BOTEC
Analysis Corporation

Cannabis Testing Labs: Standards and Accreditation

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Executive Summary

The Washington State Liquor Control Board (LCB) has been compelled by the enactment of I-502 to develop a plan for the regulation of cannabis testing labs. The protection of cannabis consumers and the general proper functioning of a legal cannabis market will require accurate product labeling and general product quality and safety monitoring. This will require a reliable infrastructure of specialized marijuana testing labs and associated performance standards. The foregoing white paper provides discussion of 1) Testing Requirements, 2) Lab Accreditation, 3) Proficiency Testing, and 4) Lab Infrastructure Development.

No U.S. state has an accreditation requirement for marijuana testing labs, and there exist no generally accepted standards for such labs. Interviews with existing industry participants indicate the need for significant improvement in testing quality and a strong desire for clear testing standards.

The main points and recommendations of this paper include:

1. **Testing Requirement:** The LCB must specify required tests for cannabis products and associated procedural standards. While no cannabis specific standards exist for testing, many useful references exist from which to draw the necessary components for the LCB Testing Requirement. Cannabis testing requires specialized equipment, procedures, training and lab space.

2. **Lab Accreditation:** The LCB must establish a protocol by which cannabis testing labs will be accredited. The LCB may rely on a) existing outside organizations and standards, b) develop its own standards and administer an accreditation process itself, c) use a combination of these two or d) rely only on Proficiency Testing.

3. **Proficiency Testing:** The LCB should develop a system to monitor the performance of cannabis labs. A possible component of this is that retail product samples are collected at the point of sale and tested by a qualified lab other than the one that first tested the retail product. This may be done by specifically designated labs or through a system of Ring Testing. Retail sampling and testing are expensive and it may suffice to perform certain tests further up the supply chain at lower cost.

4. **Lab Infrastructure Development:** Currently, there are certain standards of performance and certification that cannot be realistically met by any lab in Washington, such as the ISO-17025 accreditation. The state must expect it to take some time, perhaps 2 to 3 years, for the cannabis lab infrastructure to develop capabilities matching those seen in some other testing industries. In the interim, the LCB may need to rely on a simplified provisional regime of Testing Requirements, Proficiency Testing and/or ring testing.

The more comprehensive, detailed and stringent the permanent testing standards specified by the LCB, the more public and private resources (i.e., time and money) it will require to develop and run compliant lab infrastructure and testing operations.

Introduction

Section 10 (11) of I-502 has specifically required that the Liquor Control Board (LCB), in consultation with the Department of Agriculture, establish accreditation requirements for testing laboratories used by recreational cannabis licensees to demonstrate compliance with standards adopted by the state liquor control board. In effect, this requires some specification of a system for product testing as well as a system for ongoing monitoring of testing lab performance. Reliable cannabis testing lab infrastructure will be necessary to help ensure that the advent of a recreational marijuana market includes accurate product labeling and adequate consumer protection in general.

While there exist documented and tested methods for various types of cannabis testing, no U.S. state has accredited or has an accreditation requirement for marijuana testing laboratories, and there exist no generally accepted best practices for such labs. Some states have mandated that testing be performed, but have not said where or how. Essentially all commercial marijuana testing labs have their origins in medical marijuana testing where standards are voluntary and not well defined. The lab may have their own standards, but they would not be industry-sanctioned standards. Recent news relating to Colorado's marijuana testing labs indicates significant variability in testing results among these labs, indicating that even in the more developed medical marijuana markets, some significant amount of testing capacity is unreliable.[1]

A meaningful accreditation program comprises several elements: a standard to determine acceptable testing procedures, quality assurance and quality control criteria, and standard operating procedure (SOP) requirements such as those that are listed in Appendix A. An inspection process is necessary to ensure that the laboratories are in routine compliance with the prescribed criteria. In addition, an acceptable proficiency testing program must be implemented.

