# ISO/IEC 17025

## *Cannabis Testing Laboratories*

## AN EXECUTIVE OVERVIEW

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# ISO/IEC 17025:2017

## *Cannabis Testing Laboratories*

### AN EXECUTIVE OVERVIEW

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# ISO/IEC 17025:2017

## *Cannabis Testing Laboratories*

### An Executive Overview

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# FOREWORD

ISO/IEC 17025:2017, *General Requirements for the Competence of Testing and Calibration Laboratories*, released in 2017, contains all the requirements that cannabis testing laboratories must meet to demonstrate that they operate a quality management system, are technically competent and can generate technically valid results.

This ISO/IEC 17025:1999 initial release of the standard replaced ISO/IEC Guide 25 and the European Union's EN 45001. ISO/IEC 17025 goes beyond both of these standards by adding new requirements, along with significant changes to previous requirements. The 2017 version of the standard was released in November of 2017 to better align the standard with the requirements of ISO 9001:2015. While many management system elements of ISO/IEC 17025:2017 mirror those of ISO 9001, the international quality management system standards, its additional technical competency requirements are unique for cannabis testing laboratories.

ISO/IEC 17025:2017 is the international basis for accrediting calibration and testing laboratories. It applies to both freestanding laboratories, as well as laboratories which are part of a larger facility. When a laboratory is part of a larger facility, ISO/IEC 17025:2017 accreditation can be achieved simultaneously with ISO 9001:2015 or IATF 16949 registration, if the auditor is working for both an accreditation body and a registrar.

Cannabis testing laboratories accredited to ISO/IEC 17025:2017 will find international acceptance of their testing results, efficiency in their operations and improved customer satisfaction.

The effects of ISO/IEC 17025 management system and competency requirements are already being felt by many laboratories around the world, with greater influence in the near future. While implementing a management system is time-consuming and sometimes difficult, accredited laboratories will be considered to have higher standards and better quality results.

This guide was created to aid those cannabis testing laboratories that are about to embark upon the ISO/IEC 17025:2017 journey. It will help smooth out the bumps as it explains the general requirements of ISO/IEC 17025:2017 step by step. Since achieving ISO/IEC 17025:2017 accreditation is a lengthy and detailed process, it is strongly suggested that laboratories seeking accreditation retain the services of a reputable consulting firm.

**PERRY JOHNSON CONSULTING, INC.**
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## THE USERS OF THIS GUIDE

This guide will be useful to lab managers and other personnel in labs that meet any of the following criteria:

- Independent testing laboratories
- Testing laboratories housed in corporate facilities
- Testing laboratories working closely with dispensaries

ISO/IEC 17025:2017 accreditation provides cannabis testing laboratories with a significant competitive edge.

## WHAT IS ISO/IEC 17025:2017?

ISO/IEC 17025:1999, *General Requirements for the Competence of Testing and Calibration Laboratories,* released in 1999, is the international standard for establishing cannabis testing laboratory quality management systems and recognizing laboratory technical competence through accreditation. ISO/IEC 17025:2017 was released in November 2017 to provide better alignment to the requirements of ISO 9001:2015.

This standard was drafted by the International Organization for Standardization (ISO) Committee on Conformity Assessment (CASCO) Working Group (WG) 10, and replaced ISO/IEC Guide 25, *General Requirements for the Competence of Calibration and Testing Laboratories,* and EN 45001, *General Criteria for the Operation of Testing Laboratories*.

All ISO 9001:2015 requirements that are relevant to the scope of cannabis testing laboratory quality management systems (QMS) have been incorporated into ISO/IEC 17025:2017, along with technical competency requirements.

The release of ISO/IEC 17025:2017 is the latest stage in the process of developing laboratory quality and competence standards, which has been going on for more than 20 years. Let's take a brief look at the history of this process.

## ISO/IEC Guide 25, ISO 9001:2015 and EN 45001

The process began with the development of ISO/IEC Guide 25 by ISO and the International Electrotechnical Commission (IEC). ISO, founded in 1946, is a federation of 132 national standards bodies. IEC, founded in 1906, is a federation of 50 national electrical and electronic engineering standards committees. The American National Standards Institute (ANSI) is the member body and national committee representing the United States in both organizations.

