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Cannabis Testing Labs Achieve ISO 17025 Accreditation: A LIMS Guide to Success

Author: Dr. Shaun R. Opie

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Author: Dr. Shaun R. Opie
Managing Director at E4 Bioscience
Scientific Advisory Board, CloudLIMS.com

Dr. Opie is the managing partner of E4 Bioscience, a strategic consulting firm that exclusively supports cannabis testing laboratories. As a previous owner/operator of both clinical and cannabis laboratories, he understands the technical, operational, and financial challenges of both start-up and established businesses. Since 2018, E4 Bioscience has helped over 40 cannabis laboratories find success in various capacities including: business planning, site selection, laboratory design, instrumentation selection, license application, technical recruiting, operational improvement, ISO 17025 accreditation, and lab sale. In addition to his consultative roles, Dr. Opie is the editor of the general reference textbook, "Cannabis Laboratory Fundamentals", a frequent invited lecturer on the cannabis laboratory sector, a participating member on multiple AOAC International - Cannabis Analytical Science Program committees, and a PJLA ISO 17025 lead assessor.

1. Introduction

The ISO/IEC 17025:2017 standard is internationally recognized and outlines the requirements for testing, calibration, and sampling laboratories to demonstrate their competence, impartiality, and consistency in business activities. The standard emphasizes the implementation of procedural and quality management mechanisms to achieve these objectives. The ISO/IEC 17025 standard differs from other quality standards, such as ISO 9001, by setting standards for unbiased operational competence and consistency in addition to promoting the use of a quality management system.

In 1999, ISO/IEC 17025 was established, which included new requirements for competency, impartiality, and consistent laboratory operation. Since then, the standard has seen two additional revisions, in 2005 and 2017, with the 2017 version placing a focus on laboratories seeking competent, impartial, and consistent results and an efficient management system. As of February 2023, ISO/IEC 17025:2017 is the latest version of the standard.

Although not all laboratories adopt the standard, those that do tend to find it rewarding, albeit challenging. Cannabis testing labs accredited with ISO/IEC 17025:2017 experience worldwide recognition of their testing outcomes, increased operational effectiveness, and enhanced customer contentment.

This eBook explores how laboratories can benefit from laboratory informatics solutions such as laboratory information managament systems (LIMS). Selecting the right LIMS is a critical decision for laboratories seeking to obtain or maintain ISO/IEC 17025 accreditation. It requires careful consideration of various factors, such as the features and functionalities that best suit the laboratory's needs, the LIMS vendor's support and training capabilities, and the cost of implementation and maintenance. This eBook provides guidance on identifying critical LIMS features that enable better compliance with the ASTM E1578-18 Standard Guide for Laboratory Informatics. Other factors to consider include cybersecurity, system flexibility, cost, implementation, and warranties. Finally, the eBook explains how to use ASTM E1578-18 Standard Guide for Laboratory Informatics to make informed decisions and ensure compliance with the standard.

1.1 ISO/IEC 17025 vs. ISO 9001

Unfamiliarity with the history of ISO/IEC 17025, may make one wonder how it differs from the ISO 9000 series. Although ISO 9001 is mentioned when complying with ISO/IEC 17025, there are several differences between the two, despite both being related to quality management. ISO 9000 standards focus on the basics of Quality Management System (QMS) [1] for an organization, including eight management principles [1][2]. ISO 9001 outlines the requirements that organizations must meet to adhere to the standard [3]. Third-party certification bodies provide independent verification that the organization meets the standard's criteria. Quality management refers to a set of organized actions that are carried out to manage and regulate an organization's quality standards [4]. ISO 9001 applies to a wide variety of organizations operating in any industry, while ISO/IEC 17025 focuses on testing, calibration, and sampling laboratories.

The ISO/IEC 17025 contains a set of criteria and specifications aimed at guaranteeing the quality, impartiality, competence, and consistent functioning of laboratories [5]. ISO/IEC 17025 accreditation recognizes a laboratory's technical competency, whereas ISO 9001 registration is limited to QMS conformance [6]. ISO/IEC 17025 is the quality management standard to comply with, particularly for non-clinical laboratories. However, ISO 9001 may provide additional guidance and inspiration for laboratories struggling with implementing the management system portion of ISO/IEC 17025 [7].

ISO/IEC 17025:2017 incorporates all ISO 9001:2015 requirements that are pertinent to QMS of cannabis testing laboratories, in addition to technical competency requirements.

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1.2 ISO 17025:2017 vs. ISO 17025:2005

To address the current industry requirements, ISO/IEC 17025:2017 has undergone changes to include:

- Risk-based thinking
- More adaptable guidelines for processes, procedures, documented information, and organizational responsibilities
- Updated terminology
- Recognition and integration of computer systems, electronic records, and electronic results and reports production
- An expanded scope that encompasses all laboratory activities, such as testing, calibration, and sampling associated with subsequent calibration and testing

The 2005 version of ISO/IEC 17025 included the following:

- Scope
- Normative references
- Terms and definitions
- Management requirements
- Technical requirements

In contrast, the current version of ISO/IEC 17025, released in 2017, includes the subsequent components:

- Scope
- Normative references
- Terms and definitions
- General requirements
- Structural requirements
- Resource requirements
- Process requirements
- Management system requirements

The following table summarizes the key differences between the two versions of the standard:

Old 2005 Version	New 2017 Revision
2 clauses with mandatory requirements	5 clauses with mandatory requirements
Greater number of mandatory procedures	Fewer mandatory procedures
Less reference to required processes	Greater reference to processes
Less reference to mandatory records	Greater emphasis on evidence-containing records
Less emphasis on risk-based thinking	New requirements include: • Actions to address risks and opportunities • Statements of conformity and decision rule

2. How ISO/IEC 17025 Affects and Benefits Laboratories

The ISO/IEC 17025:2017 standard comprises a globally accepted collection of prerequisites for laboratories that perform testing and calibration. It was developed by the ISO/CASCO Committee on Conformity Assessment with the goal of promoting confidence in laboratory operations and demonstrating competence in generating valid results[1]. Adoption of the standard has been steadily increasing since 2010, but it can be difficult for small and academic laboratories [2][3], as well as regions facing cultural, educational, and cost barriers [4][5].

When it comes to cannabis testing laboratories, achieving ISO/IEC 17025:2017 accreditation gives them a substantial advantage over their competitors. Some of the potential benefits of achieving ISO/IEC 17025 accreditation for cannabis testing laboratories are as follows:

- Enhances credibility
- Reduces operational costs
- Reduces risks and liabilities
- Meets compliance with state and local regulations
- Boosts cross-border trade

