, best practice is for a laboratory to script a stand-alone procedure for validation. There are also specific attributes and data quality objectives that ISO/IEC 17025:2017 requires to be considered in support of validation:

- Accuracy
- Precision
- Specificity
- Detection limit
- Limit of quantitation

- Linearity
- Range
- Ruggedness and/or robustness

If all the data quality objectives are achieved and premised on the review and analysis of the data, then the test method is considered to be validated in accordance with ISO/IEC 17025:2017. The National Association of Testing Authorities (NATA) in Australia has developed a list of questions that can be employed to frame the scope of the method requiring validation:

- What is the purpose of measurement (what is to be identified and why)?
- What are the likely sample matrices?
- Are there interferences expected, and, if so, should they be determined?
- What is the scope (what are the expected concentration levels or ranges)?
- Are there any specific legislative or regulatory requirements?
- Are there any specific equipment accommodations and environ- mental conditions that need to be considered?
- What type of equipment is to be used?
- Is the method for one specific instrument, or should the method be used by all instruments of the same type?
- What is the method used for the preparation, subsampling, proce- dure, and included equipment? (NATA, Australia, 2012)

To understand the concept of measurement uncertainty, one must first understand the measurement process. A measurement is nothing more than the output of a series of operations being executed to calculate or determine a value. The measurement process essentially transforms inputs into outputs. Regardless of how

well defined a measurement process is, it is nearly impossible to obtain repeat observations that are identical. This is due to the introduction of variability into the measurement process. Variables introduced into the measurement process—such as laboratory environmental conditions, test methods employed, use of different technicians, materials employed, and equipment employed—each result in measurement uncertainty; each needs to be accounted for as part of the measurement process (Type-B estimates of uncertainty). Statistically, estimating uncertainty can be broken down into two categories: Type-A estimates (an estimate obtained from sample data) and Type-B estimates (uncertainty estimates for measurement process errors resulting from reference attribute bias, display resolution, operator bias, and computation and environmental factors)—also known as heuristic estimates. For laboratories, it is essential that procedures are scripted and applied to the estimation of measurement uncertainty for all calibrations. It is important to remember that measurement uncertainty values are required to be stated within the calibration certificates and test reports. Questions to consider during a conformity assessment:

- Are testing and calibration methods employed by the laboratory documented within written procedures and/or work instructions?
- Does the laboratory have an established procedure for TMV?
- Are work instructions and procedures available at their point of use?
- Have laboratory designed test and calibration methods been properly validated?
- Does the laboratory employ nonstandard test and calibration methods for testing and calibration?
- Are nonstandard methods validated prior to their use?
- Are range, accuracy, measurement uncertainty, detection limits, measurement linearity, reproducibility, and repeatability consid- ered when validating test methods?

- How does the laboratory evaluate measurement uncertainty?
- Does the laboratory have an established procedure for addressing measurement uncertainty?

7.3. Sampling

Laboratories are required to establish and implement procedures employed for the purpose of sampling materials, substances, and products being tested. It is imperative that the sampling plans be premised on recognized statistical methodologies and that such plans be made available at the point of use. The procedure established for sampling plans must delineate: (a) sample selection, (b) sampling plan, (c) sample withdraw, and (d) sample preparation. In support of achieving compliance with clause 7.3 of ISO/ IEC 17025:2017 it is considered best practice to ensure that sampling plans can be directly correlated to a recognized sampling standard, such as the American National Standards Institute/American Society of Quality (ANSI/ASQ) Z1.4. It is essential that the approach to sampling does not influence the accuracy and validity of test and calibration results. In sup- port of the sampling requirement, laboratories are also required to establish a procedure for the recording of data collected during the performance of testing and calibration activities. Laboratories are required to have and employ sampling plans and establish procedures for the governance of sampling plans and/or delineating custom sampling plans.

According to the NIST *Engineering Statistics Handbook:* A sampling plan is a detailed outline of which measurements will be taken at what times, on which material, in what manner, and by whom. Sampling plans should be designed in such a way that the resulting data will contain a representative sample of the para- meters of interest and allow for all questions, as stated in the goals, to be answered. (NIST/SEMATECH 2012). Depending on the type of test or calibration work being performed within the laboratory, established sampling plans, such as those authored by ANSI and ASQ, may be practical, depending on the application. Sampling plans—such as (a) attribute acceptance plans (e.g., ANSI/ASQ Z1.4); (b)

zero acceptance number sampling plans (*C* = 0) and (c) variable acceptance plans (e.g., ANSI/AQS Z1.9)—have proven to be effective in a laboratory environment Development of a Sampling Plan. There are eight salient steps that must be taken into consideration for the sampling plan to be statistically relevant (i.e., capable of providing a result that accurately reflects the population from which a sample is being selected) and effective:

1. The sampling plan must contain purpose and scope statements.
2. The sampling plan should contain references (as appropriate).
3. The sampling plan should contain a section for roles and responsibilities.
4. The sampling plan must contain: (a) the parameters selected to be measured, (b) the range of the values to be measured, and (c) the accuracy and resolution required to obtain these measurements.
5. The process for how and when samples will be taken and obtained must be specified.
6. Actual sample sizes need to be specified within the plan.
7. The sampling plan must contain requirements for data collection, data recording, and storage.
8. The sampling plan must be verified prior to its release for use within the laboratory.

If a laboratory is asked by their customer to deviate from established sampling plans, then such a deviation should always be documented. In some cases, a laboratory's customer may have their own sampling plans. These sampling plans should always be reviewed as part of the initial quotation request that is received from the customer and be built into the laboratory's testing and/or calibration documentation that is established for the customer. It is imperative that, when stating the results of testing or calibration work, the sampling data should be included in the test reports or within the calibration certificate.

The process of recording data should be included. ISO/IEC 17025:2017 specifically requires the sampling plan employed for sampling to be identified

- The environmental conditions to be recorded if it is relevant to the process
- The accurate identification of the location(s) of the samples taken
- The statistical plan the sampling plan is premised on (if appropriate)

Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure for the use of sampling plans?
- Are sampling plans available at their point of use in support of testing and calibration?
- Are deviations from the sampling plans documented?
- Are sampling plans verified prior to their release?
- Are the sampling plans statistically relevant?

5.1 7.4. HANDLING OF TEST AND CALIBRATION ITEMS

Similar to clauses outlined in ISO 9001:2015, ISO/IEC 17025:2017 requires laboratories to establish procedures that delineate: (a) transportation, (b) receipt, (c) handling, (d) protection, (e) storage, and (f) retention and disposal of test and calibrated items, as applicable. Similar laboratory procedures are required to prevent damage, deterioration, or loss of test and calibration items during storage, handling, and preparation. The salient goal in mind for laboratories should be the fundamental protection of the integrity of the test item or the equipment submitted for calibration. Laboratories are also required to implement a process for identification and traceability test and calibrated items. Finally, laboratories must be able to reasonably assess items submitted for test and calibration and to ascertain the suitability of the item prior to the commencement of testing or

calibration work.

Laboratories are required to establish procedures for the transportation, receipt, handling, protection, storage, and retention and/or disposal of test and/or calibration items. These elements can be placed into a number of different laboratory procedures, or the laboratory can choose to script a stand- alone procedure. As long as the requirements are documented in a procedure and the laboratory complies with the procedure, then compliance to clause 7.4 can be claimed. As part of the procedure, the laboratory should include a listing of the designated areas within the lab impacted by the procedure. For example, the receipt and transportation of items by the laboratory will occur in one of two ways: (a) it is collected by laboratory's personnel, at a customer site, and transported back to the laboratory by employing a laboratory vehicle; or (b) it is shipped to the laboratory through the use of a commercial shipping carrier (e.g., UPS or FedEx). In any event, the entry point into the laboratory will be the receiving dock. If the laboratory routinely performs customer pickup and delivery of test and calibration items, then the transportation of these items needs to be documented by procedure. It is also a best practice to document all shipping modalities, including packaging, into an established procedure.

The laboratory should perform an initial assessment of the items received for damage relating to handling and transportation when the item is received by the laboratory. If the item is damaged, the event should be documented and the customer contacted for further instructions. It is recommended that laboratories have a holding area for items received as damaged. If the item is received as acceptable, the receipt should be logged into the laboratory's receiving log. Note: the receiving log can be electronic (e.g., a material requirement planning [MRP] system). It is important that receiving person- nel are properly trained and are capable of documenting the "As Received Condition" of test and calibration items. As part of the receiving process, the laboratory will: (a) assign a unique work order number (employed for ID and traceability) to the item, (b) affix a tag or label to the item reflecting the work order number, and (c) print the work order that delineates all the processing steps. For electronic MRP systems, the work order may simply be a compiled number of sequential steps that contain a brief description of the work to

be performed and a barcode.

Depending on the type of test or calibration item received, a more thorough inspection may be required versus the typical identification and damage per- formed on receipt. All additional inspection and assessment activities per- formed on items as part of the inspection will need to be documented. In many cases, the inspection information can be recorded onto the work order. If a test or calibration item is found to be unfit for testing or calibration, the item should be placed on hold and the customer notified, which is similar to the receiving process. Since the test or calibration item has now entered into the laboratory's work stream, the nonconformance should be documented.

It is imperative that laboratories properly handle items to protect them from damage and deterioration while in the custody of the laboratory. For test items, the best practice is to place these items (if possible) into protective storage totes. For equipment sent to the laboratory for calibration, the best practice is to use the manufacturer's carry case for each piece of equipment. The employment of adequate protection schemes is never optional. It is inevitable that storage, even for very brief periods of time, will be required for test and calibration items. Storage is nothing more than an exercise in material handling assuming the laboratory has properly identified such items as they enter the laboratory and the items have been placed into protective bins or their cases. If there are environmental considerations associated with the storage of test samples, the requirements for the control of monitoring the environment must be delineated within a procedure. For example, if a storage area requires the control of temperature and relative humidity, these parameters must be defined in a procedure and evidence of the sustainability of the environment collected. Additionally, the storage of test and calibration items should be in a manner that facilitates the easy retrieval of these items. Further, security should always be a concern for laboratories. Storage areas should be considered restricted access areas, with access limited to laboratory personnel with functional responsibility of item storage. Retention and disposal pertain to test samples, as equipment sent to a lab- oratory for calibration will ultimately be returned to its owner (customer). Depending on the customer, some will want the samples returned with the test report.

Sometimes the laboratory is asked to retain the samples. Since there is no predefined retention time denoted within ISO/IEC 17025:2017, the retention time for the samples will need to be defined by the laboratory. If the test samples do not degrade over time, then best practice would be to retain the sample for the same duration as the test report. If samples do degrade over time, then ninety days would be a reasonable duration to retain samples prior to their disposal. However, regardless of the approach for sample retention and disposal, the time frames must clearly be delineated within a procedure and the retention periods clearly conveyed to the customer. Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure for the handling, receipt, transportation, protection, storage, retention, and, if applicable, disposal of test and calibration items?
- How does the laboratory identify test and calibration items?
- Are items received by the laboratory evaluated on receipt for dam- age and operational performance anomalies?
- Are laboratory customers promptly notified when items are received as damaged or in a nonoperational or degraded condition?
- Does the laboratory have the appropriate facilities for avoiding deterioration, loss, or damage to the test or calibration item during storage, handling, and preparation?
- Does the laboratory have an established procedure for handling items that are required to be secured?