The LCB will have to consider options for the design of testing and accreditation standards and associated systems of monitoring and enforcement keeping in mind the issues of both total cost to the public and private sectors as well as the level of direct state involvement in the operation of the system. The LCB may develop testing and accreditation protocols of greater or lesser detail and rigor involving more or less time and money to administer. As well, the LCB may propose to undertake direct responsibility for lab accreditation and monitoring or rely on a system of self-regulation or other "light handed" regulatory design. While clearly the most cost effective, any "light handed" approach will provide the least assurance that laboratories are providing acceptable performance.

[1] Wall Street Journal, "States Wrestle With How to Label Pot", August 20, 2013

[2] Testimony of Richard Fitzpatrick, President of the **Cannabis Standards Institute** Concerning Proposed Regulations of the Department of Public Health, April 19, 2013

The State of Washington has the opportunity to set the standard for laboratory accreditation that so many states have shied away from. Standards for laboratories or accreditation of laboratories would put Washington in a leadership role in the testing of cannabis.

Cannabis Testing Requirements

Section 11 of I-502 states "On a schedule determined by the state liquor control board, every licensed marijuana producer and processor must submit representative samples of marijuana, useable marijuana, or marijuana-infused products produced or processed by the licensee to an independent, third-party testing laboratory meeting the accreditation requirements established by the state liquor control board, for inspection and testing to certify compliance with standards adopted by the state liquor control board. … Licensees must submit the results of this inspection and testing to the state liquor control board on a form developed by the state liquor control board."

The types of testing in comprehensive marijuana testing laboratories usually include moisture content, potency, pesticides, microbial contamination, physical contamination and residual solvents. Few existing laboratories perform the complete battery of testing. The LCB will have to prescribe the specific tests and associated procedural standards required for lab accreditation and consumer safety.

It is likely that a suitable set of tests and testing procedures can be comprised in consultation with current medical cannabis industry participants. There are useful cannabis specific materials to reference. For example, the upcoming cannabis monograph from the American Herbal Pharmacopoeia is expected to provide detailed testing recommendations for key cannabis attributes. As well, at least one industry expert has recommended the application of the US Food And Drug Administration's *"Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, Or Holding Operations for Dietary Supplements"* Rule.[2]

Once the LCB has decided what they wish the laboratories to test for, they must publish the required tests. If pesticide testing is required, then each pesticide should be listed; the same principle applies to testing of metals, microbial agents, etc. The LCB must also decide if a laboratory must perform all of the required testing in-house or if a lab may subcontract a portion of the testing to a fully equipped laboratory. If that option is chosen, it is important that the subcontracted laboratory be accredited by Washington State. Other considerations for testing include when the testing is to be done and how the product is to be selected for testing.

[2] Testimony of Richard Fitzpatrick, President of the **Cannabis Standards Institute** Concerning Proposed Regulations of the Department of Public Health, April 19, 2013

Cannabis testing requires specialized equipment and procedures, associated training and dedicated lab space, all of which require considerable time and expense to assemble. The more extensive and stringent the testing requirements, the more expensive it is to develop and maintain working cannabis testing capacity. The LCB will have to identify a set of tests and procedures that achieve the desired regulatory goals at acceptable cost.

Options for Developing an Accreditation Program for the State of Washington

The LCB has several options in designing an accreditation program. It could choose to design and implement the entire accreditation process by itself. Alternately, the Board could mandate that certification by a recognized accrediting body, such as ISO 17025, be the only requirement of the laboratories; similarly, it could require instead that laboratories demonstrate competence with and utilize specific methods for cannabis testing, such as the upcoming cannabis monograph from the American Herbal Pharmacopoeia referenced above. This approach should be used with some degree of caution. There may be more than one acceptable method for performing a specific assay. The Board could also use a blended approach, mandating that the laboratories be accredited by an outside accrediting body **and** imposing additional requirements specific to cannabis and unique to Washington State. Regardless of the choice of an accreditation program, the LCB will have to design and ensure the proper administration of lab proficiency testing (discussed in more detail below). A proficiency testing program could conceivably be the sole mechanism through which labs are accredited, being an example of "light handed" or self regulation. A "light handed" approach provides the least consumer protection.

