BOTEC
Analysis Corporation

Assessing the Current Capacity of the Unlicensed Testing Industry

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Final

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BACK OF THE ENVELOPE CALCULATIONS

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Executive Summary

This report is presented to assist the WSLCB in determining the benefits of regulating the laboratories that provide testing services for the legal marijuana industry, and to develop a baseline understanding of the existing marijuana testing industry in Washington State. Our research yields observations and considerations relevant to laboratory testing of marijuana that are intended to inform the WSLCB in drafting policies and processes to support I-502 implementation. The existing unregulated laboratory capabilities in the state are compared against the benchmarks in other states and in existing, relevant regulated laboratory environments. Study areas include performance targets likely to predict strengths, weaknesses, obstacles, risks, and benefits to the ultimate user and the emerging "seed to sale" cannabis industry. This report describes the labs' varying operational capacities (tests per day), range of tests offered, operating procedures, and qualifications at the Director level. We also include feedback from the labs on offering their services in a regulated environment.

Existing labs will need additional instrumentation, staff and procedures in order to comply with the scope of tests Washington will likely require. All laboratories surveyed indicated intentions to make needed enhancements and expansion to meet future WSLCB testing standards and to increase capacity in response to I-502-released demand. The consensus from the existing laboratories is that additional time may be required to allow the laboratories to plan and execute operational changes, to comply with the final requirements for testing, and increase capacity.

A small number of laboratories currently test medical marijuana in WA, and existing capacity and capabilities may be inadequate to serve the emerging commercial market. The current capacity, scope of testing, instrumentation, staffing and number of locations will have to expand to adequately address the regulated and non-regulated testing needs of WA State. The magnitude of this increase in capacity will depend upon the amount of products requiring regulatory testing through the WSLCB policies and the routine quality assurance testing driven by the open market competition. All of the existing laboratories in Washington State have expressed willingness to continue testing under a regulated environment and comply with the WSLCB requirements

Current Unregulated Washington State Medical Marijuana Testing Laboratories

Three independent medical marijuana testing laboratories[1] were initially identified in the State of Washington. All three agreed to participate in a survey. A fourth lab, Cannatest,

[1] For the purpose of this study, a laboratory is defined as a business licensed in the State of Washington that operates a laboratory within a physical building containing laboratory instrumentation, staff, procedures and inventory that focuses on the quality testing of medical marijuana. Dispensaries or growers that claim to have testing capabilities with on-site "tests" were not included in these initial surveys due to the large variability of performance claims by the growers and dispensaries , un traditional methodologies and lack of objectivity of the users. “On-site” testing should be evaluated by the WSLCB in the future.

offering mobile onsite testing in Seattle and greater Western Washington, was recently identified, but could not be included in the formal survey response due to late identification.

Washington State is not an anomaly in having no system of state regulation for laboratory testing of medical marijuana. Our research identified only one medical marijuana testing laboratory in the United States that has been accredited by a recognized International Standard Organization (ISO 17025), and it did so voluntarily. This laboratory is Canna Safe Analytics, located in Irvine, CA. Due to the unregulated environment of laboratories performing testing, there is limited standardization of analytical best practices, quality assurance, methods, and documentation of Standard Operating Procedures.

There are numerous claims of laboratory testing of marijuana by entities (both within WA and other states and countries). The WSLCB should be careful to examine the nature and scope of these service claims. "Laboratory testing" in many instances, may refer to any one of many "testing" processes that have a wide range of scientific subjectivity, accuracy, reproducibility and utility. Testing may denote actual and useful laboratory testing, or unspecified "field tests" performed with non-standard instruments sold for the purpose of identifying marijuana compounds. These tests may include methods as subjective as gross visual examination, self-testing by growers and other non-objective methods. The terminology of "laboratory" and "testing" should be defined or understood for the purposes of the WSLCB I-502 policies.

The four current WA laboratories identified include (see Appendix A for details):