7.5. Technical Records

Technical records have been given a stand-alone section within ISO/IEC 17025:2017 to place an additional emphasis on the importance of technical records. In general, technical records fall under the guise of clause 8.4 of ISO/IEC 17025:2017. They need to be adequately controlled, protected from deterioration, and retained

as demonstrated evidence of compliance. As the title of this section suggests, these records are technical in nature. This brief chapter will discuss the importance of technical records and their proper management; however, it is not possible to separate this chapter from the chapter on control of records. Regardless of record construction or type, some level of control is required by this standard.

Effective tools for complying with the requirements for technical records are quite simple. The standard requires that a laboratory script a procedure that clearly delineates the steps that will be taken to comply with technical requirements. As part of the procedure, the data collection and storage should be adequately addressed. Additionally, the procedure should have the requirements for handling deviations and nonconforming results. It is acceptable to reference the procedure for control of records regarding the requirements for technical record retention. The primary technical record col- lection will be the report. The collection and recording of technical data are important steps in the technical record process. However, the final report is where the actual data are summarized and the final decisions made, premised on the data collected.

All relevant data collected as part of a laboratory's work is required to be appropriately recorded. For example, records should reflect (as appropriate) the following pieces of information:

- The actual measurement results
- Factors influencing the measurement results
- Influencers that impact measurement uncertainty
- Environmental conditions
- Equipment used to obtain measurement results (including calibration status)
- Individual(s) performing the actual work
- Date(s) and time measurements were obtained

- Deviations from test procedures and protocols
- Nonconforming results
- Additional actions pursued that are relevant to the report, and
- The actual report

Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure for technical records?
- Does the procedure identify the appropriate content for technical records?
- Have requirements for handling deviations and nonconforming results been defined?
- Have record retention and storage requirements been defined for technical records?

7.6. Evaluation of Measurement Uncertainty

NIST's definition for measurement uncertainty is: "A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand (the measurand is the actual quantity that is being measured). (www.nist.org)".

ISO/IEC 17025:2017 requires laboratories to identify the contributing factors that can influence measurement uncertainty. There are multiple factors that can influence measurement uncertainty, such as variations in temperature, accuracy of the equipment being used, and even the technical skills of laboratory personnel. It is important to remember that at the most basic level, a measurement is nothing more than the attainment of a value. For example, when performing a final test or a mechanical inspection and obtaining mea- surement values associated with measuring and monitoring equipment used, the values being obtained through measurement will include: (a) volts, (b) temperature, (c) centimeters, (d) grams, etc. However, once a measured value is obtained, it is important that the quality of the

value obtained be deter- mined. Measurement uncertainty is essentially the primary element that will influence the accuracy of the measurement(s) obtained. There are tools that can be used to mitigate the challenges associated with measurement uncertainty. For example, ensuring that the output of a measurement process is repeatable and consistently reproducible will drive the reduction in measurement variability. TMV is a key ingredient needed to support the obtainment of accurate measurement results. Additionally, ensuring that the measurement and monitoring of equipment is validated, maintained, and appropriate for the measurement value that is necessary to obtain is equally important. For example, the use of a caliper to obtain a measured value of ≤ 0.001 is not appropriate when a micro- meter should be the tool of choice to obtain an accurate measured value. Further, operator performance is essential when it comes to the use of measuring and monitoring equipment. All staff members tasked with using measuring and monitoring equipment are required to be appropriately trained. Simple concepts, such as knowing how to hold a component when measuring a mechanical parameter or selecting the correct tool to actually obtain a measurement value, requires experience and training. Questions to consider during a conformity assessment:

- Is the determination of measurement uncertainty being adequately addressed by procedure?
- How is measurement uncertainty being determined?
- Is measuring and monitoring equipment being calibrated?
- Are calibration activities traceable to a national standard (e.g., NIST)?
- Have personnel tasked with using measuring and monitoring equipment been appropriately trained?

7.7. Assuring the Validity of Results

If one considers that obtaining and reporting accurate test and calibration results are the primary goals of testing and calibration laboratories, assuring the quality of the results should be considered a mission critical activity. In support of compliance

with ISO/IEC 17025:2017, laboratories are required to establish quality control procedures. The quality control procedures are needed to monitor and assess the validity of the data obtained from testing and calibration activities and from the identification of statistical trends. Similar to the requirement for sampling, the employment of applied statistical methodologies should be applied as a tool for data assessment. It is important to remember that the monitoring process must be planned. Elements such as the retesting or recalibration of retained items must be considered as part of the overall monitoring process. A final point that needs to be made pertains to the steps required when analyzed data falls outside of the pre-defined parameters. In this chapter, proactive steps that can be employed in support of achieving compliance with clause 7.7 of ISO/IEC 17025:2017 will be discussed. Laboratories are required to establish quality control procedures to ensure that the data obtained during the execution of testing and calibration are valid. When developing new procedures for testing and /or calibration, laboratories shall consider carefully all requirements necessary for effective quality control. These requirements should be documented as part of the quality control procedures. Where necessary, the existing quality control procedures should be assessed for their adequacy. The procedure scripted by the laboratory must contain sufficient granularity to prevent erroneous results of testing and calibration from being reported to the customer. When establishing a procedure, the following suggestions for monitoring the validity of results and detecting trends using planned and structured methods should be considered.

The definition for certified reference materials (CRM) is: “reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. (ISO 2008)”.

According to the Institute for Reference Materials and Measurements (IRMM): Public confidence in measurement results is important in many aspects of modern society, including consumer protection in food consumption, health-care, environmental protection, and fair trade. CRMs are cornerstones of modern

analytical quality assurance because they allow calibration of instruments, validation of methods, and quality control of methods and laboratories based on traceability and comparability of measurement results. (IRMM 2015).

There are numerous CRMs available commercially that a laboratory can procure and quickly employ in support of testing and calibration activi-ties. When a laboratory procures a CRM from a supplier, best practice is to have procurement specifications for each CRM purchased. It should be noted that some CRMs will require controlled environmental conditions for storage to ensure that the validity of the CRM is sustained. Special requirements for handling and storage should be documented within each CRM's procurement specification (as applicable).

CRM, when procured, should always be accompanied by a certificate. The certificate should state the property and values certified and the procedure by which traceability to SI units or a national standard has been established. Each value certified on the certificate should be supported by a statement of measurement uncertainty at a stated level of confidence. Another source for CRMs is NIST.

NIST maintains 1000 different high quality reference materials that can be employed by laboratories in support of testing and calibration. There are also numerous commercial entities, such as Sigma- Aldrich, that are capable of providing high quality standards. As the author of this book, I recommend visiting the Sigma-Aldrich website. It contains a plethora of information pertaining to CRM and links that can provide laboratories with relevant regulatory and statutory information.

As previously stated, there are companies that provide detailed traceability and assay results with their standard reference materials. Laboratories must ensure that traceability requirements for secondary reference materials are defined within the quality control procedure. Copies of all certifications for secondary reference standards must be retained. A requirement for certification retention, including retention periods, should be specified within laboratory procedures.

According to NIST: "A proficiency test (PT) is simply a method that you may use to validate a particular measurement process". The artifact's reference value is

not known by the participating laboratory at the time of its measurement (test). In a well-designed proficiency test, the reference value for the artifact should be principally deter- mined by a competent laboratory with appropriate traceability to the International System of Units (SI). The reference laboratory should also have demonstrated its competency though key com- parisons, inter-laboratory comparisons, or proficiency tests appro- priate to validate their measurement capability. It is also preferable that the laboratory has had its competency independently assessed through the process of laboratory accreditation. Lastly, in order to appropriately validate the measurement capability of the par- ticipating laboratory, the uncertainty assigned to the artifact by the reference laboratory should be sufficiently smaller than the expanded uncertainty reported by the participating laboratory. (www.nist.org).

It is strongly recommended that a laboratory participate in at least two PT programs annually for each laboratory discipline. The PT program must cover all functional areas for which the laboratory has received accreditation. Failure to perform PT testing can result in the laboratory's loss of accreditation.

NIST recommends that laboratories develop and employ a proficiency testing plan (PTP) to substantiate the quality, accuracy, and repeatability of test and calibration results. Employing PTPs are an excellent way for laboratories to support the requirement of monitoring the validity of test and calibration results and the overall validation of a laboratory's measurement process.

According to the National Association for Proficiency Testing: Several different methodologies are used to evaluate and report the results of a proficiency test. ISO Guide 43, *Proficiency Testing by Inter-laboratory Comparisons—Annex A,* provides guidance. NCSLI Recommended Practice, *Guide for Inter-laboratory Comparisons*, is another excellent source of information. The most widely accepted method compares the measured data against established reference values. The result is the En (called E sub n) number. When the En is between +1 and –1 no corrective action is required. A second method for evaluating and reporting proficiency test results centers around determining the inclusion and/or overlap of a participant's

measured values and associated uncertainties with that of the artifact's reported reference values and uncertainties. This evaluation is simply given as "Within," "In," and "Out." Both of these evaluations can be displayed using charts/graphs, making a relatively simple comparison. Besides being compared in the reference values, a report is also prepared showing the data from all participants. With this information it is relatively easy to note individual performance compared to that of peers within the industry. (NAPT 2015).

According to ORA Regulatory Laboratories Laboratory Manual of Quality Policies: Replicate testing may be performed on samples which are found to be violative. The original sample results are verified by using an alternative method or by rechecking results by the same method. A violative chemistry result may be verified by a second instrument, another method, a second analyst or repeated by the same analyst. A violative microbiology result by a rapid screening method is verified by a culture method. (US FDA Office of Regulatory Affairs 2014)

The retesting of retained items is nothing more than the reintroduction of retained items into the normal testing and/or calibration environment to assess the ongoing performance of the laboratory. The expectation is to establish a history of repeatable testing and calibration results.

According to ORA Regulatory Laboratories *Laboratory Manual of Quality Policies:* Checking for correlation means evaluating the interrelated characteristics (analytes) of the sample. By comparing results from different analyses on the same test item, one checks for reason- ableness (i.e., Does the data make sense or correspond as anticipated?). Certain characteristics within the sample will maintain an analogous relationship to one another with regard to the type of test being performed. If one characteristic is dependent on or at all indicative of another characteristic, they should be compared for consistency. The supervisor or designated reviewer should be able to anticipate and recognize an analogous relationship with different characteristics of the same sample. Any deviation such as the absence of expected primary characteristics or the sudden appearance of previously unobserved characteristics of the sample, signals the probability of error.

(US FDA Office of Regulatory Affairs 2014).

One way to accomplish this task is the employment of applied statistical methodologies for the analysis of data collected. Best laboratory practice is to ensure that all data sheets containing test results or calibration results should be assessed for accuracy and acceptability. Control limits should be established by the laboratory and documented within a procedure. If, during the execution of testing or calibration, the measured data are found to fall within the control limits, then the data should be deemed acceptable.

Other tools, such as accuracy and control charts, can be employed to determine if the measurement system process employed by the laboratory is capable of providing accurate and repeatable results. Control charts are great tools that can be used for quickly identifying data patterns in support of identifying process variation and assignable causes.

When data are found to be outside the predefined criteria “control limits” then corrective action is required to mitigate the out of tolerance condition. The first steps pursued should be verifying the data results for transcription, calculation errors, equipment set-up errors, or sample preparation errors. It may be necessary to use a new set of standards or recalibrate the instrument employed for the initial measurements.

It is important to note that reliable and valid results, although a limited relationship exists, are not the same when it comes to measurements. For example, a measurement process can be reliable in that repeatable results are obtained; however, these results may not be valid. For example, if a voltmeter is out of tolerance and producing repeatable results that are always one volt lower than the actual value, the measurement can be considered reliable but not valid. To ensure validity is sustained, it is imperative that the validity of the output is determined and continuously monitored.