Option 1: Washington State Being Solely Responsible for the Accreditation Process

This approach would require the State to design a list of criteria similar to that of AOAC (Association of Analytical Communities) or GLP (Good Laboratory Practice) procedures that would constitute a list of required practices. These criteria would form the basis of an inspection checklist. See Appendix A for some of the components of an inspection checklist. This would require the LCB to produce documents that clearly delineate what is required of the laboratories. An on-site inspection would be required to ensure that these practices were being followed and that procedures were adequate. This approach would require an individual(s) within the LCB to have an intimate knowledge of the cannabis industry and the procedures that are acceptable for cannabis testing laboratories. Developing the protocols for all aspects of certification would impose a logistical and financial burden to the State. It would also slow the accreditation of laboratories.

Option 2: ISO 17025 Accreditation

ISO 17025 is an international standard recognized around the world. ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. It does not specify methods or techniques.

The standards required by ISO 17025 are for all testing laboratories, irrespective of what is being tested, i.e., they are not cannabis specific. For a method to be accepted, it must meet defined criteria for accuracy and precision. Accreditation by ISO 17025 standards or some other published and recognized standards offers several advantages to the State. Requirements for testing methods, validations, quality assurance and record keeping requirements are published and do not have to be developed. Since these are international standards, their acceptance is essentially universal.

ISO certification requires an inspection by an organization or company that has been recognized to perform the inspection by the international group. There is only one ISO 17025 certified marijuana testing laboratory in the US at the moment. At least one other laboratory states on its website that it is pursuing ISO 17025. Neither of these laboratories is in the State of Washington.

It should be noted that there will be a considerable financial burden to the laboratories if ISO 17025 is required. It would also take a period of time for the laboratories to meet all the requirements of this accreditation. A period of two years, no more than three years, should be adequate to attain ISO 17025 accreditation. (The author has personal experience with accreditation via ISO 17025 standards.) It is a bit of work to transform a laboratory to meet all the requirements in these standards, but once that is accomplished, all it takes to stay in compliance is diligence on the part of the laboratory and the will to do so, rather than extraordinary expertise or economic cost.

Option 3: Blended Approach to Accreditation
The WSLCB could mandate ISO-17025 accreditation and implement additional standards such as cannabis specific testing requirements to be described in the upcoming American Herbal Pharmacopeia monograph. The LCB could make periodic inspections of the laboratories to ensure compliance, complementing accreditation checks by the outside inspection agency for ISO-17025 compliance. This approach would be comprehensive in nature and provide the best assurance of accuracy and reliability in the marijuana testing industry. It would, no doubt, be the most expensive, and run the risk of establishing requirements that cannot be met by the current industry.

Option 4: Proficiency Testing
As mentioned above, a system for monitoring lab performance in terms of test accuracy (and associated labeling accuracy) may complement any system of accreditation. This approach would involve the collection of previously tested samples from the point of sale or somewhere within the supply chain. These samples would be tested by a lab of known reliability and the results would be compared to determine the accuracy of the regular commercial testing lab.

The Proficiency Testing approach for certification of laboratories offers a degree of simplicity, but there are inherent difficulties with this approach. If labs are allowed to do testing before they demonstrate competency, there is a risk of there being inaccurate test results and labeling up until the lab fails a proficiency test.

Proficiency Testing

Regardless of the design of an accreditation program, Proficiency Testing is a vital component. Proficiency testing is a way to check the performance of a laboratory on a specific sample. It does not check the overall laboratory performance nor does it ensure that all standards of quality assurance are being met. It simply provides a grade of performance on a specific sample. If a laboratory consistently fails the Proficiency Tests, there is an obvious problem with the performance of that laboratory. However, a proficiency test cannot spot all deficiencies of a laboratory.

There are no nationally recognized proficiency testing systems for cannabis testing laboratories. What is done in most locations is voluntary ring testing. A laboratory sends samples to other laboratories and results are compared. This type of testing is all that the labs can do at the present and they arrange and administer these systems on a voluntary basis. An official system of ring testing has the advantages of a "light handed" regulatory approach including cost but gives the state less transparency and control over such things as sample collection and the reporting and qualification of results.

