For the record, Dan Steele

CCB:

I understand current policy is a combination of multiple agencies handing the torch over, and I think it's important to continue to develop policy that is easy to interpret, reduces diversion opportunities, and allows the local public opportunities.

As an example I think it's important to fix the home cultivation laws.
Which are:
Adults over 21 may cultivate up to 6 plants as long as they live more than 25 miles from a dispensary, with homeowners approval. Medical patients may cultivate up to 12 plants as long as they live more than 25 miles from a dispensary or they're cultivating a strain that's not available at the dispensary, with home owners approval. Cultivation cant be within x distance from a school.

So for rec cultivation,"25 miles from a dispensary". Well this suggests that home cultivation is not an issue of public safety, but it's perceived as a problem by an industry.. This policy just criminalizes local communities over rights that Nevadans have. Some people would love to follow the rules as they should exist (see below), instead they are forced to break the laws to consume clean cannabis. And of course, as always, being kicked out of their homes because industry moved to a town near you. That's what growing means to people, they will move out of town, or out of state to grow their own unharassed.

For medical, "cultivating a strain that's not available at the dispensary". Well that just doesn't work, because the cultivators get their plants from medical patients, by regulation. So the dispensaries would have a strain gotten from a medical patient, so the medical patient can't grow now because they gave a strain to a facility for it to operate… Licensed medical patients trying to follow the laws is more than the industry is doing. And if there are any medical growers still alive in Nevada, they deserve better.

There is also a part in cultivation policy where you can't be within X miles from a school, I think that could be cleaned up to differentiate outdoor being not good to have around school children, and undetectable indoor cultivation not being an issue.

To me it should read.
Cultivation allowed with homeowner approval,
per residence: 6 plants rec (21+), 12 plants medical.
Outdoor can't be x distance from a school.
Homeowners are allowed to possess their yields from their respective plant counts within their homes.
And then you would develop some fines for people being caught going over their plant counts.
Allowing the public to make concentrates for personal use at home, should be legal too. As long as it's not BHO.

COOPER LEVENSON
ATTORNEYS AT LAW

3016 W. Charleston Blvd., Suite 195
Las Vegas, NV 89102
Phone (702) 366-1125
Toll Free (800) 529-3161
Fax (702) 366-1857
www.cooperlevenson.com

Direct Phone: (702) 832-1900
Direct Fax: (702) 832-1901

KIMBERLY MAXSON-RUSHTON
EMAIL: krushton@cooperlevenson.com

September 17, 2024

Adriana Guzman Fralick, Chair
Nevada Cannabis Compliance Board
700 E. Warm Springs Rd., Suite 100
Las Vegas, Nevada 89119

Re: GTI – Petition Requesting Adoption / Amendment to CCB Regulations 1, 6, & 11

Dear Chair Guzman Fralick and Cannabis Compliance Board Members:

On behalf of Citizens Public Safety Alliance ("CPSA"), please allow this correspondence to serve as a formal request, pursuant to Nevada Cannabis Compliance Regulation ("NCCR") 4.145, to dismiss the above referenced Petition filed by Green Thump Industries ("GTI") on or about August 7, 2024. Succinctly stated, the Petition is not ripe for consideration by the Cannabis Compliance Board ("CCB") as the statutory deadline for agency action / adoption of regulations has passed. *See*, Nevada Revised Statutes ("NRS") 233B.063. Furthermore, the Petition, as presented, does not merit consideration and action as either an emergency or temporary regulation as defined by NRS 233B.033 and NRS 233B.0385 respectively.

Pursuant to multiple provisions contained in Nevada's Administrative Procedures Act, NRS 233B, non-exempt administrative agencies may not adopt / amend regulations between July 1 of an even year and July 1 of an odd year. Thus, consistent with the clear Legislative directive, regulatory workshops and actions are limited to either emergency regulations or temporary regulations. *See*, NRS 233B.063. Additionally, the Petition does not meet the statutory standards specific to an emergency regulation; nor does it present such a pressing issue that it warrants consideration as a temporary regulation, which would otherwise require the CCB to revisit this matter *again* before November 2025. *See*, NRS 233B.0613 (**Emergency Regulations**) and NRS 233B.0633 (**Temporary Regulations**).

As the CCB records reflect, this Petition, in one form or another, has previously been presented to the CCB with little to no support from Staff or other members of the cannabis industry. For this specific reason the matter has never elevated to a regulatory workshop and should not now.

In addition to the legislative timing factor noted above, equally important to the CCB's consideration of whether to proceed with a regulatory workshop on this Petition, is the direct impact it will have on the cannabis industry. Specifically, the material changes that licenses will be required to make to

their operating standards, coupled with the significant financial impact it will have on small businesses, such as Nevada's cannabis testing labs.

For the reasons set forth herein, CPSA respectfully request that GTI's Petition be denied.

Sincerely,

/s/ Kimberly Maxson-Rushton

Kimberly Maxson-Rushton, Esq.

NEVADA CANNABIS ASSOCIATION

September 18, 2024

Cannabis Compliance Board
700 Warm Springs Road, Suite 100
Las Vegas, NV 89119
Via email to: CCBMeetings@ccb.nv.gov

Subject: Hearing on Petition Submitted by Silver State Government Affairs

Dear Cannabis Compliance Board Members and Director Humm,

On behalf of the members of the Nevada Cannabis Association, we are submitting this comment in advance of the Board meeting on September 19, 2024.

We are writing in support of the petition submitted by Silver State Government Affairs (SSGA) on behalf of Green Thumb Industries (GTI). The petition raises a handful of issues for consideration, some of which have been workshopped previously, but most of which have not been presented to the Board.

The issue of lot sizes is worth exploring, as Nevada's maximum lot size of five pounds for flower makes it an outlier among states. On behalf of the NCA, earlier this year we retained experts GMP Collective to conduct a review and analysis of literature, standards, and regulations related to lot/batch sides and sampling protocols, and to make recommendations. That report contained the following core findings:

- National trends and the development of voluntary standards have moved away from the five-pound testing limit, which Nevada adopted 10 years ago. Among the 38 states with legalized cannabis marketplaces, an overwhelming 92% permit lot/batch sizes exceeding five pounds, with 13 states imposing no maximum limitations at all.
- ASTM International's Committee D37 on Cannabis published a Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches (ASTM D8334/D8334M-20), describing a scalable and composite sampling methodology. This standard recommends increasing the number of containers sampled and the sample increments for larger lot/batch sizes, providing guidelines for lots/batches up to 1102.7 pounds, thereby ensuring representativeness and accuracy in laboratory analyses of larger sized lots.
- The most effective means for protecting public health is to implement market-relevant, accredited standards and best practices, such as Quality Management Systems and Good Manufacturing Practices (GMPs), rather than restricting batch sizes at the lab testing stage. Nevada's current regulations of cannabis products already reflect many of these practices.

We also wanted to support the petitioner's request that the Board consider revising the definition of a production run to not include a specific amount of concentrated cannabis, but instead indicate the test can be done on a single run regardless of the quantity of concentrated cannabis produced. There is no need for a limit, and removing the limit would significantly lower the cost to produce a finished product.

Further, we support petitioner's request to require that only the end product be tested. If the rationale for testing is to protect public safety, then only the final consumer-ready product should require testing.

Finally, we support petitioner's request that the Board review aspergillus testing requirements. The Board should consider either setting a maximum amount allowable for the existence of aspergillus (which exists in the air) and/or require a warning. The current pass/fail test for aspergillus is overbroad – even the existence of aspergillus would not mean the product is unsafe for most uses for most people, yet the presence of aspergillus in cannabis requires an entire lot to fail testing.

We appreciate that the CCB extends the opportunity to stakeholders to file petitions requesting regulatory changes, and we are grateful for the Board and CCB staff's thoughtful consideration of the issues raised in SSGA's petition.

Respectfully,

Layke A. Martin, Esq.
Executive Director
Nevada Cannabis Association

2580 SORREL STREET
LAS VEGAS, NV 89146

JENNINGS & FULTON
LAW FIRM

TELEPHONE
(702) 979-3565
TELECOPIER
(702) 362-2060

September 13, 2024

Sent Via Email

Cannabis Compliance Board
700 East Warm Springs Road, Suite 100
Las Vegas, NV 89119
CCBmeetings@ccb.nv.gov

Re: Opposition to Green Thumb Industries ("GTI") August 7, 2024, Petition related to cannabis laboratory regulation changes.

Dear Chair Guzman Fralick and Members of the Cannabis Compliance Board,

Please accept this correspondence as an objection to GTI's August 7, 2024, Petition related to cannabis laboratory regulation changes on behalf of all but one of all cannabis laboratories here in the State of Nevada. Most of the information presented herein, and in the attached documents, has previously been provided to the CCB. But, for the benefit of the new CCB Board Members, who haven't previously had this information presented to them, and to provide the CCB with additional developments, which support maintaining Nevada's current testing and sampling regulations, I submit the following and urge the CCB to deny the petition.

The current petition is very similar to the petition Mr. Adler brought forth in late 2022 wherein I appeared in front of you at that time opposing the same. Changing the sizes for test sampling requirements has recently been extensively reviewed, discussed, and the topic of multiple workshops in 2023 and 2024. These workshops were the result of the industry working with Staff to update testing regulations. The changes being asked for have been requested previously and after extensive discussion denied. Such changes would not "preserve long-term prosperity of Nevada's cannabis industry" but rather likely result in dramatically worsening the economic conditions for the vast majority of Nevada's cannabis establishments and the public safety as a whole.