Trending of calibration data consists of tracking the results of calibration over time. For example, a calibration report/certificate should contain the results of the

actual calibration, including the recording of all adjustments made. Upon receipt, the contracting establishment should review the certificate and determine if the results are acceptable prior to placing an instrument or gage back into service. Additionally, this data should be trended so the short term and long-term predictability of instrument or gage performance can be determined.

For a manufacturing organization, the receipt of an out of tolerance event can be a scary proposition, especially if the manufacturer is a medical device establishment. Products already in use that are considered suspect have to be evaluated to ensure that the out of tolerance event has not resulted in device performance, safety, and efficacy issues. If devices are determined to be nonconforming, a market product withdrawal may become a reality for the manufacturer. In any event, the owner of the piece of equipment or gage found to be out of tolerance will be required to perform an investigation and pursue an appropriate level of corrective action to remedy the issue. Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure for monitoring the validity of testing and calibrations performed?
- Are the results of testing and calibration recorded in such a manner so that trends in data can be assessed?
- Does the laboratory apply statistical techniques in support of data review and analysis?
- How does the laboratory handle data when the data show that the results obtained were outside the defined limits?
- Is corrective action being pursued when incorrect results have been reported to a customer?

7.8. Reporting the Results

Reporting the results is as equally important as the importance of protecting

the integrity of testing and calibration measurements and data noted in Chapter 7.7. In accordance with clause 7.8 of ISO/IEC 17025:2017, the results of testing and calibration activities must be: (a) accurate, (b) clear, (c) unambiguous, (d) objective, and (e) in accordance with instructions and methods employed for calibration. Depending on the structure of the contract, results may not actually be reported but retained by laboratories and made available on customer demand. Calibration certificates created and issued by laboratories have specific reporting requirements. Information such as title, laboratory name and address, and customer name and address are examples of some of the basic information required. Similar mandatory inputs are also required for test reports. The standard has very specific requirements that will be reviewed as part of this chapter's material. If testing and calibration was performed employing a subcontractor, this too must be reported. The good news is there are no set formats or style requirements for a test report or calibration certificate; however, it is strongly recommended that laboratories create a format or template for consistency. A sample of a test report and calibration certificate will be presented as part of this chapter's material. When all the test and/or calibration work has been completed, laboratories need to quantify the results and report them in a test report or calibration certificate. To ensure that customers are able to quickly find and review relevant information in test reports or calibration certificates, it is incumbent on laboratories to standardize the formats of these documents. If there are specific pieces of information a customer requires to be reported in a test report or calibration certificate, the requirement should be placed into the contract.

ISO/IEC 17025:2017 has specific requirements for information required to be placed into each test report. It is imperative that laboratories include this information. Once the test report has been printed and issued, the laboratory must ensure that the data used to populate the test report are retained for the time period specified within the laboratory's control of records procedure.

At some point in time, it may be necessary for a laboratory to revise a test report or calibration certificate or to issue a new (replacement) test report or calibration certificate. The process of revision or replacement cannot be performed

informally. If a test report or calibration certificate is revised, the word “revised” must makes its way onto the report or certificate. If the test report or calibration certificate is replaced, a reference to the original report must be placed in the replacement report or certificate. Retention of records supporting all amendments must be retained. Questions to consider during a conformity assessment:

- How does the laboratory report the work results of testing and calibration?
- Do test reports contain information relevant to the testing per- formed and in accordance with requirements delineated in 5.10.3 of ISO/IEC 17025:2017?
- Do calibration certificates contain information relevant to the calibration performed and in accordance with requirements delineated in 5.10.4 of ISO/IEC 17025:2017?
- Are calibration certificates free of recommendations for calibration intervals?
- If equipment has been repaired prior to calibration, is this information documented on the calibration certificate?
- Does the laboratory offer opinions and interpretations of test and calibration results?
- Are opinions and interpretations being made by qualified individuals?
- When the laboratory employs subcontractors for testing and calibration, are the subcontractors required to provide test reports and calibration certificates?
- Does the laboratory permit the electronic transfer of report and calibration certificates?
- How does the laboratory handle the amendment of test reports and calibration certificates?

7.9. Complaints

Having to deal with a complaint from a customer is never a pleasant ordeal. Unfortunately, laboratories are not immune from customer complaints and face perils similar to product manufacturers. ISO/IEC 17025:2017 requires laboratories to establish a policy supported by a well written procedure to delineate the process of addressing customer complaints that also include the investigative process and subsequent corrective action. Although there are always negative connotations associated with complaints, world-class organizations have the ability to use critical feedback received from the customer to drive continuous performance and actually turn a customer complaint into an event with a positive outcome. The fundamental key is to treat each complaint event proactively while striving to resolve the concerns of the customer. In this chapter, proven methods employed by organizations to manage customer complaints will be reviewed in support of achieving compliance with ISO/IEC 17025:2017 requirements. Complaints coming from a customer are never pleasant events. Regardless of fault, customers believe they are always in the right. This perception makes the handling of a customer complaint all the more challenging. There are a variety of different tools that can be employed to assist with the complaint mitigation process. Regardless of the approach pursued, the complaint management process needs to be a closed loop event. The salient steps associated with:

Step 1. Collect Data

It is imperative that all relevant data be collected. A good source of data could be similar complaints from other customers or information gleaned from customer satisfaction surveys (the topic of Chapter 7.8). If the com- plaint information collected is insufficient, do not be afraid to contact the customer(s) to obtain as much useful information as possible.

Step 2. Take Action

It is not enough just to collect the data. Once collected, the data must be properly analyzed to hopefully draw a conclusion as to the root cause of the complaint. If the

data are inconclusive, revisit step 1, “Collect Data,” and collect more data. Tools such as the Eight Disciplines of Problem Solving and DMAIC (define, measure, analyze, improve, and control) are useful when they are employed as part of the investigative process.

Step 3. Communicate Feedback

Once the complaint investigation has been completed, it is important to communicate the results of the investigation back to the customer. If the results of the root-cause analysis are inconclusive, do not be afraid to state that fact to the customer. However, work should continue to determine the root cause. Typically, a failure to ascertain root cause should be a suffi- cient reason to open up a formal corrective action request (CAR) to fur- ther diagnosis the cause(s) behind a complaint. If step 2, “Take Action,” results in a definitive root cause being determined, share the results with the customer(s) along with a solemn pledge to work hard to prevent such a recurrence.

Step 4. Refine the Changes

If the first three steps are executed properly, then it is important to imple- ment the changes necessary to prevent a recurrence of the complaint. Until formal action is implemented and a Verification of Effectiveness (VOE) is performed, there is no guarantee that the issue causing the initial complaint has been resolved. Having a repeat complaint, after the customer has been notified that the problem has been resolved, will be a game changer.

Formalize the Process

The management of complaints needs to be a formalized process. Clause 7.9 of ISO/IEC 17025:2017 requires laboratories to establish a policy and written procedure to delineate the complaint management process. It is essential that a complaint form be created to support the complaint process. Granted, even though the complaint form created will be tailored for use in a specific laboratory

environment, there are going to be many similarities in regard to most complaint forms. Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure for complaint management?
- Are customer complaints thoroughly investigated?
- When the results of an investigation support the need for corrective action, is corrective action actively pursued?
- Are records of complaints being maintained by the laboratory?

5.2 7.10. NONCONFORMING WORK

It is inevitable that at some point in time a nonconforming event will impact a test or calibration performed by a laboratory. Clause 7.10 of ISO/IEC 17025:2017 was scripted to provide laboratories a blueprint for working through nonconformances identified during the execution of testing and calibration services. A salient point that needs to be made is that a nonconformance can fall into two categories: (a) a nonconformance against a laboratories internal procedures and methods or (b) a nonconformance against failing to meet a customer specified requirement. Regardless, once a nonconformance has been identified, the standard requires immediate and decisive action to resolve the problem. The laboratory is required to investigate the nonconformance, determine the appropriate action (e.g., accept the nonconformance or repeat the testing), notify the customer if such a notification is deemed appropriate, and pursue formal corrective action to prevent the recurrence of a nonconformance. This chapter will explore a proactive approach for complying with the management of nonconformance in a laboratory environment. Similar to other salient requirements delineated in ISO/IEC 17025:2017, the management of nonconforming testing and calibration requires the establishment of a procedure. For readers familiar with the management of nonconforming product in the traditional sense (typically employed in support of an ISO 9001:2015 QMS), there are many similarities. It is always considered a best practice to establish a stand-alone

procedure for the management of nonconforming testing and calibration.

Some of the elements that will need to be incorporated into the laboratory's procedure for the management of nonconforming testing and calibration are:

- A clear definition of the roles and responsibilities of all laboratory personnel tasked with the handling of nonconforming testing and calibration
- The detailed assessment of the nonconforming work and/or activity
- The pursuit of immediate corrective action
- The decision process for determining the acceptability of non-conforming work and/or activity
- The customer notification process
- The recalling of nonconforming work
- The process for authorizing the resumption of work and/or activities

Depending on the nature of the nonconformance, formal corrective action may be warranted. It can be a difficult task at best to identify what type of nonconformance warrants a CAPA. One way to streamline the process is to categorize the different types of nonconformances that should result in CAPA being pursued. For example, operator error, the use of out of tolerance equipment, or the use of past due calibration equipment are worthy of consideration. If formal corrective action is required, clause 8.7 of ISO/IEC 17025:2017 should be employed for guidance.

There are two important pieces of documentation needed to assist with the identification and documentation of a nonconforming test and/or non-conforming calibration. These are the nonconforming tag and the NCR form. For example, once a piece of equipment associated with a nonconforming calibration event is identified, a non-conforming tag should be affixed to it and the instrument quarantined. The form documenting the nonconforming calibration should be opened at the same time. As previously stated, if there is a need for formal corrective action, or if the

nonconformance is premised on work outsourced to another laboratory, the form has the ability to document the corrective action decision. Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure that governs the handling of nonconforming testing and calibration results?
- Does the procedure delineate the responsibilities of the laboratory personnel tasked with the review and disposition of nonconforming work?
- Are formal investigations pursued for nonconforming testing and calibration work?
- What is the laboratory's process for correcting nonconforming work?
- If nonconforming work has been shipped to the customer, what is the process for recalling the nonconforming work?
- Is the customer notified of all nonconformances affecting their test or calibration?
- How is the customer notified?
- Which laboratory employee is responsible for the authorization for work to continue?
- If it has been determined through the investigative process that a non-conformance has the potential for reoccurrence, is formal corrective action being pursued to remediate the potential for reoccurrence?

7.10 Control of Data and Information Management

Laboratories are required to validate their data control and information management systems. Considering that ISO and other regulators such as the FDA require documentation control systems to be validated and records protected from damage or loss, the fact that laboratories are required to validate their systems is

not a foreign concept. Many of the systems employed by laboratories come with validation packages that include written protocols for installation of qualifications and user validations.

Additionally, if third party service providers are retained (either for maintaining the information system platform or for hosting the actual soft- ware employed for data and information management), these suppliers shall be appropriately qualified and managed. Considering the expense associated with state-of-the-art information management systems, laboratories need to protect their investment at all costs.

Two thoughts come to mind when thinking about information management systems and the storage of data: (a) system reliability and (b) data secu-rity. State of the art laboratories rely heavily on their technology. Data control and information management systems must be reliable to drive internal operations and must be able to provide reliable access through a secure intranet that allows customers access to their calibration and or test reports. Reliability is achieved through system validation and a robust PM program.