Toward creating an official system, the LCB could work with an existing state agency to design Proficiency Testing procedures and standards based on the system of cannabis product testing the LCB requires. The LCB could then work with growers, processors and retailers to obtain cannabis at various stages of production and then prepare the proficiency test materials. The difficulty with this is that unless the correct results are known or certified, the Proficiency Test becomes a ring test. Laboratories of known reliability must be available to provide this level of proficiency testing service.

A potential component of a Proficiency Testing system is Retail Label Claims Validation (RLCV) whereby appropriately specified samples are collected at the point of sale and tested by a qualified laboratory other than the one that first tested the retail product. This helps to ensure product safety all the way to the point of sale and specifically tests the accuracy of the information available to the consumer on the product label. This may be done by specifically designated labs or through a system of ring testing. This approach works well for contamination and potency testing, but may be more expensive for pesticide testing than testing specimens collected in the field.

It might, in fact, be most efficient overall to only test products at the point of sale rather than from elsewhere within the supply chain in a comprehensive RLCV and product safety testing system. According to this scheme, uniformed officers of the LCB could go to the retail outlets and obtain products from shelves for submission for testing. At that point, a state-run or otherwise qualified independent lab would test the products for potency and purity in order to verify the testing results reported on the product label and otherwise ensure the absence of contaminants and other desired aspects of product quality. By carefully selecting retail samples in order to represent each and every lab participating in I-502 testing, and by keeping a running record on each lab's performance, this method could easily identify those laboratories with the best and worst performances.

Relying on a third-party provider to develop, prepare, and distribute the proficiency samples would be more efficient than the state undertaking this activity itself, but does have its challenges. This approach still requires the state to ensure that the provider is capable of certifying the test results. Another potential problem with this approach is the shipping of controlled substances across state lines. Unless specific exemptions are granted, the third-party provider would have to reside in the State of Washington. Laboratories at the University of Washington or Washington State University may be able to provide this service but not without significant new investment and operating expense as discussed further below.

In general, it would seem that testing final packaged product at the point of sale should involve higher cost per sampled unit than testing upstream in the supply chain, particularly for marijuana-infused products and for impurities that may be more easily detected earlier in the supply chain. Since it is known when pesticides and fertilizers are applied to marijuana crops, it was suggested that tests for pesticides and metals be conducted by testing plants in the field and soil samples. This way, a fairly large sampling could be taken with much less monetary impact. Agents from the LCB or designated laboratory personnel from accredited labs could perform the collections. The LCB will have to consider cost and reliability and general suitability of performing different tests at different points in the system.

For any Proficiency Testing system to work, many details would have to be ironed out. First, there is the actual inspections and testing apparatus, by which state agents would remove product from production and processing sites and retail stores and deliver the sample to state-approved laboratories. Second, there is the statistical logic guiding the sampling patterns, intended to provide samples representative of each laboratory. Authorities would have to determine the number of samples required in order to confidently measure the performance of a laboratory; since it is expected that some laboratories will operate on much larger scales than others, the number of samples required for each lab will vary accordingly. It would also be necessary to select a product profile representative of each lab, representing each laboratory's work in useable marijuana and various types of marijuana-infused products.

As discussed above, a Proficiency Testing regime could be implemented either as a substitute to all other accreditation requirements, such that any laboratory could test product for I-502 until their results were shown to be unreliable, or as a complement to other accreditation requirements. The former version is cheaper for the State and is easier to implement, but it does not have the assurances of consumer protection and regulation that the later approach provides.

The most obvious consumer protection would be to screen laboratories before they could service the I-502 market, but in possibly less rigorous ways than would be necessary without the addition of the retail label claim validation component. That screening requirement might be staff qualifications, or checking against a "black list" or unreliable laboratories, or demonstrated proficiency relating to the upcoming cannabis monograph,

for instance. The guiding logic for determining the screening requirement would be for the requirement to be rigorous enough to protect the integrity of the I-502 market but parsimonious enough to minimize the costs of compliance for laboratories and to encourage innovation and improvement in methodologies. This approach would allow laboratories to begin testing while they worked towards whatever standards are required for eventual accreditation.