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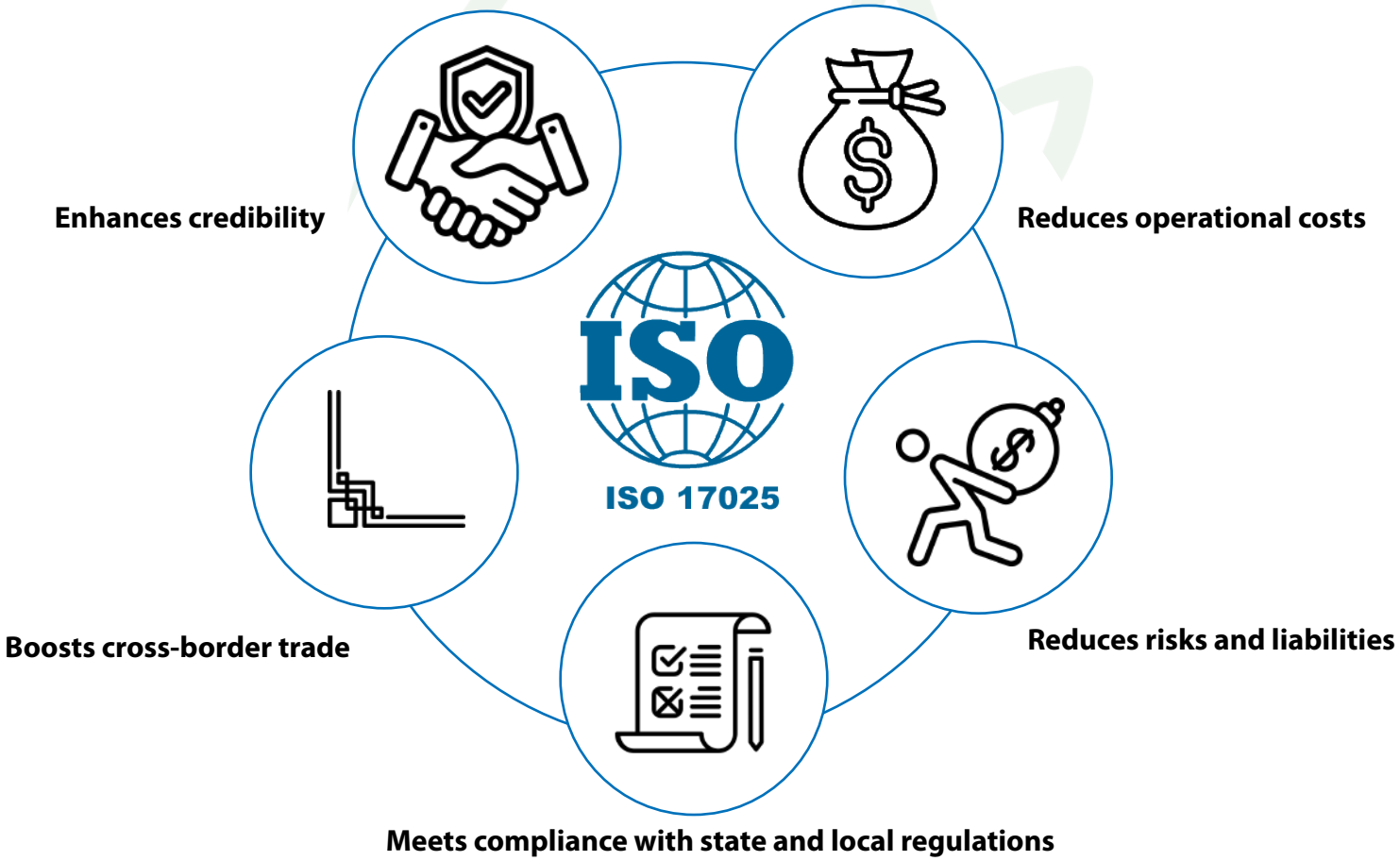


2.1 The ISO/IEC 17025 Requirements Cannabis Testing Laboratories Must Meet

Implementing any international standard within a regulated business is rarely a simple process, and it presents several challenges for all but the most well-organized and resourced entities.The ISO/IEC 17025 standard emphasizes quality, and it does so by focusing on a laboratory's ability to demonstrate its competence, impartiality, and consistency across all of its operations. This section will provide more detail on these three characteristics, as well as the specific obligations that the standard places on the cannabis laboratory.

2.1.1 Competence, Impartiality, and Consistent Operations

The "Scope" segment of ISO/IEC 17025:2017 specifies the overall prerequisites that laboratories must meet in order to exhibit their proficiency, neutrality, and consistent functioning. However, the standard only defines "impartiality," leaving laboratories to interpret the meanings of "competence" and "consistent operation". To help clarify, ISO 15189 and ISO 17034 are cited as references for "competence," with ISO 15189 defining it as the ability to apply knowledge and skills effectively. Meanwhile, "impartiality" is defined as objectivity, requiring the laboratory to remain free from conflicts of interest, bias, and prejudice while maintaining neutrality in its analytical results. Although "consistency" is not defined in ISO/IEC 17025:2017, its definition in other ISO standards and Merriam-Webster's definition suggest that it involves maintaining a firm and persistent adherence to a stated expectation [1][2][3].

2.1.2 The Requirements Placed on Cannabis Testing Laboratories

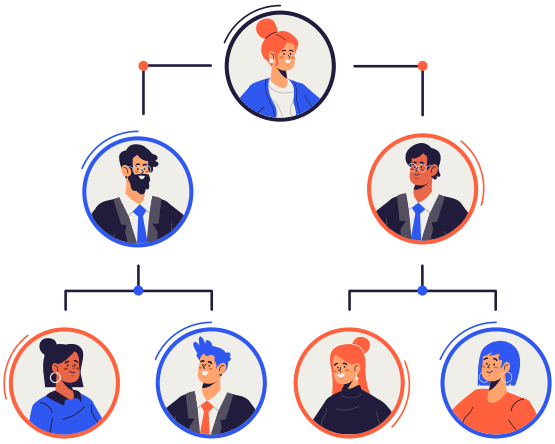
ISO/IEC 17025 standard outlines specific requirements that laboratories performing testing, sampling, and calibration activities - such as cannabis testing laboratories - must meet to demonstrate competence, impartiality, and consistent operation. These requirements are covered in five sections: General requirements (Section 4), Structural requirements (Section 5), Resource requirements (Section 6), Process requirements (Section 7), and Management system requirements (Section 8). Each of these sections outlines procedural and policy expectations on the laboratory while also providing benefits, both tangible and intangible [1].

General Requirements:

Section 4 of ISO/IEC 17025:2017 outlines the general requirements for laboratories, focusing on two main areas: impartiality and confidentiality. The impartiality requirement emphasizes the laboratory's obligation to remain unbiased and to take action against any potential threats to impartiality. Similarly, the confidentiality requirement mandates that all information generated or collected during laboratory activities must be treated as confidential and secured appropriately to prevent unauthorized access. In cases where the release of confidential information is required by law or contract, the laboratory must communicate such release in a timely and appropriate manner [1].

Structural Requirements:

To fulfill the three primary objectives of competence, impartiality, and consistent operations, Section 5 of ISO/IEC 17025:2017 focuses on the fundamental organizational requirements of a laboratory. This includes being a legal entity with clear management responsibilities and documentation of all activities, procedures, and methods under the scope of the standard. It emphasizes the significance of human resources, requiring the laboratory to provide the necessary authority and resources for individuals to monitor and address deviations from procedures, methods, and the quality management system [1].



Resource Requirements:

Section 6 of ISO/IEC 17025:2017 emphasizes the significance of resources in enabling a laboratory to achieve its objectives and maintain high standards of practice. This section covers five areas: personnel, facility and working environment, equipment, metrological traceability, and third-party products and services. The first aspect relates to the competence and impartiality of personnel, which must be demonstrated and documented, and they should be provided with the necessary resources to perform their duties. The second aspect focuses on the suitability of the facility and working environment, which should not negatively affect the accuracy of analytical results. The third aspect highlights the importance of having proper equipment and ensuring it is calibrated and properly maintained to deliver accurate results, with documentation for all equipment activities. The fourth aspect deals with metrological traceability, which refers to the ability of measurement results to be related to a reference through an unbroken chain of calibrations. Finally, the fifth aspect addresses third-party products and services and requires the laboratory to ensure their suitability through review and approval, and to communicate their requirements clearly to third parties [1].

Process Requirements:

ISO/IEC 17025:2017 Section 7 is a substantial part of the standard that specifically focuses on the laboratory's actual work processes. It discusses 11 different aspects of workflow in the laboratory, providing a brief overview of each aspect without going into great detail [1].