Additionally, data backup is a fundamental requirement for all information systems. Without an effective way to: (a) store and retrieve data, (b) ensure data security, (c) ensure integrity, and (d) maintain record confidentiality, the information system will quickly lose its allure as an effective tool.

Data accuracy is a fundamental requirement for a laboratory. Laboratories should implement a system for verifying the accuracy of the data collected. If the process employed for data collection is automated or is used by a computer, the software needs to be validated. The equipment employed in support of an automated data collection system (including the computers) needs to be placed in an appropriate environment and maintained to preserve functional capabilities. The laboratory will be required to establish a procedure that clearly defines their entire process for data collection. In accordance with ISO/IEC 17025:2017, the procedure generated for data control will need to include:

- Data protection

- Data integrity and confidentiality associated with data collection and date entry
- Data storage and backup
- Data retrieval
- Data processing
- Data accessibility
- Data transmission

Questions to consider during a conformity assessment:

- Does the laboratory perform a cursory review of obtained data for accuracy?
- Does the laboratory employ computer software for testing and calibration?
- Has the computer software been properly validated?
- Does the laboratory have an established procedure for handling storage, transportation, and PM of equipment?
- Is the information management system self-hosted or cloud based?
- What types of security protocols have been implemented?
- Are third party service providers retained to service the information management system?
- What types of supplier qualifications are required for third party service providers?

8.1 Options

ISO/IEC 17025:2017 allows organizations to pursue two pathways regarding compliance with the establishment of an effective management system, or, as most industries recognize the term, QMS. The first pathway, which will be explored in

greater detail within Section 8.0 of this book, is identified as “Option A.” The second pathway, identified as “Option B” within ISO/IEC 17025:2017, entails achieving compliance with a known standard, such as ISO 9001:2015. However, for organizations that claim compliance with Option B, they have to demonstrate that the management system appropriately addresses the requirements delineating within ISO/ IEC 17025:2015. Simply stated, Option A and Option B are nothing more than equivalent approaches to achieving an effective and compliance management system. Most competent laboratories that I have assessed over the years have dual certifications: (a) ISO 9001:2015 and (b) ISO/IEC 17025. It is essentially a logical progression to have the management system, which aligns with recognized QMS standards, qualified to ISO 9001:2015. In fact, having an ISO 13485 accreditation would also be considered acceptable, because this standard clearly addresses all the management system elements required of ISO/IEC 17025:2017. For organizations that do not have a QMS accreditation, the expectation is that the appropriate processes be established to meet Option A requirements. This means that written procedures would be required to be scripted that address:

- Document control
- Control of records
- Management responsibility
- Management review
- Risk management
- Internal audits
- Continuous improvement
- CAPA

Questions to consider during a conformity assessment:

- Does the laboratory possess an ISO 9001:2015 or ISO 13485 accreditation

from a recognized registrar or notified body?

- Has the laboratory's management system been recently audited by their registrar or notified body?
- What were the results of the laboratory's most recent audit?
- Were any nonconformances (minor or major) issued?
- What are the strengths of the laboratory's management system, and conversely, what are their weaknesses?
- Is there demonstrated evidence that the laboratory strives for continuous improvement?
- Does the CAPA system appear to be effective?
- Are audits being performed in accordance with a published audit schedule?

8.2 Management System Documentation (Option A)

A salient requirement for any organization operating in a regulated environment is the establishment of a fundamentally sound and effective QMS that complies with regulatory requirements, statutory requirements, and recognized standards, such as those authored by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). AS9100, ISO 9001:2015, and ISO 13485 are standards that have been developed to support the development and implementation of effective approaches to quality management. They are recognized blueprints for the establishment of a QMS for many diverse industries. Similar to these recognized QMS standards, ISO/IEC 17025:2017 serves a unique purpose: laboratory accreditation. One thing the reader should keep in mind is the importance of the link between ISO 9001:2015 and ISO/IEC 17025:2017. Laboratories that are accredited and operate in accordance with ISO/IEC 17025:2017 are expected to comply with clauses of ISO 9001:2015 as they pertain to the laboratory environment. It is not uncommon for laboratories such as a metrology lab to possess dual certification or accreditation in ISO 9001:2015 and ISO/ IEC 17025. However,

there are requirements unique to ISO/IEC 17025:2017 versus ISO 9001:2015. For example, the technical competency of laboratory personnel, the employment of validated testing methodologies, and ongoing proficiency testing for laboratory personnel are salient requirements specific to ISO/IEC 17025:2017. One way to view the differences between these standards is that ISO 9001:2015 provides guidance for an effective QMS while ISO/IEC 17025:2017 drives technical competency within a QMS.

The management system will form the fundamental foundation for any facility wishing to achieve accreditation to ISO/IEC 17025:2017. Similar to ISO 9001:2015, the quality manual becomes a core document employed for describing the management system. Other requirements that need to be addressed in support of complying with ISO/IEC 17025:2017 are: (a) written procedures; (b) creation of a concise quality policy statement; (c) management's commitment to develop, implement, and continuously improve the management system; (d) management's communication and reinforcement to the organization of the importance of meeting customer and regulatory requirements; (e) reference(s) to procedures placed into the quality manual; (f) the definition of the roles and responsibilities for technical management and the organization's quality manager; and (g) ongoing sustainment of the integrity of the management system by quality. The path toward accreditation begins with the basic understanding that a laboratory must have an established QMS. Two of the main purposes driving the need for an established QMS are: (a) the ability to provide accurate and repeatable testing results, supported by data, to the customer; and (b) the ability to maintain accurate records to support the quality of the data pro- vided. Like regulatory requirements enforced by the FDA, the accreditation bodies (see *ISO/IEC 17011:2017—Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies*) require documented evidence of compliance. The fundamental requirement for achieving compliance with clause 8.2 of ISO/IEC 17025:2017 is the establishment of an effective QMS, including:(a) policies, (b) procedures, and (c) work instructions. Additionally, a well written and succinct quality policy manual is an excellent tool for linking all the requirements of QMS at a macrolevel. One tool that has proven to be

effective in support of developing an effective QMS is the creation of a requirements matrix that maps an organization's QMS to ISO/IEC 17025:2017.

The quality policy manual will become the cornerstone of the laboratory's management system. It is the umbrella document that links all the elements of the management system together. The laboratory's quality objectives and quality policy statement are extremely important pieces of information that are required to be embedded into the quality policy manual. The laboratory's objectives, once established, should be reviewed during the management review process (detailed in Chapter 8.9). The quality policy, similar to ISO 9001:2015, should be appropriate for the organization and state a commitment to meeting the requirements of ISO/IEC 17025:2017, including a commitment by management to continuous improvement. Please note: this is a significant departure from the 2005 version of the standard, which was extremely onerous with specific compliant statements required to be embedded in the policy.

Additional requirements that need to be addressed by laboratory management to achieve compliance with this standard are:

- Evidence of commitment to the development and implementation of a management system
- Evidence of continuous improvement activities in pursuit of improving the management system
- The communication to laboratory personnel of the importance of meeting customer, regulatory, and statutory requirements
- The maintenance of management system integrity when changes to the management system are planned and implemented

These bullet points should be woven into the fabric of the laboratory's management system, with the processes specific to meeting these requirements placed in the quality system procedures. For example, management review, corrective action, preventive action, customer complaints, and continuous

improvement are examples of tools employed to gauge the overall effective- ness of a laboratory's management system. ISO/IEC 17025:2017 requires written procedures to address these tools. Well written procedures, employed to measure the overall effectiveness of the management system, will meet the intent of the requirements delineated within clause 8.2 of the standard.

Questions to consider during a conformity assessment:

- Is the laboratory's management system adequately documented by written policies, procedures, and work instructions?
- Does the laboratory have a released quality policy manual?
- Does the laboratory have a documented quality policy?
- Is the quality policy appropriate for the organization?
- Has the quality policy been placed into the quality policy manual?
- Have the laboratory personnel been trained to the quality policy? Is there documented evidence of the training?
- Is there evidence of continuous improvement activities being pursued?
- How does management communicate the importance of meeting customer requirements?
- Does the quality policy manual contain a list of quality procedures or does it make reference to the location of the master list of procedures?
- Has the role and responsibilities of the laboratory's technical manager been defined?
- Has the role and responsibilities of the laboratory's quality man- ager been defined?
- How is the integrity of the management system maintained when changes to the management system are planned and implemented?

8.3. Control of Management System Documents (Option A)

Organizations cannot place enough emphasis on the importance of the document control function. In a regulated environment, the control of documentation should be treated as a mission critical process. It is not enough for organizations to just "control" documents; they must manage and control all aspects associated with effective document management. For example, the requirements delineated within ISO/IEC 17025:2017 include: (a) the establishment of documents and procedures, (b) the review of documents and procedures, (c) the approval of documents and procedures, (d) the issuance and control of documents and procedures, (e) the change control process for documents and procedures, and (f) the removal of obsolete documents and procedures. Experienced quality professionals understand the importance of document control and realize that effective document control can be employed as a tool to facilitate successful internal and external quality audits. Although some organizations and laboratories continue to support a manual approach to a document control, there is an abundance of software platforms that can automate the document control process. Regardless of the approach pursued (manual or automated), this chapter will explore the essential requirements needed to comply with ISO/IEC 17025:2017, clause 8.3—Control of Management System Documents (Option A). There is an abundance of commercial off the shelf software available that can be quickly implemented to solve the management of documents dilemma; however, a procedure still needs to be written. That being said, the most effective tool that can be employed in support of meeting the document control requirement is a well scripted procedure. Key elements of the document control must include:

- The document numbering system
- The use of revision/version control
    - Pagination
    - Initial document review and approval

- A master document list
- Any document changes
- Control of external documents
- Document availability
- Document storage
- Redline changes
- Document obsolescence

It is recommended that the document numbering system have some intelligence built into the number. For example, the use of prefixes such as SOP (Standard Operating Procedure), TM (Test Method), WI (Work Instruction), FM (Form), TP (Test Procedure), and QIP (Quality Inspection Proce- dure) should be considered. Since the functional structure and the industries served for each laboratory may differ, it is acceptable to create prefixes relevant to the laboratory. There is no set standard, although SOP is for the most part universally understood.

As for the physical number, this may be a sequence starting with 1001; for example, SOP-1001 “Document Control” would be an acceptable for- mat. It is also acceptable to align high level documents, such as a document control procedure with the actual standard. For example, SOP 8.3 “Document Control” would also be considered an acceptable approach.