In addition to the accreditation standards and/or Proficiency Testing system the LCB puts in place, procedures must also be developed to: 1) determine the status of a laboratory after they fail a test; 2) what types of remedial action must be taken; 3) how must the remedial action be documented; 4) what must the laboratory do to resume testing product? Some variation of the claims validation scheme could be the basis or a part of State sponsored Proficiency Testing program.

Marijuana Testing Lab Capacity

The testing labs within the State of Washington that were interviewed for this report, Analytical 360 and Northwest Botanical Analysis, appear to be operating in good faith to comply with what they believe to be valid quality assurance measures.

Appendix A describes the testing that today's labs typically perform and outlines suggested minimum elements of a manual for Standard Operating Procedures (SOP) covering analytical, quality assurance, and administrative procedures. It should be noted that at this time no laboratory in the State of Washington provides all of the comprehensive testing services mentioned during conversations with the LCB, e.g., testing for potency, microbial contamination, physical contamination, comprehensive pesticide screening, residual solvents, and heavy metals. Every laboratory interviewed would have to substantially increase their testing capacity in order to serve the recreational marijuana market.

The directors of two medical marijuana testing laboratories in the Seattle area stated during interviews that they would attempt to comply with any future requirements, especially if medical marijuana is subjected to the same regulations as recreational marijuana. But the existing medical cannabis testing infrastructure is unlikely to be sufficient to accommodate the expected increased and size and testing requirements of the recreational use market. Further, existing private labs that test agriculture products are unlikely to participate in the cannabis industry while it remains illegal at the federal level and existing law enforcement and university labs also face various constraints.

For example, a laboratory that provides criminalistics support for law enforcement may be able to do the testing if material is submitted by law enforcement personnel. A laboratory such as this has not been identified in the State of Washington. Several options are available outside the state and these laboratories routinely receive controlled substances via express courier or by mail. But most assuredly, these laboratories would have to be certain that their operation would not be placed in legal jeopardy by participating in this type of testing. It is also doubtful that a forensic lab could provide pesticide testing without a significant amount of method development.

The Department of Agriculture and the Forensic Lab at the Washington State Patrol are two in-state possibilities. However, they would need to mount a steep learning curve to perform the full range of tests typically wanted for marijuana, and they may have difficulty gearing up in the needed time frame. The forensic lab at the Washington State Patrol could provide the potency testing function, but probably has little or no experience in testing for pesticides or microbial contamination of marijuana. They meet the security criteria for a forensic lab and have procedures in place for ensuring the integrity of the samples at all times, i.e., general building security, sign in logs for visitors, and escorts for all visitors and cleaning staff, and a chain of custody to document the document all handling of the specimens. They are already ISO 17025 certified through their ASCLD Lab accreditation.

It is doubtful that they currently have the financial and personnel resources to take on a comprehensive testing program. The Department of Agriculture would have to develop

testing protocols and most likely partition their facility for security reasons. One would not want the testing of controlled substances to occur while testing for other items are going on in the same room. This would be too great a risk for sample integrity. A university laboratory may be an option, but space and resources are often at a premium at such facilities. There is also little chance that such a program could be easily incorporated into an ongoing operation. Ultimately, any of these options is likely to be more costly to the State of Washington than allowing the private sector to perform the tests.

Summary and Conclusions

There are many alternatives for the LCB to consider while developing an accreditation program for laboratories. To summarize all the discussed options, the LCB could:

1. Develop a list of criteria for laboratory performance and quality assurance, develop an inspection protocol, provide inspectors, and accredit laboratories based upon these criteria. They could base these requirements on those suggested by the **AHP® or the AOAC®**
2. Make accreditation by the LCB contingent upon the laboratory being certified by an international standard such as ISO 17025.
3. Make accreditation by the LCB contingent upon prior certification by an accrediting body such as ISO 17025 *and* impose additional criteria that the LCB would deem necessary, including Proficiency Testing.
4. Mandate some system of Proficiency Testing of final product as the only requirement for accreditation with initial, provisional accreditation requiring some cursory application, review and qualification process. This approach provides the least consumer protection and overall monitoring of laboratory performance.

Regardless of criteria for accreditation formalized systems for product testing and laboratory Proficiency Testing must be developed.

All of these options would be a step above what most states require for medical marijuana testing laboratories. Requiring ISO 17025 accreditation, as a component of accreditation by the LCB, is the most stringent option and provides the state with the most assurance that the laboratory is performing acceptably. It would also provide the public with the most assurance that the state is doing all it can to ensure integrity of testing. Unfortunately, it is also the most expensive for the laboratories.

There would be a substantial investment to the laboratories for initial certification, including hiring a consultant to help them with compliance, and the ongoing expense of having a full-time person who is primarily responsible for ensuring the continued compliance of the laboratory. There are no ISO 17025 accredited laboratories in the State of Washington. It would be necessary for the State to have other criteria in place prior to attainment by the labs of international accreditation.

Appendix A: Testing Programs and Best Practices

The types of testing in comprehensive marijuana testing laboratories usually include moisture content, potency, pesticides, microbial contamination, physical contamination and residual solvents. Not all laboratories perform the complete battery of testing. The WSLCB will have to determine if they will license laboratories that perform only a minimal amount of tests.

The techniques for testing fall into two broad categories: instrumental testing (potency, pesticides and residual solvents) and microscopic and microbiological testing. Some labs use ELISA techniques for screening; all ELISA positives should be confirmed by another method. Common instrumental techniques utilize gas chromatography with a variety of non-specific detectors and HPLC with ultraviolet detection. HPLC methods are required for THCA in most laboratories. These techniques are adequate for potency testing; however they may not be adequate for pesticides and residual solvents. The penalty for a positive result for pesticides or residual solvents can be quite severe and requires state of the art identification.

It is prudent to couple these screening tests with mass spectrometry for a definitive identification. The exact technique of choice, GC/MS or LC/MS/MS, will depend upon the analytes in question. If a laboratory does not own a mass spectrometer, it would take a good deal of effort and expense to purchase the instrument, train the staff, and validate the methods developed with them. This does not change the fact that mass spectrometry based techniques are state of the art for compound identification. If allowed by the WSLCB, a laboratory could perform the screening tests as it does now, and then send the expected few positives to an accredited laboratory capable of performing the confirmation.

Since there are no mandated quality assurance standards, the quality control and quality assurance measures are up to the individual laboratory. There appears to be a good faith effort by the laboratories to comply with what they believe to be valid quality assurance measures. They seem to want to embrace any quality assurance guidelines that are developed. Quality assurance concerns begin with a comprehensive standard operating procedure manual (SOP) that describes every aspect of the quality assurance system as well as defining analytical and administrative procedures. At a minimum an SOP should contain sections that address:

- Security of the facility, encompassing:
  - the type of security in place, lock and key or security cards
  - who has access to the facility
  - security cameras or alarm systems in place
- Organizational Chart
- Credentials requirements for the senior scientist and laboratory staff
- Training records for the staff, including competency statements for each procedure
- Administrative procedures for sample acceptance or rejection
- Sampling protocols

- Analytical procedures for each test that is performed
- Validation data for each procedure be maintained and available for inspection
- Quality control procedures
- Proficiency testing results, if available.
- Calibration and maintenance data for equipment that is used
- How and to whom results are reported.
- Disposition of excess sample
- Record retention

There are no generally accepted best practices for marijuana testing laboratories. This is true inside and outside the State of Washington.

Appendix B: Definitions

> List of definitions of terms and acronyms used in the Marijuana Testing Industry, Washington State I-502 Legislation, and common vocabulary used within the International Organization for Standardization (ISO) and Regulated Laboratory Environment (as applied to I-502 initiative). Efforts have been made to put these definitions in terms that are understandable to the expected readers of this report: BOTEC Consultants and the WSLCB.

Accreditation- a process whereby a professional organization or nongovernmental agency grants recognition of a demonstrated ability to meet predetermined criteria for established quality and performance standards. Accreditation differs from "license" in that license is not voluntary. A license requirement can include a specific accreditation requirement, as a prerequisite to obtaining a license. In the context of this report, laboratories are accredited and individuals are certified by an appropriate organization.

AHP – the American Herbal Pharmacopoeia, a non-profit organization that formed in 1995. Their mission is to produce the responsible use of herbal products and herbal medicines.

AHPS — the American Herbal Products Association, a non-profit organization founded in 1982. Their mission is to promote the responsible commerce of herbal products.

AOAC International — the Association of Analytical Communities, an international organization committed to being a proactive, worldwide provider and facilitator in the development, use, and harmonization of validated analytical methods and laboratory quality assurance programs and services.

CBGA – Cannabigerol- Acid

CBDA – Cannabidiol Acid

CBC – Cannabichromene

CBD – Cannabidiol

CBG – Cannabigerol

CBN - Cannabinol

Certification—a written assurance by a third party of the conformity of a product, process, person, or service to specified requirements.

Δ- 8 THC – Delta 8 Tetrahydrocannabinol

Δ- 9 THC – Delta 9 Tetrahydrocannabinol

Department—the Department of Health.

ELISA– Enzyme linked immunosorbent assay. A screening technique that relies upon an antigen/antibody reaction. This test is not a confirmatory test and positive results should be confirmed by a more specific technique.

GC/MS – Gas Chromatography/Mass Spectrometry, a laboratory method that uses sophisticated instrumentation to identify and quantitatively measure compounds. In the Marijuana Testing industry this method can be applied to potency testing, residual solvent testing, and pesticide testing.

HPLC/DAD– High Performance Liquid Chromatography/Diode Array Detector (used by some laboratories to quantitatively measure the concentrations of Cannabinoid Compounds in Marijuana and Marijuana Edibles)

GLP – Good Laboratory Practices. GLP, a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

LC/MS/MS – Liquid chromatography/mass spectrometry/mass spectrometry or tandem

LC/MS, a very sophisticated technique that uses liquid chromatography coupled with two mass filters. It is capable of very good sensitivity and signal to noise. It is applicable to measuring a small concentration of analyte in a complex matrix.

ISO — the International Organization for Standardization; it is the world's largest developer of voluntary International Standards

ISO 17025 – 17025— the unique number assigned by ISO for standards specific for a Management System for Testing and Calibration Laboratories

ISO 9000 – 9000 —the unique number assigned by ISO for standards specific to Quality Management Systems

License — a non-voluntary process by which an agency of government regulates the activities of an institution, profession or individual

Marijuana or "marihuana" — all parts of the plant Cannabis, whether growing or not, with a THC concentration greater than 0.3 percent on a dry weight basis; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted there from), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

PCR - polymerase chain reaction, laboratory method that amplifies DNA to generate millions of "copies" of the original DNA sequence. One of the applications of this method is the identification of Fungus, or Bacteria by their unique DNA

Potency Testing - the analytical testing of Marijuana to measure compounds that are considered psychotropic

Proficiency Testing - the Quality Assurance component of laboratory testing that involves the laboratory testing of a Reference or Standard material, intended to represent the materials that the laboratory will routinely be testing and resulting to their clients. The accurate assessment of the material by the laboratory assures independent assessment of the proficiency of the laboratory to delivery accurate results to their clients

Quality - the totality of characteristics of an entity that bare on its ability to satisfy stated and implied needs.

Quality Assurance - all the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will full fill requirements for quality

Quality System - organizational structure, procedures, processes, and resources needed to implement quality management

Quality Management - means all activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement within a quality system.

Quality Control - operational techniques and activities that are used to fulfill requirements for quality. The terms internal "quality control" and "external quality control" are commonly used. The former refers to activities conducted within a laboratory to monitor performance and the later refers to activities leading to comparison with other reference laboratories or consensus results amongst several laboratories.

THC – Tetrahydrocannabinol

THCA – Tetrahydrocannabinol Acid

THCV - Tetrahydrocannabivarin

THC concentration in product - percent of delta-9 tetrahydrocannabinol content per dry weight of any part of the plant *Cannabis*, or per volume or weight of marijuana product.

Traceability - that all steps in a procedure can be checked by reference to documented results, calibrations, standards or calculations.

Useable marijuana - dried marijuana flowers. The term "useable marijuana" does not include marijuana-infused products.

Appendix C: Sources

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