1. The section about **bid opportunities and contracts** in ISO/IEC 17025:2017 outlines the need for clear communication and documentation between laboratories and their clients regarding work requirements, test methods, and adherence to specifications or standards, including any changes or deviations that may occur.
2. The section on **laboratory methods** provides a detailed account of the necessary degree of care and suitability of procedures for all laboratory activities. It covers the process of developing, verifying, validating, and documenting methods, as well as how to manage any deviations from those methods.
3. The section on **laboratory sampling** discusses the significance of creating high-quality sampling plans and methods and highlights what they should consist of.
4. The **test and calibration item management** section of ISO/IEC 17025:2017 covers the appropriate handling and storage of test and calibration items throughout the laboratory's workflow. It also specifies the methods for the identification of these items.
5. The section on **record management** briefly discusses how technical records should be managed, and what information they should include.
6. The section on **management uncertainty** discusses the requirement for the evaluation of measurement uncertainty by identifying and considering significant contributors to result variance.
7. The **result validation** section describes the components required to ensure valid results and how result validation should be carried out, which includes monitoring and validating results, performing proficiency testing and comparing results obtained from different laboratories, and making continuous improvements to further enhance quality.
8. The section on **result reporting** is about how to report results, including what kind of information must be included in testing reports, calibration certificates and sampling reporting. It also covers statements of conformity, opinions, and interpretations, as well as any amendments that might be necessary.
9. The **complaint management** section involves outlining how the laboratory should handle both internal and external complaints related to its activities and services. The focus is on promoting transparency and effective communication.
10. **Nonconformity management** pertains to the methods necessary for efficiently managing and minimizing noncompliant work.
11. The **management of data and information** acknowledges that these elements are the most vital outcomes of the laboratory. It specifies how these should be managed efficiently to ensure the laboratory operates optimally and achieves success.

Management system requirements:

ISO/IEC 17025:2017's Section 8 pertains to the laboratory's management system. Although the standard doesn't explicitly label it as a "quality management system" or QMS, the opening paragraph suggests that it addresses quality by mandating a management system capable of supporting and demonstrating consistent adherence to the standard's requirements, while ensuring the quality of the laboratory results.

This section offers two options for the management system: Option A for laboratories that require a newly created system, or Option B for those with an existing management system driven by ISO 9001 to help reduce documentation redundancy.

2.1.3 Reconciling shortcomings in ISO/IEC 17025

It is worth noting that ISO/IEC 17025 does not include provisions for laboratory safety compliance [4][5]. Laboratories that adopt this standard may wish to consider incorporating elements of other QMS frameworks, such as the "Facilities and Safety" quality system essential (QSE) found in Clinical and Laboratory Standards Institute's (CLSI's) QMS01- A Quality Management System Model for Laboratory Services [5], and the World Health Organization's (WHO's) Laboratory Quality Management System: Handbook. The "Facilities and Safety" QSE outlines the essential elements for a laboratory's personnel, design, and safety to prevent and control physical, chemical, and biological hazards that may affect operations. Adhering to these elements through a laboratory safety program enhances the laboratory's ability to provide quality data and services by protecting the personnel, facility, equipment, and work environment.

Besides safety, ISO/IEC 17025 has a few minor gaps in addressing laboratory assessment tasks and personnel requirements, in contrast to the "Assessment" and "Personnel" QSEs of CLSI and WHO. For instance, the "Assessment" QSE deals with external audits, unlike ISO/IEC 17025, while the "Personnel" QSE provides more detailed competency assessment methods, policy development, procedure writing, training, and performance appraisal compared to ISO/IEC 17025's documentation of competence requirements. Laboratories seeking accreditation to ISO/IEC 17025 may wish to compare the nuances of these QSEs with the ISO standard to exceed the minimum requirement for meeting ISO/IEC 17025 compliance requirements.

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2.2 The Advantages Cannabis Testing Laboratories Gain by Conforming to ISO/IEC 17025

The cannabis market is growing rapidly in the wake of increasing decriminalization and legalization of cannabis around the world. Unsurprisingly, the effect has made ripples in the global cannabis testing industry which is expected to reach USD 1,806 million by 2025. Cannabis and cannabis infused products are available in a very wide array of formulations and matricies, including the unaltered flower, extracted oils, beauty and skincare products, beverages, edibles, capsules, creams, and patches. The requirements of the market differ depending on the state or country, but testing for safety and quality are consistent needs. Testing frequently involves analysis of potency and cannabinoid content (), terpenes, microbiological contaminants, residual solvents, heavy metals, or pesticides. Because of consumer protection laws cannabis safety and quality testing will always be necessary.
Obtaining ISO/IEC 17025:2017 accreditation for a laboratory can bring a wealth of benefits. A significant advantage is that the laboratory will be globally recognized for its dedication to quality and technical expertise. Accreditation to this standard indicates that the laboratory adheres to an internationally acknowledged benchmark, which simplifies entry into the global market. In the cannabis industry, being an accredited laboratory provides the credibility and authority to play an important role in improving the health and well-being of people who suffer from various conditions and use cannabis products to find relief.

ISO/IEC 17025:2017 accreditation provides an unbiased means to provide confidence to a laboratory's customers that the laboratory is delivering testing services that are of high quality and is technically proficient. The objectivity of accreditation stems from the fact that an external third-party accreditation body performs yearly evaluations to verify that they laboratory complies with all the ISO/IEC 17025:2017 standards. This impartial evaluation is crucial to the customer because it offers confidence that the laboratory is operating at the highest level.

In places that do not require obtaining ISO/IEC 17025:2017 accreditation, getting it offers the advantage of distinguishing the laboratory from its competitors. Whether required or not, this standard is an excellent management system model for laboratories because it strives to regulate quality costs

enhance measurement precision, minimize waste, and promote technical proficiency. When properly implemented, the components of ISO/IEC 17025:2017 complement each other to ensure that necessary quality standards are attained and that customer expectations are met. This can serve as a potent strategic tool [1][2][3][4][5][6][7].

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3. Selecting Laboratory Informatics Software to Enhance Adherence to ISO/IEC 17025 Standards in a Cannabis Testing Laboratory

ISO/IEC 17025 offers many advantages to a cannabis testing laboratory, but it also requires a significant effort from the laboratory to meet the standard[1]. Currently, it is challenging for laboratories to conform to ISO/IEC 17025 without an information management system due to requirements for timely data retrieval and security. Therefore, laboratories are increasingly adopting Laboratory Information Management Systems (LIMS) to modernize their operations, enhance quality, and ensure compliance with ISO/IEC 17025 [2][3]. However, not all LIMS are created equal, and laboratories must carefully consider which LIMS vendor provides the best solution to help them meet ISO/IEC 17025 requirements. This chapter provides guidance to laboratory managers and staff on selecting an informatics system that addresses the demands of ISO/IEC 17025, including specific LIMS functionality that aligns with the standard's compliance requirements.

3.1 Assessment and Selection

Laboratory professionals often face the challenge of finding software for their ISO/IEC 17025 cannabis testing laboratory and have many questions, including if a LIMS is even necessary, and if so, how to compare different options. This can make the task seem overwhelming. To begin the search for a LIMS, it's important to understand the informatics needs of the laboratory, including analysis requirements, reporting and data sharing constraints, instrument interfacing needs, barcoding and tracking requirements, and quality assurance processes. However, LIMS systems vary in many ways, and factors such as price and value must also be considered. While determining which products to investigate further, it's important to understand how a LIMS can empower the laboratory to meet its regulatory, workflow, and standard-driven needs. It is helpful for laboratories to think through a variety of questions related to licensing such as the following:

- Is it more advisable to acquire software licenses or opt for a subscription-based model where the software is rented?
- Is it more practical to have the software physically installed on premises, or would a SaaS-hosted option be more suitable?
- Which system is more suitable for our needs: a modular or a complete system?
- Which licensing or rental plan would suit us best?
- What onboarding training and long term support are provided?
- What features does the software offer to assist our laboratory in adhering to the ISO/IEC 17025 standard?

3.1.1 Technology Considerations

When choosing which technology to invest in for a cannabis laboratory, factors such as workflow, instruments, data management requirements, budget, technological expertise, business goals, and risk tolerances all need to be taken into consideration. Additionally, the laboratory should be interested in how the technology can help with optimizing workflow requirements and assist the laboratory in meeting the requirements of the standard.