Please keep in mind that there are some computerized document control systems that will not permit much flexibility, so extreme care must be taken if the laboratory is looking to purchase a software solution with a plan to migrate an already existing document numbering structure. The most widely accepted approach to revision control is the use of alpha- numeric characters. Depending on the laboratory, the actual term employed may be either “revision” or “version.” It is also an acceptable practice to control revisions through the use of a date, although this practice is not nearly as common. In fact, some organizations include both a

revision and a date. Another practice needing to be considered is the use of alpha revision characters for released documentation and numeric revision characters for developmental or engineering documentation. The following examples of revision control would be acceptable:

- SOP-1001 Revision A or SOP-1001 Version A
- SOP-1001, 02/24/18
- SOP-8.3 Revision A (02/24/18)

All documentation should require some level of oversight, review, and approval. For example, the inputting of a regulation or standard may be as simple as the person tasked with document control responsibilities logging the receipt date and entry date of this document into the document control system. For SOPs or TMs that are scripted by the laboratory, a detailed review and approval is probably warranted. Typically, a document change order (DCO) or an engineering change request (ECR) would be used to document this review. Although not required by the standard, it is a common practice to create a master list of documents (MDL). Many organizations choose to list the documents relevant to the QMS in the quality manual; however, all that is required is a pointer to where the list is located. The MDL is an excellent tool that can be used to quickly find a document. Make sure the MDL also contains a reference to the document revision. Remember, it is extremely important to have this type of document available for external audits. The auditor will ask for the MDL, as it really is a road map for the laboratory's document structure. Similar to the initial review and approval of new documents, all revisions to documents require the same level of scrutiny. A detailed review and subsequent approval are core requirements of a document control system. Additionally, the laboratory needs to ensure that the reviews of document changes are performed by a cross functional group. For example, if the document being changed is a test procedure, then engineering, quality, and operations are going to want to review it and, if appropriate, provide input into potential changes. In some cases, customer review and approval may be required, so it is important for the laboratory to remain vigilant when processing document changes. Further, the standard requires a periodic review of

documents. A common practice is to associate a planned review date with each document.

The document control system needs to be able to manage external standards as well; for example: (a) customer drawings and specifications; (b) standards, such as ISO/IEC 17025:2017; (c) regulatory and statutory documents, such as 21 CFR § 820; and (d) test methods, such as ASTM International that need to be input and tracked by the document control system. It is imperative that laboratories always have the latest version of a document on file. Companies like IHS Markit (2018) can augment the document control process by ensuring that laboratories have the latest and greatest version of a standard. The most current version of a document must be made available at the point of use. Considering the abundance of available technology, laboratories should consider placing monitors or other remote terminals that are capable of accessing real time documentation at each location to facilitate the ease of access. If a manual system is in place, build a kiosk to house the most current documentation and to ensure availability of the documents at the point of use. Remember, this is a requirement in accordance with clause 8.3.2(d) of ISO/ IEC 17025:2017. The established procedure must contain sufficient granularity to describe the document storage process. If an electronic system is employed for document control, then the process employed for scanning documents (e.g., PDF format) should be in the document control system. If the control is manual, then the storage location needs to be clearly identified—including levels of access granted to the document storage area. Do not forget about the preservation of these documents, as they need to be protected from damage during routine storage. Although the redlining of documents, in support of making document changes, is acceptable under ISO/IEC 17025:2017, it is better to dissuade laboratory personnel from the practice. This author has seen far too many cases of where redline changes were not properly accounted for when a revision to a document was made. The end result was a nonconformance from the accreditation body and/or a repeat of calibration work. Obsolete documentation needs to be clearly identified as such and removed from point of use as quickly as possible. If it is necessary to retain obsolete documentation at the point of use for historical purposes, then employ a stamp that describes the status of the document.

Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure for the control of documents?
- Does the control of documents procedure address both internal and external documents?
- Are documents reviewed and approved prior to their issuance for use within the laboratory?
- Are procedures and work instructions available at their point of use?
- What is the laboratory's approach to revising documents?
- Are obsolete documents identified and removed from use?
- Are obsolete documents retained as permanent records?
- Are management system procedures uniquely identified?
- Are document changes reviewed and approved by the same functional groups tasked with reviewing and approving the initial release?
- Does the procedure employed for the use of documents allow for redline changes to documents?
- Does the organization employ a computerized system in support of the control of documents?

8.4 Control of Records (Option A)

The effective control of records is a salient requirement for organizations operating in a regulated environment. Similar to ISO 9001:2015, ISO 13485, and AS9100, ISO/IEC 17025:2017 has specific requirements for the control and management of records. The requirements delineated within clause 8.4 (*7.5 for technical records*) are prescriptive and require an established procedure that contains: (a) record identification, (b) record collection, (c) record indexing, (d)

record access, (e) record filing, (f) record storage, (g) record maintenance, (h) record disposal, (i) quality records, and (j) technical records. Records falling under this clause can be in the form of a variety of different media; however, for most organizations records are typically in a hard-copy format (paper) or in an electronic format (e - file). Regardless, laboratories must implement adequate systems to preserve records and to retain records in accordance with regulatory, statutory, and customer requirements. First and foremost, the records must be protected and secured to preserve the confidential nature of record content. Establishing a policy for the implementation of good documentation practices (GDP) is paramount to establishing effective record control. Records must always be accurate, and, when errors are made, these errors must be corrected and remain legible. In this chapter, the control and preservation of records, the establishment of a table for record retention for quality and technical records, and the implementation of GDP will be discussed, and tools needed in support of 17025:2017 compliance will be presented. Because of the significant importance ISO/IEC 17025:2017 places on record legibility, record retention (times), record protection from deterioration, record security, data accuracy, reports, GDP, certifications, and electronic records, it is imperative that a laboratory establish a procedure with sufficient granularity to manage all records. As part of the procedure development process, it is important for laboratories to consider: (a) general requirements, (b) record storage, (c) record retention periods, (d) GDP, (e) packaging and identification of records, (f) indexes of archived records, (g) shipment of records, (h) storage accessibility and security of records, and (i) record inspection and audits.

All laboratory records need to be maintained internally or at an approved off-site storage facility. It is important that laboratory records be readily available to laboratory personnel or customers and regulatory bodies on request. It is also important that laboratory records be adequately protected from deterioration. When deemed necessary, adequate security measures will be employed to protect the confidential nature of customer records. All records must be legible and stored in appropriate filing containers to minimize deterioration and loss. Records stored electronically need to be backed up on a regular basis. Quality records and technical

records need to have their retention periods specified in the procedure. It is recommended that a table be constructed for the purpose of listing each laboratory record and the records retention time. Record retention periods should be linked to regulatory, statutory, and customer retention requirements. Laboratories are required to implement GDP when it comes to corrections and revisions made to records. When records are stored off-site, it is imperative that records are properly identified to facilitate their retrieval. Off-site storage facilities such as Iron Mountain will be able to provide guidance in support of the packaging and identification of records. The laboratory will be required to index all records processed for archival storage. It is important that laboratories audit archived records to verify accuracy and integrity of the archived records process. The laboratory will need to coordinate the movement of records to be archived and will act as liaison with the storage provider. All archived records need to be stored with a provider that will protect the integrity of the records and ensure protection against unauthorized access. Additionally, when external facilities are chosen for record storage, the record storage areas need to be maintained in a manner that prevents the deterioration and loss of records. Annual record inspection and audits should be scheduled as part of the internal audit program. The purpose of an annual record inspection and audit is to ensure that the archival record storage areas are adequately protecting the safety, integrity, and security of the records. Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure for the control of records?
- Does procedure address the identification, collection, indexing access, filing, storage, maintenance, and disposal of quality and technical records?
- Does the procedure contain a record retention requirement (length of record retention)?
- Are records legible?
- Are records being stored in a suitable environment capable of protecting the

records?

- Are records properly secured as to protect their confidentiality?
- Does the laboratory have an established procedure for the storage of electronic records?
- Does the established procedure for storage of electronic records contain a process for the backup, security, and access to electronic records?
- When mistakes are made in records, does the laboratory employ GDP to correct the errors?

8.5 Actions to Address Risks and Opportunities (Option A)

Preventive action is often viewed as one of those gray areas where organizations have some difficulty explaining preventive action or what constitutes preventive action. However, preventive action is also closely aligned with the concepts of risk management and risk mitigation activities. According to ISO/IEC 17025:2017, mitigating risk and employing opportunities to drive organizational improvements and identify potential sources of non-conformities before such nonconformities result in a nonconformance by negatively impacting the laboratory are essential requirements of a management system. It is not enough for the laboratory to simply identify potential opportunities for preventive actions; they must act by employing risk mitigation activities. Laboratories are required to draft preventive action plans, implement preventive action plans, and monitor the effectiveness of preventive action activities pursued. In support of achieving and sustaining compliance with clause 8.5 of ISO/IEC 17025:2017, a proactive approach to mitigating risk and driving opportunities for improvement will be discussed in this chapter. The continuous improvement piece is one that is often overlooked by organizations, since organizations move straight into corrective action when problems manifest so quickly. ISO/IEC 17025:2017 requires laboratories to establish a procedure for the mitigation of risks and continuous improvement. This is typically accomplished through preventive action. Although there is no directive to do so, it

makes perfectly good sense to marry the corrective action and preventive action/continuous improvement requirements into one procedure. Essentially, the steps taken for preventive action mirror the requirements for corrective action.

The fundamental goal of continuous improvement is to keep potential non-conformances from occurring while ensuring all potential risks are appropriately identified. Identification and mitigation of potential nonconformances are rooted in three basic concepts: (a) the identification of risk, (b) the identification of potential deficiencies, and (c) the prioritization of solutions to drive improvement. There is no better tool to drive these concepts that failure mode and effects analysis (FMEA). There are some important things to be considered when creating an FMEA. The following bulleted points need to be considered when constructing an effective FMEA:

- The FMEA must drive design or process improvements as the primary objective
- The FMEA must address all identified high-risk modes
- The FMEA must consider all lessons learned—internal and external to the laboratory.
- The FMEA must identify key characteristic candidates as appropriate
- The FMEA should always be completed when it provides the most value and not after a nonconformance has occurred
- The FMEA requires input from subject matter experts to ensure that the FMEA content is adequate
- The FMEA should always be thoroughly completed, with no short- cuts taken
- The FMEA process should always be evaluated for effectiveness

Improvement projects supported by project plans are another approach that can be deployed for effective preventive action. When creating a project plan to support an improvement project, elements to be considered are:

- ✓ A clear definition of the actions to be taken
- ✓ A definitive time line for each activity
- ✓ Assignment of a resource to each activity
- ✓ Project reviews and status reports that delineate progress
- ✓ A guarantee that there are clear channels of communication for the dissemination of project information
- ✓ A formal review and closeout of each improvement project and plan

A SWOT (strengths, weaknesses, opportunities, and threats) analysis may also be considered as an effective tool, albeit much simpler to implement, when it comes to driving continuous improvement. A SWOT analysis is a tool that allows organizations to quickly identify internal and external factors that could impact their ability to achieve tactical and strategic objectives.

Another tool to consider using is the probability risk matrix. The risk matrix is a tool that can be used to allow organizations to have an increased visibility to risks that could adversely influence the organization. The matrix allows an organization to gauge not only the probability of occurrence but also the potential severity to each identified risk. Questions to consider during a conformity assessment:

- ➢ Does the laboratory have an established procedure for continuous improvement?
- ➢ Are preventive action plans developed when opportunities for improvement are identified?
- ➢ Are records of continuous improvement activities being maintained by the laboratory?

8.6. Improvement (Option A)

Continuous improvement is a fundamental goal of proactive organizations. W.