Analytical 360 LLC

4035 Stone Way N

Seattle, WA 98103

http://www.analytical360.com

G.O.A.T Labs LLC - Genesis Organic Assurance Testing

6501 NE St. Johns Rd.

Vancouver, WA 98686

http://goatlabs.us

Northwest Botanical Analysis LLC

127 N. 35th St

Seattle, WA 98103

206 545 7233

http://nwbotanicalanalysis.com

Cannatest

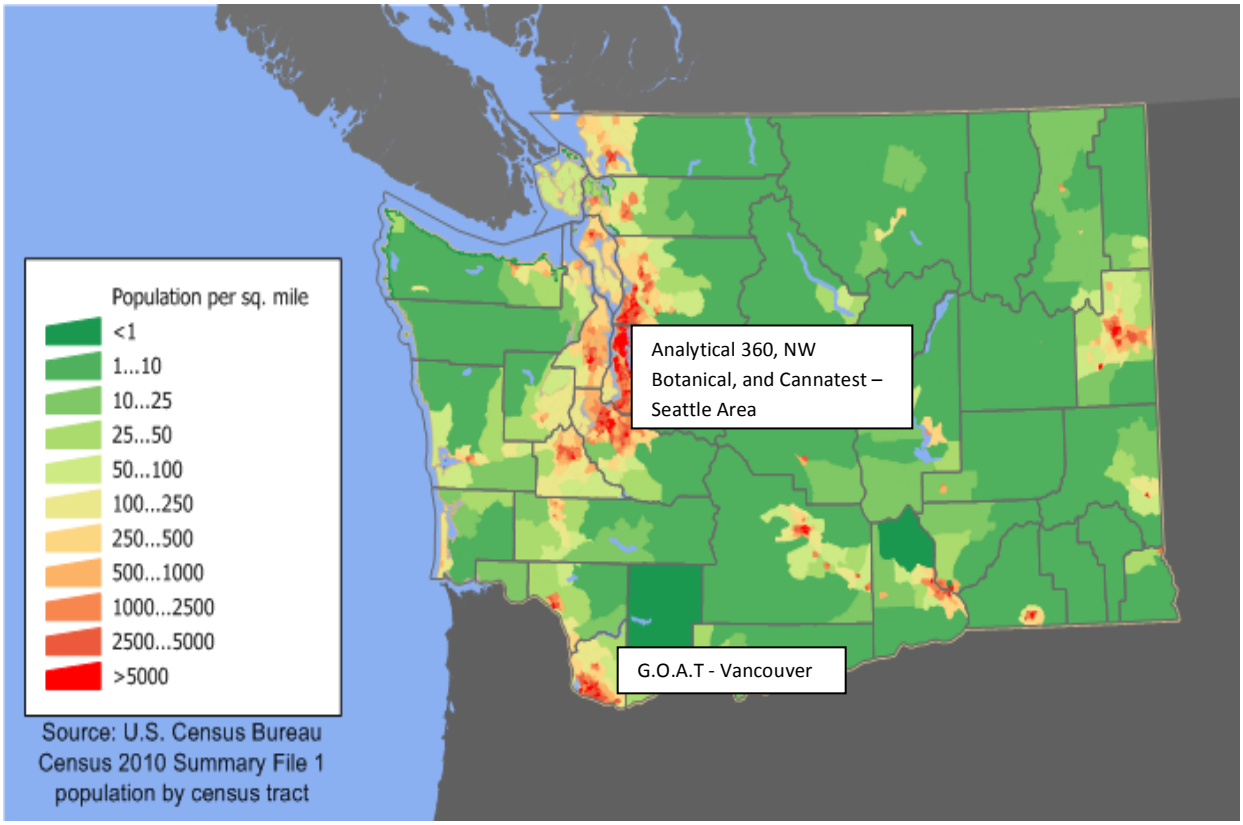
Headquarters located on Bainbridge Island, WA

Mobile On Site Testing Offered

www.canna-test.com

Current Laboratory Locations – WA State 2010 Census Map

Two of the laboratories studied are within one mile of each other, in Seattle, the most densely populated part of Washington. The third laboratory is in Clark County, near the Oregon State border.



Washington's eastern counties currently have no laboratories. If the board anticipates a significant need for licensing in the Eastern Counties, this will need to be addressed.

Scope of Testing Services presently conducted at WA laboratories

Potency

Potency testing measures the amount of cannabinoid compounds found in products. The labs determine the scope of compounds for which it will test is variable, driven by interest from clients and tempered by the instrumentation and methods available. At a minimum all labs claim to test for THC, CBN, and CBD. The capability to detect THCA requires additional instrumentation that would be an additional expense for the laboratories that do not currently have the capability.

Pesticides

All the labs surveyed screen for pesticides, but quantitative capabilities vary, as does the scope of pesticides investigated. Comprehensive residual pesticide testing will require additional instrumentation and method development in some of the laboratories.

Molds, Fungus, Bacteria

Screening is performed by all labs using a variety of methods including microscopy.

Additional Testing

Some labs also can test for Butane and Terpenes upon request.

Instrumentation

Instrumentation in WA for potency testing includes high performance liquid chromatography (HPLC) or gas chromatography (GC). The instruments themselves have a variety of detectors and injection ports to increase versatility. Each of the WA laboratories currently relies on a single instrument for potency analysis. The required scope of analysis anticipated to emerge from the regulations will require additional instrumentation within the labs surveyed.

Increased volume of testing can be addressed with acquisition of multiple units, auto samplers and upgrades to instrumentation with higher capacities. All laboratories expressed a willingness to increase capacities to support I-502 testing policies.

In addition to acquiring suitable instrumentation to increase scope and increased volumes, it will be important that validated methods for the new compounds are developed on the instruments. Method validation is equally as important as the acquisition of the appropriate instrumentation.

Staffing

Laboratory Director

Currently only one laboratory has staff that would fulfill the requirements in the draft guidelines (WAC 314-55102 Quality Assurance), by having a chief scientist with a PhD in a relevant discipline. The other laboratories are in the process of interviewing staff to fulfill the requirements for laboratory director. The laboratories anticipate that their efforts to attract qualified staff will improve when the WSLCB policies are finalized.

Employees

All surveyed laboratories were independent small businesses with fewer than 10 employees. Their scientific expertise and experience was variable and ranged from many years of relevant analytical laboratory experience to limited formal scientific education. This variability is to be expected in an emerging, unregulated laboratory environment dedicated to testing a product s that continue to be illegal under Federal law.

Quality Assurance Programs

Since there are currently no requirements for any of the WA laboratories to follow a formal quality assurance program, participating labs will need to adopt QA protocols acceptable to the WSLCB. The acceptable practice in a regulated laboratory environment is for on-site audits to be performed on a regular schedule, by an individual educated and trained in the requirements for the specific accreditation or quality system. Since none of the existing laboratories have accreditations or certifications, they have not had to show proof of compliance with any well-recognized scientific quality assurance programs with on-site audits or by obtaining voluntary accreditations that would have requirements in the areas of quality systems.

The surveyed labs did have some familiarity with FDA's 21 CFR 58 for Good Laboratory Practices (GLP) and appear to make efforts toward meeting those standards. Compliance would need to be confirmed with on-site audits. International Organization for Standardization (ISO) 17025 for Management System for Testing and Calibration Laboratories was also referenced as a potential voluntary accreditation standard that would be considered in the future.

All laboratories expressed a willingness to comply with the future requirements of the WSLCB guidelines in this area and expressed a hope that a reasonable period of time would be afforded form them to become compliant with regulatory standards.

Proficiency Testing

None of the laboratories currently participate in an independent proficiency-testing program, and there is no industry-recognized proficiency testing program for medical marijuana, as there is in other laboratory testing areas. Cooperative Inter-laboratory comparisons of results on the same marijuana samples have been used in WA to

demonstrate the ability of WA labs to duplicate results. There has been good cooperation between laboratories, but there is no formal Inter-laboratory comparison program at this time. The small number of labs in WA also means that this type of Inter-laboratory challenge would have limited statistical rigor.