During the process of exploring technology options, it is important to align the laboratory's objectives with the appropriate informatics solutions. For instance, does the laboratory plan to make a small investment with limited goals and gradual analytical requests, or do they envision substantial expansion into multiple testing areas? If the laboratory anticipates future growth, it may be necessary to consider investing in technologies that could impact data management and security processes. Additionally, the laboratory must consider how ISO/IEC 17025 compliance will affect future expansion and technological requirements.

Secondly, to guide hardware and software investment at the laboratory, it is important to consider the kind of work the laboratory will be doing and the regulatory responsibilities that come with it. For example, if the laboratory conducts extractable and leachable testing, chromatography and spectroscopy instruments must be considered, along with requirements for retaining analytical results for regulatory and certification bodies. The data management system of an ISO/IEC 17025-accredited laboratory must be robust enough to meet the standard's needs. For laboratories operating in heavily regulated spaces, the system may need to interface with government reporting systems or export test results in the regulatory body's specific format. Other factors must also be considered.

Next, the budget of a laboratory is a crucial factor to consider. Can the budget accommodate on-site hardware and software systems, along with the necessary staff to maintain and manage them? Would it be more feasible and operationally efficient to make an upfront payment or look for a vendor who can offer leasing or rental options? Would it be more beneficial to invest in a slightly more expensive system that can provide the functionality required for easier compliance with ISO/IEC 17025 standards?

Lastly, it's crucial to determine who will be responsible for resolving any technology-related issues that may arise, such as software setup and maintenance. If a laboratory lacks local technical support, the laboratory may want to explore the distribution model for an installed software and consider Software-as-a-Service (SaaS) options. Cloud computing is becoming an increasingly popular choice for hosting software, as it can be reliable when executed properly [4]. Opting for a hosting provider means they will bear a significant portion of the responsibility for technology, upkeep, security, and backup.

It's also essential to consider the cybersecurity of a laboratory's overall operations, including the software solution. Has a cybersecurity plan already been implemented, or is it still pending? It's crucial to invest in ensuring the security of sensitive data, and it's necessary to assess how well the laboratory's cybersecurity goals align with the requirements of ISO/IEC 17025. Keep in mind that the preparedness and the implementation of the cybersecurity plan will determine the investment decisions in technology.

3.1.1.1 Laboratory Informatics Options

Considering the information mentioned earlier, what are the software solutions commonly used in ISO/IEC 17025 compliant cannabis testing laboratories? One of the widely discussed options is the laboratory informatics management system, also known as LIMS, which helps laboratories manage their testing workflows, data, and other aspects of their operations.

The use of a LIMS in cannabis testing laboratories is not a new concept [4][4][5][6][7]. However, there is surprisingly limited data available about the percentage of laboratories currently using LIMS in their workflow [8]. Nonetheless, the focus on laboratory competence, impartiality, and consistent operations by ISO/IEC 17025 standard developers, and the potential to improve quality through appropriate informatics solutions such as LIMS, suggests that many laboratories may turn to LIMS to help achieve their quality and compliance goals.

LIMS solutions can enhance laboratory workflows, productivity, sample management, and regulatory compliance, while also improving safety and quality [10]. A well-implemented LIMS can integrate and secure information and data, provide traceability and real-time monitoring, and act as a central integrator and maintain an audit trail for analytical, sampling, and calibration testing activities in the laboratory [10][11][12]. This also enables rapid action on insights gained from real-time dashboards and faster reaction to issues that may compromise compliance with ISO/IEC 17025 and other regulatory requirements.

3.1.1.2 LIMS and the QMS

To achieve maximum success and comply with standards and regulations, laboratories must prioritize a culture of quality [13]. One way to do this is through the implementation of a Quality Management System (QMS) [14], which ISO/IEC 17025:2017 implicitly promotes through its requirements for a management system. Although ISO/IEC 17025:2017 never directly refers to a QMS, it is evident that the standard addresses quality through its management system requirements [15]. Discussions surrounding the role of a LIMS in managing a laboratory's quality system have been ongoing for decades [16][17]. Laboratory managers and staff members have emphasized the importance of practical and consistent LIMS functionality to maintain quality in the laboratory. With the increasing adoption of ISO/IEC 17025:2017 and the need for LIMS to improve their efforts in addressing a laboratory's need for quality control, laboratories must consider not only what the standard demands but also what LIMS functionality is required to comply effectively [18]. Therefore, a software-based QMS alone is not as useful as a combination of LIMS and QMS in managing compliance requirements and bringing positive benefits to the laboratory. Nowadays, there are some LIMS in the market that have an in-built QMS, purporting to eliminate the need to separately deploy a QMS for quality management. The next section explores the necessary LIMS functionality to better manage compliance and improve laboratory quality.

3.1.2 Features and functions for ISO/IEC 17025 compliance

Clearly, a laboratory should align its quality objectives with standards such as ISO/IEC 17025, and a LIMS can aid in achieving compliance with the standard. However, to be effective in assisting the laboratory in achieving its goals, a LIMS must have more than just basic functionality. Table 1 demonstrates how a modern LIMS requirements specification, correlates with ISO/IEC 17025 requirements. By utilizing ASTM E1578-18 Standard Guide for Laboratory Informatics, a laboratory can select appropriate functionality based on current standards, regulations, and guidance. This section will focus on the intersection of ISO/IEC 17025 with ASTM E1578-18 Standard Guide for Laboratory Informatics, highlighting their importance. Table 1 outlines the relevant ISO/IEC 17025 sections and associated ASTM E1578-18 Standard Guide for Laboratory Informatics requirements, along with an explanation of how the requirements impact the laboratory's compliance with ISO/IEC 17025.

ISO/IEC 17025:2017 Clause No.	Associated ASTM E1578-18 Standard Guide for Laboratory Informatics requirement	What it means
7.3.3	The system shall be able to define the collection and sampling details for registered samples, including container size and type, number of containers, collection date and time, temperature, name of the collector, lot number, storage location, preservation method, collection methods used (standard and nonstandard), sampling methods used, safety concerns, and retention period.	If a laboratory's LIMS is capable of fully capturing all the data and metadata associated with the collection of registered samples, the laboratory would be able to comply better with the requirements of ISO/IEC 17025. This is because there are various details related to the collection of samples, and the LIMS should have the flexibility to capture all necessary information during the entry process.
7.4.2	The system shall assign each sample registered in the system a unique identifier using methodologies such as an ID with an incrementing integer or a user-defined naming format.	If a LIMS is capable of assigning a unique and permanent identifier to every sample, as well as any sub-samples that are derived from it, the laboratory would be able to comply more effectively with the requirements of ISO/IEC 17025. This means that each sample and sub-sample would have a distinct and unchanging identifier associated with it.

7.4.3	The system should provide a means to document any undesirable or unexpected characteristics of a submitted sample.	If a LIMS permits authorized users to enter free-form data related to a registered sample, including the condition of the sample when it was received and any issues identified at the time, the laboratory would be better equipped to meet the requirements of ISO/IEC 17025. This means that the LIMS should allow the authorized user to enter any relevant information about the sample upon its reception, including any problems or defects.
7.4.2	The system should allow for the accurate identification of a physical sample in the system via barcode or RFID technology.	If a LIMS enables the issuance of a unique barcode or another type of scannable identifier to samples and sub-samples, and links the complete record of each sample to that identifier, the laboratory would be better equipped to meet the requirements of ISO/IEC 17025. This is because the barcode or scannable identifier can be used to automate workflows and allow authorized individuals to quickly review or act upon the sample record by scanning the identifier.
7.7.2	The system shall allow samples and tests to be created and used specifically for capturing data related to unique forms of sampling and testing such as representative sampling, calibration testing, quality control testing, preventative maintenance testing, stability testing, proficiency testing, and service-event-related testing.	For a laboratory to comply better with ISO/IEC 17025 requirements, its LIMS should be able to support a diverse range of sample types and test methods, especially those mandated by regulations and standards. At a minimum, the LIMS should have the flexibility to handle a sufficient number of sample types and test methods. Ideally, the LIMS should be preconfigured with a broad range of sample types and test methods, while also allowing authorized users to add new ones quickly and easily to meet the laboratory's business goals and regulatory requirements.