Edwards Deming, Kaoru Ishikawa, and Genichi Taguchi dedicated their lives to the development of tools to assist organizations in their drive for continuous improvement and to the implementation of quality driven tools that were effective. The requirements delineated within clause 8.6 of ISO/IEC 17025:2017 reinforces the spirit of these quality pioneers by requiring laboratories to assess the effectiveness of the laboratory's management system. At a minimum, laboratories are required to employ a well written quality policy, clearly defined quality objectives, results of internal and external audits, corrective action, preventive actions, and management reviews to drive continuous improvement. Proactively seeking customer feedback can also result in the obtainment of valuable critical feedback that can enhance a laboratory's pursuit of improvement. In this chapter, valuable tools needed to drive continuous improvement activities while supporting compliance with ISO/IEC 17025:2017 will be discussed. Clause 8.6 is essentially a catchall type of clause that reinforces the need for laboratories to employ all the tools afforded them in the pursuit of improving their management system. It is simply not enough to publish a quality policy, to assemble and publish a few quality objectives, to pursue corrective and preventive actions, to perform a critical assessment of collected data, or to hold an annual management review. Improvement is essentially the sum of multiple salient elements required by ISO/IEC 17025:2017. Since most of these requirements are inputs into an effective management review, it is recommended that specific requirements delineated under clause 8.6 be included into the management review agenda. However, since the information is vital to effective laboratory management, reviewing this information annually is not sufficient to drive real time laboratory improvement. The quality policy, although reflective of the laboratory's operating policies and principles, is typically cast in stone. However, it needs to be revisited from time to time and adjusted to reflect the current business environment. It is essential that laboratory employees also receive training for the quality policy, including training in policy meaning. Best practice is to retrain to the quality policy annually. This can be accomplished through an all-hands meeting. The laboratory's quality objectives should be set early in the fiscal year. All laboratory personnel should be aware of the objectives, and the objectives should be posted throughout the laboratory. Quality objectives should be rea- sonable and be supported by collectable and objective

metrics. Best practice is to update quality objective results at least monthly. Progress against an internal audit schedule and the results of internal audits are fairly easy to track. It is recommended that nonconformances identified little more subjective, as input is coming from customers and regulatory bodies. However, the feedback coming from external audits should be treated as valuable advice that can be used to drive improvement of the management system. Nonconformances received as a result of external audits should definitely be loaded into the CAPA system.

Information critical to the effective operation of the laboratory needs to be collected and analyzed for trends. For example, data collection associated with customer complaints, nonconforming testing or calibration, supplier CARs, and so on should analyzed and trended to ensure that performance expectations are being achieved. Without the collection and analysis of critical data, it is nearly impossible to ascertain the effectiveness of ongoing laboratory operations.

CAPA, when properly employed, is an effective tool to drive improvement. In fact, any adjustments that need to be made to improve the effectiveness of the management system will be driven by the CAPA program. When in doubt, it is always better to side with caution and ensure that CAPA is pursued for audit nonconformances, unfavorable data trends, nonconforming tests, non- conforming calibrations, and customer complaints.

Management review is one of the important elements used to drive continuous improvement. Management reviews are required to be held at planned intervals. Common practice is to hold reviews annually. It is important to understand that, although management review is a mandatory requirement because of the annual requirement typically adhered to by laboratories, its value as an effective tool is limited. The primary purpose behind management review is for senior management to review and gauge the overall effectiveness of the management system for the preceding twelve-month period. Senior management may request that formal corrective action be assigned and pursued if concerns over the performance of the management system are noted.

It is imperative that laboratories query their customer base. Information can be gleaned from customer surveys, informal calls, and formal complaints received as part of the complaint management system. Laboratories can use this information to drive improvements in laboratory performance. For example, if there are errors in customer reports, it is incumbent on the laboratory to ascertain why these errors are occurring and to fix the problem. Direct customer feedback is an excellent forum to identify improvement opportunities. Questions to consider during a conformity assessment:

- Does the laboratory strive to continuously improve the management system?
- What are the examples of the tools employed by the laboratory to drive improvement activities?
- Are improvement activities included in the management review?
- Are customer surveys being routinely issued to customers?
- What tools are being used to collect customer feedback?
- Is customer feedback being used to drive laboratory improvements?

8.7 Corrective Actions (Option A)

The ability for an organization to pursue corrective action for the remediation of nonconformances is a cornerstone for a QMS. Similar to ISO 9001:2015, establishing documented policies and procedures for corrective action is a salient requirement for ISO/IEC 17025:2017. While establishing a systemic approach to corrective action, inputs that need to be considered are: (a) nonconforming work, (b) deviations from audits (internal and external), (c) customer feedback (typically complaints), and (d) observations made from laboratory employees. Another important influencer of a laboratory's approach to corrective action is the ability to frame the problem and to diligently work toward the identification of root cause. Pursuing effective actions to remediate the root cause of nonconformances will be a daunting task if an effective and exhaustive approach

to root cause analysis is not pursued. Once root cause has been established and corrective actions are implemented, it is imperative that these actions be monitored for effective- ness. If necessary, follow up audits should be planned to preclude future nonconformances.

Laboratories are required to establish a policy and procedure to ensure that an effective approach to corrective action is pursued. As part of the policy and procedure, the laboratory must designate an individual(s) responsible for the oversight of the corrective action process. There are several software options available commercially that can be deployed to support meeting the requirements delineated within clause 4.11 of ISO/IEC 17025:2017. For example, CATS web and Master Control are software products dedicated to a proactive approach for corrective action. If a laboratory is not inclined to spend money on a software solution, using basic software products such as Microsoft Word and Excel with secured and password protected spreadsheet access given only to the designate for oversight of the correction action process is an acceptable solution.

As part of the corrective action process, much emphasis must be placed on ascertaining root cause. There are tools available that can be implemented immediately to assist in the performance of root cause analysis. Ishikawa's Seven Basic Quality Tools are an excellent place to begin. The application of tools such as: (a) cause and effect diagrams, (b) check sheets, (c) control charts, (d) histograms, (e) Pareto charts, (f) scatter diagrams, and (g) stratification are frequently employed in support of failure investigations. Regardless of the approach used in the pursuit of the root cause, the expectation set through ISO/IEC 17025:2017 is that a reasonable attempt be made in determining root cause.

When a laboratory has determined that corrective action is required to mitigate a nonconformance, the corrective action must be appropriate to the problem and include the assessment of risk. When corrective action has been taken, it is imperative that all proposed changes are documented, reviewed, and approved prior to implementing the changes. One area to be cognizant of when changes occur to procedures is the training piece. It is imperative that laboratory personnel are

retrained, as appropriate, when changes occur to a procedure. In most cases, the retraining will be as simple as reviewing and understanding changes made to a procedure. Regardless of the level and detail of training as a result of corrective action activities, ensure that the training is documented. An important piece of the corrective action process is the VOE. It is imperative that a laboratory verify not only that corrective action has been formally implemented but also that the corrective action taken was effective. Depending on the type of corrective action taken, the verification process will usually occur within thirty, sixty, or ninety days. It will be a rare event when the VOE is performed immediately. Once the VOE has been successfully completed, then and only then can the corrective action be closed.

One final thought relates to performing additional audits as required to ensure that the nonconformances identified and the subsequent corrections implemented are not influencing potential compliance issues with the laboratory or ongoing compliance with ISO/IEC 17025:2017. It may be necessary to adjust the internal audit schedule to ensure that problems requiring corrective action receive additional oversight to be sure that nonconformances do not continue to manifest themselves within the laboratory. The internal audit program (discussed further in Chapter 8.8) should be flexible enough to add additional audits as required to drive laboratory compliance with its own policies, procedures, regulatory and statutory requirements, and ISO/ IEC 17025:2017. Questions to consider during a conformity assessment:

- Does the laboratory have an established policy and procedure for corrective action?
- Does the corrective action procedure require inputs from: (a) nonconforming work, (b) noncompliance's with policies and procedures, (c) internal audits, (d) external audits, (e) customer com- plaints/feedback, and (f) employee observations?
- Does the corrective action process require root cause analysis?
- Is there evidence that adequate corrective actions are being pursued?

- Is verification of effectiveness being performed for all corrective actions?
- Is there a master log sheet for corrective actions?
- Are all corrective actions current?
- Are follow up audits being performed when required?

8.8 Internal Audits (Option A)

Internal audits, when properly implemented, are proactive tools for assessing an organization's ongoing compliance with a standard or regulation. Similar to ISO 9001:2015:2015, ISO/IEC 17025:2017 requires laboratories to periodically conduct internal audits to verify that continued laboratory operations are being performed in accordance with established policies and procedures and with ISO/IEC 17025:2017. Specifically, the internal audit program must be constructed to ensure all aspects of the management system are evaluated. Audits should be planned and a schedule created and published to support the internal audit program. Laboratory personnel tasked with performing audits must be trained and qualified. When deviations are noted during the performance of internal audits, corrective action should be pursued to remedy the nonconformance. In this chapter, implementing an effective internal audit program, including the creation of a viable schedule, will be presented.

In an effort to successfully drive management system improvements, internal audits are an incredibly valuable tool to a laboratory. Enough emphasis cannot be placed on the importance of performing timely internal audits and when warranted, reaudits of laboratory functional areas that are identified as problematic. First and foremost, laboratories are required to establish an internal audit program documented by a written procedure. All elements of the laboratory's management system are required to be assessed at least once annually. When corrective action opportunities have been identified, VOE of the instituted corrections must be performed. The results of internal audits need to be documented and retained as a quality record.

It is strongly recommended that an internal audit schedule be assembled and

approved prior to the start of each year. This schedule should be published and qualified auditors assigned in advance. Note that ISO 19011 (Guidelines for Auditing Management Systems) should be reviewed prior to establishing an internal audit program and auditor requirements. This schedule can be extrapolated to meet a monthly format. Another option would be for the laboratory to subcontract the internal auditing function to a qualified auditor or consulting firm.

From a trained auditor perspective, having a certified auditor, although preferred, is not a requirement of ISO 19011. Auditors must be appropriately trained and have adequate technical knowledge of the function or process they are auditing. Auditors must never have functional responsibility for the areas they are auditing to prevent any undue influence. Auditor objectivity and independence is crucial for the performance of an internal audit.

Unfortunately, execution of a successful audit is much more than having the auditor show up with a pencil and a pad of paper. A good audit takes planning and preparation to ensure that the audit is effective and beneficial to the laboratory. There are many components associated with an internal audit. Depending on the size of the laboratory, some of the components may be skipped or greatly reduced in scope.

Prior to executing the actual audit, the auditor will need to become familiar with the area to be audited. The creation of an audit plan is nothing more than creating a road map for the audit. The audit plan will typically contain the scope, purpose statement, area/function to be audited, list of audit team members (if applicable), and the relevant documents. Depending on the scope of the audit and if multiple functional areas are being audited, it may be prudent to develop and audit agenda to support the plan. An audit checklist should also be created to support the internal audit. To save time during the day of the audit, the auditor should request and review the relevant documents in advance.

The opening meeting is a useful tool for establishing the boundaries for the audit, reviewing the audit plan, reviewing the audit agenda, and discussing other issues influencing the audit. The dynamics of the audit, including the closing meeting,

should be reviewed at this time. It is important that a sign in sheet be employed to document attendance at the opening meeting.

Execution of the audit is nothing more than the execution of the audit plan. If a checklist has been created for the audit use the check- list as a guide. The checklist can be used to collect objective evidence of compliance and assist the auditor during the interview process. However, it is important to remember that the audit report will be the primary deliver- able in support of providing objective audit evidence.

During the audit, it is important to collect objective evidence and to document compliance and, if applicable, nonconformances identified during the audit. Documented evidence will be needed to support the writing of nonconformances associated with the audit. Additionally, documented evidence of compliance is needed to support the audit report.

If the audit results in a nonconformance from a policy, procedure, standard, or regulation, the nonconformance will need to be documented. When writing the nonconformance, it is important to specify the requirement (e.g., ISO/IEC 17025:2017, clause 8.9—Management Review) and the finding (no evidence of management reviews being performed). The nonconformance should always be clear and concise, with no evidence of subjectivity.