It should be noted that the majority of laboratories outside of Washington State do not participate in independent proficiency programs, due to the challenges associated with accessing and moving acceptable proficiency testing materials. There have been better-organized efforts within California testing laboratories for participation in Inter-laboratory comparisons, but there is no formal program at this time.

Operational Capacity

Testing Volumes

Individual laboratories in WA are currently testing between 80 – 1,200 samples per month. This represents a significant variability in each individual laboratory's operational capacity. No laboratory was operating at full capacity and each believed that it had capacity to manage a doubling of existing volumes within 30 days. All laboratories had interest in handling additional testing volumes with adequate time and finalized guidelines from WSLCB.

The largest capacity plan was from a Seattle based laboratory, Analytical 360, that has a target to be able to perform 2,000/samples per day, if the market can support the growth plan.

The ability of the existing laboratories to support the expectations of the legalized marijuana market in WA State are heavily dependent upon the requirements set forth by the WSLCB and the competitive landscape among producers, processors, and distributors.

Turn Around Time (TAT)

Turnaround times for testing did not vary widely between laboratories in WA. Potency testing can be done with a twenty-four to seventy-two hour window, and molds, microbials and pesticides require approximately five days. These TAT's are not out of line with the majority of testing labs outside of WA. There are a few labs outside of WA that offer a twenty-four hour TAT on certain tests, and on site tests are referred to as "immediate or instant."

Security

All the surveyed labs had some form of premises security supplied by motion detectors and special locks and some had cameras and sound detectors. All labs either returned samples to the submitting client or discarded samples in a manner in alignment with new WA LCB Guidelines for disposal. When products are retained on premises, the amount of Cannabis stored is minimal due to the small amount of representative sample required (approximately 1 – 2 grams and single servings) to perform testing.

Customer Support Services

All surveyed labs have active public websites that publicize their hours of operation, services, location, scope of testing and e-mail and phone access. All were responsive to both phone and e-mail inquiries. Hours of operation varied from 7 days a week to 5 days per week, and each had some level of Saturday availability.

The public information reported on the websites for testing results was variable. One laboratory did not have test results publically posted, other labs included photos, dates tested, comprehensive results for potency, chromatography results, microbiology surveys, and collated results of products tested in the past 60 days.

All labs had social media presence with Facebook, Twitter, Instagram and other sharing software.

Result Reporting

All surveyed laboratories issue printed or electronic results in formats that are consistent within their own laboratory protocols. One laboratory issues a “certification card” that is a small card that includes name of sample, potency profile, photo, and QR Code for scanning of detailed result report.

Laboratories in WA and in other states do not use standard result reporting formats or units of reporting. Some labs do not include units of measurement on results so the ultimate user cannot easily compare products. One example is the term "% weight," where weight might be the non-dried weight of the purchased product or instead its (smaller) dry weight. Consistency of units of measurement required for analysis, result reporting and subsequent labeling using the results would be useful for consistent tracking of product quality, ultimate user comparisons and safety in a statewide regulated environment.

Lab Feedback on Offering Services in a regulated environment

Management of the labs surveyed expressed concern that hesitancy by banking, insurance, and transportation industries to enter the arena of commercial marijuana due to legal exposure. Without access to customary business supports in these areas, the labs have concerns about their ability to increase capacity and to expand services and offerings.

All labs recommended a grace period to allow them to achieve compliance with new regulatory requirements, since all are concerned that regulatory requirements might be beyond their current capabilities and they would not have adequate time to respond. Time frames suggested were from 6 months - 2 years depending on final requirements.

Staff also expressed concern that the present unresolved question of potential intervention by the DEA will stymie their ability to attract qualified scientific directors.

Unregulated Marijuana Testing Laboratories Outside of Washington

We identified some fifteen medical marijuana testing laboratories outside the state of Washington, in Arizona, California, Colorado, Michigan, Oregon and Montana. Several new laboratories were forced to shut down due to changes in the state legal statutes or degrees of intervention from local or federal law enforcement. Currently no state has any regulatory requirements for medical marijuana testing laboratories, although there are some active discussions in different states. Virtually all states have regulations in place requiring specific accreditations for forensic laboratories that are testing marijuana for law enforcement purposes.

California has the longest history of supporting medical marijuana testing laboratories, as well as the highest number of active laboratories (at least 5 laboratory sites) and the only laboratory with voluntary ISO 17025 Quality Accreditation, Canna Safe Analytics. A few additional laboratories plan to work towards ISO 17025 Accreditation and mention working at the level of FDA and ELAP requirements, but there is no ability to confirm this without on-site audits.

Laboratories outside of Washington similarly have a broad range of testing capabilities. The minimum testing offerings are potency, mold, fungus, microbials, terpenes and pesticides. Instrumentation includes HPLC, GC, and GC/MS for potency testing.

There are voluntary trade organizations that have been founded to support laboratory testing of medical marijuana. These industry groups vary in number of members, mission, level of scientific support and level of engagement in the community. California has one of the better established industry groups, the Association of California Cannabis Laboratories (ACCL). ACCL is a not-for-profit organization in the State of California founded by representatives from Steep Hills Labs, CW Analytics and Pure Analytics, which now has 8 member laboratories.

Regulated Laboratories in State of Washington Testing Marijuana

The only regulated laboratories that test marijuana in the state of Washington are the State Patrol's forensic laboratories, testing for law enforcement purposes. These laboratories are accredited under the American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB) International ISO:IEC 17025:2005.

Universities and research and pharmaceutical companies in WA may also have DEA licensing allowing them to test marijuana and marijuana compounds for research purposes. Such laboratories are not included in this study, due to the fact that their work is for research purposes and prescription drug development applications only.

Quality Assurance (QA) Program Features for Regulated Laboratories in Relevant Markets

Laboratory regulation schemes typically require laboratories to participate in proficiency testing programs, which, in their most basic terms, require the laboratory to test certified reference material (CRM) or standard reference material (SRM) with known properties and achieve matching results. A proficiency-testing program demonstrates the ability of the

laboratory to identify and measure materials in a given sample within defined parameters. These proficiency-testing programs are not the same as Inter-laboratory comparisons. In the arena of medical marijuana testing the term "inter-laboratory comparison" refers to sharing representative samples from a single lot of marijuana with multiple labs and determining if results of testing are similar. This is a minimal step towards quality assurance, but would not typically be accepted as the only proficiency component to support a laboratory accreditation. Currently there is no industry standard inter-laboratory comparison proficiency program, nor do the labs participate in external proficiency testing programs from independent providers of proficiency testing materials. The WSLCB may want to consider strengthening the marijuana testing lab environment by requiring more rigorous inter-laboratory comparisons.

BOTEC's complementary report on "Feasibilities and Trade-Offs in Determining Accreditations and Laboratory Standards" (task 430-2b) identifies specific QA components of well-respected national laboratory accrediting bodies that can be considered for compliance, accreditation, and certification or licensing in a regulated environment.

The components of QA accreditations for laboratories are designed to demonstrate the accuracy and quality of the laboratories. Accreditation may cover laboratory management, sample handling, Standard Operating Procedures (SOPS), reproducibility, bias, security, delivery of results, customer satisfaction metrics, instrumentation, traceability, rigor of methods, method validation, proficiency testing, quality control and many other components of good laboratory procedures. This section will outline the types of standards that would support a regulated laboratory environment for testing marijuana and marijuana products. This area will show the accepted laboratory standards that are used to "prevent and detect aberrant behaviors" in other lab environments. Potential related areas include ISO 17025 Testing and Measurement Laboratories, Nutritional Supplement Testing Labs, Agriculture and forensic laboratories testing marijuana.

Benefits and Considerations to WA State of Regulating Laboratory Testing

Regulation of the laboratories testing medical and recreational marijuana will increase consumer confidence in the quality and safety of the product, and will support legitimacy of the enterprise. The entire marijuana supply chain will can gain confidence in the quality of product at each point in the handoff of products from producers to processors to retailers, if quality assurance testing is required.

Currently the majority of laboratory testing in the United States that supports patient care, consumer products and public safety has some level of regulatory oversight. Without standard accreditations or regulatory oversight in for laboratories themselves, the entire purpose of laboratory testing is frustrated.

By raising the bar for laboratories, Washington State will foster quality and higher level of performance for all stakeholders in the initiative. Furthermore, efforts by Washington to instill regulatory rigor that supports highest quality and safety of products will decrease the likelihood of a perception in the Federal government of a state system that is lacks adequate oversight.

Appendix A: 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).

"Accreditation" means 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. A license requirement may include a specific accreditation requirement, as a prerequisite to licensure.

CBGA – Cannabigerol- Acid

CBDA – Cannabidiol Acid

CBC – Cannabichromene

CBD – Cannabidiol

CBG – Cannabigerol

CBN – Cannabinol

“Certification” means a written assurance by a third party of the conformity of a product, process or service to specified requirements.

"Deliver" or "delivery," means the actual or constructive transfer from one person to another of a substance, whether or not there is an agency relationship.

"DEA" Drug enforcement administration - means the drug enforcement administration in the United States Department of Justice, or its successor agency.

Δ- 8 THC – Delta 8 Tetrahydrocannabinol

Δ- 9 THC – Delta 9 Tetrahydrocannabinol

"Department" means the department of health.

"Dispense" means the interpretation of a prescription or order for a controlled substance and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes

"GC/MS" – Gas Chromatography Mass Spectrophotometry, a laboratory method that uses sophisticated instruments to identify and quantitatively measure compounds. In the Marijuana Testing industry this method can be applied to potency 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)

"ISO" International Organization for Standardization is the world's largest developer of voluntary International Standards

"IEC" International Electrotechnical Commission

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

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

“License” in general refers to the granting of permission to do an act that would otherwise be unlawful as a matter of civil or criminal law. In this context, the term "license" refers to a revocable instrument issued by a governmental authority, attesting to the authorization that a particular laboratory is authorized to perform defined laboratory functions, and that the findings of such a lab may be used for defined governmental purposes.

"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" means 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" means the totality of characteristics of an entity that control or shape its ability to satisfy stated and implied needs

"Quality Assurance" means 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" means 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" means 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**" means percent of delta-9 tetrahydrocannabinol content per dry weight of any part of the plant *Cannabis*, or per volume or weight of marijuana product.

"THC concentration in **blood**" means nanograms of delta-9 tetrahydrocannabinol per milliliter of a person's whole blood. THC concentration does not include measurement of the metabolite THC-COOH, also known as carboxy-THC.

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

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

Appendix B: Sources

Personal Phone Interviews

Cottrell, Steve, Arizona Med Testing (5/23/13) Interview by Pat Haneman. TASK - 430-2(a)- Assessing Current Integrity of Unlicensed Testing Industry.

Luce, Dana, G.O.A.T. Labs (5/28/13) Interview by Pat Haneman. TASK - 430-2(a)- Assessing Current Integrity of Unlicensed Testing Industry

Marris, Andrew, Analytical 360 (5/30/13) Interview by Pat Haneman. TASK - 430-2(a)- Assessing Current Integrity of Unlicensed Testing Industry.

Oliver, Randall, Analytical 360 (5/30/13) Interview by Pat Haneman. TASK - 430-2(a)- Assessing Current Integrity of Unlicensed Testing Industry

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Appendix C: Surveys

Washington State Liquor Control – I-502 Consulting Contract

TASK - 430-2(a) - Laboratory Survey - Current Cannabis Testing Laboratories

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Laboratory Name - Analytical 360

Laboratory Address- 4035 Stone Way N, Seattle, WA 98103

Respondent's Name and Title - Randall Oliver , Chief Scientist

Date of Response – 05/29/13, supplemented with Verbal Interview on 5/30/13

Laboratory Experience

1. How long has your laboratory been performing Cannabis Testing?

   Analytical 360 has been performing Cannabis testing since November 2011.