6.2.6 **7.7.1** **7.8.1.1**	The system shall provide one or more levels of review, as well as interpretation and documentation of results—whether entered manually or via an automated process—before release.	If a LIMS can automatically mandate that an analytical test result be retained in the system and not progress through the workflow until it has been reviewed and approved by one or more levels of authority, whether through authorized human or automated processes, the laboratory would be better equipped to comply with ISO/IEC 17025 requirements. This means that the LIMS should be able to enforce a hold on the analytical test result until the necessary review and approval have been completed.
7.5.1 **7.8.1.1** **7.8.2.1** **7.8.3.1**	The system shall substantiate the status of verified results using certificates of analysis, which shall include details like unique identifiers; analysis procedures used; reference intervals; environmental conditions; who provided the results; additional comments, opinions, and interpretations and who provided them; and applicable times and dates.	If a LIMS comes preconfigured to generate certificates of analysis (CoAs) and other documents used to verify results, the laboratory would be better equipped to comply with ISO/IEC 17025 requirements. Ideally, these documents should be populated with relevant data and metadata that meet specific industry or regulatory needs and are formatted consistently and legally durable for the intended recipient. This means that the LIMS should be capable of producing accurate and comprehensive CoAs and verification documents in a standardized and legally valid format.

7.8.8	The system shall clearly identify a changed, amended, or re-issued report and clearly identify any change of information and reason for change in such a report.	For a laboratory to comply better with ISO/IEC 17025 requirements, its LIMS should require analytical reports that have been changed, amended, or reissued to be transparent about the changes made and the reasons for those changes before they can be issued. This means that the LIMS should have a mechanism that demands transparency in the reporting process, making it clear to the recipient what was changed and why it was changed before they receive the report.
5.3 **5.5** **8.3.2**	The system should possess the ability to generate, handle, and safely store diverse kinds of documents, as well as facilitate their review and approval through version and release controls.	A laboratory can enhance its adherence to ISO/IEC 17025 standards by utilizing a LIMS that offers strong assistance in generating, uploading, handling, and preserving a variety of document formats within the system. Additionally, the laboratory gains advantages when the LIMS enables document versioning and grants approval and release controls to authorized users.
ISO/IEC 17025:2017 (throughout)	The system shall have the ability to readily provide authorized access to electronic documents such as standard operating procedures, quality manuals, laboratory management plans, instrument manuals, employee medical records, material safety data sheets, information exchange agreements, confidentiality agreements, and other applicable documents to designated personnel and officials.	For a laboratory to comply with ISO/IEC 17025 requirements, it's not enough for the laboratory's LIMS to just offer robust document management support; the LIMS must also allow swift access to stored documents for authorized users.

7.5.2 **8.3.2**	The system shall be able to clearly provide the most current version of a document and archive prior versions.	To enhance compliance with ISO/IEC 17025 requirements, a laboratory's LIMS should restrict access to solely the latest authorized version of a document, unless the user has the proper authorization to access older archived versions of the document. In that case, the LIMS must unmistakably indicate that the version being accessed is an older, archived version.
6.5 **7.2.1.3** **7.3.1–2**	The system shall allow the creation, approval, rejection, and management of sampling and test methods performed at the laboratory, capturing details about the test method, method reference, specifications, assigned limits, holding times, etc. as required by a reference method or regulation.	To enhance adherence to ISO/IEC 17025 requirements, a laboratory's LIMS should have sufficient flexibility to enable authorized users to produce, sanction, deny, and handle modifications to sampling and test procedures in the system, while including all mandatory descriptive data and metadata stipulated by a reference method or regulation. Some of this descriptive data may be unrestricted in form, and the LIMS should be capable of supporting that.
6.2.6 **7.2.2.1** **7.2.2.4**	The system shall provide a means for recording validation information for modified existing or new in-house test methods, either as a method itself or through some other means. Validation information such as procedures used, specifications, performance characteristics, and results obtained shall be allowed as input.	To improve conformity with ISO/IEC 17025 standards, a laboratory's LIMS should mandate that any recently included or altered sampling and test procedures be appropriately validated before they are employed, as well as necessitate the input of all pertinent information about the validation process for verification by authorized individuals.

6.2.2 **6.2.3** **6.2.5** **6.2.6**	The system shall maintain training and certification records for personnel and allow the assignment of available training paths and certifications to specific personnel, such that only trained, certified, and experienced personnel are able to perform assigned tasks.	For a laboratory to improve its conformity to ISO/IEC 17025 requirements, its LIMS should incorporate a system for integrating training and certification records for personnel and contractors, and connecting those records with the respective individuals. These records must include internal indicators that can be linked to one or more operations within the system so that only users with those indicators (related to the training and certification records) can execute those operations or be planned for specific laboratory tasks.
8.3.2	The system shall be capable of uniquely identifying documents created in and added to the system.	To enhance conformity to ISO/IEC 17025 standards, a laboratory's LIMS should automatically add a distinctive identifier to documents produced and uploaded to the system, as well as new versions of existing documents.
7.9	The system shall allow authorized personnel to document complaints and problems reported to the laboratory.	For a laboratory to enhance its conformity to ISO/IEC 17025 requirements, its LIMS should have a mechanism that enables authorized users to enter formal complaints and issues in a uniform manner, arising from within the laboratory or related to it. Ideally, the LIMS should also permit the proper and authorized administration of existing complaints and problems recorded in the system, so that evidence can be provided not only of who filed the complaint but also of who marked it as resolved.

6.2.2 **6.2.3** **6.2.5** **6.2.6**	The system shall map available system tasks (such as approved test methods) or sample types to available training paths and certifications, such that only trained, certified, and experienced personnel are able to perform assigned tasks.	To improve conformity to ISO/IEC 17025 standards, a laboratory's LIMS should provide a method to connect a training or certification category to an executable system operation, sample type, or method (among other things). Therefore, a user with that training and certification would be authorized to carry out activities associated with the action, sample, or method.
6.4.7 **6.4.8**	The system shall allow for the configuration of calibration and maintenance frequency and time frames for—as well as the manual and automatic scheduling of calibration or maintenance of—equipment, instruments, and systems. Available intervals should include days, weeks, months, and years.	For a laboratory to enhance its conformity to ISO/IEC 17025 standards, its LIMS should facilitate both manual and automated scheduling of calibration and maintenance tasks at a specified and reasonably detailed frequency, preferably informing assigned individuals ahead of time about such tasks.
6.4.4 **6.4.9**	The system shall clearly identify any instrument that is out-of-calibration, beyond its preventative maintenance due date, or under investigation and prevent it from being selected for use.	To improve conformity with ISO/IEC 17025 standards, a laboratory's LIMS should be capable of preventing the use of a connected instrument and locking it out from all system activities when specific requirements are met. Such requirements commonly include missing a scheduled calibration or maintenance date or an authorized user flagging the instrument as unusable or under review. However, the LIMS should ideally be adaptable enough to enable the inclusion of additional requirements.