Similar to the opening meeting, the closing meeting may be deemed optional depending on the size of the organization. If a closing meeting is held, an attendance sheet should be circulated to capture attendance. During the closing meeting a review of the audit results are provided by the auditor. It is important to highlight the positives as well as the nonconformances noted. If a follow up audit will be required, it should be noted during the closing meeting along with next steps to support the mitigation of nonconformances.

The audit report is a written detailed summary of the entire internal audit. It is strongly recommended that a written report be completed within seven days of the audit and no later than thirty days from the audit.

Nonconformances identified during the audit need to be corrected without undue delay. Depending upon the nature and severity of the nonconformance (e.g., systemic), formal corrective action may need to be pursued. Simple corrections can be performed and the correction documented in the audit report by the auditor.

The Verifying Effectiveness of Corrective Action (VOE) of audit corrections typically occurs during the next audit cycle. However, if the audit nonconformance is systemic, and the nonconformance has been moved to the laboratory's CAPA system, VOE will be performed as part of CAPA. Even if the VOE is performed as part of CAPA, it will be incumbent on the individual selected to perform the next audit to verify that the nonconformance has been closed and that the action taken was effective. Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure that governs the internal audit program?
- Is there a published audit schedule?
- Are internal audits being performed in accordance with the published schedule?
- Is the laboratory employing auditors that have been properly trained or certified for the performance of audits?
- When nonconformances have been identified, does the laboratory pursue corrective action to resolve the nonconformances?
- Is the audit schedule being adjusted when there is evidence that a functional area within the laboratory requires additional oversight?
- Is verification of effectiveness being performed to verify that corrections resulting from internal audits are effective?
- Are records being maintained for internal audits?

8.9 Management Reviews (Option A)

Management review is an important tool employed by organizations to ensure that the management system continues to remain effective. Included in the management review process—a process required to be held at planned intervals (common practice is to typically hold meetings at least once per year)—are a variety of quality records and collected records that capture the ongoing effectiveness of testing and calibration activities. Clause 8.9 of ISO/IEC 17025:2017 contains prescriptive requirements pertaining to specific metrics to be reported as part of the management review process. Similar to the management review inputs associated with ISO 9001:2015, ISO/IEC 17025:2017 requires the results of audits, customer feedback, and recommendations for improvement as a few of the requirements requiring incorporation into management review meetings. It is imperative that management reviews are well attended, that the results are recorded in detailed meeting minutes, and that, when deemed appropriate, the outcomes of the management review (such as corrective action) are documented. When actions are assigned, it is the responsibility of management to ensure that corrective actions are actively worked and completed. In this chapter, a review of best-in-class management review practices, including the creation of the agenda and signature sheet, will be discussed.

There is no question—a management review is a valuable tool needed by management to ensure that the laboratory's management system and the application of tools needed to support the technical requirements are adequate and performing as expected. It is a generally accepted practice to per- form management reviews at least annually; however, more frequent reviews will drive improved laboratory performance. Although holding management reviews monthly would be considered a best practice, quarterly reviews are effective and economically viable.

When establishing the procedure for management review, ISO/IEC 17025:2017 requires that specific elements be included in the procedure. The summary box for clause 8.9 lists all the review inputs and outputs that should be incorporated in the procedure for management review. These requirements are somewhat aligned with the review inputs and outputs delineated within ISO 9001:2015 and ISO 13485.

There are six succinct steps needed for the pursuit for management reviews to be successful: (a) a published schedule for management reviews, (b) an agenda for each management review, (c) a sign in sheet for the management review meeting, (d) the actual management review meeting, (e) management review meeting minutes, and (f) a link to CAPA (should corrective action be assigned by the management team), premised on the data/ results presented during the management review meeting.

It is imperative that the schedule for management reviews be published at the beginning of each year. If the management review is held once annually, then the process is as simple as stating that the management review will be held in a specific month (e.g., January) for the preceding year. If reviews are held quarterly, reviews can be scheduled for the month following the close of a quarter. Since the laboratory owns the management system, the review schedule is premised on the laboratory's schedule. Note: if a quorum is not available to attend a management review, it is acceptable to reschedule the meeting. However, the rescheduling of the management review meeting should be documented.

To ensure consistency in the management review agenda, the agenda items should be spelled out in advance and aligned with the minimum requirements depicted in clause 4.15 of ISO/IEC 17025:2017. It is considered a best practice to list the agenda items as inputs and outputs in the management review procedure. Doing so reduces the risk of omitting information from the management review that is relevant to the ongoing performance of the management system.

Due to the confidential nature of the information, the content of management review meetings is not information that is required to be shared with laboratory customers or regulatory bodies such as FDA. However, evidence that the meetings are occurring is required. Management review meetings need to be supported by a sign in sheet containing the name, function, and actual signature of each attendee. If a member of the management team is not in attendance, it is an acceptable practice to send an alternate. If more than 50% of the management team is absent, the meeting should be rescheduled.

There is no industry standard for the duration of a management review meeting. The meeting should be long enough for the presentation, review, and discussion of each agenda item. Although not always practical, having the management review meeting off-site will reduce the number of potential interruptions, resulting in a more fruitful meeting.

One individual should be assigned the task of taking a copious number of notes and assembling them into the management review meeting minutes. Typically, the assignment is given to a member of the quality organization. It is important to have the meeting minutes reviewed and published as quickly as possible. Once again, there is no industry standard that drives how long a time period should be before meeting minutes are issued; however, seven days should be a realistic goal, and thirty days should be the absolute maxi- mum amount of time permitted for publication.

From time to time, management may decide that further actions are required to ensure that the management system remains in compliance with ISO/IEC 17025:2017. The action requested by management could be relatively benign and be handled informally (but still be documented). Typically, actions emanating from management review require formal corrective action. If formal corrective action is required, the request for action out of a management review should be placed into the CAPA system. It is much easier to track assigned actions that have been placed into the CAPA system versus those that are tracked informally. Regardless, actions taken must be reviewed at the next (immediate) management review. If reviews are being held annually, then one can now see how management oversight can lose some effectiveness. Questions to consider during a conformity assessment:

- Does the laboratory have an established procedure for management review?
- How often are management reviews held?
- Is there a published schedule for management reviews?
- What information is presented and reviewed during management reviews?

- Do outputs from management reviews feed into the corrective action and preventive action system when the result of management reviews dictate that corrective action is required to address an issue?

- Is there a sign in sheet that reflects attendees of management review meetings?

- Are records of management reviews being maintained by the laboratory?

Chapter 6: Conclusions

ISO/IEC 17025:2017 represents progress and harmony, for before ISO/IEC 17025:2017 came on the scene, calibration and testing laboratories dealt with ISO/IEC Guide 25 and EN 45001, which contained overlapping and contradictory requirements. This problem has been eliminated by streamlining these two standards into one commonly used and more thorough set of quality and technical competence requirements.

For this reason, ISO/IEC17025:2017, the international solution to better laboratory quality, is having an enormous impact on thousands of calibration and testing laboratories around the world and is pointing them to accreditation.

As accreditation typically takes 12 to 18 months to complete, laboratories are advised to start moving now. Accreditation should not be put on the back burner. Laboratories shouldn't delay accreditation, but should take full advantage of the competitive edge such status carries.

There are many benefits to be derived from implementing a well-structured laboratory management system such as ISO/IEC 17025:2017, and the accreditation process is rigorous and timely. For this reason, not to mention the high rate of failure that afflicts laboratories seeking accreditation for the first time, it's a good idea to seek the services of an outside professional consulting firm.

A competent quality consultant can walk laboratory through ISO/IEC 17025:2017 requirements and identify any problems that may halt the accreditation process.

Quality management is always a challenging topic in terms of planning, implementing and evaluating. The perception of quality differs between each individual is one of the reasons for challenges. Each individual in an organization will have a diverse method and action towards the quality objective. Therefore, it is generally tough to have a compromise between all staff. Awareness of variances in quality perception will support the management team to have more effective

concentration and effort on quality training and quality management system. The readiness analysis of ISO/IEC 17025.2017 in the case company was broad and covered the processes. Some of the teams were resistant to the transformation during the readiness analysis, which might have affected the outcomes. If the person would have been more committed to the alteration from the beginning, the readiness analysis might have been more precise and the ultimate outcomes in the internal audit would have been better. Implements the gaps of requirements to achieve ISO/IEC 17025:2017 is the main goal of the study. Overall, the project reached its goals in the restricted schedule and the theory covered each important area.

Accrediting any laboratory to ISO/IEC 17025:2017 can produce a gold mine of benefits. One of the major advantages is that your laboratory will gain international recognition for its commitment to quality and technical competence. ISO/IEC 17025:2017 accreditation signifies that your laboratory conforms to an internationally recognized standard that eases access to the global marketplace.

ISO/IEC 17025:2017 accreditation is an objective way to assure your customers that your laboratory is providing quality and technically competent calibration or testing. Accreditation is objective because an independent third-party accreditation body performs annual assessments to verify whether your laboratory is meeting all ISO/IEC 17025:2017 requirements. This independent evaluation is important to the customer, because it is an unbiased guarantee that your laboratory is performing at its highest level.

Another benefit of achieving ISO/IEC 17025:2017 accreditation is that it will set your laboratory apart from your competitors. ISO/IEC 17025:2017 is an ideal management system model for laboratories because it aims to control quality costs, improve measurement accuracy, reduce waste and guarantee technical competence. When implemented correctly, the elements of ISO/IEC 17025:2017 work meticulously together to ensure that required quality levels are met and that customer needs are satisfied. This can be a powerful strategic tool.

Laboratories accredited to ISO/IEC 17025:2017 are presented with a certificate of accreditation, which can be used to show current and potential customers their commitment to quality and technical competence.

Bibliography

1. Squirrell, A.; *Accredit. Qual. Assur.* 2008, *13*, 543.
2. Gomes, P. J. P.; *Cadernos BAD.* 2004, *2*, 6.
3. Berhe, L.; Gidey, T.; *Intelligent Information Management* 2016, *8*, 143.
4. Olivares, I. R. B.; *Gestão da Qualidade em Laboratórios*, 2nd ed., Editora Átomo: Campinas, 2009.
5. Staats, G.; *Fresenius' J. Anal. Chem.* 1993, *345*, 739.
6. Christelsohn, M.; Meyer, J. C.; *Accredit. Qual. Assur.* 1997, *2*, 82.
7. Dizadji, F.; Anklam, E.; *Accredit. Qual. Assur.* 2004, *9*, 317.
8. Masson, P.; *J. Chromatogr. A* 2007, *1158*, 168.
9. Rozet, E.; Marini, R. D.; Ziemons, E.; Hubert, P.; Dewé, W.; Rudaz, S.; Boulanger, B.; *TrAC – Trends Anal. Chem.* 2011, *30*, 797.
10. Bodnar, M.; Namieśnik, J.; Konieczka, P. *TrAC – Trends Anal. Chem.* 2013, *51*, 117.
11. Wong, S-K.; *Accredit. Qual. Assur*. 2017, *22*, 103.
12. Dos santos, L. L.; Mainier, F. B.; *Anais VI Congresso Nacional de Excelência em Gestão*, Niterói, Brasil, 2010.
13. https://ilac.org/about-ilac/, accessed in February 2021.
14. https://www.iso.org/about-us.html, accessed in February 2021.
15. https://www.iec.ch/about/?ref=menu, accessed in February 2021.
16. Van de Leemput, P. J. H. A. M.; *Accredit. Qual. Assur*. 2000, *5*, 394.
17. UNIDO; *Complying with ISO 17025: A practical guidebook for meeting the requirements of laboratory accreditation schemes based on ISO 17025:2005 or equivalent national standards*, United Nations Industrial Development Organization: Vienna, 2009.
18. RMMG; *Interpretação e Aplicação da ABNT ISO/IEC 17025:2017*, Rede Metrológica de Minas Gerais: Belo Horizonte, 2018.
19. NATA; *General Accreditation Guidance - ISO/IEC 17025:2017 Gap analysis*, National Association of Testing Authorities: Australia, 2018.