Under a formal agreement, ISO and IEC, both based in Geneva, Switzerland, form the specialized system for worldwide standardization and operate joint technical committees, with IEC safeguarding electrotechnical interests in matters of international standardization not related to any particular technology. These international standards are designed to facilitate world trade by removing technical barriers.

ISO/IEC Guide 25 was first released in 1978 and underwent minor revisions in 1982. These first two editions were primarily focused on requirements for assessing the technical competence of testing laboratories.

In 1987, the ISO 9000 international quality management system standards were issued, sparking a greatly increased focus on management systems. This event had a major influence on laboratory standard developments.

The first such standard to be influenced by ISO 9000 was EN 45001, issued in 1989 by the European Union (EU), which consists of 15 member states: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom. The EU comprises a marketplace of some 370 million people. EN 45001 focused on competence and operation, including the management system, of testing laboratories.

Further developments in the laboratory quality approach were incorporated in the 1990 revision of ISO/IEC Guide 25. These two standards contained overlapping and inconsistent requirements, creating the need for a common laboratory standard that would allow mutual acceptance of test results. In 1994, ISO CASCO WG 10 began the joint revision process.

## ISO/IEC 17025:2017

The process of drafting ISO/IEC 17025:1999 took five years, with the Draft International Standard (DIS) issued in 1998, the Final Draft International Standard (FDIS) appearing in 1999 and the standard published later that year.

Revisions to the 17025 standard for the 2017 release were made to ensure compatibility with ISO 9001:2015. This became necessary because of the generalized adoption of quality management systems conforming to the requirements of ISO 9001:2015. Numerous changes were made to the overall structure of the standard.

ISO/IEC 17025:2017 also explains that while compatible with ISO 9001:2015, the two standards are not interchangeable. Both standards provide evidence of laboratory's commitment to customer satisfaction and continual improvement, only ISO/IEC 17025:2017 can be used to demonstrate technical competence.

ISO/IEC 17025:2017 outlines requirements laboratories must meet to be recognized as competent to carry out cannabis tests, including sampling. Its most important provisions are Clause 4, which specifies general requirements, Clause 5, which specifies structural requirements, Clause 6, which specifies resource requirements, Clause 7, which specifies process requirements, and Clause 8, which specifies management requirements.

Laboratories meeting ISO/IEC 17025:2017 requirements comply, for cannabis testing activities, with the relevant ISO 9001 requirements. Many management system elements of ISO/IEC 17025:2017 mirror those of ISO 9001:2015. Its technical competency requirements go beyond QMS registration and relate specifically to the qualifications needed with regard to personnel, equipment, facilities and laboratory methods.

# ISO/IEC 17025:2017-ISO 9001:2015 Comparison Chart

| ISO 9001:2015 | ISO/IEC 17025:2017 |
|---|---|
| Clause 1 | Clause 1 |
| Clause 2 | Clause 2 |
| Clause 3 | Clause 3 |
| 4.1 Understanding the organization and its context | 4.1, 4.2 |
| 4.2 Understanding the needs and expectations of interested parties | 7.1 |
| 4.3 Determining the scope of the quality management system | 5.1, 5.2, 5.3, 5.4 |
| 4.4 Quality management system and its processes | 5.5 |
| 5.1 Leadership and commitment | 4.1, 4.2, 5.1, 5.2 |
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| 6.1 Actions to address risks and opportunities | 8.5 |
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| 7.2 Competence | 6.2 |
| 7.3 Awareness | 6.2, 7.11, 8.2, 8.3 |
| 7.4 Communication | 6.2, 7.11, 8.2, 8.3 |
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| | |
|---|---|
| 8.7 Control of nonconforming outputs | 7.10 |
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# ISO/IEC 17025:2017 ACCREDITATION

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 cannabis tests.

Accreditation can be a valuable tool, demonstrating that a laboratory operates an efficient QMS and is competent to perform cannabis 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 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.

## Key Steps to Achieving Accreditation

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 cannabis tests within its scope.

The scope of accreditation for testing laboratories is normally identified in terms of standard test methods.

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 cannabis tests; 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 cannabis tests 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 cannabis test results, can have 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 cannabis 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 cannabis tests, 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 auditors.

- Have personnel on its executive (accreditation) committee or governing board with experience and expertise in the appropriate cannabis testing scope.

- Conform to ISO/IEC 17011, *General Requirements for accreditation bodies accrediting conformity assessment bodies.*

# What to Look For in an Auditor

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

1) Auditors 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 auditors who have successfully completed this training.