6.4.8	The system shall be able to show all instances of scheduled calibration, preventative maintenance, and service dates for an instrument.	For a laboratory to improve adherence to ISO/IEC 17025 standards, its LIMS should consistently and securely preserve a comprehensive history of calibration, maintenance, and servicing for each instrument, including dates, times, parties involved, and the outcomes of the activities, and ensure that authorized users can access these records when needed.
6.4.13 **6.5**	The system shall be able to link a calibration activity to certified reference material or designated measurement processes.	To enhance compliance with ISO/IEC 17025 regulations, the laboratory's LIMS should be capable of mandating, as necessary, the incorporation of or association with a certified reference material or suitable measurement procedure whenever an approved user or automated system logs a new calibration operation in the LIMS, to ensure that the calibration activity can be validated as appropriate.
6.4.8 **6.4.13**	The system shall be able to uniquely identify each instrument and any associated components and maintain that and other information—such as manufacturer, model number, serial number, and calibration and maintenance history—within the system.	To improve compliance with ISO/IEC 17025 requirements, it is essential for a laboratory's LIMS to have a mechanism for distinct and unambiguous identification of an instrument that is connected or disconnected to the system, preventing any confusion with other similar instruments. In addition, the LIMS should allow for the entry of supplementary information about the instrument, such as its source, to enable easy reference by authorized users.

6.4.4–5 **6.4.13**	The system shall be capable of chronologically logging details for scheduled and unscheduled calibration and maintenance activities for each instrument, including calibration status, calibration standard, date and time of calibration or maintenance, work performed, who conducted it, and signatures of those verifying the completed activities.	To enhance compliance with ISO/IEC 17025 requirements, a laboratory's LIMS should keep a secure, time-stamped audit-trail of both planned and unplanned calibration, maintenance, and servicing activities for each registered instrument. This audit trail must contain critical information such as the date and time of activities, the parties involved, outcomes, and signatures to guarantee the reliability of analytical results related to the instrument.
7.2.1.7 **7.2.2.1** **7.10.2** **8.7**	The system shall be able to record instances of identified nonconformance and method deviation, as well as the actions required to restore the process to conformity. In the case of a planned deviation, the system shall require documentation, justification, proof of validation, adjusted reference intervals, and authorization for the deviated process.	A laboratory can improve its compliance with ISO/IEC 17025 requirements by using a robust LIMS that can automatically and manually record instances of noncompliance and deviations from methods, whether intentional or unintentional. The LIMS should be flexible enough to handle both types of nonconformance and deviation and require additional information about the incident, such as who was involved, what happened, why it occurred, and how it was resolved. Additionally, the system should be able to capture any additional details needed for laboratory inspections or audits.
7.7.1	The system should allow authorized users to configure the generation of statistical trending and control charts.	The compliance of a laboratory with ISO/IEC 17025 requirements can be improved if the laboratoy's LIMS permits users to effortlessly set up preferences and produce statistical trending and control charts. These charts enable the laboratory to promptly identify and correct analytical bias and refine laboratory procedures.

8.8.2	The system shall allow for the documentation and management of internal and external audit activities while allowing samples, methods, tests, results, reports, documents, and more to be clearly associated with that corresponding audit activity.	To enhance ISO/IEC 17025 compliance, a laboratory should have a LIMS that allows the establishment, documentation, and administration of both internal and external audit activities. Additionally, the LIMS should have the capability to associate specific entries in the system, such as samples, methods, and tests, with corresponding audit activities.
8.4.2	The system shall provide a means to choose—based on date and type of data—electronic data and metadata to archive.	If a laboratory's LIMS has reliable ways to archive internal data and metadata, complying with ISO/IEC 17025 requirements becomes easier. To achieve this, the LIMS must offer both automated archiving methods based on creation data or data type, as well as manual methods that can be executed by authorized users.
8.4.2	The system shall provide a guaranteed means to retrieve and restore archived data and metadata that is readable and accurate.	A laboratory can enhance compliance with ISO/IEC 17025 standards by using a LIMS that enables authorized users to easily and accurately access and restore data and metadata in a legible format. This functionality is particularly important during an audit, allowing the laboratory to take prompt and effective action based on the retrieved data and metadata.
8.4.2	The system's data storage tools shall provide data backup and retrieval functions that meet or exceed industry best practices, including producing exact and complete backups that are secure and encrypted from manipulation and loss.	To improve compliance with ISO/IEC 17025 requirements, a laboratory should have a LIMS that offers both automated and manual options for creating and storing exact copies of data and metadata, including entire databases. These backup methods must ensure the security, retrievability, and readability of

		the backed-up data through measures such as encryption and access control, and should be easily accessible to authorized users in case of data loss.
6.3.3 **6.3.4**	The system should allow for other types of facility monitoring (such as alarm, light, lock, and door statuses) and send notifications when necessary with recommendations for immediate and corrective action. The system should also maintain a log of all such monitored systems and their status changes.	To enhance compliance with ISO/IEC 17025 requirements, it is beneficial for a laboratory's LIMS to have the capability to link with and monitor sensors connected to facility infrastructure, such as alarms, lights, locks, and doors, and to send notifications to authorized users when sensor readings reach certain levels. Furthermore, the system should be capable of maintaining an up-to-date record of the status changes for such facility infrastructure.
6.3.3 **6.3.4** **7.4.4**	The system should allow for environmental control and monitoring of equipment (such as incubators and refrigerators) and send notifications when necessary with recommendations for immediate and corrective action. The system should also maintain a log of all such monitored equipment and their associated status changes.	To improve compliance with ISO/IEC 17025 requirements, a laboratory should have a LIMS that is capable of connecting to, monitoring, and notifying authorized users about the status of equipment such as laboratory refrigerators and incubators. The LIMS should also be able to maintain an accurate log of the status changes of each equipment.
8.4.2	The system must be equipped with a secure data retention mechanism for a specified duration and provide safeguards that guarantee the prompt and accurate retrieval of that data throughout the records retention period.	To improve compliance with ISO/IEC 17025 requirements, a laboratory should have a comprehensive data retention system in its LIMS. This system should enable both automated and manual retention of data and metadata. Authorized users should be able to configure retention periods for specific data and item types, and the system should allow for prompt and accurate retrieval of archived data and metadata for review as required.

4.2.1 **7.11.3**	The system shall provide a security interface usable across all modules of the system that secures data and operations and prevents unauthorized access to data and functions.	To achieve compliance with ISO/IEC 17025, it is important for a laboratory's LIMS to have strong security mechanisms and cover all system functions and modules. This helps prevent unauthorized access to functions, data, and metadata. There are several ways to accomplish this, such as implementing role-based access control and password control.
7.11.5	The system should be well documented by the vendor in comprehensive training material for all aspects of system use, including administration, operation, and troubleshooting.	To ensure compliance with ISO/IEC 17025 requirements, a laboratory can benefit from a LIMS that includes detailed instructions and training resources on how to effectively use, maintain, and troubleshoot the system. It is the vendor's responsibility to provide these materials, and it is important for laboratories to consider this when selecting a LIMS.
7.11.2	The system shall be validated initially and periodically, with those validation activities being documented, to ensure the accuracy, consistency, and reliability of system performance and its electronic records.	To enhance compliance with ISO/IEC 17025 requirements, a laboratory should ensure that its LIMS is validated by the vendor during implementation and periodically revalidated, particularly after major updates or modifications. This is especially important in regulated industries, where the dependability and consistency of system performance are essential.

7.8.7.1 **7.11.3** **8.3.2**	The system shall support the ability to define, record, and change the level of access for individual users to system groups, roles, instruments, processes, and objects based on their responsibilities, including when those responsibilities change. The system should be able to provide a list of individuals assigned to a given system group, role, machine, process, or object.	A laboratory can achieve better compliance with ISO/IEC 17025 requirements if the laboratory's LIMS allows for precise control over access to data and functions, with the ability to define, record, and modify access levels at the group, role, instrument, method, sample, or object level. This approach provides greater flexibility and helps ensure that only qualified individuals can access specific tasks in the system. It also benefits the laboratory when the LIMS can quickly generate a list of users assigned to each of these access levels.
7.11.3	The vendor shall restrict logical access to database storage components to authorized individuals. If providing a hosted service, the vendor should also restrict physical access to database storage components to authorized individuals.	To comply with ISO/IEC 17025, a laboratory can enhance its compliance by ensuring that only authorized users have logical access (access via remotely/virtually interacting with hardware and software tools and databases) to critical components of the laboratory's LIMS. The laboratory is responsible for controlling physical access when it installs the LIMS locally. However, if the laboratory uses a cloud-hosted LIMS from a vendor, it should still ensure that the vendor has stringent policies and practices in place regarding physical access to hardware and software systems.