The Nevada independent cannabis testing laboratories desire to provide accurate testing results to ensure accurate labeling and to keep unsafe product from reaching the consumer. The goal of Nevada's testing program is to safeguard the health of Nevada consumers, which is essential to the long-term prosperity of Nevada's cannabis industry and Nevada's reputation as a safe place for tourist and locals to purchase cannabis.

Mr. Adler states the following in the Petition:

> this petition is primarily focused on streamlining the cannabis testing process. These changes will allow Nevada's cannabis cultivation production facilities to simplify the procedures, reduce the number manual steps, and clarify what gets tested and when. As these changes are designed to streamline operations of positive impact on the operations of Nevada's cultivation and production licenses can be expected….. Cannabis testing laboratories may need to change operations around testing cannabis products and may need to increase sample sizes in conjunction with any change in testing practice.

The proposed changes might reduce some steps while definitely increasing others and would do nothing to "clarify what gets tested and when", since this is already extremely clear and has been in place for a decade, making Nevada's cannabis testing program the **'Gold Standard.'**

The regulations in NCCR 11 were extensively discussed in workshops and in meetings, rewritten in March 2024 and would have to be completely rewritten yet again if the requests in this petition were enacted. To be clear, if the request to change lot sizes were ultimately enacted, Nevada's entire testing regulations would require another complete rewrite. Nevada's current regulations are based on statistics and science. Some other states have increased their lot size testing and are now again decreasing their lot sizes, having learned some lessons from their misadventures and having had to deal with the problems which made national news in California, Michigan, Colorado, and other states.

There are many reasons why these changes should not be made, both science-based reasons related to consumer safety and reasons related to the overall viability and very integrity of the cannabis testing industry.

The statistics and science support maintaining Nevada's "best practices" testing program have been extensively workshop over the last two years, and are supported by hundreds of pages of studies, manuals, government regulations, and reviews. I will attempt to succinctly explain some of the main points, many of which are extracted from documents previously submitted by the laboratories related to this issue.

1. <u>Nevada's Current testing regulations incorporate standards set by other governmental regulatory bodies.</u>

Nevada's cannabis testing regulations incorporate the standards set by many governmental regulatory bodies and standard-setting bodies which mandate certain testing procedures. The CCB has recently reviewed and confirmed these as the standards which the laboratories must follow. Adoption of the petition's requested changes would result in violation of the standards. (See Exhibit #1 Letter dated Sept 21, 2023 and CCB's 2024 final NCCR sections 1, 6, 11 revisions)

The American Herbal Pharmacopoeia sets forth standards for analysis of cannabis using detailed and established methodologies related to the acceptable limits for microbial, fungal, metals and pesticides. The testing for pesticides is discussed in great detail and affirms the testing methodologies as "recommended by the EPA Residue Analytical Methods or those of the Food and Drug Administration (FDA Pesticide Analytical Manual (PAM), should be

employed when appropriate." These findings clearly acknowledge the necessity of testing the plant material prior to any processing.

The American Herbal Pharmacopoeia, when discussing microbial and fungal limits, points out that "limits must also be appropriately applied to the various preparations being made. Typical microbial and fungal limits may not be appropriate for materials that are to be subjected to processing, such as infusing, decocting, or extracting with heat, alcohol, or other processes that introduce a microbial reduction step prior to consumption." Testing of the plant material prior to any processing is standard in the food testing industry wherein organizations, such as the International Commission on Microbiological Specifications for Foods, set standards which require the testing of plant material prior to processing. The FDA's Bacteriological Analytical Manual goes through great lengths in setting out standards for food substance sampling and homogenization strategies to ensure safety in products which are consumed by the public.

Similarly, the FDA's Pesticide Analytical Manual (PAM) serves as a repository of analytical methods used in FDA laboratories to examine food for pesticide residues. Only since the start of the cannabis testing programs, such as Nevada's, have methods been developed and validated to examine cannabis extracts, rich in THC, for pesticide residue. The standard analysis for residual pesticides in products consumed by people begins with analysis of the food matrices. Here, such would involve analyzing the cannabis plant material, as is mandated by the NCCR's.

2. <u>BOTEC Analysis supports current Nevada regulations</u>.

BOTEC Analysis (BOTEC) is a completely independent "think tank" with a 40-year history that assists state, provincial, and national governments around the world develop sound, evidence-based policies for many issues, especially and importantly, including cannabis. Government regulators around the world rely on their research to provide an independent, unimpeachable resource for policy development.

I urge you to please explore their website so you can understand the who and what of BOTEC, and fully appreciate the extensive scope of their worldwide work. The following is from their website:

> There is nothing simple about how government policies affect public health and safety. BOTEC Analysis is a group of researchers, practitioners, and former policymakers who help governments and NGO's deliver public goods to their citizens through the intersection of scholarship and practice. BOTEC forges connections between experienced policymakers and groundbreaking researchers to solve problems of public health and safety. BOTEC combines the capabilities of a consultancy and a think tank, resulting in service that is nimble and responsive but also grounded in evidence and ethical accountability.
>
> BOTEC unlocks the power of academia. We leverage the capacities of scholars at universities, policy institutes, and non-profits to assist government agencies and NGO's with policy problems. But unlike universities and think tanks, BOTEC strips away cumbersome administrative burdens to deliver research products at lower cost.

> BOTEC empowers practitioners to be scholars. Policy problems do not start and end with contract periods. We believe in leaving agencies better than we find them. We train agency staff to engage in empirical research and evaluation, and we give them the tools to continue to evaluate their performance long after we've left.
>
> At BOTEC, Research + Practice = Better Policy

In 2013, BOTEC worked for the I-502 project in Washington state to develop cannabis policies including Sampling Cannabis for Analytical Purposes, (See Exhibit #2 BOTEC 2013 "Sampling Cannabis for Analytical Purposes"). The data in this paper was used when Nevada formulated its initial testing regulations and established the 5 pound lot size.

In 2023, BOTEC revisited the topic and published, Sampling Cannabis for Analytical Purposes: Evidence Review and Best Practices, (See Exhibit #3 BOTEC 2023 Sampling Cannabis for Analytical Purposes). The BOTEC 2023 published review affirms that, despite the evolution of the cannabis industry over the last decade, Nevada's current 5-pound lot size sampling policy is the "best practices" policy. I will not lay out every argument contained therein, but recommend that each board member review this publication.

3. Larger lot sizes jeopardize public safety

Larger lot sizes and production runs danger consumers because they result in less accuracy in the package labeling and statistically are more likely to result in contaminated products making their way to the consumers. (See Exhibit #4 "Larger Lot Size and Production Runs Jeopardize Consumer Safety").

4. Citizens Public Safety Alliance (CPSA) Supports Nevada's current regulations.

In March 2023, the Citizens Public Safety Alliance (CPSA) addressed this issue which states in part:

> While there have been several ill-conceived proposals to dramatically increase the lot size required for sampling, apparently in an effort to benefit large MSO cannabis operations at the expense of smaller Nevada-based cannabis establishments. Such unscientific measures would damage Nevada's carefully constructed, independent cannabis laboratory testing program and should be permanently stopped. The legislature should require that any changes made to the existing testing programs be done only after careful review, extensive discussion and with full consideration of the potential negative effects on the safety of the cannabis products the consumer uses. BOTEC has reviewed Nevada's sampling procedures and lot size. Consistent with their recommendations, we strongly urge that Nevada maintain the 5-pound lot size for sampling and testing in order to protect the consumer and by extension the integrity and survival of Nevada's regulated cannabis program." (Exhibit # 5 CPSA letter)

5. Only testing finished products is a danger to the Public Safety

This petition requests that only the finished products be tested once before reaching the consumer ("testing for cannabis product should be done once the end cannabis product has reached its final form"). There are no scientific papers nor support of this position. This would violate consumer protection standards and norms across almost all industries as established by government and other regulatory bodies. This was detailed in Section 1 above but will be repeated here because of its importance as a widely accepted standard across many, if not all, industries.

The American Herbal Pharmacopoeia sets forth standards for analysis of cannabis using detailed and established methodologies related to the acceptable limits for microbial, fungal, metals and pesticides. The testing for pesticides is discussed in great detail and affirms the testing methodologies as "recommended by the EPA Residue Analytical Methods or those of the Food and Drug Administration (FDA Pesticide Analytical Manual (PAM), should be employed when appropriate." These findings clearly acknowledge the necessity of testing the plant material prior to any processing.

The American Herbal Pharmacopoeia, when discussing microbial and fungal limits, points out that "limits must also be appropriately applied to the various preparations being made. Typical microbial and fungal limits may not be appropriate for materials that are to be subjected to processing, such as infusing, decocting, or extracting with heat, alcohol, or other processes that introduce a microbial reduction step prior to consumption." Testing of the plant material prior to any processing is standard in the food testing industry wherein organizations, such as the International Commission on Microbiological Specifications for Foods, set standards which require the testing of plant material prior to processing. The FDA's Bacteriological Analytical Manual goes through great lengths in setting out standards for food substance sampling and homogenization strategies to ensure safety in products which are consumed by the public.

Similarly, the FDA's Pesticide Analytical Manual (PAM) serves as a repository of analytical methods used in FDA laboratories to examine food for pesticide residues. Only since the start of the cannabis testing programs, such as Nevada's, have methods been developed and validated to examine cannabis extracts, rich in THC, for pesticide residue. The standard analysis for residual pesticides in products consumed by people begins with analysis of the food matrices. Here, such would involve analyzing the cannabis plant material, as is mandated by the NCCR's.