20. UNIDO; *Tested & accepted - Implementing ISO/IEC 17025:2017*, United Nations Industrial Development Organization: 2020

21. American Association for Laboratory Accreditation (A2LA). 2018a. "F117—Technical Staff Matrix for Accreditation—ISO/IEC 17025" (MS Word file). American Association for Laboratory Accreditation, March 5. Available from https://portal.a2la.org/documents/resultspubdocuments.cfm.

22. "R103—General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories." The American Association for Laboratory Accreditation, March 5. https://portal.a2la.org/requirements/A2LA_R103.pdf.

23. American National Standards Institute (ANSI) and American Society for Quality (ASQ). 2008. *ANSI/ASQ Z1.9–2003 (R2013): Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming*. Milwaukee, WI: ASQ Quality Press.

24. ———. 2013. *ANSI/ASQ Z1.4–2003 (R2013): Sampling Procedures and Tables for Inspection by Attributes*. Milwaukee, WI: ASQ Quality Press.

25. AssurX. N.d. *CATSWeb* (blog). https://www.assurx.com/tag/catsweb/. Bizmanualz. 2016. "What Is the Difference between Document Control and

26. Record Control?" *Bizmanualz.com*. https://www.bizmanualz.com/implement-iso-quality/what-is-the-difference-between-document-control-and-record-control.html.

27. Bullen, Peroska B. 2013. "How to Choose a Sample Size (for the Statistically Chal- lenged)?" http://www.tools4dev.org/resources/how_to_choose-a sample size/.

28. Carlson, Carl S. n.d. "Key Factors for Effective FMEAs." *ReliaSoft.com*. http://www.reliasoft.com/newsletter/v6i2/fmea_factors.htm.

29. Doiron, T., and J. Beers. 1991. *The Gauge Block Handbook*. Gaithersburg, MD: Dimensional Metrology Group, Precision Engineering Division, National Institute of Standards and Technology, September. http://xa.yimg.com/kq/groups/2573836/494330063/.

30. Dono. 2010. "File:SI base unit.svg." *Wikipedia.org*, February 16.

https://en.wikipedia.org/wiki/File:SI_base_unit.svg.

31. Hogan, Rick. 2014. “How to Calculate Test Uncertainty Ratio.” *ISO Budgets* (blog), October 27. http://www.isobudgets.com/calculate-test-uncertainty-ratio/.

32. Horizon. N.d. “What Are Reference Standards?” *Horizon Discovery*. https://www.horizondiscovery.com/reference-standards/what-are-reference-Standards.IHS Markit. 2018. Website. https://ihsmarkit.com/index.html.

33. Institute for Reference Materials and Measurements (IRMM). 2015. *Certified Reference Materials 2015*. Geel, Belg.: IRMM. https://ec.europa.eu/jrc/sites/jrcsh/files/rm_catalogue_0.pdf.

34. International Organization for Standardization (ISO). 2008. *ISO Guide 30:1992/ Amd 1:2008 Revision of Definitions for Reference Material and Certified Reference Material*. Geneva, Switz.: ISO, December. https://www.iso.org/standard/46210.html.

35. *ISO 19011:2011 Guidelines for Auditing Management Systems*. 2nd ed.

36. Geneva, Switz.: ISO, November. https://www.iso.org/standard/50675.html.

37. *ISO 9001:2015 Quality Management Systems—Requirements*. 5th ed. Geneva, Switz.: ISO, September.

38. *ISO 14644–1:2015 Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration*. 2nd ed. Geneva, Switz.: ISO, December.

39. *ISO 13485:2016 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes*. 3rd ed. Geneva, Switz.: ISO, March.

40. International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). 2017a. *ISO/IEC 17011:2017 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*. 2nd ed. Geneva, Switz.: ISO, November 2017.

41. *ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories*. 3rd ed. Geneva, Switz.: ISO, November 2017. https://www.iso.org/standard/66912.html.

42. International Society for Pharmaceutical Engineering (ISPE). 2011. *GAMP Good Practice Guide: A Risk-Based Approach to Calibration Management*. 1st ed.

North Bethesda, MD: ISPE, December.

43. Joint Committee for Guides in Metrology (JCGM), Working Group 1. 2008. "Evaluation of Measurement Data—Guide to the Expression of Uncertainty in Measurement." *JCGM 100: 2008*. Sèvres, Fr.: Bureau International des Poids et Mesures (BIPM), September. https://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf.

44. Leito, I., L. Jalukse, and I. Helm. 2018. "1. The Concept of Measurement Uncertainty (MU)." From the course "Estimation of Measurement Uncertainty in Chemical Analysis," University of Tartu, Republic of Estonia. https://sisu.ut.ee/measurement/introduction-concept-measurement-uncertainty

45. Mind Tools Content Team. 2012. "Managing Complaints and Feedback: Improving the Way That You Do Things." *MindTools.com*. http://www.mindtools.com/pages/article/managing-complaints.htm.

46. Mistretta, Phil. 2014. "As-Found: Out-of-Tolerance—What to Do Next?" *In Compliance*, March 1. https://incompliancemag.com/article/as-found-out-of-tolerance what-to-do-next/.

47. National Aeronautics and Space Administration (NASA). 2010. *Measurement Uncertainty Analysis Principles and Methods, NASA Measurement Quality.*

48. *Assurance Handbook—ANNEX 3*. Washington, DC: NASA, Document No. NASA-HDBK-8739.19-3, July 13. https://standards.nasa.gov/standard/nasa/nasa-hdbk-873919-3.

49. National Association for Proficiency Testing (NAPT). 2015. "The Value of Proficiency Testing." St. Louis Park, MN: NAPT. http://www.proficiency.org/portals/0/pdfs/The-Value-of-Proficiency-Testing.pdf.

50. National Association of Testing Authorities (NATA), Australia. 2012. "Guidelines for the Validation and Verification of Quantitative and Qualitative Test Methods." *Technical Note 17*. Sydney, AUS: Commonwealth of Australia, June.

51. National Institute of Standards and Technology (NIST). 2010. "National Voluntary Laboratory Accreditation Program: On-Site Assessment Checklists."

NIST.gov, February 4. https://www.nist.gov/nvlap/publications-and-forms/site-assessment-checklists.

52. "NIST Policy on Metrological Traceability." *NIST.gov*, July 23. https://www.nist.gov/traceability/nist-policy-metrological-traceability.

53. National Institute of Standards and Technology (NIST)/SEMATECH. 2012. *Engi- neering Statistics Handbook*. Gaithersburg, MD: NIST, April. http://www.itl.nist.gov/div898/handbook/index.htm.

54. Question Pro. N.d. "Short Customer Satisfaction (CSAT) Survey Template." *Ques- tionPro.com*. http://www.questionpro.com/a/showSurveyLibrary.do?surveyID=227&mode=1.

55. Sheahan, Kyra. 2017. "What Is a Complaint Management System?" *bizfluent*, September 26. https://bizfluent.com/facts-6401656-complaint-management-system.html.

56. Sigma-Aldritch. 2018. Website. http://sigmaaldrich.com.

57. Stimson, W. A. 2001. "Internal Quality Auditing: Meeting the Challenge of ISO 9000:2000." *Quality Digest*, November 1. https://www.qualitydigest.com/magazine/2001/nov/article/internal-quality-auditing.html.

58. SurveyMonkey. N.d. "How to Create Online Customer Satisfaction Surveys." *SurveyMonkey.com*. http://www.surveymonkey.com/mp/customer-satisfaction-surveys/.

59. Tague, N. 2004. *The Quality Toolbox*. 2nd ed. Milwaukee, WI: ASQ Quality Press. TransCat Calibration Services. 2008. "Risk Management: The Critical Role of Measurement and Calibration." TransCat Services White Paper, Rochester, NY. http://www.transcat.com/media/pdf/Risk%20Management.pdf.

60. United Nations Industrial Development Organization (UNIDO). 2006. "Role of Measurement and Calibration in the Manufacture of Products for the Global Market." United Nations Industrial Development Organization Working Paper, Vienna, Austria. https://www.unido.org/sites/default/files/2009-04/Role_of_measurement_and_calibration_0.pdf.

61. *Complying with ISO 17025: A Practical Guidebook for Meeting the Requirements of Laboratory Accreditation Schemes Based on ISO 17025:2005 or Equivalent National Standard*. Vienna, Austria: United Nations Industrial Development Organization, October. http://www.unido.org/fileadmin/user_media / Publications/ Pub_free/Complying_with_ISO_17025_A_practical_guidebook.pdf.

Appendices

Appendix

Quality Manual, Procedures and Forms implemented for the conformance according to International Standards ISO/IEC 17025:2017 regarding the Management System of Testing Laboratory “X” for chemical and microbiological tests.

After the Gap Analysis that was done in Laboratory "X", together with the Management and the Staff, we proceeded with the Review of the Management System of the laboratory. For this reason, two internal inspections were initially carried out and then the Management System took its final form. In this form, the Management System was evaluated by the Accreditation body and finally accreditation was granted to the laboratory.

Next, we quote a list of the documents that make up the Management System. Documents are opened by double-clicking each icon.

1. ISO_17025-2017-Quality Manual
2. Annex1 of Quality Manual-The organizational chart
3. Densometer Verification-validation report
4. Flash point Verification-validation report
5. pH Verification-validation report
6. UNCERTAINTY
7. QF-002-List of Authorized Personnel
8. SOP-01-General Guidelines.
9. SOP-02-Facilities and Environmental Conditions.
10. SOP-03-Ensuring the Validity of Results.

11. SOP-04-Test Equipment.
12. SOP-05-Method Validation.
13. SOP-06-Evaluating Uncertainty, Ensuring Quality.
14. SOP-07-Equipment Control Calibration Maintenance.
15. SOP-08-Control of Externally Provided Processes Services and Products.
16. SOP-09-HR Procedure
17. F-07-JD-Finance Manager
18. F-07-JD-Gov Manager
19. F-07-JD-HSE
20. F-07-JD-Lead Chemist
21. F07-JD-Logistic
22. F-07-JD-Operations Supervisor
23. F-07-JD-QA-QC Chemist
24. F-07-JD-Yard Supervisor
25. F-13-Customer Feedback Form
26. F-27-Emergency Drill Report
27. F-28-Accident Register
28. F-38-Laboratory Ambient Environment Monitoring Log-July2023
29. F-55-Commissioning & Re-Commissioning Checklist
30. F-62-Calibration Sheet-Analytical Balance
31. F-62-Calibration Sheet-Densitometer
32. F-62-Calibration Sheet-Flash Point (PMCC)
33. F-62-Calibration Sheet-pH Meter
34. F-70-Risk & Opportunity on Impartiality & Confidentiality
35. F-74-Confidentiality Agreement-Dimitris

36. F-75-Employee Code of Ethics, Impartiality & Confidentiality Agreement-Dimitris

The following documents are opened if you double-click the respective icon: