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# CANNABIS TESTING POLICY:

## RECOMMENDATIONS FOR MORE THOUGHTFUL AND CONSISTENT REGULATIONS

# ACKNOWLEDGEMENTS

## NCIA'S POLICY COUNCIL

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# TABLE OF CONTENTS

# INTRODUCTION AND KEY TAKEAWAYS

**SINCE CALIFORNIA first legalized medical cannabis in 1996 and the first state-licensed cannabis businesses emerged across the west more than a decade later, there has been a vast array of complex policy developments. The paradigm of state legalization occurring under federal illegality creates new responsibilities for state regulators in areas often governed by federal law. Cannabis testing and the creation of a parallel testing industry for state-licensed cannabis businesses is just one of these new regulatory responsibilities. As a result, states have implemented a variety of different approaches and have created a true public policy laboratory where dozens of experiments are running simultaneously. From these experiments, best practices – as well as cautionary tales for future regulators – have started to emerge. The goal of this paper is to convey, based on the insights and guidance from experts in the field, what we see as potential best practices for the future. This work is consistent with the mission of the National Cannabis Industry Association's Policy Council, which is to develop and promote sensible policy for the cannabis industry.**

## KEY TAKEAWAYS

**In the following pages, we provide 16 detailed recommendations for state and federal officials to consider when developing cannabis testing policy. From those, here are six key takeaways:**

1. **Maximize flexibility and responsiveness in the system.** Establish an ongoing Commission of policy makers, industry representatives, and scientists to formulate recommendations for regulations and adopt official policies covering certain aspects of the testing program.

2. **Ensure sampling is independent, representative, and consistent with scientific best practices.** Require trained laboratory employees or third-party contractors to collect all samples in accordance with regulations for statistical representation established by the Commission.

3. **Enable business growth while accounting for the variation within cannabis for testing.** Allow cultivators and manufacturers to determine their own batch size for testing but require that additional sample increments are taken in proportion to the size of the production batch.

4. **Set high standards for testing laboratories -- and give the laboratories time to reach that standard.** Accredit cannabis laboratories to ISO/IEC 17025 for required analytical tests but allow for initial provisional registration so labs can conduct the testing necessary to receive accreditation.

5. **Increase efficiency by reducing duplicative testing along the supply chain.** Only require testing on products in their final form because those products will reach consumers and will more effectively protect public health or safety.

6. **Expand the reach, benefits, and profitability of cannabis testing.** Allow licensed laboratories to accept cannabis samples from home cultivators, patients, journalists, and other individuals who are legally able to possess cannabis.

# DEFINITIONS

**Throughout this document, we employ some terms that may not be familiar to all readers. We have therefore included the following definitions to aid in the reader's understanding:**

**Accreditation body**
An impartial non-profit organization that operates in conformance with the International Organization for Standardization/International Electrotechnical Commission standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement for testing.

**Action level**
The threshold value that provides the criterion for determining whether a sample passes or fails an analytical test.

**Active ingredient**
Any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

**Batch**
A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.

**Cannabis Laboratory Advisory Commission**
A commission created in law and comprised of government, public health, and relevant industry experts tasked with creating official policy and providing recommendations to the state on cannabis testing.

**Cannabis testing facility (or cannabis testing laboratory)**
A facility licensed to perform analytical testing on cannabis.

**Certificate of analysis**
The report prepared by the laboratory about the analytical testing performed and results obtained by the laboratory.

**Certified reference material**
Reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

**CLAC official policy**
Memorandums created by the Cannabis Laboratory Advisory Commission governing the specific processes of cannabis testing and actions of licensed marijuana establishments.

**Commercial release**
Cannabis, cannabis concentrates, and cannabis products that pass mandated testing performed by an accredited laboratory and are permitted to be sold to consumers.

**Consensus method**
A method that has undergone an extensive peer-review process, through which participants have reached consensus on the utility and specification of a given method.

**ISO/IEC**
The International Organisation for Standardization/International Electrochemical Commission (ISO/IEC).

**ISO/IEC 17025**
The standard published by the International Organization for Standardization (ISO) titled "General requirements for the competence of testing and calibration laboratories."

**Laboratory Director**
An individual of suitable education and experience responsible for training all employees, developing standard operating procedures, and generally ensuring the scientific validity of all testing analysis performed by the licensed laboratory.

**Method validation**
The process used to confirm that an analytical procedure employed for a specific test is suitable for its intended use. Results from method validation can be used to judge the quality, reliability and consistency of analytical results.

**Proficiency test**
An assessment of the performance of a cannabis testing facility's methodology and processes. Proficiency testing is also known as inter-laboratory comparison.

**Reference material**
Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

**Remediation**
The process by which cannabis or cannabis products, which have failed contaminant or other testing, are processed, reformulated, refined, other otherwise altered to remove or otherwise eliminate the source of failure and then retested.

**Sample**
A representative sample.

**Third-party sampler**
The laboratory employee or other permitted individual responsible for obtaining samples of cannabis or cannabis products.

## RECOMMENDATION #1

# CANNABIS LABORATORY ADVISORY COMMISSION ("CLAC")

Establishing regulations to govern a product safety testing program is incredibly complex in any industry. But this task is substantially more difficult for the cannabis industry for a number of reasons. The science of cannabis testing is still evolving and there are no long-existing laboratory standards to leverage as best practices. Unlike other fields, there are no federal or international standards for cannabis testing nor easily identifiable experts to rely upon. This creates problems for legislators, regulators, and other state officials (hereinafter, "policy makers") who are forced to make decisions on complex policy issues outside their scope of expertise. Complicating matters, the information needed to create good policy is not aggregated into a single government agency and the necessary cannabis experience was only held by black-market actors until very recently. To bridge this knowledge gap, we recommend that state officials create a ten- to fifteen-person Cannabis Laboratory Advisory Commission ("CLAC") comprised of government regulators and scientists as well as experts in the field of general laboratory testing science, certification, and policy; cannabis cultivation, extraction, and testing; and public and human health in order to increase the depth and breadth of experience and knowledge available when developing policy and regulatory recommendations for cannabis testing.