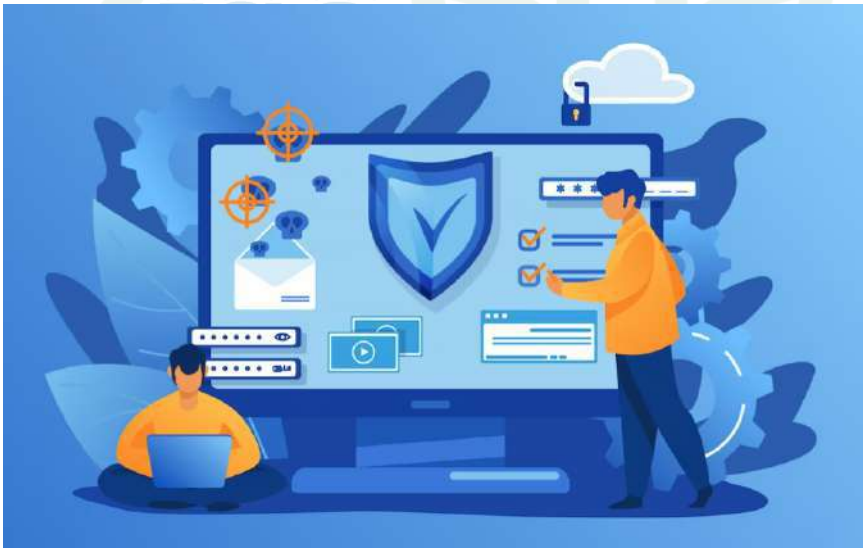
3.1.3 Cybersecurity Considerations

The need for cybersecurity is becoming more apparent across various industries, from law firms[26] to automotive manufacturers [21]. According to a report from the Center for Strategic & International Studies, cybercrime is estimated to cause nearly $600 billion in damages to the global economy annually [22], though underreporting of crimes may mean the actual number is even higher. Additionally, businesses of all sizes typically experience around $200,000 in losses due to a cybersecurity incident [26], and nearly 60% of small and midsize businesses go bankrupt within six months as a result [23][24][25][26].

Cannabis testing laboratories are also at risk of cybersecurity threats, regardless of their size. Even small laboratories with a basic digital footprint can be vulnerable to malware, data theft, and other cyberattacks. For laboratories that handle sensitive proprietary data, additional cybersecurity considerations are necessary [26][27][28].

Although the ISO/IEC 17025:2017 standard does not explicitly mention cybersecurity, it does address the proper control of data in section 7.11. The standard emphasizes that LIMS, whether hosted locally or in the cloud, should be protected from unauthorized access, tampering, and unexpected loss. The LIMS should also be maintained to ensure the integrity of the data and information, with any nonconformance or breaches of security promptly recorded and addressed.

To conform to the ISO/IEC 17025 standard, laboratories should integrate cybersecurity into their LIMS selection [30]. This can be done by creating a cybersecurity plan, considering cybersecurity frameworks, and incorporating cybersecurity controls into the user requirements specification (URS) for LIMS software. A pre-built URS that includes cybersecurity controls can help laboratories evaluate and select informatics software more easily.



3.1.4 Regulatory Compliance Considerations

One approach to regulatory compliance is to adopt well-designed standards, such as ISO/IEC 17025, which can help organizations improve their operational culture and outcomes. Regulations can be imprecise or disconnected[36], so adopting standards may provide a clearer path for organizations to conform to regulations and improve quality and security. Reputable LIMS vendors should adopt their own industry standards and understand how ISO/IEC 17025 and LIMS requirements intersect to ensure that the software meets regulations and standards and is of good quality.

If a laboratory is considering buying a LIMS solution but is not entirely informed about how a LIMS can help the laboratory conform to ISO/IEC 17025 and other regulations and standards, it can turn to a URS like ASTM E1578-18 Standard Guide for Laboratory Informatics for further information. A laboratory's own list of requirements can then be used as a personal checklist and given to the vendor, giving it more confidence in the acquisition and its integration into the laboratory workflow.

3.1.5 System Agility

A laboratory should have internal discussions about a solution's offered services and future plans before selecting it. This includes considering whether the current or potential LIMS system can handle adding other types of testing, protocols, and workflows in the future. A flexible LIMS that allows for creating and configuring various aspects of the system, such as sample registration screens, test protocols, labels, reports, and measurement units, is essential for smoothly integrating expanding test menus and workflows.

When evaluating a vendor's system, it is important to understand what makes it user-configurable and how easy it is to make changes. The vendor should provide information on the necessary knowledge and skills required for making changes, as well as whether their system's functions can make changes without requiring programming skills. This information will ensure that the system can adapt to changes in the laboratory and industry while reducing costs and minimizing the time needed for modifications.

3.1.6 Cost Concerns

A laboratory must have a clear understanding of what will be incorporated into the sales agreement. This can be achieved through an estimate or statement of work (SOW), which should detail exactly what is anticipated with as much specificity as possible. This will serve as the complete contractual obligation for both the laboratory as the buyer and the vendor.

Ideally, the estimate or SOW should encompass the following elements: the cost of licensing or subscription, the necessary core items to comply with federal, state, and local regulations, the total cost of any additional optional items, and the required services such as implementation, maintenance, technical support and training, instrument and software integration, product upgrades, and optional add-ons.

There are two main methods for pricing LIMS solutions: a one-time license fee or a subscription rate for cloud-hosted SaaS. If laboratory has an internal IT team, it may prefer the one-time fee, but if not, a SaaS subscription may be more cost-effective. The subscription rate will be included in the upfront cost, and for subscription-based solutions, it will also be part of the first-year and ongoing expenses. A laboratory should expect to pay the first year's subscription costs at the time of signing. Vendors may require upfront payments for the first year, so one should be prepared to include that in the upfront costs. However, in most cases, a subscription rate is less expensive than paying a license fee, especially when a laboratory factors in IT costs and annual maintenance, support, and warranty expenses.

Aside from the two primary types of software pricing, there are also different sub-types that may be based on the number of users accessing the LIMS system. The counting method may vary depending on the pricing structure.

The "named users" method prices the software based on the actual individual users of the system, regardless of how often they log in. Users must not share their login credentials, for regulatory reasons and good laboratory practice.

The "concurrent users" method prices the software based on the maximum number of users who will be logged in at any given time. While the system can have an unlimited number of named users with their own login credentials, only the number of users specified in the license or subscription can be logged in at once. For instance, if there are ten staff members, but only up to six will be logged in simultaneously due to work processes or shifts, a concurrent user license for six users would suffice instead of a named user license for ten.

For very large laboratories, typically 30 to 50 users or above, a flat fee may be charged for a license or subscription that allows an unlimited number of users.

To accurately represent the various pricing nuances, the estimate or SOW should detail whether the costs listed are for monthly or annual subscription services, hourly support and training, or a one-time fixed cost. It's important to be cautious when dealing with fixed costs, as they can fall into two categories. The first is the final fixed cost, which is determined by the vendor to cover their worst-case hourly labor total. If a line item isn't considered "worst case," then the cost may be too high. The second is the "expandable" fixed cost, which can be even worse than the final fixed cost because it can be surprising. Initially, the fixed cost seems low, but additional hourly services may be needed to deliver the item, which is typically found in the small print.