2) Auditors must comply with ISO 19011:2011, *Guidelines for quality and/or environmental management systems auditing*, regarding their qualifications.

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

4) At least one member of an audit team must have relevant industry experience in the appropriate cannabis testing 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 auditors have met the above qualifications.

# THE BENEFITS OF ISO/IEC 17025:2017 FOR CANNABIS LABS

In 1973 Oregon became the first U.S. state to decriminalize cannabis. In 1996 California became the first state to legalize the medical use of cannabis. In 2012 Colorado and Washington became the first states to legalize recreational use. As of January 2019, thirty-three states, four of the permanently inhabited U.S. territories, and the District of Columbia have legalized medical cannabis. In addition to that an additional fourteen states have adopted laws that are more restrictive but still allowing for access to products containing cannabidiol (CBD). As of June 2019, eleven states have legalized the recreational use of cannabis. Fifteen additional states have decriminalized cannabis. Globally forty-four countries have legalized medical cannabis with four countries legalizing recreational use.

As an industry worldwide growth is expected to reach $146.4 billion by 2025, with $100.3 billion of that being U.S. alone. Growth within the industry has already led to 243,700 full time jobs being created in U.S. alone. This is projected to grow on average by 21% through 2022. There are numerous forms of consumption of cannabis with oils, beauty and skin care products, beverages, edibles, capsules, creams, patches.

Market needs vary from state to state and country to country, however all have a need for testing of cannabis. Whether in the form of cannabinoid content and potency, terpenes, microbiological contaminants, residual solvents, heavy metals, or pesticides testing of cannabis will always be a necessity.

As an accredited lab you will be contributing the overall health and wellbeing of people with numerous afflictions that cannabis helps as a remedy. Studies show the following benefits of cannabis usage in patients:

1. Addiction and usage to dangerous opioids is reduced in areas where cannabis is legal.

2. Elderly report improvement in sleep quality, cognitive function, and decreased blood pressure to name a few.

3. Reduction of the need for anxiety medications in addition to reduction of the effects of social anxiety disorder.

4. Autism symptoms have decreased in problematic behavior and improved communication capability.

5. Epileptic seizures in children reduced as compared to those without cannabis use.

Accrediting your 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.

# ISO/IEC 17025:2017 REQUIREMENTS

## 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.*

# 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 of 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 which is required for the correct performance of laboratory activities and which can influence the result.*

*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. Reference materials from producers meeting the requirements of ISO 17034 come 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. Reference materials should be used from producers that meet ISO 17034.*

*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*** *In those cases where 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, and 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 the measurement shall be capable of achieving the measurement accuracy 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, OR*
- *calibration of the equipment is required to establish the metrological traceability of the reported result.*

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

- *those used for the direct measurement of the measured, 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 program, 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 labeled, 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, 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 labeled 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 one of the following:*

*a) calibration provided by a competent laboratory;*

*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;*

*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.*

*c) the appropriate methods or procedures are selected and are capable of meeting the customer's requirements.*

*NOTE 2: For 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 purpose.*

**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 - Control of management system documents).*

***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.*

***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 customer's needs and consistent with specified requirements.*

*NOTE: Performance characteristics can include, but are not limited to, the measurement range, accuracy, the 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) 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 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*** *Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions which 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 5725 and ISO 21748.*

## 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 analyzed, 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

***7.8.1.1*** *The results shall be 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.*

*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.*

***7.8.1.2*** *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.*

*The laboratory should include a statement specifying that the report shall not be reproduced except in full, without approval of the laboratory.*

***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 measured or in a term relative to the measured (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, 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 measured or in a term relative to the measured (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 (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 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, 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 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, 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*

### 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 releases 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 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, 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 -** *At 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 action (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, "document" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, textbooks, 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 the actions into its management system;*
- *evaluate the effectiveness of these actions.*

*NOTE: Although this document specifies that the organization 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 and 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 analyzed 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 Action (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 analyzing 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 program 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 program 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.*

# CONCLUSION

ISO/IEC 17025:2017 represents progress and harmony, for before ISO/IEC 17025:2017 came on the scene, cannabis 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 many cannabis 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 your laboratory through ISO/IEC 17025:2017 requirements and identify any problems that may halt the accreditation process.