CLAC will serve three main purposes: (1) to formulate recommendations for regulations governing cannabis testing, (2) adopt official policies covering certain, limited aspects of the testing program, and (3) set standards for laboratory accreditation. First, CLAC will serve to provide guidance to administrative agencies that are tasked with adopting regulations governing cannabis testing. This will ensure that state regulations are based upon input from many different stakeholders with varying expertise. Second, CLAC will be authorized to adopt official policies that govern certain aspects of the testing program that are too volatile to be put into state regulations. The field of cannabis testing is advancing so rapidly that certain details, such as permissible contaminant levels or permitted methods of product remediation, should be left out of regulations so they can be easily adjusted and changed outside of standard regulatory timelines and processes. Third, CLAC will require standards, such as those developed by International Laboratory Accreditation Cooperation ("ILAC"), for accreditation bodies engaging in the auditing of production facilities, third-party samplers, and cannabis laboratories. These aspects of the program are constantly evolving and are also best suited to be set as policies and not regulations at this time.

Given the amount of authority provided to CLAC, policy makers should adopt specific requirements to ensure its policies conform to state interests. First, all CLAC decisions should be governed by the following codified guiding principle: "To ensure a legitimate, statistically-valid, and efficient cannabis testing program, balancing public safety and industry economics." Additionally, CLAC meetings and decisions should be based upon government principles and conform with all state sunshine laws in order to increase stakeholder participation. All CLAC meetings should be open to the public, documents and recordings should be provided on a government webpage, and standards should be established for changes to or creation of official policy.

The following are our recommendations for potential members of a Cannabis Laboratory Advisory Commission:

**Government**

1. Co-chair: Representative of government agency in charge of regulating cannabis businesses
2. Co-chair: Representative of government agency in charge of regulating environmental, food, and/or pharmaceutical testing laboratories
3. Representative of government public health or consumer product agency in charge of ensuring food and consumer product safety
4. Representative of the office of the governor in charge of cannabis policy coordination

**Cannabis Industry and Cannabis Consumers**

5. Representative of cannabis testing lab
6. Representative of cannabis cultivation facility
7. Representative of cannabis manufacturing facility
8. Representative of cannabis consumers or patients

**General Industry and Public Health**

9. Representative from government or private industry with experience operating or auditing food and/or consumer products manufacturing facilities
10. Representative from government or private industry with experience operating or auditing food, medicine, and/or consumer product testing laboratories
11. Representative within the field of medicine with knowledge of cannabinoids, contaminants within cannabis, and human physiology
12. Representative from government or private industry with experience in the policy and science for product sampling for laboratory testing

## RECOMMENDATION #2

# EMPLOYING LAW, REGULATION, OR CLAC POLICY

The decision about whether certain cannabis testing issues should be adopted as law, regulation, or CLAC official policy is complicated and policy makers must carefully consider how best to allocate responsibility for different facets of the testing program. Since cannabis testing is a new and quickly developing field, regulatory policy will need to be flexible and adaptable to changing best practices, industry dynamics, and federal law. Many state legislatures do not meet year-round and, even when in session, the legislative process is complicated, time-consuming, and not designed to rapidly modify policies at the pace of change seen in cannabis testing today. With this in mind, very few areas of cannabis testing policy should be established in statute with the rest delegated to regulation and policy. The legislature should create or designate the agency that will oversee testing policy and authorize the creation of the CLAC. Statutes should also authorize the state agency to adopt or delegate to CLAC policies governing the entities that will sample, audit, and test cannabis. Further, statute should provide legal protections to licensees and define prohibited acts for these regulated entities that are sensitive issues unrelated to the science of cannabis testing, such as multi-license and cross-license ownership limitations for cannabis testing laboratories. Finally, statute should clearly direct state public health and state scientific agencies to provide support to the administrative agency that oversees the cannabis testing program and CLAC.

The majority of remaining cannabis testing policy issues should be established through regulation. We strongly recommend adopting as regulation any policy that would have a significant economic impact on financial planning, as businesses will need to budget for those future expenses. Examples of these policies include the frequency of testing, application requirements for laboratories and samplers, and required types of analyses. The process for establishing regulations is governed by state administrative procedure acts, which are designed to resolve technical issues with a significant economic impact by providing timelines for public notice, opportunities for debate, and legal rights for judicial review. Although flexibility is crucial, it is also important that major changes to a state cannabis testing program be deliberated in a public forum where all stakeholders are provided an opportunity to be heard and industry participants receive the advanced notice necessary to change business plans. Technical testing terms should be defined in regulation and mirror definitions in federal law and international standards, which will allow state regulation to seamlessly integrate with eventual federal oversight. When regulatory issues cover areas of cannabis science or testing policy, CLAC should provide recommendations and supporting information to help regulators make decisions grounded in research and existing best practices.

Finally, certain issues within cannabis testing are so new or scientifically detailed that they should be established by the group of subject matter experts within CLAC, outside of normal regulatory processes. These types of issues include sampling procedures, permissible levels of contamination, types of pesticides required for testing, and procedures for proficiency testing. When creating official policy, CLAC should reference existing federal and internationally recognized standards when possible to prevent conflicting and duplicate requirements. This process of requiring cannabis standards to conform to existing national and international requirements will also ease the process of eventual federal regulation. If established standards do not yet exist, CLAC may decide to develop their own requirements until consensus methods or processes are created.

Unlike issue areas that should be established in regulation, the topics of CLAC official policy development should not have a major economic impact on the industry that would require significant advanced notice. For example, industry members would not require a long lead-time to implement an improved sampling protocol. To ensure the force of law, regulated entities must be required in regulation to follow official CLAC policy. CLAC must establish standards for the creation of or changes to existing official policy, which should include an opportunity for public comment and notification to regulated entities any time changes are made that will affect their business.

For illustrative purposes, we have included below a non-exhaustive list of policy issues, arranged according to whether they would be best handled in statute, regulation, or CLAC official policy.

**Issues for Statute**

- Creation of a testing laboratory license
- Creation of a third-party sampler permitting program
- Multi-license ownership limitations for cannabis testing laboratories
- Legal protections and prohibited acts for testing labs, employees, and samplers
- Ability for third-party private entities to engage licensees to certify increased batch size

**Issues for Regulation**

- Application requirements for testing laboratories
- Batch testing frequency
- Batch size limitations
- Composite batch size limitations
- Contaminants to be tested

**RECOMMENDATION #2** | CONTINUED |

- Cannabinoids, terpenes, and flavonoids to be tested
- Retesting and remediation process for failed tests
- Permissible sources of cannabis for testing
- Stages at which required and/or optional testing should occur
- Record and sample retention requirements
- Testing results required to increase batch size, compositing, skip-lot, etc.
- Educational and experience requirements for laboratory directors
- Training requirements for laboratory staff
- Criteria for producer and laboratory facility third-party auditing and SOP review (for advanced testing/ production abilities)
- Criteria for sampler permit approval
- Physician and bio-security requirements for facility and for sample storage
- Sample waste disposal requirements and recordkeeping
- Defined technical testing terms used in regulation

**Issues for CLAC Official Policy**

- Permissible contaminant levels
- Timeline for ISO/IEC 17025 accreditation
- Pesticides required to be tested
- Standardized procedures for sample collection as well as sample acceptance or rejection by a laboratory
- Record requirements for developing and validating test methods
- Specifications for maintaining equipment calibration and inspection data
- Accepted procedures for intra- and inter-laboratory proficiency testing
- Accepted procedures for composite and increased batch size sample preparation
- Number of sample increments required for different batch sizes of cannabis products
- Permissible methods for remediation
- Defined technical testing terms used in CLAC policy when required

# RECOMMENDATION #3

## THIRD-PARTY FACILITY AUDITING AND ACCREDITATION BODIES

As mentioned in Recommendation #1, the third component of CLAC's mission will be to establish regulatory standards and requirements for third-party private entities providing technical and scientific auditing and accreditation for testing facilities, permitted samplers, and other cannabis business types. When applicable, these standards should be based on existing nationally- and internationally-recognized requirements for accreditation and certification bodies. Currently, multiple different third-party accreditation bodies openly work with cannabis testing laboratories to provide accreditation with international standards, such as the American Association for Laboratory Accreditation (A2LA) and ANSI-ASQ National Accreditation Board (ANAB). In addition to accrediting the laboratories, a well-balanced and safe cannabis testing program will also require technical and scientific approval for third-party samplers, production facility processes, and inter-laboratory proficiency testing.

CLAC should be directed to adopt official policy that sets minimum standards for organizations authorized to certify cannabis licensees and permitted samplers. Policy makers can license, register, or simply require that the accreditation organizations comply with standards established by CLAC, ILAC, or ISO/IEC 17011. In addition, CLAC should adopt minimum standards against which the accreditation agencies will review cannabis licensees and permitted samplers for compliance. These standards can be based upon a growing body of work, including traditional ISO/IEC; the Americans for Safe Access Patient Focused Certification program (ASA-PFC); and forthcoming contributions from ASTM International, the American Herbal Products Association, the National Association of Cannabis Businesses, AOAC International, and the American Oil Chemists' Society (AOCS). This type of regulatory guidance will reduce stigma associated with working with the cannabis industry, thereby increasing participation by existing professional accreditation bodies and encourage entrepreneurs to form new accreditation companies. Furthermore, CLAC's standards and collaborative work with different stakeholders will foster an improved relationship and dispel misconceptions cannabis industry members may have of existing accreditation bodies.

## RECOMMENDATION #4

# OWNERSHIP LIMITATIONS

Almost all existing state cannabis programs mandate third-party testing from a licensed cannabis laboratory, despite most other regulated industries allowing for in-house testing and quality control to satisfy regulatory requirements. Policy makers mandate independent testing to protect public health and safety by ensuring that potency is accurately labeled and production practices produce safe products for consumers. To maintain the integrity of an independent system and prevent conflicts of interest, states typically prohibit any shared ownership interest between a testing lab and other licensed cannabis businesses.

A cannabis testing laboratory is an expensive and difficult business to operate, combining the security costs of a cannabis facility with testing industry's high capital costs and expensive salaries. There are significant fixed costs to operating any laboratory and revenue is based the volume of samples that can be processed. Despite having even greater fixed costs than non-cannabis laboratories, most states actually prohibit licensed cannabis testing facilities from testing non-cannabis products or cannabis products from patients or individuals of legal age; thereby reducing the size of the overall testing market. Many non-cannabis testing laboratories service clients across multiple states and industries in order to maximize volume and reach profitability. Federal law makes this interstate testing impossible for cannabis laboratories. As a result, it is difficult to operate a private cannabis testing laboratory profitably in a large market like California but potentially impossible in a smaller market with limited licenses.

Therefore, we recommend that policy makers consider the economic balance that must be struck when mandating independent testing. If it is not possible for a state to have a profitable and competitive testing market, then we suggest consideration of a variety of policy options:

- Allowing cannabis laboratories to research and develop new infused products, but still require that all final products for consumption be tested by a separate licensed and accredited cannabis testing facility
- Authorizing owners of cannabis laboratories to also own minority and non-controlling interests in other license types in order to increase the potential investment pool
- Permitting licensed cannabis testing facilities to test non-cannabis samples and cannabis samples from patients and individuals of legal age

## RECOMMENDATION #5

# MAXIMUM BATCH SIZE

A central component of any effective testing program is ensuring that samples are representative of the batch from which they are derived. The ratio between the size of a batch and the size and number of samples is essential to determine the accuracy and representativeness of any analysis. The more samples that are collected, the more likely the test is to represent the total batch, and the more samples that are tested, the lower the chance that a contaminated batch will slip through the cracks. Each sample taken and tested, however, represents a direct cost to producers and eventually consumers. Therefore, regulations need to strike a balance between public safety and industry economics when establishing the mandatory size of samples and numbers of tests that must be conducted per batch.

Cannabis testing programs use different methods to ensure that samples are representative. Some states, such as Colorado and Maryland, allow producers to determine their own batch sizes and then set requirements for the number of samples required for batches of different sizes. Other states, such as Nevada and Alaska, limit the size of cannabis flower batches to no more than five pounds. Oregon provides licensees with flexibility to create batches of no more than fifteen pounds but may permit larger batches of concentrate, extract, or product after establishing standards of production through repeated testing in what Oregon regulations call a "control study."

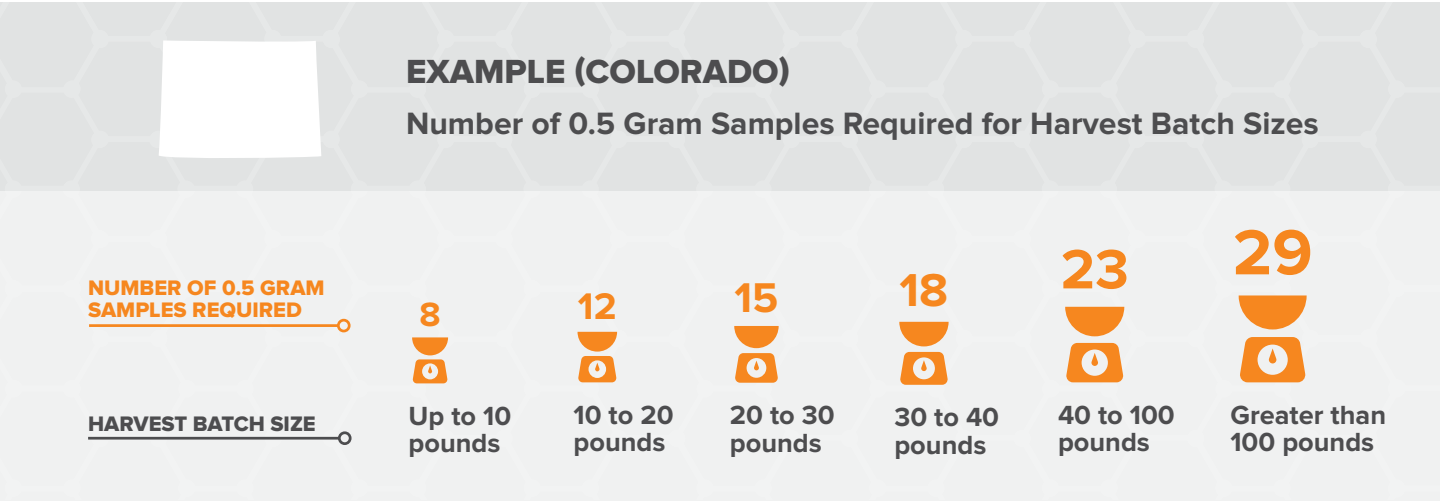
In states that cap batch size, producers are required to structure their production around the testing program and not normal business decisions. Regardless of experience and the consistency of past results, operators are prohibited from

**RECOMMENDATION #5** | CONTINUED |

producing larger batches to reduce testing costs. A grower or manufacturer that trusts its internal quality control and standard operating procedures to reduce the potential for contamination should be afforded the ability to reduce costs of external third-party testing, like in any other industry. Instead of capping batch size, regulations should seek to control the ratio between batch size and the number and weight of samples required in a manner consistent with the science on representative sampling and similar to other requirements in other industries.

Despite the potential benefits of providing operators the ability to effectively sample and analyze batches regardless of size, large batch sizes can pose public health and safety risks that should be mitigated in regulation. As discussed above, the state needs to set standards for representative sampling. But facility conditions and replicability of standard operating procedures can affect batch variation and increase the risk of contamination evading the testing program. In addition, cannabis testing laboratories must use sufficiently sensitive methodologies and equipment to detect low levels of contamination when authorized to test larger batches. If multiple samples from a large batch are combined into a composite sample, there is a risk that otherwise detectable levels of contamination will be diluted and the batch will improperly clear testing. Therefore, regulations should also address facility oversight, sampling oversight (see Recommendation #6), and laboratory oversight to minimize the risk that contaminated product will reach the market.

At this time, there is not an accepted and scientifically-validated methodology for determining the appropriate size of a sample of cannabis nor the number of samples necessary to ensure a batch is statistically representative. The State of Colorado is currently working towards developing standards in this area; however, current regulations leverage other statistical models to best approximate appropriate sample size per batch pound. The chart below, from Colorado's regulations,[1] uses the UN Drug Policy Guidelines to set the number of 0.5-gram samples required to achieve a high degree of statistical confidence, but this model was not designed for cannabis. Given the evolving nature of our understanding of best practices, the corresponding number of samples required for different size batches of various types of cannabis products should be established by CLAC in separate official policy.




**Regulations need to strike a balance between public safety and industry economics when establishing the mandatory size of samples and numbers of tests that must be conducted per batch.**

1. CCR 2012-2 1504(B)(1)

## RECOMMENDATION #6

# CERTIFIED THIRD-PARTY CANNABIS SAMPLERS

There are a variety of reasons why a cannabis sample may not be representative of the entire batch. For example, cannabis plants tend to have higher concentrations of cannabinoids and terpenes at the top with decreasing concentrations appearing further down on the plant. Also, growers may selectively spray pesticides to control early contaminant outbreaks in just one portion of a cultivation room. If a producer was able to select their own samples for testing, there would be significant incentives to choose the most ideal buds with the highest concentrations of cannabinoids and the lowest potential for contamination. These samples might show high levels of THC and no detectable pesticides, but they would not be representative of the entire batch and therefore could cause harmful products to end up on store shelves. So, it is important that samples collected for testing are representative of their batch. To ensure the samples are representative, standards must be established for sampler training, sample collection, sample storage, and sample transportation.

To reduce the incentives to selectively choose optimal rather than representative samples, state officials should establish an independent third-party sampling program for the collection and transportation of samples to a cannabis testing laboratory. This approach does not fully resolve the sample collection issue since producers would still need to contract with a third-party permitted sampler that would selects samples from batches, composite samples as necessary, and physically transport samples to a cannabis testing laboratory of the cultivator or manufacturer's choosing. This means there may be incentives for the third-party sampler to retain customers by selecting favorable samples. But there is at least some separation created between the decision.

Finally, individual samplers should be certified by CLAC to further protect against fraudulent sampling and provide the regulators with a means to enforce oversight on the sampling process. The sampler certification should include a written test, practical assessment, and ongoing reviews. Standard and uniform sampling procedures for cannabis, concentrates, and infused products should be established within CLAC official policy and enforced by the regulatory agency that oversees cannabis testing laboratories. These sampling procedures can be based upon best practices for other commodities when sufficient standards for cannabis do not exist. The CLAC standard should include but need not be limited to:

- the number of samples required for each cannabis batch category based on size,
- the minimum and maximum size of samples,
- processes for ensuring samples are not inadvertently contaminated during sampling, storage, or transportation, and
- processes for onsite composite sampling, if permitted

## RECOMMENDATION #7

# INVESTIGATORS ABILITY TO SELECT PRODUCTS FOR TESTING

Inspections by government investigators and public health officials at meat and other food production facilities have been an important component of ensuring general food safety in the United States for more than 100 years. For example, the Food Safety and Inspection Service within the US Department of Agriculture draws its legislative authority from the Federal Meat Inspection Act of 1906. A similar practice can be applied to cannabis cultivation and manufacturing by directing cannabis regulatory enforcement officers to identify potential sources of contamination and randomly select products for testing.

There are many government officials and inspectors who regularly visit cannabis facilities, such as field investigators for enforcement divisions and local public health officials. Both state and local officials should be authorized to require a specific or randomly selected product to be tested during a facility audit. Field investigators for regulatory agencies can also be trained to identify potential sources of contamination in addition to regulatory violations. CLAC can support regulators when determining the number of samples to be submitted during facility audits. State inspectors should be able to require that licensees utilize specific licensed cannabis testing laboratories or have samples submitted to a state government testing facility. Finally, these tests should be in addition to, and not a substitute for, batch testing.

## RECOMMENDATION #8

# REQUIRED PROFICIENCY TESTING

Proficiency testing is a critical component of any testing program. It is the process by which test results of identical samples from multiple private labs are compared to determine interlaboratory accuracy. In many other laboratory testing industries, proficiency testing is performed by providing a controlled reference sample to each participating laboratory that was already tested by an ISO/IEC 17043 accredited proficiency testing provider. Proficiency testing in the food, tobacco, and other testing industries requires at least one proficiency testing analysis from a commercial provider each year for all methodologies within a laboratory's scope of accreditation.[2] The participating laboratories analyze the known sample and each should get the same results regardless of the methodology, within an acceptable margin of error. Proficiency tests allow laboratories to identify failures within its processes and improve methodologies. It also helps regulators and accreditation bodies identify underperforming laboratories requiring remediation.

Unlike normal proficiency tests, there are no ISO/IEC 17043 accredited proficiency testing programs for cannabis because a single source of controlled reference samples cannot be evaluated by a single ISO/IEC 17043 provider distributing samples across state lines. Alternatively, proficiency testing can be performed without certified reference material by submitting an identical sample in a "round-robin" testing format to multiple different testing laboratories to determine the consensus results and then evaluate each laboratories competency based upon that average. Laboratories with outlier results may have to reevaluate their methodologies or see where testing errors may have occurred.

Interlaboratory "round-robin" comparison proficiency testing should be required by each state cannabis testing program. CLAC should set requirements and procedures for interlaboratory proficiency testing and each cannabis testing facility licensed in the state should be required to participate. For each state program, CLAC should determine how frequently proficiency testing should occur, which types of samples should be used, and what types of results should be considered outliers. Retesting, physical inspection, and methodological re-validation can be required for any laboratory whose results are an outlier during round-robin proficiency testing. CLAC could solicit request for proposals from private entities to run and operate such a proficiency testing program. In addition, CLAC should investigate whether a state ISO/IEC 17043 reference laboratory could be used to provide certified and controlled reference samples from which cannabis laboratories can be evaluated.

## RECOMMENDATION #9

# REQUIRED CONTAMINANT TESTING

To protect consumers from potentially hazardous microbes and dangerous chemical residues, each state with a cannabis testing program requires testing for various types of harmful contaminants. Just like any other type of consumer product, it is not feasible or realistic to test cannabis for every single potentially hazardous compound. Instead, contaminant testing must be targeted to the most likely forms of cannabis contamination that pose the greatest potential health hazards. Typically, states have adopted mandatory contaminant testing in cannabis programs centered around screening for hazardous microbials, heavy metals, residual hydrocarbon solvents used during extraction, foreign particulate matter, and mold and yeasts. As the science and cannabis markets have evolved, however, certain states have adopted requirements for water activity, mycotoxins, pesticide residuals, and cultivation chemicals. These regulatory developments are largely guided by publications from the American Herbal Pharmacopeia and the United States Pharmacopeia detailing specific lists of contaminants that should be screened.

The frequency of mandated testing for different types of contaminants is a direct driver of the cost of testing and, as such, should be established in regulation to allow businesses to appropriately plan their finances. The health risks and prevalence of different potential cannabis contaminants should be studied by CLAC with recommendations on the frequency of required testing submitted to state officials for formal regulation. Impurities that pose greater hazards could be tested for more frequently, thereby increasing efficiency and public health protection. Since the research on the health risks

2. For instance, A2LA guidelines require all methodologies to go through proficiency testing within four years with a minimum of one per year to satisfy the ISO/IEC standard.

**RECOMMENDATION #9** | CONTINUED |

of certain contaminants is still evolving, the levels for passage or failure should be left to CLAC policy rather than being mandated through regulation. In addition, CLAC should establish shelf-stability testing and labeling standards for cannabis-infused products that require refrigeration or hot-holding. CLAC should regularly review the available scientific literature, contaminant testing requirements and data from other states with the goal of harmonizing permissible contaminant levels nationally. This approach will allow policy to be based on the best available scientific evidence of acute and long-term public health risks from contaminants commonly found in cannabis. The list of contaminants to include within this scientific review and consider for recommendation should include, but not be limited to:

- Microbiological contaminants, including Shiga-toxin producing Escherichia coli and Salmonella
- Yeast and molds, including *Aspergillus fumigatus, A. flavus, and A. niger*
- Heavy metals, including lead, arsenic, cadmium, and mercury
- Residual solvents, including butane, propane, heptane, isopropyl alcohol, ethanol, propane, pentane, and other trace chemicals found in extraction solvents
- Mycotoxins, including aflatoxin and ochratoxin
- Pesticides commonly used in cannabis cultivation
- Water activity
- Moisture content
- Cultivation additives
- Packaging and other plastic container residues

# RECOMMENDATION #10

## REQUIRED POTENCY AND ACTIVE INGREDIENT TESTING

Raw cannabis and manufactured cannabis products are used medicinally and recreationally because they contain biologically active cannabinoids and terpenes, only some of which are psychoactive. The most common and well known of these cannabinoids is delta-9-tetrahydrocannabinol, often referred to as "THC," which causes the primary psychoactive effects associated with cannabis consumption. Although there have been no scientifically reported overdose deaths directly related to cannabis consumption or THC, overconsumption can cause acute anxiety, paranoia, drowsiness, and general discomfort. In addition, THC can cause difficulty with multi-tasking and is considered to impair cognitive functioning while an individual is under its influence. These potentially adverse reactions create legitimate public health concerns about the consumption of THC while operating a motor vehicle and the potential dangers caused by over-consumption of cannabis generally. Therefore, it is vital for states to ensure that cannabis products are accurately dosed and labeled to protect public safety.

Although THC is the most common and well-studied cannabinoid, it is just one of dozens of different active chemical constituents in the cannabis plant. Cannabinoids, terpenes, and other molecules can all have pharmacological effects and act synergistically in the body to produce what is known as the "entourage effect." Rather than a single component, many scientists believe that the combination and levels of concentration of different cannabinoids and terpenes modulate the therapeutic benefits for patients suffering from conditions ranging from chronic pain to multiple sclerosis to epilepsy. This entourage effect is a critical factor to consider when creating potency testing requirements, though it must also be recognized that the science about the particular impacts associated with different cannabinoids and terpenes is not fully understood.

All state cannabis testing programs require cannabis and cannabis products to be tested for potency, which means identifying the presence and level of concentration of specifically identified cannabinoids and terpenes. Most states, at a minimum, require the testing and labeling of total THC and cannabidiol ("CBD").[3] The inclusion of CBD is notable because it is the second most researched cannabinoid, is non-psychoactive, and has been shown to have therapeutic benefits treating certain types of epileptic disorders. Certain states, such as Alaska, Connecticut, and Maryland, seek to identify a wider array of active constituents and require testing for the cannabinoids cannabinol ("CBN") and cannabigerol ("CBG"), as well as terpenes commonly found in the cannabis plant. Currently, there are available reference standards for about fourteen different cannabinoids, which are required to accurately determine the chemical concentration within a sample. Requiring testing for every cannabinoid and terpene for which an analytical reference standard is available, however, could increase costs significantly and provide most consumers with little benefit. Our understanding of the pharmacology of many of these cannabinoids and terpenes is limited and they frequently

3. **Total THC or Total CBD refers to the combined potency of the primary cannabinoid as well as its acidic precursor THCA and CBDA, which turns to THC or CBD when heated.**

**RECOMMENDATION #10** | CONTINUED |

exist only in trace amounts for most cannabis products. Instead, state-mandated cannabis potency testing requirements should focus on protecting public health by analyzing psychoactive THC levels and ensuring accurate testing and labeling of all other *marketed* cannabinoids and terpenes.

Similar to contaminant testing, the frequency of required potency testing for cannabinoids, terpenes, and other active ingredients should be established in regulation based on formal recommendations from CLAC and the state Department of Health. In addition, CLAC should study risks of terpene sensitivities at high doses to determine whether additional testing or warning labels are needed. The selected compounds for potency testing should be based on the best available scientific evidence regarding the psychoactive and non-psychoactive properties of cannabinoids and other compounds commonly found in cannabis, while balancing industry efficiency and the public's understanding of these compounds. Required potency testing ***can*** include testing for: any cannabinoids, terpenoids, and other compounds in which reference standards are readily available. Potency testing ***must*** include the concentration of maximum[4] delta-9-tetrahydrocannabinol (THC)[5] and all other marketed cannabinoids and terpenes. CLAC may wish to consider establishing separate requirements for potency testing between cannabis products sold for medical or adult-use purposes. Finally, all tested cannabinoids and terpenes with concentrations greater than or equal to 0.5% by weight must be displayed on the product label.

# RECOMMENDATION #11

## WHERE TO TEST ALONG THE SUPPLY CHAIN

After identifying which products need to be tested, what they need to be tested for, and how frequently testing should occur, policy makers must then determine where along the supply chain cannabis products should be tested. Many current cannabis testing programs require that cannabis products be tested multiple times prior to sale, providing very little value to customers and improvements in public health outcomes. For example, certain states would require that an edible cannabis product be tested three separate times by a third-party for potency during the production process – the raw cannabis plant material, the cannabis concentrate infused into the product, and finally the product itself. Only the potency of the final edible product is relevant to a consumer and public health. Although there may be business reasons to test the inputs for potency, there are not substantial public safety risks to justify government mandated third-party testing.

Frequently, policy makers have assumed that "over-testing" is harmless and only creates negative impacts on a cannabis business's bottom line. This assumption is false. There is a finite amount of time, capital, and labor resources any business has that can be allocated toward different business and regulatory activities. Every minute that a business spends complying with an unnecessary testing mandate is a minute not invested into other compliance activities. Legal cannabis businesses across the country are still competing with black market actors who are not subject to mandatory testing requirements or any other compliance costs. Therefore, "over-testing" is not just a harmless policy that only impacts an owner's bottom line; it actually damages public safety by shifting resources away from compliance initiatives that protect public safety and increasing the competitiveness of black market actors.

Policy makers can improve public safety by increasing the efficiency of cannabis testing and eliminating duplicative testing. Instead of current inefficient testing policies, states should only mandate independent third-party laboratory testing for cannabis products in their final form, prior to transfer to a retail store or delivered to a customer. Intermediate cannabis products intended for further manufacturing that will not be sold to consumers without further processing should be exempt from mandatory testing requirements. Testing at the final stage guarantees that the products tested are representative of the products consumers will purchase, while leaving testing farther up the supply chain for businesses to decide on their own. Many responsible businesses will still conduct potency and contaminant testing of intermediate products; however, such testing can be conducted internally at a lower cost and faster turnaround time. This will allow businesses, and in particular smaller operators, to efficiently allocate resources while ensuring that the state can fulfill its obligation to protect public health and safety by requiring contaminant and potency analyses prior to sale.

4. We recommend the use of the term "maximum" rather than "total" THC as it is more scientifically accurate. Not all THCA will decarboxylate and turn into THC when heated. As such, the THCA conversion ratio used to provide a consumer-friendly label for THC quantity will represent the maximum THC available in the product not the total quantity a consumer is likely experience.
5. The concentration of THC and other compounds should be expressed as a percentage by weight for raw flower and concentrates but expressed as a number of milligrams for infused-products.

## RECOMMENDATION #12

# CANNABIS LABORATORY ACCREDITATION

States require cannabis and cannabis products to be tested for potency and contaminants to protect the health and safety of cannabis consumers. This mandatory testing is only an effective guard against public health hazards if the analyses performed are accurate and consistent, which requires that laboratory operations conform with the best available science, employ validated methods, and are closely scrutinized. Therefore, it is not sufficient to simply license a testing laboratory. States must also ensure that these labs are certified to competently preform the required tests. The state can confirm compliance with these high standards by requiring that cannabis laboratories be audited by certified third-party entities that review all types of laboratories for quality and hold cannabis testing facilities to the same internationally recognized standards as many other testing and calibration laboratories.

ISO/IEC section 17025 established "general requirements for the competence of testing and calibration laboratories" and is recognized as the gold standard for testing laboratory accreditation across all industries. Only a couple of states require cannabis laboratories to be "ISO accredited" today, while the majority of states allow cannabis laboratories to operate under less stringent accreditation standards. Cannabis laboratories should be held to the most likely regulatory expectations after federal legalization, which are the internationally recognized standards set in other industries, ISO/IEC 17025. ISO/IEC 17025 accreditation, however, should not be imposed on testing facilities as a condition of licensure because accreditation requires laboratories to use cannabis samples to develop their methods[6] and procedures, which would not be possible without a state license to possess, store, and test cannabis samples.

Instead, state-licensed cannabis testing facilities should be able to accept samples, test methods, and run analytical tests for cannabis customers on a voluntary basis while working through the accreditation process. But for state-mandated testing, regulation should require that all testing laboratory analyses used to satisfy requirements for commercial release be accredited to ISO/IEC 17025 standards. Until there are a sufficient number of accredited cannabis laboratory facilities for required testing analyses to begin, CLAC should provide recommendations for required disclaimer language when labeling untested products or products tested by an unaccredited laboratory and provide notice to cannabis businesses when testing for different active ingredients or contaminants becomes mandatory. Even after these requirements come into full effect, a state-licensed testing facility that is not ISO/IEC 17025 accredited should be permitted to continue to possess, store, and test cannabis samples, but those analytical evaluations would not count towards a licensed cannabis business's regulatorily mandated tests for commercial release.

ISO/IEC 17025 accreditation takes into account a very wide array of testing processes and procedures ranging from sampling to certificates of analyses and submission of final data reports. The standards established do not specify certain procedures a laboratory must follow or equipment it must purchase. Therefore, the ISO/IEC 17025 standard is applicable for all laboratories regardless of size, scope, or method of testing, which is critical here because many cannabis testing facilities are smaller and less capitalized than testing facilities in other industries. Furthermore, this accreditation is not a binary accreditation for all lab operations and is flexible enough to review each testing method and procedure individually. Laboratories are able to define the scope of their accreditation with the third-party certifying body and have each analysis and method accredited as they are ready. This piecemeal process of accreditation allows a cannabis laboratory to start small and only offer cannabis screening for the types of analyses it has the technical competency and equipment to conduct. Although a testing laboratory may only be accredited for a certain set of required analyses, the laboratory should be permitted to run any type of analytical test it desires in order to validate new methods. Cannabis laboratories must be able to test in whatever way they choose, but only analyses included on the facility's scope of accreditation should count towards state-mandated testing requirements for commercial sales.

ISO/IEC 17025 is flexible enough to evaluate competency for standardized test methods, non-standard test methods, and laboratory-developed test methods. The standard balances the need for laboratories to use best practices by requiring the use of a recognized methodology within a year of its publication but permitting internal method validation when one is not yet available or published for the requisite period. This is essential for cannabis testing laboratories because existing standardized test methods are not currently available. In these circumstances, internally developed methods for cannabis testing and the associated validation studies undergo review by ISO/IEC 17025 auditors during the accreditation process to ensure the laboratory is competent to perform the test and their analyses methods are accurate and consistent. Finally, ISO/IEC 17025 contains many requirements that may run parallel with recommendations established in this paper or requirements set by CLAC. As part of its role in establishing testing policy, CLAC must closely review ISO/IEC 17025 to minimize potential conflicts and provide direction to licensees when requirements diverge.

6. Developing internal methods will be necessary until such time that compendial voluntary consensus methods are available.

## RECOMMENDATION #13

# LABORATORY DIRECTOR EDUCATIONAL AND EXPERIENCE REQUIREMENTS

States across the country establish educational requirements for laboratory directors, and sometimes managers and employees, as a way to further bolster the credibility of state cannabis testing programs. These requirements detail the required university degree and corresponding levels of experience needed to be hired for the position and often strike a balance between practical laboratory work and educational credentials. For instance, California's recently adopted medical and adult-use cannabis program regulations require a laboratory supervisor or management employee to have earned either:

- A doctoral degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university;
- A master's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least two years of full-time practical experience; or
- A bachelor's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least four years of full-time practical experience

This ability to substitute higher education requirements for longer periods of full-time practical laboratory experience recognizes that educational attainment and practical work experience can sufficiently demonstrate competency. While this is true in any field, it is particularly important for cannabis because advances in the field have largely developed outside of traditional academia.

We recommend that policy makers follow the lead of California by creating the same type of tiered education and experience requirements for laboratory directors. All required education should be in relevant scientific fields and full-time practical experience should be in a similar style testing or calibration laboratory facility and have occurred after the individual completed their initial degree. A cannabis testing laboratory should be required to continually have a laboratory director who meets these requirements. If a testing facility laboratory director is fired or otherwise terminates his or her employment, the laboratory should not be permitted to test cannabis products for commercial release until they have hired a new laboratory director or have promoted a qualified employee.

Some other states extend these education and experience requirements further for lower-level analysts and even entry-level laboratory technicians. Although these proposals are well-meaning and designed to ensure all employees are competent, they improperly erect employment barriers for aspiring scientists who need to gain practical laboratory experience for higher-level work. Standard laboratory protocols and ISO/IEC 17025 require a laboratory to ensure competency of each of their employees in the proper techniques and testing methods. The standard requires laboratory management to ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. It even sets forth requirements for supervising staff who are undergoing training. Instead of creating new standards in regulation, policy makers should simply reference ISO/IEC 17025.

## RECOMMENDATION #14

# CANNABIS PRODUCT RETESTING AND REMEDIATION

Given the potential costs associated with the destruction of a batch of cannabis, licensees should be afforded the opportunity to remediate, decontaminate, and retest failed product. Testing laboratories strive for complete accuracy but are never perfect. Mistakes happen, and it is possible that a sample could test positive for contaminants when none are present. Even if the failed test was accurate, a variety of methods have been developed that can remove contaminants without rendering the product unsaleable. In such circumstances, product would have to be retested prior to release into the stream of commerce. Therefore, regulators should authorize retesting and remediation by establishing requirements for licensees to follow.

Rather than believing their facility is culpable for producing a product that does not pass required testing, cannabis cultivators and product manufacturers sometimes blame a failed test on the laboratories results,. This perspective could corrode confidence in the regulated system without an opportunity to retest. When a laboratory can confirm its result or correct a mistake, stakeholders will gain confidence in the system and cannabis products will be safer.

Additionally, there are a variety of remediation, decontamination, and reformulation methods that can be used to treat cannabis that has failed initial contaminant or potency testing. For example, contaminated cannabis can be placed into a CO2 extraction

**RECOMMENDATION #14** | CONTINUED |

system and the process will kill certain microbial contamination, resulting in a concentrate that can pass contaminant testing. There are other methods to address contamination that are readily used in other industries, such as pasteurization and concentrated ozone. Producers should be offered the opportunity to leverage these options, provided the resulting product can pass required contaminant and potency tests.

CLAC should develop official policy governing a licensee's ability to retest. This would include a determination of the types of failed tests that a licensee is permitted to retest. Different failed contaminant or potency tests pose varying risks to public health and safety. For example, re-sampling and retesting requirements would be different for a batch that failed homogeneity testing than a batch that failed for Shiga-toxin producing *Escherichia coli*. Additionally, policy must establish the number of retests that must be conducted, requirements for use of different laboratories, and re-sampling a quarantined batch for additional testing. While some states have adopted blanket regulations for retesting, the nuanced safety risks of different types of contamination must be considered and a more narrowly tailored approach should be considered by regulators. If established by CLAC in official policy rather than in regulation, retesting can provide for differentiated processes that effectively protect public health and safety while maximizing business flexibility. As new science develops on the safety of different levels of contamination, CLAC official policy can quickly change to accommodate.

Similar to retesting, batch remediation procedures should differ depending on the product form as well as the source and type of initial contamination or testing failure. Simple molds and yeasts can be remediated using a solvent-based extraction process, but that same process could potentially concentrate other contaminants such as pesticides or heavy metals. The microbiological contaminant could leave behind toxic remnants that survive the remediation process, such as mycotoxins, that must be included in the retesting to ensure the resulting product is safe for human consumption. CLAC should develop official policy detailing: the types of testing failures that can be remediated; unacceptable forms of remediation; sampling and testing procedures for remediated product; and the frequency of permitted remediation. This policy must be flexible enough to allow for innovation while still ensuring that remediation or reformulation is performed safely. Once remediated, the new batch must be re-sampled and undergo retesting for all required analyses. Like retesting, policy for remediation is best handled by CLAC official policy rather than regulation, as this area of science is rapidly advancing and processes for product remediation are outside the scope of experience for most regulators. Changes to remediation policy should not significantly impact the financial wellbeing of licensees.

# RECOMMENDATION #15

## SAMPLE AND RECORDS RETENTION REQUIREMENTS

State cannabis testing programs often require laboratories to retain an untested portion of a sample for a specific period of time in case retesting is required to protect public health or to provide evidence during a recall. Each state differs in the way that samples and records must be retained. In many states, regulation requires samples to be retained for weeks or months but do not prescribe the method for retention. If a sample of cannabis is retained in a manner that does not prevent potency degradation or the growth of mold and other contaminants, then the retained cannabis is no longer representative of the initial batch. Traditional sample retention in a refrigerated environment, however, can be prohibitively expensive for a cannabis testing facility, requires significant dedicated facility space, and poses increased security risks. Therefore, the retention of cannabis samples beyond the time necessary to conduct contaminant or active-ingredient analyses should not be required by the state. A cannabis testing laboratory should be permitted to retain samples as it deems necessary, but at this time there is insufficient evidence to necessitate a period of sample retention in regulation or law. Instead, CLAC should study the issue of cannabis sample degradation and the risks of a product recall, to provide recommendations to regulators on any changes that may be needed to sample retention requirements.

Electronic records of all cannabis tests performed are much easier to retain than physical samples. Therefore, regulation should require laboratories to maintain records of all tests for at least five years to ensure that state investigators can determine the potential source of contamination during a recall and evaluate historical compliance with testing requirements.

Such records should at a minimum include:

- The name of the individual or business that requested the testing;
- The date of the order and date of the testing;
- The type of product tested, including the size and type of sample received;
- The analyses included;
- The results of testing;
- Whether the sample passed or failed state-requirements;
- Any follow up retesting or remediation; and
- Further correspondence with the customer or state officials regarding the results of analyses

## RECOMMENDATION #16

# TESTING OF CANNABIS FROM NON-LICENSED ENTITIES

When states establish medical and adult-use cannabis markets, they typically also remove criminal penalties for individual cultivation, possession, and transfer. These personal rights are vital for consumers and patients who want to grow their own medicine or share homemade infused products with friends. Despite these enshrined individual rights, state law and regulation often restrict certified testing to only those products produced and transferred by a licensed cannabis business. These laws hinder public health and safety by creating barriers for individuals who want to evaluate the potency and safety profiles of their own plants and products before legally sharing their harvest. They also prohibit journalists from investigating potentially false potency claims or the sale of contaminated products, removing a critical public safety function performed by "the fourth estate."

State-licensed cannabis testing laboratories should be permitted to accept samples from individuals, patients, home-cultivators, hemp farmers, journalists, public health advocates, and any other person legally able to possess and transfer cannabis samples. All sample transfers from non-licensed entities must be limited in weight so that the testing facility does not accept more cannabis than the individual is legally able to possess. In the case of a private individual requesting testing, the samples would be provided by the customer rather than an independent sampler and the results would be provided to the individual for their own personal information.

States that restrict testing facilities from accepting samples from outside of the state seed-to-sale tracking system generally do so for reasons of "product accountability."[7] Additionally, regulators have asserted their desire to prevent illegal actors from gaining the benefits of a commercial system by touting their black-market product as tested by a state-licensed and accredited laboratory. Regulators try to keep federal officials at bay and separate legal from illegal by circumscribing the licensed system within a tight box in which cannabis produced outside that system cannot enter. But cannabis samples that are transferred to a testing laboratory are either used during the testing process or destroyed. An individual that provides cannabis to a state-licensed laboratory will only receive information in return. Any potential benefits criminal actors may gain from testing illegally produced cannabis are overwhelmingly outweighed by the public health gains from having legally produced home-cultivated cannabis and homemade products assessed by a certified laboratory.

Furthermore, these restrictions unnecessarily reduce the revenue potential for certified cannabis testing laboratories. Cannabis testing is an expensive endeavor with high capital requirements and laboratories are only profitably operated when there is enough demand for their services. Allowing licensed testing facilities to evaluate samples from all individuals legally able to possess cannabis will bolster the testing market without increasing costs for commercial growers or products manufacturers. Finally, extending testing to consumer advocates, journalists, and public health researchers who purchase products from retail stores and then submit them for analysis will add an additional check and balance to the commercial regulatory system and ensure that all cannabis products produced and consumed are safe.

7. https://www.denverpost.com/2014/05/02/marijuana-testing-labs-barred-from-taking-samples-from-individuals/

## PROVIDING FEEDBACK

# THANK YOU FOR YOUR INTEREST IN THE RECOMMENDATIONS CONTAINED IN THIS DOCUMENT

As you know from our Acknowledgements section, we have endeavored to solicit significant input from testing experts and individuals experienced in the cannabis industry in order to produce these recommendations. That said, we fully expect that there are ideas we may have left out. It is also possible (or likely?) that some readers may disagree with the recommendations themselves. We therefore welcome feedback from you or your colleagues. That feedback can be sent to **PCtesting@thecannabisindustry.org**. Please understand that we probably will not be able to provide a thorough response to every email we receive, but know that it will be reviewed and given serious consideration for future writing and advocacy efforts.