2. What is the education and years of relevant experience of your scientific director or (lab director, chief scientist)?

   Each of our Chief Scientist's at Analytical 360 have an extensive track record isolating and analyzing molecules spanning over twenty years. They helped found Analytical 360 and developed the services offered by the Laboratory. Prior to the successful launch of 360's , Randall Oliver had been working his way to become a research and development scientist first with Zymogenetics and then with GlaxoSmithKline where he designed and implemented processes to analyze and produce biopharmaceutical s for the clinic. He holds a Bachelor degree of Science and Associate in Business Administration and is an author in several peer review journal articles. Lara Taubner has an extensive publication record , holds an advanced Doctorate degree in Biophysics and has received various awards and honors. She is a molecular structural expert specializing in high resolution NMR characterization. In her most recent endeavor she has been investigating the molecular interactions leading to amyloid diseases which include Parkinson's, CJD, Alzheimer's and Diabetes for which she received a National Health Institutes Director award.

3. How many full time and part time employees do you have on staff?

   Analytical 360 currently has 9 full time employees and 2 interns. There are also a total of 5 partners at Analytical 360.

4. How many scientific staff members are employed by your laboratory?

   7 full time employees have completed their education with a focus in science and hold relevant positions at Analytical 360. The Laboratory operations and quality assurance team consist of:

   Caitlin Reece, Lead Lab Technician/Manager; B.S., Chemistry, Evergreen State

   Steven McNalley, Lab Technician; B.S., Organic Chemistry, Evergreen State

Cory Fry, Lab Technician; B.S., Chemistry; Evergreen State

Timothy Henry, Lab Technician; B.S., Environmental Science, Evergreen State

Virginia Webber, Quality Control; B.S., Herbal Sciences; Bastyr University

Katherine Martello, Quality Control; B.S., Herbal Sciences; Bastyr University

Halldin Bridges, Lab Assistant; Undergraduate, A.S., Biology; Bellevue Community College

5. What are your current operational hours of the laboratory?

   Operation hours at Analytical 360 are from 10AM to 11PM, 7 days a week.

6. What security is in place at your laboratory facility?

   Analytical 360 uses a local security company for general monitoring services. We have a large counter to separate cash box from main room, lock our doors after hours and have a motion detector alarm installed which alerts the authorities. When you see Wallingford you will understand our seemly lack of concern over security if you don't already.

7. How are samples secured for storage after testing?

   Samples are held in designated cabinet in the lab.

8. How do you discard excess sample that is not consumed during testing?

   Excess samples and spent retains are rendered unusable by mixing with waste Methanol prior to disposal with the King county .

Scope of Services

9. What are your scopes of Services offered?

At 360 we basically test natural products in this case Cannabis or preparations mixed with or derived from Cannabis for active ingredients and provide the consumer with some assurance that the products are not tainted with harmful contaminates. We currently offer dry weight analysis, visual inspection, yeast and mold counts, aerobic bacteria counts, and test for the absence of food borne pathogens including E.coli and Salmonella. We determine the cannabinoid concentrations of CBD acid, CBN, CBD, CBC, CBG, CBG acid, THC and THC acid. Another test offered test concentrates and extracts for organic solvent levels using our Residual Solvent Test. We are currently exploring our options and are in the development phase for multiple residue pesticide and heavy atom analysis and will be offering these services depending on demand.

What scope do you think should be concern of WA LCB – Consumer Safety vs. product enhancements ? – *final product only , responsible businessman will perform testing at producer and processor levels with either internal or third party testing labs, WA LCB not expected to regulate testing at all levels*

10. Do you test Marijuana Infused Products? If yes what types? How do you demonstrate recovery of Cannabis in varied matrices?

    Analytical 360 tests a wide variety of Marijuana infused edibles, beverages, tinctures and topical products. An example of each matrices has been spiked with a known amount and

the recovery calculated to ensure adequate recovery and potential interference of from other material to validate the extraction methods.

11. What Instrumentation do you have on the premises and what testing is performed on each of the instruments?

    2– Agilent 1050 HPLC / DAD – Cannabinoid Profiling

    1-Incubator- Microbial

    1-Dry oven- Dry weight analysis

    1 -Microscope- Visual inspection and mold identification.

    1 -Scale

    1 - Gastec sampling pump- solvent testing

1 What are the Quality Assurance guidelines that are used in your laboratory? If no formal guidelines are currently used, do you have any plans to use any guidelines in the future?

We are striving to implement a Good Laboratory Practice, GLP, environment in our Laboratory.

2 Do you currently have any voluntary laboratory accreditations or certifications? If not, do you plan on acquiring any in the future? If so which ones?

No, we do not currently have any accreditation or certification. We have been exploring obtaining an ISO certification if deemed a requirement. Otherwise without a mandated regulation or a real or deemed market driven competitive edge will be content working in a GLP environment which self regulates.

Which ISO do you think is most relevant? *ISO 17025 is the one most frequently mentioned*,

3 Do you participate in any internal quality control program? External quality control or proficiency testing?

The HLPC units are regularly tested for system suitability, calibrated and the standard results validated for accuracy and precision. We monitor for process outliers on a batch per batch bases and have a recall system in place. Our VOC testing is validated at the factory by GASTEC technologies. The microbial plates are produced externally in a quality controlled validated system to ensure consistency and functionality. We use check weights on scales and use calibrated pipets for dispensing. Everything is done by trained

individuals using standardized procedures. We have also compared or results to other laboratory results in a mock proficiency test at a local scale.

No Proficiency testing performed

Cerriliant, Restek – Stds are used

4 What information is included on a routine result report for your clients?

All results are posted online and include:

Unique Identifier

Photos from visual analysis

Image of HPLC Chrotomagraph Results

Cannabinoid Profile including; CBGA, CBG, THCA, Delta 8 and 9 THC, CBN, CBDA, CBD, CBC,

Moisture Analysis

Activated Cannabinoids

Microbial Bio-burden Results

Residual Solvent Results

5 What format is used to deliver result reports and what delivery conduits are available? Ex. Paper faxed, secured web portal, e-mail Adobe PDF files etc

All results are either openly reported online or reported in a password-protected site online, and accompanied by a PDF CoA, Paper CoA, or a CoA flash card.

Laboratory Capacity

6 What are your current testing volumes? (# samples/time unit (day or week or month)

Analytical 360 is performing 1,200-1300 tests per month for the medical market, and is seeing 5-10% growth in samples submitted month to month. We are testing an average of 40-45 samples a day.

7 What is the average turnaround time for routine potency and Pesticides, Mold, Fungus testing of a sample?

Cannabinoid profiling and residual solvent testing is guaranteed in 72 hours or less, and Microbial bio-burden/fungus is reported in 5 days.

What Potency Scope will be important for WALCB Regulations ? – Psychotropic only exclude (CBD, CBG and others) THC, CBN, THCA,

Eedibles are a bigger issue, self regulating immediate effect need to be addressed, oral consumption intoxicating level X 10 for body size,

8 What increased capacity of sample testing volumes, would you estimate that you can achieve in:

a. 30 days?

We only have the capacity and space to double potency testing volume in our current space.

b. 60 days?

Triple current capacity

c. One Year?

We are targeting the ability to process 2,000 samples or more per day (60,000 per month), within a year, if the demand in the market supports the need.

9 How would you achieve the increase in capacity?

We would purchase redundant systems and bring on line as demand required . We are planning to move into a larger space within 180 days.

10 What is the range of prices for sample testing and what testing is included at that price?

Cannabinoid Profiling Standard - $60 ea.

Cannabinoid Profiling Bulk Testing 1-20 test per month - $50.00 ea

Cannabinoid Profiling Bulk Testing 20 or more samples guaranteed per month - $40.00 ea

**Cannabinoid Profiling includes CBGA, CBG, THCA, Delta 8 & 9 THC, CBDA, CBD, CBC, Visual Analysis, Moisture Analysis, Activated Cannabinoids, results posted online, CoA card, Certificate, or PDF. Analytical 360 provides Cannabinoid profiling for flowers, edibles, beverages, concentrates, tinctures, topical, and more.

Microbial Bioburden Starting @ $60 ea., with the same bulk pricing schedule as potency. We offer Microbial @ $25.00 when ordered w/ potency in order to promote testing.

Residual Solvent Testing @ $60 ea., with same bulk pricing schedule as potency. We offer Residual Solvent Testing @ $25.00 when ordered w/ potency in order to promote testing.

11 How do you receive your samples for testing? Ex. Customer drop off, sampling performed at customer site, courier pick up, mail, commercial carrier etc.

We currently service nearly 100 access points with 3 account managers who pick up samples and drop off results twice a week. We have plans to offer testing in Spokane with a resource center to service Eastern WA by August 1st. All access points act as drop off stations, where patients and vendors can leave samples for testing. Samples are picked up from the access points by the account managers on their scheduled pick-up days. That being said, 1/3rd of our business is from walk-ins, of which a large portion consists of patients testing personal home gardens, or vendors (processors).

12 Do you currently offer product "certification"? If yes, what are your current certification standards?

Analytical 360 uses tolerance levels set by the United States Phamacopendia to safety certify products to help ensure top quality products for the consumer.

13 What other value added services to you offer to your clients beyond potency, pesticides, mold and fungus testing?

Analytical spends a lot of time consulting and educating our customers , the patient, the producers and processors to fine tune their operations. We help them design or produce more robust efficient processes or grow with higher yield more active products. We work with them to help produce safe reliable products with a posted amount of active ingredients on their label.

Marketplace Issues

14 Do you anticipate that offering Cannabis Testing under I-502 will be more or less profitable for your laboratory, than under current unregulated environment? Why?

Our general consensus is that we will be more profitable due to the mandated testing requirements that will increase demand for our services substantially. There also are concerns that an over taxed and over regulated system may put unreasonably price restraints on labs. The testing at each point of sale and the fact everyone will be required to test works in our favor. However if we are required to test each lot using a Multiple residue pesticide screening method or test for heavy atoms using the compendia requirements the price per test may be unreasonable due to the cost of equipment and man hours required. One may not be able to charge enough to cover the cost per test on these two specific examples. We are most concerned about being able to function as normal business with lack of axillary services like banking, accounting, and even transporting material without risk. And finally legalization has also brought on a surge of interested parties with major investors, this increased competition could result in a saturated market with to much competition.

15 What future challenges do anticipate as a laboratory to retaining quality and profitability?

Here it is clear that a push to have a fully functional GLP environment will actually increase the quality of service above current practices. Estimation of volume expectations, and growing at the right pace to meet demand, maximize investments, while remaining competitive industry leaders within the market will be key to our success. Here again having unrealistic demand for pesticide and heavy atom test on each lot may put a stain on our lab to afford the type and number of units required to meet demand. I might suggest a raw material specification or initial test or a periodic test interval other than lot for the products for these tests.

16 What additional issues or concerns does your laboratory have regarding the WA LCB Draft Guidelines WAC 314-55 for Marijuana Licenses, Application Process, Requirements and Reporting?

Are concerns that if consumption estimates are inflated, losses on capitol expenses could be of major concern if investments are not being maximized. Are multiple residue Pesticide testing and Heavy atom testing a requirement? Do labs require licensure and other requirements placed on producers and processors?

17 Can your laboratory be identified and can this survey information be shared with the Washington State LCB to support their efforts to establish policies and guidelines for I-502 in the State of Washington?

Yes

Survey performed in support of WA State LCB I-502 Consulting Contract:

BOTEC – Prime Contractor

NMS Labs Subcontractor,

Task Manager - NMS Labs, Contact Pat Haneman patricia.haneman@nmslabs.com 1 800 522-6671 X1284

Laboratory Name – Genesis Organic Assurance Testing Laboratories, LLC (G.O.A.T. Labs)

Laboratory Address- 6501 NE St Johns Rd, Vancouver, WA 98661

Respondent's Name and Title – Dana Luce, Senior Partner

Date of Response – 5/28/2013, Interview 5/29/13

Laboratory Experience

1. How long has your laboratory been performing Cannabis Testing? 1+ Year

2. What is the education and years of relevant experience of your scientific director or (lab director, chief scientist)? I am currently in negotiations with 2 possible candidates for this position.

3. How many full time and part time employees do you have on staff? 2

4. How many scientific staff members are employed by your laboratory? None

5. What are your current operational hours of the laboratory? Noon-6 PM Tues thru Sat

6. What security is in place at your laboratory facility? Internal Camera System with Auto Call.

7. How are samples secured for storage after testing? Samples are currently destroyed after testing.

8. How do you discard excess sample that is not consumed during testing? Normal procedure at this time is to return excess to the Client.

Scope of Services

9. What are your scopes of Services offered? Moisture Analysis, Bio, Fungus, and Mold Testing (3M ThinFilm – 3-5 Days), Pesticide Screen (GC – NPD & DELCD Detectors), Potency (GC – FID, HPLC _ DAD). Microscopic exam for Bugs and Foreign Matter.

10. Do you test Marijuana Infused Products? If yes what types? How do you demonstrate recovery of Cannabis in varied matrices? Not on varied matrice products , we prefer to test the base product (ie – oil, kief, bud) that is used to make the product and calculate the results based on Batch quantities. On single structure product (Suckers, Elixers, Gummies, etc.) it's pretty much a standard potency test.

11. What Instrumentation do you have on the premises and what testing is performed on each of the instruments? SRI 8610 GC – Potency (Activated Cannabinoids), Pesticides. Agilent 1050 w/DAD – Potency (Unactivated Cannabinoids).

12. What are the Quality Assurance guidelines that are used in your laboratory? If no formal guidelines are currently used, do you have any plans to use any guidelines in the future? No Formal Guidelines but we are working toward GLP Standards.

13. Do you currently have any voluntary laboratory accreditations or certifications? If not, do you plan on acquiring any in the future? If so which ones? No but would be open to the idea as soon as accreditations or certificates are established for Cannabis Labs

14. Do you participate in any internal quality control program? External quality control or proficiency testing? Again, there are no established quality programs for Cannabis Labs, however, we apply an SPC Process in our internal Quality Program.

15. What information is included on a routine result report for your clients? Pesticide Contamination, Fungal/Mold – present in sample, Pest/Foreign Matter Contamination, Residual Moisture, and Potency

16. What format is used to deliver result reports and what delivery conduits are available? Ex. Paper faxed, secured web portal, e-mail Adobe PDF files etc Generally direct delivery to the Client but have Dropbox and secured email capabilities.

Laboratory Capacity

17. What are your current testing volumes? (# samples/time unit (day or week or month) We currently test between 10 and 30 samples per week. This is due to Clark County still being a "Dry" County. We have the ability to do approximately 100 tests per day.

18. What is the average turnaround time for routine potency and Pesticides, Mold, Fungus testing of a sample? Currently Pesticide and Potency within 24 Hours Mold/Fungus 3 to 5 days.

19. What increased capacity of sample testing volumes, would you estimate that you can achieve in:

    a. 30 days? Unknown, it depends on the Federal Government, as long as IRS 280E is in place Bank financing is out of the question and if the Feds take a hard stance investment monies would be non-existant.

    b. 60 days? Ditto

    c. One Year? Ditto

20. How would you achieve the increase in capacity? I have been contacting Manufacturers of high volume testing equipment.

21. What is the range of prices for sample testing and what testing is included at that price? This will vary depending on types and extent of mandated testing.

22. How do you receive your samples for testing? Ex. Customer drop off, sampling performed at customer site, courier pick up, mail, commercial carrier etc. Patient Drop off.

23. Do you currently offer product "certification"? If yes, what are your current certification standards? Yes, we issue a Certificate of Compliance – NO Pesticides, Fungus or Mold in Sample.

Potency – CBC, CBG, CBN, delta 9 and delta 8 THC – ID and % wt to Vol , THCA on HPLC, use HPLC for medic, turpens

24. What other value added services to you offer to your clients beyond potency, pesticides, mold and fungus testing? Plant sexing, crop timing.

Marketplace Issues

25. Do you anticipate that offering Cannabis Testing under I-502 will be more or less profitable for your laboratory, than under current unregulated environment? Why? More, because in the current situation MOST do not test. It's not required so they just get numbers from the internet.

26. What future challenges do anticipate as a laboratory to retaining quality and profitability? The Federal Governments response.

27. What additional issues or concerns does your laboratory have regarding the WA LCB Draft Guidelines WAC 314-55 for Marijuana Licenses, Application Process, Requirements and Reporting? The Laboratory Manager requirements. It's going to be difficult at best to attract someone willing to risk their freedom, let alone their Degree, on a chance.

28. Can your laboratory be identified and can this survey information be shared with the Washington State LCB to support their efforts to establish policies and guidelines for I-502 in the State of Washington? By all means….

Survey performed in support of WA State LCB I-502 Consulting Contract:

BOTEC – Prime Contractor

NMS Labs Subcontractor,

Task Manager - NMS Labs, Contact Pat Haneman patricia.haneman@nmslabs.com 1 800 522-6671 X1284

Washington State Liquor Control – I-502 Consulting Contract

TASK - 430-2(a) - Laboratory Survey - Current Cannabis Testing Laboratories

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Laboratory Name - **Northwest Botanical Analysis LLC http://nwbotanicalanalysis.com**

Laboratory Address- 127 N. 35th St Seattle, WA 98103 206 545-7233

Respondent's Name and Title - Andrew Marris - amarris@nwbotanicalanalysis.com

Date of Response – May 30, 2013, Phone Interview w/Pat Haneman

Laboratory Experience

1. How long has your laboratory been performing Cannabis Testing?

   Over 2 years

2. What is the education and years of relevant experience of your scientific director or (lab director, chief scientist)?