6. Aspergillus Testing.

The petition also wishes to introduce an "experimental pilot program" related to Aspergillus testing. One can only assume this stems from a desire to remove Aspergillus testing of cannabis products. There is ample evidence that Aspergillus testing of cannabis is warranted to safeguard consumer well-being.

While Aspergillus is a ubiquitous fungal species complex found throughout the environment, Nevada state regulations only require testing for certain species that are known to cause human disease.

The petition again requests a review of Aspergillus testing. It implies that a positive (failing) Aspergillus test followed by a passing (negative for Aspergillus) retest of the same (5#) lot somehow should result in the first 'positive' test being labeled as a 'false positive' result. This is very unlikely.

A simple way to think about it is: The cannabis lot being tested is very heterogeneous. If there is Aspergillus contamination present in a lot it will likely not be present in every sample that is sampled from that lot, but if the sample taken from the lot tested positive, Aspergillus is very likely present in the lot. A sample could be taken from the lot that might be negative, even if the Aspergillus was present elsewhere in the lot. The sampling and testing of the lot is more likely to have a 'false negative' result than to have a 'false positive' result assuming the lab's testing is performed accurate, simply because of sampling statistics.

In summary, testing is more likely to have a false negative result than a false positive result. If there is a positive result, resampling the product from another location, even if the result is negative, doesn't mean the positive result was incorrect. A positive Aspergillus test should result in the product failing and not making its way to the consumer.

7. Larger lot sizes increase the probability of collusion and economically harm the industry.

The creation of larger lot sizes and production runs would create massive incentives for collusion between laboratories and their clients (cultivation and production establishments). The NCCRs, the ISO/IEC 17025:2017 standards, and the CCB all recognize such risks and require cannabis laboratories to maintain impartiality during testing.

The CCB is well aware of the collusion (lab shopping) that can occur between laboratories and the cultivators and producers for which they providing testing services. Increasing the lot size and production run would create even more massive incentives to never "fail" product being tested. A test "failure" would be so prohibitively expensive that only the largest most well-funded cultivators and producers would be able to tolerate it financially. (See Exhibit # 6 SCS November 10, 2022, Letter)

For many reasons, larger lot sizes work dramatically to the advantage of the largest cannabis companies. Large growers are more able to take advantage of large lot sizes which disadvantages growers who don't produce enough cannabis to make a large number of large lots. Additionally, large multistate operators have the financial resources to deal with failures of larger lot sizes which might be financially devastating to smaller growers. I have spoken to multiple smaller independent cultivators who are in opposition to increasing the lot size.

8. Financial impact.

GTI and Mr. Adler state that, "In speaking with licensees, between 5% and 10% of the final retail cost of cannabis can be traced back to laboratory testing expenses." While laboratories are unable to ascertain the veracity of this statement what they are willing to equivocal state is that the income laboratories receive related to their testing is certainly NOT "5% to 10% of the final retail cost of cannabis". The Nevada Department of Taxation-cannabis tax revenue for

the "Fiscal Year to Date- FY-24" through June 2024 show a taxable sales reported by adult use retail stores and medical dispensaries in the amount of $829,225,193. Any implication that laboratory testing costs account for $41.5 to $82.9 million dollars is erroneous.

The breaking down of harvests into smaller units which ultimately are sold would, to a large degree, be required regardless of the size of the testing lot. Only the cultivators and producers or the CCB can determine what proportion of the overall costs that the cultivators and producers incur is related to actual 'laboratory testing fees' and what percentage "can be traced back to laboratory testing expenses". The independent cannabis testing laboratories in Nevada operate on razor thin margins and are suffering the same financial problems as other cannabis establishments. If the 'size of the lots' and 'production runs' on which laboratories are required to perform tests, before these products can be sold to the consumer's, increase to 10# or 15# lot sizes, laboratories' revenue will be cut by 50% to 66%, unless the price per test increases by two to three times, all other things being equal. This will likely more than offset any theoretical cost saving associated with increasing the size of lots and production runs.

CONCLUSION

The changes requested by Mr. Adler and GTI would significantly, if not totally, disrupt the independent cannabis testing laboratory system created by the legislature with the second order effect of creating massive instability in Nevada's cannabis industry threatening its very existence. These issues have already been addressed through prior workshops and regulation modifications. To have additional workshops or change to existing regulations is simply not warranted.

Based on the science and the statistics the laboratories do not believe any modifications proposed in the Petition will result in any net savings to the consumer nor to any cannabis establishments. Laboratories believe the petition would endanger the public by making it more likely that contaminated product could reach the consumer.

In the interest of public safety and to protect the ongoing viability of the Nevada cannabis industry, the laboratories respectfully request that the CCB decide today and deny the petition brought forth by Mr. Adler and Silver State Government Relations on behalf of GTI to schedule yet another "public workshop for deliberation and amendment of NCCR's 1, 6, and 11". The regulations governing the independent Cannabis testing laboratories procedures for testing cannabis are based on statistically sound science and have been reviewed and revised multiple times since they were first put in place by the legislature. These regulations have safeguarded the cannabis consumers, locals and tourists alike. They have avoided any serious problem that might have tarnished Nevada's reputation as a safe location for tourists to indulge.

The specific issues related to size of the "lots" and "production runs" being tested have been reviewed, workshops have been held to extensively deliberate and discuss these issues, volumes of data and statistics have been reviewed and the decision has been made repeatedly to uphold Nevada's current "best practices" **Gold Standard** as implemented by the Nevada legislature and maintained and regulated by the Nevada Cannabis Compliance Board.

Based on the foregoing, I urge the CCB to deny the petition today.

Sincerely,

Adam Fulton

Adam R. Fulton, Esq.

Exhibits:

1. Letter dated Sept 21, 2023 and CCB's 2024 final NCCR sections 1, 6, 11 revisions.
2. BOTEC 2013 "Sampling Cannabis for Analytical Purposes."
3. BOTEC 2023 Sampling Cannabis for Analytical Purposes: Evidence Review and Best Practices.
4. Larger Lot Size and Production Runs Jeopardize Consumer Safety.
5. Citizens Public Safety Alliance letter.
6. SCS November 10, 2022 Letter.

2580 SORREL STREET
LAS VEGAS, NV 89146

JENNINGS & FULTON
LAW FIRM

TELEPHONE
(702) 979-3565
TELECOPIER
(702) 362-2060

September 21, 2023

SENT VIA EMAIL

Cannabis Compliance Board
P.O. Box 1948.
Carson City, NV 89701

Dear Nevada Cannabis Compliance Board,

Please accept this correspondence on behalf of every independent cannabis testing laboratory in Nevada: 374 Labs LLC, G3 Labs LLC, LettuceTest LLC, Digi Path Labs Inc., ERP, LLC, NV Cann Labs LLC, Canalysis Nevada, LLC, DB (Kaycha) Labs LLC, MA & Associates LLC (the "Laboratories"). The Laboratories have come together to address the proposed changes to NCCR regulations 5, 7, and 11. The Laboratories have relied upon the following publications in support of the positions outlined herein:

1. Sampling Cannabis for Analytical Purposes: Evidence Review and best practices, BOTEC February 2023.
2. Standard ISO/IEC 17025 published by the International Organization for Standardization.
3 Pesticide Analytical Manual. Volume 1: Multiresidue Methods;
4. Investigating Out-Of-Specification Test Results for Pharmaceutical Production, Guidance for Industry.
5. "Standard Guide for Requirements for Analytical Laboratory Related Professions Within the Cannabis and Hemp Industries" ASTM D8347 21a
6. Standard ISO/IEC 16140-3 "Microbiology of the Food Chain- Method Validation- Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory",
7. Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses1. D8334/D8334M – 20
8. Standard Guide for Analytical Laboratory Operations Supporting the Cannabis Industry D8244 − 20

Further, the Laboratories have reviewed and discussed the proposed changes extensively with their internal staff and lead experts before reaching these conclusions. These experts hold a minimum of the following degrees: 7 PhDs, 7 MS, 2 MDs.

We believe that the primary purpose of the independent cannabis laboratory testing program in Nevada is to safeguard the consumer's well-being by allowing the customer to have accurate information regarding the contents of the cannabis product purchased and to ensure that cannabis products that don't meet the stringent requirements imposed by the state do not make their way into the marketplace.

While we believe that the current regulations dealing with the chemical and microbiological analysis of cannabis products, i.e.. the "testing of cannabis" provides a sufficiently stringent

and robust framework to accomplish this we are open to some of the proposed regulatory changes.

We strongly agree that improvements can be made to strength the ability of Nevada's Independent cannabis laboratory testing program to prevent unsafe and or inaccurately labeled cannabis products for making its way to the consumer. We wholeheartedly believe the best way to achieve these desired results will be to enforce the existing rules.

If laboratories are not following the existing regulations, we believe there is no reason that they will follow any newly imposed rules, some of which will create more ambiguity. Because of this we do not believe that most of the proposed changes will achieve, what we believe are their intended results. We will detail some specifics below.

We wholeheartedly want to work with the CCB to improve the quality and integrity of the independent cannabis testing laboratory program; it is the cornerstone of Nevada's entire cannabis program. We believe that the most efficient and cost-effective way to improve the cannabis testing program and, thereby, improve the overall quality of Nevada's cannabis industry while providing the consumer with accurate information about the cannabis products on the marketplace and safeguarding the consumer's well-being is for the CCB to maintain and enforce the existing regulations. Specifically, we believe that the most cost-effective approach would be implementation, and following through with appropriate action on the results, of NRS 678B.540 and NRS 678B.635. (Attached at end of document).

We believe such action would very rapidly and simply allow the CCB to identify and deal with labs producing anomalous results. To the best of our knowledge the information that results from each of these methods has been utilized at least once by the state in the past and presented the state with actionable information. Those cannabis establishments that choose to "not follow the rules" will not be deterred by additional available testing methods that have undergone validation by more third parties to a list.

Quite frankly, frequently the published method which has been "third-party validated" (e.g. AOAC) is not the most cost-effective, most precise, nor best method. It usually is a method that the developing entity wishes to market either directly or indirectly on its instruments without appropriate consideration of the constraints imposed by the needs to optimize and scale-up production with a multitude of cannabis products."

These methods are often published for "moneymaking" business purposes, not to improve the science. Having reviewed many AOAC approved analytical and microbiological methods we are quite certain that our laboratories have developed some methods of analysis that are more accurate, more efficient, more cost-effective, methods of analysis then validation studies published by "equivalent third-part(ies)".

Having carefully reviewed the proposed regulatory changes, the laboratories wish to make the following comments.

****

Below we have addressed some, but not all, specific issues in the proposed regulations:

5.075 (7) - AGREE. We believe that biennial inspections are sufficient for laboratories, especially if the enforcement described above is implemented.

11.010 - AGREE in principle. Although we respectfully request that the new regulations acknowledge the difficulties and alternatives noted within the document referenced in NCCR 11.010 1. (d). Ambiguity can hopefully be minimized if specific criteria were listed, rather than being 'incorporat(ed) by reference,' in these documents.

This is especially relevant since ASTM D8347 21a: at "4. Summary of guide_4.5 The sourcing of personnel meeting these qualifications may be difficult in an emerging sector. In situations where post-secondary degreed personnel or post-secondary institutions are not available or applicable, the phasing-in of staff is acceptable in the first three years of employment along with sector training or apprenticeship programs reflecting the content of the professional Body of Knowledge ("BoK"). The validation process can occur through proctored exams." recognizes the inherent difficulty in finding appropriately credentialed individuals in this emerging sector in our state.

11.010 4. WORD "IMMEDIATELY" NEEDS CLARIFICATION The term "immediately" in the first sentence needs to be clarified with a time specification such as "within 48 hours" or "within 72 hours." Otherwise, the time frame is subject to different interpretations of tardiness by various board agents.

11.015 – AGREE with the new requirements in the proposed change BUT the deletion of the existing 11.015 creates an error that MUST be corrected.
The existing regulations, which were just amended July 2022, are stricken from these new proposed regulations and replaced with language requiring laboratories to implement an OSHA compliant safety program. While we are not opposed to the OSHA requirement, we do not see where the previous regulations contained within 11.015 - which are essential for laboratories to be able to operate in Nevada - have been included in these proposed regulatory changes.

11.020 – AGREE.

11.025- DISAGREE with these publications as requirements unless specific requirements are delineated.

Specifically, 11.025 proposes to specify various ASTM and AOAC publications as requirements for testing laboratories to adhere to. The CCB should be aware, as are the lab staff who are representatives to the ASTM and AOAC, that these publications are issued as guidelines for standardization rather than requirements to be imposed on independent laboratories. There should be no impositions of guidelines as requirements. The CCB should not expect to find strict compliance to documents intended as guidelines.

We need to point out that 11.025 6. incorporates the Pesticide Analytical Manual of the Food and Drug Administration as a reference source. This then creates a direct conflict with current CCB policy which is more explicitly detailed and is incorporated into this proposed regulatory change at 11.075 4., (see 11.074 for a more detailed discussion). Specifically, 11.025 6. conflicts with the recent CCB AOAC microbial mandate slated to be put into effect on or before March 1, 2024 and at 11.025 6. and 7. creates unnecessary ambiguity if laboratories are still allowed to independently validate methods which would be approved by the CCB before being implemented. We believe the following language would add clarity: Additionally, an independent cannabis testing laboratory may use alternative testing methods that have undergone internal full Single-Laboratory Validation (SLV) in accordance

with the applicable Standards Method Performance (SMPRs) found in AOAC website (AOAC Cannabis SMPRs) or with the requirements of ASTM D8282-19 Standard Practice for Laboratory Test Method Validation and Method Development. The cannabis independent testing laboratory may use an alternative testing method upon demonstrating the validity of the testing method to and receiving the approval of the Board which shall be granted if the testing method fulfills the aforementioned standards.

The current regulation proposal (11.025 6), including the June 12, 2023, amendment from the CCB, mandates cannabis independent testing laboratories to use AOAC certified methods "exactly as specified by the manufacturer IFU", effective March 1, 2024. In addition, "Any deviations from an AOAC PTM method will require a full validation in accordance with the applicable Standard Method Performance Requirements ("SMPRs")". Because of the need to adapt to the cannabis industry demands, testing laboratories must continuously refine existing methods or develop innovative technologies to improving accuracy, speed, data volume thruput, sensitivity, specificity and reducing cost. Therefore, the existing regulation must include options for testing laboratory to develop and validate internal innovative methods through AOAC Standard Method Performance Requirements program, which are, in some respects, more stringent than AOAC the certified Performance Tested Methods. Importantly, such an option would allow testing laboratories to submit internal method validations through AOAC program, allowing unbiased and independent scientific peer review evaluation by qualified subject matter experts.

11.025 (8) We do not understand the purpose of naming and identifying such references. Will the aforementioned references be used to enforce or regulate laboratories? The concern regarding these references is that they can be too general in nature and therefore create ambiguity in the regulations and do not streamline, clarify, reduce or otherwise improve the regulations.

11.030 - DISAGREE, We would need very specific guidance on how to achieve compliance at NCCR 11.030 2, 3 and 4? We currently are uncertain regarding what specific steps and/or actions are required for compliance. We don't believe we are in a position as labs to have that information.

11.045 - DISAGREE We respectfully need very specific guidance on the steps required to achieve compliance. We don't understand how labs are in a position to know this and /or ensure this occurs. NCCR 11.045 (2-7)

At, 2. (a-f) in light of the CCB's seeming intent to place more responsibilities on the lab we would respectfully seek clarification on which parties are specifically responsible for which portions of this regulation.

At 3.a. We seek clarification that this is applicable only and specifically for R & D testing.

At 11.045 6 - DISAGREE. The cannabis independent testing laboratory who performed the limited testing on a lot or production run in accordance with subsection 3 must be the same laboratory who performs the final testing of that lot or production run." Without a requirement on the cannabis establishment to proactively declare whether any prior R&D had been done in the samples how would we :1 -know if any R&D had been done, and 2 -be compliant with this?

11.050 3 - DISAGREE.

Increases the minimal sample size to at least 20 grams.

It seems likely that this originated from "ASTM D8334 Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses 7. Sampling procedure at 7.8, 7.8.1. and as further referenced in 11.070. This ASTM D8334/D8334M-20 standard at 1.2 specifies that "where procedural aspects of this practice differ from local regulatory or jurisdictional requirements the local regulatory or jurisdictional authority directive shall take precedence." In light of Nevada's carefully developed sampling protocol we do not believe such changes are warranted nor will improve the statistical soundness of Nevada's testing program which has regulations that can allow it to be the gold standard for the country. The ASTM D8334/D8334M-20 was primarily developed for large outdoor cannabis grows. It references the 2013 BOTEC cannabis sampling analysis which we discussed below but with regard to selection of the samples from the product to be tested it primarily focuses on large, outdoor, agricultural sampling methodology developed by the Association of American Feed Control Officials and USDA Field Grade Inspection Services (FGIS) as it relates to feed crops and hops. Nevada can rest assured that it's sampling protocol is state-of-the-art as recently analyzed by BOTEC.

In light of this proposed 'minimal sample size weight change' and other proposed sampling changes we would like to make the CCB aware of the thorough and timely (February 2023) BOTEC analysis entitled, **"Sampling Cannabis for Analytical Purposes: Evidence Review and best practices"**. We have attached a cover letter, signed by Jay Matos, from the Citizens Public Safety Alliance which details some important aspects of BOTEC's analysis. It is our understanding that the authors of this paper are willing to explain the importance of their analysis to the CCB. In summary, BOTEC states their 2023 analysis is valid in order to ensure that public health and safety are kept at the forefront while maintaining trust in the regulated cannabis market.

11.050 9 – AGREE with A "time-limited/expiration date" COA may be appropriate.
DISAGREE with the 'valid for 1 year' without further evidence-based analysis.

We believe shelf-life studies would be required and the laboratories are not in a position to provide such services. We would welcome the opportunity to learn more about the CCB's determination for the appropriate duration for such "expiration".

And, there would need to be clarification as to what actions to take after COA expires. Would there be a retest requirement or do the products with expired COAs need to be destroyed. If retesting is required, would the new COA extend the "life" of that product for another year?

11.053 - DISAGREE as written. Can accept some but not all proposed changes, see below discussion and details.

There are many complex issues raised within these proposed changes and to properly explain, discuss, and evaluate some of the very real problems and inevitable errors and inaccuracies that would arise from incorporating the changes as specified a detailed scientific discussion will be required. Laboratory scientists would gladly engage in discussions with CCB scientists to discuss and explain these issues.

Below are several examples of the problems these proposed regulatory changes would create:

11.053 2.(2) (d) ***"One standard for each analyte shall be at or near the State action level,"***, when testing for metals, mercury specifically sticks to glass at high concentrations. If we were going to add a standard that is 400 ppb of mercury, it will require multiple washes at the end of the calibration to rinse it out of the instrument's introductory system in order to prevent carryover and contamination of (false positives) subsequent samples being tested. Testing other analytes utilizing these new proposed requirements would result in many issues, errors and inefficiencies which would severely and adversely impact the quality of the Nevada cannabis testing program.

11.053 (5 A) The requirement of separate lots or sources requires the laboratory to purchase twice the number of standards. This creates a financial impact on the labs. Additionally, most of the vendors the laboratory has approved as vendors, do not currently sell multiple lots. This requires new vendors to be added. Additionally, over the last couple of years with Covid requirements and impacts, shipments of standards have been delayed. Suggest removing or workshopping with the labs.

11.053 (5 C) The range of acceptable QC results specified in this section, without specific methods and linear ranges established, is concerning. For instance, the metals range of +/- 10%, looks to be taken from EPA method 200.8 or 6020B. For environmental samples the CCV is typically in the 20 – 50 ppb range, where for cannabis samples, based on sample prep and dilution, these analytes linear range can be 0-2 ppb for mercury, or 0-5 or 10 ppb for the other analytes. Assigning a fixed range of 10% at these low levels would be overtly stringent. We recommend to utilize the ranges California's regulatory body (BCC) has established at 30% across all analytes, or, if that is not acceptable, a range no tighter than 25% should be implemented.

This streamlines the ranges across all testing assays and allows for greater ranges for lower analytes were uncertainty and lower analytical range will make compliance overtly challenging, while at the same time not producing better analytical data.

The discussion of 11.053 in its entirety:

11.053 Requirements for instrument calibration and quality control
1. A cannabis independent testing laboratory shall ensure that all instruments and equipment used for testing cannabis and cannabis products are:
(a) Set up, tuned, and calibrated according to the laboratory's validated methods and
(b) Applicable for the analytes to be tested
2. A cannabis independent testing laboratory meet the following requirements related to calibration and standards:
(a) A minimum of:
(1) Five standards shall be used for an average response factor or for a linear model ***AGREE***
(2) Six standards shall be used for a quadratic model. ***AGREE***
(b) The calibration curve must not be forced through the origin ***AGREE***
(c) At least one calibration standard shall be at or below the limit of quantitation. ***AGREE***

(d) One standard for each analyte shall be at or near the State action level, where State action levels are applicable**. DISAGREE** ***This will cause problems in the detector such as saturation and carryover issues since some analytes have very high state limits. It will also have a negative effect on the linearity of the curve and accuracy at low levels.***
(e) One calibration standard must be a mid-level standard. **DISAGREE/CLARIFICATION REQUIRED** ***We seek clarification of the definition of 'mid-level'-so long as it is defined, can it be any calibration point in the middle of the curve, or must it be a level with specific concentration between lowest and highest point?***
(f) A minimum of one calibration standard must be between the mid-level standard and highest-level standard ***AGREE***
(g) The correlation coefficient (r) for standard concentration to instrument response is greater than or equal to 0.995 ***AGREE***
3. A cannabis independent testing laboratory may not:
(a) Remove data points from within a calibration range while still retaining the extreme ends of the calibration range ***AGREE***
(b) Use non-linear calibrations to compensate for detector saturation or to avoid proper instrument maintenance ***AGREE***
(c) Apply a calibration fit which was not validated for that method **DISAGREE**
EPA 8000D reference method allows for different calibration models if a calibration curve fails without requiring each curve fit to be validated. A calibration verification standard is analyzed after the calibration which verifies the validity of the curve.

11.5 Calibration models and acceptance criteria

SW-846 chromatographic methods allow the use of three different calibration models: average calibration factor or response factor (Sec. 11.5.1), linear regression (Sec. 11.5.2), and non-linear regression (Sec. 11.5.3). Any of these models can be applied to either external or internal standard calibration data. This section also provides suggested criteria for calibration models; however, method- or project-specific criteria will always supersede general guidance.

Choice of calibration model may begin with the simplest approach, the average calibration factor or response factor model, and then progress through linear and then non-linear regression until the calibration acceptance criteria are met. Another appropriate approach is to choose a calibration model based on previous experience, knowledge of the physics of the detector, or specific manufacturer's recommendations. For the calibration model to be usable, it must be continuous and monotonic throughout the calibration range. More calibration points are required for more complex models. The chromatographic methods in SW-846 employ a minimum of five standards for average response factor or linear (first-order) calibration models, six standards for a quadratic (second-order) model, and seven standards for a cubic (third-order) model.

These calibration models and calculations may be applied to any sort of chromatographic instruments in use, such as, but not limited to: GC, GC/MS, liquid chromatographs (LC), LC/MS or HPLC. They may also be applied to any instruments using various types of detectors, including anything from traditional GC detector types (FID, ELCD, ECD, NPD, diode array, UV, visible light wavelengths, and MSs (whether single, MS/MS, ion trap or time-of-flight).

NOTE: The option of using non-linear calibration may be necessary to address specific instrumental techniques. However, it is not EPA's intent to allow non-linear calibration to compensate for detector saturation or avoid proper instrument maintenance. Regardless of the calibration model chosen, an *X* value of zero should not be included as a calibration point.

4. For test methods using internal standards for calibration, the following requirements must be met. **DISAGREE/*CLARIFICATION REQUIRED*** ***Before putting a requirement for***

internal standards, the state needs to require labs to use internal standard for Mass Spectrometer analysis.

(a) For chromatographic methods, internal standards must:
(1) Have retention times similar to the analytes being tested for; and
(2) Not interfere with any of the analytes; and
(3) Have similar chemical properties as the analytes being tested for

(b) For heavy metals testing, the internal standards must
(1) Be appropriate for the analyte and the instrumental method used; and
(2) Not interfere with any of the analytes

5. A cannabis independent testing laboratory shall implement and adhere to the following quality control (QC) practices:
(a) Initial calibration verification:
(1) Must be prepared from a different source than that from which the initial calibration standards were obtained or from a different lot of standards from the same source
(2) Must be run at the beginning of the analytical sequence
(b) Continuing calibration verification:
(1) Must be prepared from the same source calibration standard used to prepare the calibration curve.
(2) Shall be included in an analytical batch at the following frequency, at Minimum:
(I) After every 20 injections and ***DISAGREE – it <u>"every 20 samples";' injections' will include rinses in the 20 count.</u>***
(II) At the end of the analytical sequence. ***AGREE***
(c) The following acceptance criteria shall not be exceeded for any quality control samples in an analytical batch, including calibration verification samples ***AGREE-****(1,2,3,5)* ***DISAGREE*** *(4)*
(1) For potency testing, 80% - 120% recovery of the true value;
(2) For testing for terpenes, pesticides, herbicides, plant growth regulators, 75%- 125% recovery of the true value;
(3) For testing for residual solvents, 75% - 125% recovery of the true value; and
(4) For heavy metals testing, 90% - 110% recovery of the true value, **DISAGREE**- **maintain 75%-125% c/w existing CCB guidance.**
(5) More stringent criteria shall be used where required by a specific analytical method.
(d) An independent testing laboratory may not report sample results which are associated with QC that has exceeded the tolerance limits specified in this section. **AGREE**

11.060 **AGREE -in principle but believe wording needs to be corrected**
3. (b) we believe the wording is incorrect and in order to determine the correct wording a discussion to determine the specific outcome desired will be required.

11.065 **AGREE – in principle but believe wording needs to be clarified**
2. (b) we believe that the way the item is worded will not achieve the desired result and we would respectfully suggest this be reworded after discussions to determine the desired outcome. Also suggest specifying limits for quantitation to clearly define detection, such as 1 ppm etc., as opposed to "positive identified".

11.070 – DO NOT AGREE IN WHOLE - NEEDS DISCUSSION

Please see above reference to comment and discussion for NCCR 11.050 3.
Also, at “NCCR 11.070 1. (f)”, the language used is incorporated from “ASTM 8334D at 7. Sampling Procedure. 7.4”. It can be applied to facilities of any size, but obviously was intended to be applicable to large, outdoor agricultural sized grows where the batch size may be up to 25,000 kg to 55,000 kg. This clearly was not developed specifically for the carefully structured sampling protocols developed for cannabis testing program which already exists.

Some specific points to consider:

Any ASTM should be identified as a guideline, without expectation for strict compliance. The cleaning solvent should be the universal industry standard 70% isopropyl alcohol (IPA) rather than ethanol. Need clarification on what is “equivalent” to 70% ethanol. Is denatured ethanol acceptable, and if so, what are the acceptable or allowed denaturants?

11.070 1 (e) – sampling the upper, middle and lower sections may be practical when dealing with powders, grains or other free-flowing items; however, it is not realistic or practical with cannabis matrices. Measuring and conforming with a depth specification is also not practical with most sample matrices with which we routinely deal.

11.070 (1 D) requires the sampler to change gloves between every sample. This creates excess waste and is burdensome. Recommend change to sanitize/sterilize using 70% ethanol or equivalent. Gloves should be replaced when they are ripped or soiled to avoid the possibility of contaminating a product, not after each lot.

At 11.070 4. and 5. They seem to be internally contradictory- we seek clarification.

Additionally,

11.070 5 – DISAGREE. because storage of samples for the 30 days minimum may present a problem for labs with limited storage space.

At 11.070 9. there should be wording added to include the recent CCB change (March 2023) requiring laboratories to upload the COA to the seed to sale tracking system.

At 11.070 12. – AGREE.

11.075 4. – DISAGREE.

At NCCR 11.075 4….
“…..A cannabis independent testing laboratory may not retest a lot, production run or test sample of cannabis or cannabis products, or implement internal retesting procedures for cannabis or cannabis products, without approval by the Board or the appropriate Board Agent.”

Now that the Pesticide Analytical Manual of the Food and Drug Administration has been incorporated as a reference a clear and undeniable conflict has been created. Additionally, the FDA's "Investigating Out-Of-Specification (OOS) Test Results for Pharmaceutical Production Guidance for Industry" document (19287685_L2-OOS) https://www.fda.gov/media/158416/download. also creates a clear conflict.

For laboratories to be compliant with the **Pesticide Analytical Manual of the Food and Drug Administration at Section 101-3** at 4 and 5 the retesting of samples is **required** in certain situations. The current CCB mandates state laboratories are not allowed to perform such testing and these proposed regulations incorporate language to expressly prohibit laboratories from doing so. The Pesticide Analytical Manual language is attached immediately below.

"Pesticide Analytical Manual Vol. I
SECTION 101
Transmittal No. 94-1 (1/94)
Form FDA 2905a (6/92)
101–3

4) If the residue level found in the original analysis exceeds an established tolerance, or if no tolerance exists for the residue in that commodity, another analysis of a second test portion of the same composited test sample must be conducted by a second analyst (normally a senior analyst); the second analysis is referred to as a "check analysis."

5) If check analysis verifies that the residue violates a regulation, *i.e.*, the results of both original and check analyses exceed a tolerance and are in close agreement or are in close agreement for pesticide residues for which there is no tolerance, the analytical findings will support enforcement action against the food consignment. If the check analysis result is below a tolerance or if the results of the original and check analyses are widely divergent, enforcement action cannot be supported. Additional analyses may be required to resolve widely divergent analytical results. "

We respectfully request to work with the CCB to develop a procedure, compliant with these associated Federal regulations, to follow and report data that has been retested.
We respectfully suggest a specific interactive dialog (focused workshop) with the CCB to develop a regulated procedure that all labs follow. Samples will need to be rerun/retested due to laboratory mistakes: incorrect preps, queue errors, etc. As a result of QC failures, and through the sound judgement of a scientist on data that does not match the results.

11.085 3. - AGREE but clarification is required.

11.085 3. (c) – DISAGREE. NEED TO INSERT CLARIFYING LANGUAGE
Specify that the costs be borne by the "laboratory being investigated"

CONCLUSION

The Laboratories are excited to work with the CCB to continue developing the regulations for testing that will ensure the Nevada cannabis industry is safe and secure for

Nevada citizens and those that visit our state. We look forward to meeting with you to discuss the regulations and address the issues raised herein.

Sincerely,

Adam Fulton

Adam R. Fulton, Esq.

NRS 678B.540 Random laboratory assurance checks.

1. The Board may establish a program to ensure the integrity of all testing performed by a cannabis independent testing laboratory by subjecting each such laboratory to random laboratory assurance checks.

2. If the Board establishes a program pursuant to subsection 1, each cannabis independent testing laboratory shall participate in the program.

3. If the Board establishes a program pursuant to subsection 1, as part of the program, the Board shall:

(a) Collect samples of cannabis or cannabis products from cannabis establishments that have already been tested by cannabis independent testing laboratories in amounts deemed sufficient by the Board;

(b) Remove identifying characteristics from and randomize such samples; and

(c) Provide each cannabis independent testing laboratory with a sample for analysis.

4. A cannabis independent laboratory that receives a sample from the Board shall perform such quality assurance tests upon the sample as the Board may require. Such tests may include, without limitation:

(a) Screening the sample for pesticides, heavy metals, chemical residues, herbicides, growth regulators and microbial analysis;

(b) A potency analysis to test for and quantify the presence of the following cannabinoids:

(1) THC;

(2) Tetrahydrocannabinolic acid;

(3) Cannabidiol;

(4) Cannabidiolic acid; and

(5) Cannabinol; and

(c) Such other quality assurance tests that the Board may require.

5. If the Board establishes a program pursuant to subsection 1, the Board shall adopt regulations necessary to carry out the program. Such regulations:

(a) Must require each cannabis independent testing laboratory to perform a random laboratory assurance check at least once every 6 months but not more frequently than once every 3 months.

(b) May modify the procedures and requirements set forth in this section if the Board determines that advances in science necessitate such a modification.

6. As used in this section, “random laboratory assurance check” means the evaluation of the performance of a cannabis independent testing laboratory in conducting quality assurance tests upon a sample if required by the Board under the program established pursuant to subsection 1.

(Added to NRS by 2019, 3810)

NRS 678B.635 Database of information relating to testing conducted on cannabis and cannabis products; maintenance of database by Board; regulations; biennial report of Board.

1. The Board shall develop, implement and maintain an electronic database whereby the public may obtain information relating to testing conducted on cannabis and cannabis products by cannabis independent testing laboratories which has been collected through computer software used for the seed-to-sale tracking of cannabis and cannabis products. Such a database must:

(a) Contain the final results of all testing performed on cannabis or a cannabis product by a cannabis independent testing laboratory which have been collected through computer software used for the seed-to-sale tracking of cannabis and cannabis products;

(b) Be electronically secure and accessible to the public; and

(c) Present the information contained in the database in a format that is exportable.

2. The Board shall adopt regulations as it determines are necessary for the administration of the database required by subsection 1. Such regulations must ensure that:

(a) The information required to be contained in the database pursuant to paragraph (a) of subsection 1 is uploaded to the database and made available to the public in a timely manner after it has been collected through computer software used for the seed-to-sale tracking of cannabis and cannabis products; and

(b) The information contained in the database is presented in a format that is easily accessible to the public.

3. The Board shall, on or before January 1 of each odd-numbered year, submit a report to the Director of the Legislative Counsel Bureau for transmittal to the next regular session of the Legislature which details the amount of data uploaded to the database required by subsection 1 and the statistical relevance of such data as it pertains to cannabis independent testing laboratories in this State.

(Added to NRS by 2021, 1883)

CANNABIS COMPLIANCE BOARD
STATE OF NEVADA

ccb.nv.gov
CARSON CITY OFFICE
3850 Arrowhead Drive, Suite 100
Carson City, Nevada 89706
Main Line: (775) 687-6299

LAS VEGAS OFFICE
700 East Warm Springs Road, Suite 100
Las Vegas, Nevada 89119

JOE LOMBARDO
Governor

JAMES HUMM
Executive Director

MICHAEL MILES
Deputy Director

ADRIANA GUZMÁN FRALICK
Chair

AMENDED NOTICE OF INTENT TO ACT UPON REGULATIONS

Notice of Hearing for the Adoption of

NCCR 1, 4, 6, 5, 7 and 11

Cannabis Compliance Board

The Cannabis Compliance Board will hold a Public Hearing at **9:00 a.m**. on **Thursday, June 20, 2024.** The purpose of the hearing is to receive comments from all interested parties regarding the adoption of the regulations that pertain to NCCRs 1, 4, 6, 5, 7 and 11.

You may attend this meeting at either of the following physical locations:

Cannabis Compliance Board
700 E. Warm Springs Rd. Room 150
Las Vegas, Nevada 89119

Department of Taxation
4600 Kietzke Lane, Suite L235
Reno, NV 89502

The public may also view the meeting at the time noticed herein by live stream link located at:
https://ccb.nv.gov/public-meetings/

The following information is provided pursuant to the requirements of NRS 233B.0603:

1. Need and purpose of the proposed regulations or amendments

The Cannabis Compliance Board drafted proposed regulation changes to Nevada Cannabis Compliance Regulations ("NCCR") 1, 4, and 6 to incorporate changes from the 2023 legislative session, clarify definitions, establish new category violations, redefine and update existing category violations, and address issues regarding disciplinary actions, exemptions and collection of fees.

As well, the Cannabis Compliance Board drafted proposed regulation changes to Nevada Cannabis Compliance Regulations ("NCCR") 5, 7 and 11 to establish requirements relating to the inspections, certifications, and laboratory testing policies, procedures and guidelines, and to provide other matters properly relating thereto.

2. How to obtain the approved or revised text of regulations prepared by LCB

You may obtain a copy of the proposed permanent regulation by writing to the Nevada Cannabis Compliance Board, 700 E. Warm Springs Rd. Suite 100, Las Vegas, NV 89119; or by calling the office at (775) 687-6299. The proposed permanent regulation is also available for review and download on the Cannabis Compliance Board website at https://ccb.nv.gov/ or on the Nevada Legislature website at https://www.leg.state.nv.us/.

3. Methods used in determining the impact on a small business

The Agency used informed, reasonable judgment in determining that there would not be an impact on small businesses due to the nature of the regulation changes. The proposed permanent regulations make minor changes to requirements already established and in place by license holders.

The Agency analyzed the written responses from the Small Business Impact Survey, public comment from the January 31, 2024 solicitation of input meeting, and public comment from the workshop held May 14, 2024 to determine the likely impact of the proposed permanent regulations on small businesses. This analysis included categorizing responses to identify themes and the frequency with which impacts were named. The Agency also looked at issues named with less frequency but could potentially have impact. The Agency has determined that there will be no adverse impacts to small businesses after making these revisions.

4. Estimated economic effect of regulation on businesses and the public

a. Adverse and beneficial effects

The Agency finds that the proposed changes to NCCRs 1, 4, and 6 will have no adverse economic effect on small business. Rather, the Agency anticipates that there will be beneficial economic effects on small businesses. The changes make updates to existing regulations and reduce financial and regulatory burdens on small businesses. The Agency anticipates that those cannabis businesses that may be impacted will realize the beneficial economic impacts by reduced civil penalties for regulatory violations, reduced investigation costs, and a new progressive disciplinary scheme that significantly reduces the risk of suspension or revocation of a license. Also, the new enforcement provisions are aimed at combating the illegal market, which should generate additional revenues for the legal cannabis market.

Regarding NCCRs 5, 7 and 11, the Agency finds the changes lessen testing requirements for certain categories, create a new testing category, and provide more clear direction to the testing laboratories; which should provide clarity and standardization to the testing requirements. This does not impose a substantial burden on small businesses. This may also reduce financial burden on cannabis cultivation and production establishments, due to the reduction in required tests.

b. Immediate and long-term effects

The proposed permanent regulation does not present any reasonable, foreseeable, or anticipated immediate or long-term economic effects on small businesses or the public.

5. Cost for enforcement of the regulations

The proposed permanent regulations present no significant foreseeable or anticipated cost or decrease in costs for enforcement. The proposed changes merely make minor updates to regulations that are already in effect.

6. Overlap or duplication of other state or local governmental agencies

The proposed permanent regulations do not overlap or duplicate any regulation of other federal, State or local governmental entities, but does reference regulatory authority granted by NRS 678A through NRS 678D.

7. Regulation required by federal law

Not Applicable

8. More stringent than federal regulations

The Department is not aware of any similar federal regulations of the same activity in which the state regulations are more stringent.

9. New or increases in existing fees

The proposed permanent regulation does not include new fees or increase an existing fee.

The proposed changes to the regulation(s) will be considered by the CCB in accordance with the provisions of NRS 233B.0603, which provides that on the date and at the time and place designated, interested persons may present their views regarding the proposed regulation. Any person desiring to present statements, arguments, or contentions concerning the proposed regulation changes may provide such in writing to the Executive Assistant at regulations@ccb.nv.gov by 5 P.M. on the day prior to the meeting. Allowances for remote appearance may be made for those with disabilities only, but such requests must be made at least eight calendar days prior to the meeting.

These item(s) will be heard by the CCB at the June 20, 2024, meeting, and may be continued and heard at subsequent meetings of the CCB as required to effectuate the above-stated purposes.

The proposed changes to the regulation language will be posted on the Cannabis Compliance Board website https://ccb.nv.gov/public-meetings/. Any questions should be directed to regulations@ccb.nv.gov.

Notice of this meeting was posted on the Internet through the Cannabis Compliance Board website https://ccb.nv.gov/public-meetings/ and on the Internet website maintained by the Legislative Counsel Bureau http://leg.state.nv.us/ and the Department of Administration website https://notice.nv.gov/. This notice has been emailed for posting at the following locations: 700 E. Warm Springs Road, Suite 100, Las Vegas, Nevada; 3850 Arrowhead Dr, Carson City, Nevada; Department of Taxation, 4600 Kietzke Lane, Suite L235, Reno, Nevada; Nevada State Library, 100 Stewart St., Carson City, Nevada; Legislative Building, 401 S. Carson St., Carson City, Nevada; and Office of the Governor, One Nevada, 1 Harrah's Court, Las Vegas; and Gaming Control Board at 1919 College Parkway, Carson City, Nevada.

Proposed Changes to NCCR Regulation 1

ISSUANCE OF REGULATIONS; CONSTURCTION; DEFINITIONS

New
~~[Deleted]~~

1.000 Title.

1.010 Promulgation, amendment, modification and repeal.

1.020 Construction.

1.030 Severability.

1.040 Definitions.

1.050 "Act" defined.

1.051 "Address" defined.

1.052 "Advertise" and "advertising" defined.

1.053 "Analyte" defined.

1.055 "Analytical portion" defined.

1.057 "Applicant" defined.

1.058 "Application" defined.

1.060 "Batch" defined.

1.065 "Batch number" defined.

1.068 "Board Agent" defined.

1.070 "CBD" defined.

1.073 "Chief Medical Officer" defined.

1.075 "Combined cannabis establishment" defined.

1.080 "Component cannabis establishment" defined.

1.081 "Conditional License" defined.

1.082 "Derived" defined.

1.083 "Diversion" defined.

1.085 "Excise tax on cannabis" defined.

1.090 "Extraction" defined.

1.095 "Fair market value" defined.

1.100 "Foreign matter" defined.

1.105 "Growing unit" defined.

1.110 "Imminent health hazard" defined.

1.113 "Intentionally" defined.

1.114 *"Knowingly" defined.*

1.115 "Label" defined.

1.120 "Letter of approval" defined.

1.125 "Lot" defined.

1.130 "Multiple-serving edible cannabis product" defined.

1.135 "Packaging" defined.

1.137 "Person" defined.

1.140 "Pesticide" defined.

1.145 "Physician" defined.

1.150 "Potential total THC" defined.

1.155 "Potentially hazardous cannabis products and ingredients" defined.

1.160 "Premises" defined.

1.163 "Private Residence" defined.

1.165 "Production run" defined.

1.170 "Production run number" defined.

1.175 "Proficiency testing" defined.

1.180 "Proficiency testing program" defined.

1.185 "Proficiency testing provider" defined.

1.190 "Proficiency testing sample" defined.

1.193 "Prospective License" defined.

1.195 "Public transportation" defined.

1.197 "Ready-to-consume cannabis product" defined.

1.200 "Sample protocols" defined.

1.205 "Security equipment" defined.

1.210 "Seed-to-sale tracking system" defined.

1.215 "Separate operations" defined.

1.220 "Single-serving edible cannabis product" defined.

1.222 "Single-use cannabis product" defined.

1.225 "Surveillance" defined.

1.230 "Taxpayer" defined.

1.234 *"Unlicensed Activity" defined.*

1.235 "Vending Machine" defined.

1.240 "Cannabis" interpreted to exclude industrial hemp.

1.245 "Immature cannabis plant" and "mature cannabis plant" interpreted.

1.083. "Diversion" defined. The term "diversion" means the illegal transfer of cannabis or cannabis product from a licensed cannabis establishment to an unlawful or illicit channel of distribution or use, including but not limited to falsification of records or intentional inaccurate reporting of inventory to facilitate unauthorized sales.

1.113. "Intentionally" defined. The term "intentionally" means voluntarily or deliberately, rather than accidentally or inadvertently. The term does not require proof of bad faith, ill will, evil intent or malice.

1.114. "Knowingly" defined. The term "knowingly" means actual knowledge that the facts exist which constitute an act or omission, or such knowledge as an ordinarily prudent person would possess using reasonable care and diligence.

1.234 "Unlicensed activity" defined. "Unlicensed activity," as used in NCCR 4.200, includes any actions or engagement in a retail transfer of, and./or the offering for sale of, cannabis or cannabis product without first obtaining the appropriate license from the CCB, including but not limited to:

1. Engaging in the cultivating, processing, distributing, transporting, selling, or offering for sale cannabis and/or cannabis product beyond the scope of an active license;
2. Engaging in cultivating, processing, distributing, transporting or selling of cannabis and/or cannabis product without the appropriate operational license;
3. Disseminating print or digital advertisements directing any person to unlicensed cannabis activity and/or delivery service that engages in an unlicensed activity; or
4. Misleading, misrepresenting, and/or deceiving any person about the nature of a cannabis-related product or any genus Cannabis sativa L. product that does not conform to NRS 557.160 or violates NRS 557.255.

Proposed Changes to NCCR Regulation 4

DISCIPLINARY AND OTHER PROCEEDINGS BEFORE THE BOARD

New
~~[Deleted]~~

4.010 Applicability.

4.012 Time.

4.020 Grounds for disciplinary action.

4.030 Imposition of civil penalty; revocation or suspension of license or cannabis establishment agent registration card; corrective action.

4.033 Category I Violations.

4.035 Category ~~[I]~~*II* Violations.

4.040 Category ~~[II]~~*III* Violations.

4.050 Category ~~[III]~~ *IV* Violations.

4.055 Category ~~[IV]~~ *V* Violations.

4.060 Category ~~[V]~~ *VI* Violations.

4.061 Category VII Violations.

4.065 Imminent health hazard.

4.070 Complaint.

4.075 Service of complaint.

4.080 Prohibition of ex parte communications.

4.085 Delegation to Chair.

4.090 Appearance through counsel.

4.095 Early case conference and hearing.

4.100 Reinstatement of license or cannabis establishment agent registration card: Application; conditions, limitations or restrictions upon reinstatement; denial.

4.105 Grounds for summary suspension; notice; request for hearing.

4.110 Discovery: mandatory exchanges.

4.115 Continuances and recesses.

4.120 Burden and standard of proof.

4.125 Motions.

4.130 Subpoenas.

4.135 Disposition of charges: Adjudication by Board.

4.137 *Settlement of Disciplinary Actions and/or Contested Cases.*

4.140 Declaratory orders and advisory opinions.

4.145 Adoption, amendment or repeal of a regulation.

4.150 *Petition for Exemption from Excluded Felony Offense Restrictions.*

4.200 *Actions Relating to Unlicensed Activity.*

4.010 Applicability. NCCR 4 shall apply to disciplinary proceedings governed by *Chapters 678A and 233B of* NRS ~~[678A.500 to 678A.640]~~. Unless otherwise ordered by the Chair, this regulation shall apply to all such proceedings that are pending on the effective date of this regulation.