To accurately determine costs for a LIMS solution, it's important to recognize that every aspect of the solution falls into either the licensing or hourly services category, regardless of how it may be portrayed. It's essential to understand which category each line item falls under, whether it's an up-front, annual, or ongoing cost. It's helpful to lay out all costs and compute them for the initial year as well as subsequent years. The initial obligation may include the first year's subscription and the first 40 hours of services. Different vendors may have different policies and payment requirements. Instrument interface or other service charges aren't usually due until they are implemented, depending on budget, SOW complexity, and urgency. The first year's expenses include everything from initial license fees to setup and training, interfaces, additional configurations, customization, and the first annual MSW. Afterward, ongoing expenses typically include subscription and maintenance and support warranty (MSW) costs, unless additional interfaces or services are needed.

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3.2 Implementation

There are many stories of implementation horrors, emphasizing the importance of discussing in detail with the vendor how they will handle installation, validation, and training for the informatics solution. It's crucial to determine if the vendor understands the industry and the laboratory's needs, assigns a project manager to work with the laboratory from planning to go-live and beyond, and can provide references of other laboratories that have gone through implementation. Additionally, the laboratory needs to assess the vendor's ability to handle issues such as data integrity of migrated data, and their flexibility to work with the laboratory schedule [1][2].

As a laboratory approaches the final decision on which vendor to work with, it's recommended to create an implementation checklist as part of the early project planning. A laboratory needs to determine if it'll receive a help desk account as part of the implementation process and what information it includes. If not, the laboratory will need to keep track of specific details such as the business associate agreement (BAA), sales agreement, scope documents, welcome letters or emails, documentation, and approved staff who can utilize the vendor's support. The laboratory will also need to share other configuration details with the vendor, such as time zone requirements, DNS and URL requirements, up-time monitors, and administrative account requirements. Finally, the laboratory needs to ensure that the laboratory and the vendor agree on any additional customization, integration, and system validation requirements to ensure a smooth and efficient roll-out period.

Laboratories often implement data management software to achieve several benefits, such as enhancing accuracy and quality, saving time, increasing productivity, and expanding capabilities. Integrating or interfacing systems, databases, and instruments is an effective way of achieving these benefits, as it minimizes human error, automates workflows, and utilizes the capabilities of each component in the most efficient way possible. To ensure that the vendor's solution is capable of such integration, the laboratory should ask about the hardware and software integration capabilities of their software. Inquire if their software can interface with all laboratory instruments and software that can output any readable electronic file, what protocols it uses to connect with other systems, and whether users can map their file imports and exports. Moreover, ask about other integrations supported by their application.

Generally, a vendor's LIMS solution will include instrument integration capabilities built into the software, but sometimes, these interfaces are separate from the main software. To support instrument integrations, LIMS must use standardized communication protocols like RS-232, RS-422, IEEE-488 (GPIB), USB, Ethernet, and more[3]. Additionally, laboratories may need their LIMS solution to communicate with other software and databases, which is often achieved using application programming interfaces (APIs) that rely on web services implementation protocols such as REST and SOAP [4][5][6]. These protocols enable the creation of an API that receives communication requests and sends responses between two software systems, allowing for integration with enterprise resource planning (ERP) applications or quality management systems (QMS). This is helpful, for example, if a laboratory has been using a dedicated electronic QMS for years and would like to interface it with the LIMS.

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3.3 Contracted Services

When purchasing a LIMS solution, it's important to consider the maintenance and support services that come with it. This is because downtime can negatively impact the customers and reputation. A cannabis laboratory should inquire about the details of the vendor's MSW to understand what is and isn't covered, as well as how much it will cost. Typically, the cost is 15% to 25% of the license fee or total contract, levied annually, or it may be included with the subscription [1]. The MSW should include a specified number of support and maintenance hours or guarantees, and the warranty should be unlimited as long as the MSW or subscription is active.

Maintenance includes updates, patches, fixes, and most upgrades, while support is dedicated to helping the laboratory operate the system, including training, password or login support, and more[2]. The warranty should cover anything that doesn't work for the designated period, including standard and additional features, but it doesn't cover issues caused by misuse or manipulation beyond normal operation.

In addition to the MSW, the laboratory may need additional services such as setup, training, and adding or modifying features. These services are especially helpful for laboratories with limited IT and systems expertise. The vendor may offer one or more of the following services for the laboratory at a cost or free of charge:

- An initial meeting to plan the implementation, identify discrepancies, and establish a schedule
- Management of the project
- Gathering and documenting the requirements
- Setting up the system initially
- Providing training for the users and administrators
- Customizing and configuring the system
- Developing and implementing interfaces
- Developing custom screens and fields
- Developing custom functions
- Creating custom reports and labels
- Developing custom triggers and alerts
- Conducting validation or acceptance testing to a third-party standard or certification or to the manufacturer's specifications, as agreed upon.

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3.4 The Role of a User Requirements Specification

In general, it makes sense to provide detailed information about a project, concept, or idea to a specific audience. This is especially important in the realm of software development, where a software requirements specification is necessary to prevent poor requirements management[1], which is the second most commonly cited reason for project failure. The ISO/IEC/IEEE 29148:2018 standard, which is a combination of the previously used IEEE 830 and other standards, is designed to specify the processes required for engineering activities that result in requirements for systems and software products and provide guidance on how to apply those requirements[2]. The standard outlines the qualities that contribute to the development of high-quality software requirements, which include elements such as [3]:

- accurately describing the behavior of the system;
- using language that is unambiguous;
- covering all aspects of the system's behavior and features comprehensively;
- prioritizing and ranking requirements accurately; and
- making sure that the requirements can be tested, modified, and traced without any confusion.

A statement outlining a requirement usually begins with "the system/user/vendor shall/should...," specifying a service provided, expected behavior, or response to input in a given situation. The statement can be either abstract or specific and may describe functional or non-functional aspects. A requirements specification is crucial for both software developers and software acquirers, providing a set of development or user requirements that can enhance the software development process and aid in software selection and acquisition. A user requirements specification (URS) can be either general or specific to a laboratory's needs[5], with prioritized requirements for system operation[4]. The vendor must demonstrate how the software meets the URS requirements. The ISO/IEC 17025 requirements can be mapped to a robust URS, which is a set of software requirements specifications for LIMS systems [6][7][8].

3.5 ASTM E1578 Standard Guide for Laboratory Informatics for Selecting an Informatics Solution

The traditional view of the user requirements specification is a way for purchasers to ensure that their software needs are met. However, this approach often results in a "wish list" that lacks finesse and can lead to "requirements creep," where unnecessary functionality is added and no vendor can meet all of the requirements. This makes selecting a solution more difficult, especially without prioritization skills [9][10][11]. To address these issues, users can adopt a requirement specification document for laboratory informatics solutions, that incorporates standards and regulations that apply to laboratories and the data they manage.

When conducting initial research towards the URS, the laboratory doesn't need to include every requirement when approaching potential vendors. Most vendors appreciate a less overwhelming approach, especially at the beginning. Instead, the laboratory should choose a limited yet practical set of requirements that matter the most to the laboratory.

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4. Conclusion

The ISO/IEC 17025 standard focuses on testing, calibration, and sampling laboratories, of which cannabis testing laboratories are an important part. The accreditation underscores the important role of quality management and technical competence in cannabis testing laboratories both from a data defensibility standpoint and in generating customer confidence.

Aside from generating high-quality laboratory results, there are other benefits to complying with and accrediting to ISO/IEC 17025. These benefits include demonstrating conformity to an international standard, expanding business opportunities, enhancing the reliability and accuracy of analytical and calibration results, encouraging compliance with other standards of practice, improving productivity and efficiency, controlling costs, improving reputation and performance in the industry, and facilitating cooperation between laboratories and other entities internationally.

By following the guidelines outlined in this eBook, cannabis testing laboratories can make an informed decision that not only ensures compliance with the ISO/IEC 17025 standard but also enhances their efficiency, accuracy, and overall performance. Overall, by following a consistent methodology and understanding the laboratory's needs, complying with ISO/IEC 17025 doesn't have to be a daunting task.