   BS – Cellular Biology and Developmental Biology, Plus 2 year's lab experience

3. How many full time and part time employees do you have on staff?

   2 managing members and two additional full time paid FTE's

4. How many scientific staff members are employed by your laboratory?

   2

5. What are your current operational hours of the laboratory?

   a. Tues – Fri 10 am 6, Sat 12-5

6. What security is in place at your laboratory facility?

   Locks , security system, sound and motion,

7. How are samples secured for storage after testing?

Ask for one gram only for testing to minimize marijuana products on site, store samples, sanitized sample containers, locked cabinet, temp gauge,

8. How do you discard excess sample that is not consumed during testing?

   WA LCB's recommended method – methanol and destroy samples, mix it appropriate garbage

Scope of Services

9. What are your scopes of Services offered?

Potency: THC CBD, CBG, CBN, delta 8 and delta 9 THC , THCV,

Direct Measurement of THCA not available– (acid is decarbox. so cannot use the GC) - $50

Pesticide - $50 (GC w/NPD detector)

Mold - $50

Butane - $50

Terpenes - $50 (GC)

Nitrogen Sealing - $10/Bag

10. Do you test Marijuana Infused Products? If yes what types? How do you demonstrate recovery of Cannabis in varied matrices?

Don't analyze the finished product, they use source materials – tinctures, oils etc., which are resulted in mg/g or mg/L , then customer applies that information to their "recipes", allows them to calculate. They are working on methods to filter out lipids and other non active ingredients.

11. What Instrumentation do you have on the premises and what testing is performed on each of the instruments?

Qty – 1

SRI - GC with multiple detectors and columns, Detectors include FID, DELCD, NPD and others , 5 different columns , multiple injector ports (heats)

(have close working relationship w/GC Manufacturer, supports method development and research needs)

X80 dissecting scope

12. What are the Quality Assurance guidelines that are used in your laboratory? If no formal guidelines are currently used, do you have any plans to use any guidelines in the future?

Try to use Good Scientific Approach to maintaining Lab environment, instrumentation, Calibration of GC

Since there are no regulatory requirements they do not follow anything specifically, but will comply once WA LCB publishes requirements

13. Do you currently have any voluntary laboratory accreditations or certifications? If not, do you plan on acquiring any in the future? If so which ones?

None, will work to any that are required by WA LCB

14. Do you participate in any internal quality control program? External quality control or proficiency testing?

No Proficiency Testing

For Quality Assurance purposes they use Stds from Restek, Checks reproducibity of injections reproducibility of injection,

No proficiency testing, no internal and external

15. What information is included on a routine result report for your clients?

Potency Profile - % active ingredient, microscopic (hair, insects, type) X80 dissecting scope

Trichome coloration, clear to amber Trichomes

Pesticide Screen – NPD detector for organophosphates – screening only – Need MS back end to do a pesticide test with definitive result . Not traditional pesticides used in agriculture (Organics) . Recommend regulate at the producers end or the testing costs will be too high

(2lb lot size is too small) 5-10 lbs – Lot Size Recommended for consideration

40% of their testing is estimated to support is R and D of growers and processors to improve their products – this type of work yields significant customization of testing and reports

16. What format is used to deliver result reports and what delivery conduits are available? Ex. Paper faxed, secured web portal, e-mail Adobe PDF files etc

PDF via e-mail to client or paper pick up at lab

Laboratory Capacity

17. What are your current testing volumes? (# samples/time unit (day or week or month)

100 tests/week depending on testing being performed

18. What is the average turnaround time for routine potency and Pesticides, Mold, Fungus testing of a sample?

Depends on mix of testing being requested and customization that may be needed for R and D

Microbial – 5 days

Turpene and Potency several days

19. What increased capacity of sample testing volumes, would you estimate that you can achieve in:
    a. 30 days? Can Double Existing Capacity to deliver approx 200 tests/week depending on testing needed

    b. 60 days? – Depends on requirements from WA LCB – Growth Plans under consideration

    c. One Year? Depends on requirements from WA LCB – Growth Plans are under consideration

20. How would you achieve the increase in capacity?

    Increased instrumentation , look at producers level and try and keep up, double or triple square footage, Acquire HPLC and autosampler, consider multiple sites duplicating processes at main lab, If significant increase is needed quickly additional capital will be needed

21. What is the range of prices for sample testing and what testing is included at that price?

    Potency: $50

    Pesticide Screen - $50 (GC w/NPD detector)

    Mold - $50

    Butane - $50

    Terpenes - $50 (GC)

    Nitrogen Sealing - $10/Bag

22. How do you receive your samples for testing? Ex. Customer drop off, sampling performed at customer site, courier pick up, mail, commercial carrier etc.

Customer Drop Off - Primarily

23. Do you currently offer product "certification"? If yes, what are your current certification standards?

    Do Product Labeling with results from testing

24. What other value added services to you offer to your clients beyond potency, pesticides, mold and fungus testing?

    Custom testing to support R and D for Growers and Processors

    Nitrogen Sealing

    Butane Testing – (Butane is used as a solvent when producing concentrates)

Marketplace Issues

25. Do you anticipate that offering Cannabis Testing under I-502 will be more or less profitable for your laboratory, than under current unregulated environment? Why?

    Will depend upon final regulations

26. What future challenges do anticipate as a laboratory to retaining quality and profitability?

    Need final regulations rolled out from WA LCB, to plan and make financial commitments to support growth and staffing if necessary

    Reasonable amount of time will be necessary to give labs time to get up to standards

27. What additional issues or concerns does your laboratory have regarding the WA LCB Draft Guidelines WAC 314-55 for Marijuana Licenses, Application Process, Requirements and Reporting?

    Size of Lot at 2lbs may be too small for large volume growers – cost of testing of every 2 lbs may be too high

    Will need time to scale up and get a scientific director, cannot do this until the LCB lock into guidelines. 6 months - a year

28. Can your laboratory be identified and can this survey information be shared with the Washington State LCB to support their efforts to establish policies and guidelines for I-502 in the State of Washington?

    Yes

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