Analytical Cannabis
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Why is ISO Accreditation Essential for the Cannabis Industry?

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Published: October 18, 2022

As medical and recreational cannabis legalization expands across the United States, it becomes increasingly important for legitimate cannabis growers and processors to meet consumer demand competently. The cannabis industry must not be built upon the backs of inconsistent and defunct illicit market vapes and cartel-grown flowers. Dangerous consequences may befall the industry if those who lay the laws fail to recognize the legitimacy of responsibly-sourced cannabis products.

Just as consumer safety has been made a priority in the food and pharmaceutical industry, it must be upheld within the cannabis industry. This presents new challenges! Consumers must hold high regard for both the quality and safety of legal cannabis.

Successful industries across the world build consumer safety upon rigorous product testing. In most industries across the United States, a federal agency has been responsible for setting requirements. For instance, the food industry had to improve its testing standards with the recent introduction of the Food and Drug Administration's (FDA) **Laboratory Accreditation for Analyses of Food** (LAAF) program, courtesy of the **Food Safety Modernization Act** (FSMA). The new accreditation program further ensures that our food supply will be safe now and in the future. The pharmaceutical industry similarly

utilizes the Center for Drug Evaluation and Research to ensure that only safe, effective drugs are available.

Standard test methods in these industries have been developed and validated over decades of utilization. In contrast, the cannabis industry is in the initial phase of the method development process, and large-scale validation is made difficult when regulations are decided on a state-by-state basis. To further complicate things, standard test methods have not been thoroughly developed for all cannabis product types.

On top of this, cannabis flower sampling is inherently heterogenous and lot size differs from state to state. State officials are responsible for determining which contaminants to test for and what levels should be considered dangerous to consumers. However, no two states agree on this, which means that cannabis products sold in Maryland are held to entirely different standards than cannabis products sold in California. Additionally, the test methods utilized to quantify these contaminants may be conventional in one state but forbidden in another. This is where ISO comes in!

What is ISO/IEC?

ISO is the **International Organization for Standardization**. The precursor to this organization was founded in 1926 as the International Federation of the National Standardizing Associations (ISA). The original goal was to generate internationally recognized standards in the field of mechanical engineering. In 1947, the new organization, now termed ISO, began operations. The organization's current goal is for laboratories and facilities across the world to be assessed to one set of international standards. Results from ISO-accredited laboratories, regardless of the location, would be analogous and trustworthy. The international standard facilitates global trade and international consumer safety.

IEC is the **International Electrotechnical Commission** that prepares and publishes international standards for all electrical, electronic and related technologies.

Over the past few decades, IEC and ISO have **developed many standards together**, including ISO/IEC 9001:2015, ISO/IEC 17043:2010, ISO/IEC 17025:2017, ISO/IEC 17065:2012 and more! Each international standard has unique applications and requirements within cannabis. We shall begin with ISO/IEC 17025.

ISO 17025 ensures that, regardless of differing state requirements, all accredited cannabis testing laboratories are assessed to, at a minimum, the same international standard requirements. ISO 17025 promotes scientifically driven methods to be performed with both impartiality and competency.

Why is ISO/IEC 17025:2017 accreditation especially important for cannabis testing?

Within the competitive cannabis manufacturing and testing industries, **lab shopping is a known obstacle**. Licensed growers and processors may pressure third-party laboratories to produce favorable results or they will utilize an alternative lab. It has been seen that laboratories will inflate potency percentages or reduce microbial counts to meet client demand. This practice does not promote a trustworthy or legitimate industry. Neglecting impartiality risks does not bode well for consumer trust and safety.

To become ISO/IEC 17025 accredited, laboratory management must make a good faith effort to identify all potential risks to impartiality. When a risk has been identified, there must be a record kept and minimization/elimination attempt documented as well as a follow up to determine efficacy. It is essential for laboratory management to implement safeguards to impartiality. Risks cannot be determined only upon initial startup but must be assessed and addressed thoroughly and continually.

Assessment to determine compliance to ISO/IEC 17025 means that regardless of whether the cannabis is sourced from Maryland or California, the testing lab has proven that it can act to safeguard impartiality.

The standard ensures that cannabis testing is not only conducted impartially but also that testing is performed by trained and competent personnel. For example, a laboratory cannot allow a high-performance liquid chromatography (HPLC) chemist to analyze and report results related to polymerase chain reactions (PCR) unless properly trained and authorized. With high sample volume and fast turn-around-time, some cannabis labs may want to rush through training to allow one analyst to perform multiple tests. However, it is imperative that an HPLC analyst can differentiate peaks and parse through signal to noise, or for a microbiologist to utilize proper aseptic technique when preparing samples for analysis. Therefore, it is important for management to make determinations and designations of capability stringently, not arbitrarily.

Only qualified personnel can be responsible for the development, modification, verification, and validation of all accredited methods. The designation of who will validate internal methods and approve outgoing results is vital because methods in the cannabis industry are not yet fully standardized, and results severely impact both the consumer and clientele.

Due to the lack of standardized test methods for all matrices and target analytes, cannabis testing laboratories must generate, validate, and verify internal methods on a regular basis. Despite the inconsistency of utilized test methods, the intense verification and validation required by ISO/IEC 17025:2017 ensure accuracy and comparability of results. This is essential for building trust with consumers and clientele.

How does A2LA ensure that a cannabis testing laboratory follows this standard?

A2LA recruits and trains cannabis-focused assessors with 10 or more years of relevant technical experience who have an in-depth understanding of both the industry and the science. The competency of A2LA assessors is reviewed and confirmed routinely, and cannabis-focused assessors have experience assessing several cannabis testing laboratories across multiple states. Our team of accreditation officers consists of members from both the cannabis production/extraction field and the cannabis testing field. We are familiar with requirements and tests performed in every state ranging from cannabinoid quantification to contaminant detection. We have the experience and know-how required to understand cannabis testing from an industrial and scientific perspective.

Morgan Keefer is an accreditation officer at A2LA, a non-profit, non-governmental, third-party accreditation body, offering internationally recognized accreditation services to testing and calibration laboratories, sampling organizations, inspection bodies, proficiency testing providers, reference material producers, biobanking facilities, and product certifiers.