4.012. Time. Wheresoever in these regulations "days" are referenced without any modifier, the term "days" shall be deemed calendar days and not business days. The number of days shall be calculated as set forth in NRCP 6(a)(1).

4.020 Grounds for disciplinary action.

1. A violation of any of the provisions of Title 56 of NRS or NCCR is grounds for disciplinary action by the Board, including, without limitation, immediate revocation of a license for a cannabis establishment pursuant to *Chapter 678A of* NRS [~~678A.450 and NRS 678.650~~].
2. A violation of any of the provisions of Title 56 of NRS or NCCR is grounds for disciplinary action by the Board, including, without limitation, immediate revocation of a cannabis establishment agent registration card.
3. Progressive discipline under NCCR 4.033(2), 4.035(2), 4.040(2), 4.050(2), 4.055(2), 4.060(2), and 4.061(2), shall be triggered from the "First Notice Date". The "First Notice Date" shall be the date that a cannabis establishment or cannabis establishment agent knew or reasonably should have known of the act or omission that is determined to be a violation, regardless of the ultimate date of that determination or adjudication. The "First Notice Date" may be established via a statement of deficiencies letter from the Board or Board Agents, or through any other competent evidence. Progressive discipline shall apply when the "Second Notice Date" occurs within three years of the "First Notice Date". The "Second Notice Date" shall be the date that a cannabis establishment or cannabis establishment agent knew or reasonably should have known of another act or omission within the same Category of violation as the violation from the "First Notice Date" and is determined to be a violation, regardless of the ultimate date of that determination or adjudication. The "Second Notice Date" may be established via a statement of deficiencies letter from the Board or Board Agents, or through any other competent evidence. The "First Notice Date" and the "Second Notice Date" may fall on the same date, if the violations found are separate and distinct violations within the same Category of violations. An act or omission may be determined a violation via an adjudication, settlement agreement, or failure to respond to a disciplinary action in a contested case.

4.030 Imposition of civil penalty; revocation or suspension of license or cannabis establishment agent registration card; corrective action.

1. The Board may:

(a) Subject to the provisions of NCCR 4, impose a civil penalty of not more than ~~[$90,000]~~ ***$20,000*** per violation on any person who fails to comply with or violates any provision of the NCCR and Title 56 of NRS. Such a civil penalty must be paid to the State of Nevada for deposit in the State General Fund;

(b) Except as otherwise provided in paragraph (c), suspend or revoke a license or cannabis establishment agent registration card. If the Board orders the suspension of a license or cannabis establishment agent registration card, the Board shall prescribe the time period of the suspension in the written decision. If the Board orders the revocation of a license or cannabis establishment agent registration card, the Board shall prescribe a period of not less than 1 year and not more than 10 years during which the person may not apply for reinstatement of the license or cannabis establishment agent registration card;

(c) If the Board orders the suspension of a license, a Board Agent will post a notice of closure at the facility, which may not be removed without approval by a Board Agent; and

(~~[c]~~*d*) If corrective action approved by the Board ***Agent*** will cure the noncompliance or violation but will not be completed within 30 days after issuance of the order, suspend for more than 30 days the license of a cannabis establishment or the cannabis establishment agent registration card of a person who fails to comply with or violates the provisions of the NCCR and Title 56 of NRS.

2. To determine the amount of a civil penalty assessed pursuant to this section, the Board will consider the gravity of the violation, the economic benefit or savings, if any, resulting from the violation, the size of the business of the violator, the history of compliance with the NCCR and Title 56 of NRS by the violator, action taken to remedy the violation, the effect of the penalty on the ability of the violator to continue in business, ***the mitigating circumstances set forth in S.B. 195 Sec. 3, 2023 Leg., 82th Sess. (Nv. 2023)***, and any other matter as justice may require.

4.033 Category I Violations.

1. The Board will determine a category I violation of the NCCR and Title 56 of NRS as follows:

(a) Category I violations are of such a severity that precludes the continuing operations of a cannabis establishment or the maintenance of a cannabis registration agent card, including, without limitation:

(1) Conviction of an excluded felony offense; or

(2) Diversion of cannabis or cannabis product.

2. Before consideration of the factors described in NCCR 4.030(2), the Board will presume that the appropriate penalty for any Category I violation is revocation of a license or cannabis establishment agent registration card.

4.035 Category [I] *II* Violations.

1. The Board will determine a category [I] *II* violation of the NCCR and Title 56 of NRS as follows:

(a) Category [I] *II* violations are of a severity that make a person ineligible to receive, renew, or maintain a license, including, without limitation:

(1) [Conviction of an excluded felony offense;] ***Intentionally failing to comply with a Board order or directive:***

(2) Operating***, working, or volunteering*** without all required permits, [certificates,] registrations and/or licenses***, including but not limited to business license, special land use permit, tax permit, or other licenses required to operate***;

(3) Making an intentionally false statement to the Board or Board Agents;

(4) Intentionally destroying or concealing evidence;

[(5) Intentionally failing to pay taxes to the Department of Taxation;]

([6]*5*) Allowing noisy, disorderly or unlawful activity that results in death or serious physical injury, that involves the unlawful use or attempted use of a deadly weapon against another person or that results in a sexual offense which is a category A felony;

([7]*6*) Operating a cannabis establishment while the license for the cannabis establishment is suspended or revoked;

([8]*7*) Transporting cannabis outside of the boundaries of this State, except where authorized by an agreement between the Governor of this State and a participating tribal government;

([9]*8*) Making verbal or physical threats to a Board Agent or Board member;

([10]*9*) Failing to immediately admit regulatory or law enforcement personnel ***with appropriate identification*** into the premises of a cannabis establishment;

([11]*10*) Refusing to allow an inspection or obstructing regulatory personnel or law enforcement officer from performing his or her official duties;

[(12) Purchasing or selling cannabis that has not passed the analysis required by a cannabis independent testing laboratory without written approval from the Board;]

([13]*11*) Purchasing, [or] selling***, acquiring, cultivating, producing, or otherwise using*** cannabis not found in the seed-to-sale tracking system ***and/or from an unapproved or unlicensed source;***

[(14) Failure to properly collect taxes;]

([15]*12*) Transporting or storing cannabis from an unlicensed source, other than patient or consumer samples stored at a cannabis independent testing laboratory;

(13) Any undocumented variance in inventory exceeding 10% of total inventory;

(14) Failure to tag more than 10% of mature plants and/or packages;

(15) Engaging in grossly negligent, unlawful or criminal conduct relating to cannabis; or

(16) Engaging in an act or omission that poses an imminent threat to the health or safety of the public.

2. Before consideration of the factors described in [subsection 1(a)] ***NCCR 4.030(2)***, the Board will presume that the following are appropriate penalties for violations of the NCCR and Title 56 of NRS:

(a) For a category [I] *II* violation which is the:

(1) First violation in the immediately preceding 3 years, a civil penalty of not more than $[90]*20*,000 and*/or* a suspension for not more than 30 days or revocation of a license or cannabis establishment agent registration card.

(2) Second or subsequent violation in the immediately preceding 3 years, ***a civil penalty of not more than $20,000 and a suspension for not more than 30 days or revocation of a license or cannabis establishment agent registration card.***
(3) Third or subsequent violation in the immediately preceding 3 years, a revocation of a license or cannabis establishment agent registration card.

~~[(b) Notwithstanding the foregoing, a single violation of NCCR 4.035(1)(a)(1) for diversion of cannabis or cannabis products requires revocation of a license~~**, certificate, and/**~~or cannabis establishment agent registration card.]~~

4.040 Category ~~[II]~~ *III* Violations.

1. The Board will determine a category ~~[II]~~ *III* violation of the NCCR and Title 56 of NRS as follows:

(a) Category ~~[II]~~ *III* violations are violations of a severity that create a present threat to public health or safety, including, without limitation:

(1) Making an unintentional false statement or representation of fact to the Board or Board Agents;

(2) Unintentionally destroying or concealing evidence;

(3) Failing to verify and/or authenticate the age of, or selling or otherwise providing cannabis***,*** ~~[or]~~ cannabis ***products, or*** paraphernalia to, a person who is less than 21 years of age ***unless the person holds a registry identification card or letter of approval***;

(4) Allowing a person who is less than 21 years of age to enter or remain in a cannabis establishment or transport vehicle unless the person ***entering or remaining*** holds a registry identification card or letter of approval;

~~[(5) Permitting sales by a person without a cannabis establishment agent registration card unless that person is deemed to be temporarily registered;~~

~~(6) Effecting a change in ownership and/or ownership interest without complying with all the requirements of NCCR 5.110 and/or any additional Board guidance and orders regarding transfers of interest.;]~~

(~~[7]~~***5***) Allowing noisy, disorderly or unlawful activity that involves use of a dangerous weapon against another person with intent to cause death or serious physical injury;

~~[(8) Allowing a person who is less than 21 years of age to work or volunteer at the cannabis establishment;]~~

(~~[9]~~***6***) Failing to cease operation and notify the Board or Board Agents during an imminent health ***hazard or resuming operation after board required cessation due to an imminent health hazard without approval***;

~~[(10) Purchasing, cultivate, produce or otherwise use cannabis from an unapproved source;~~

~~(11) Not properly segregating medical patient retail sales from adult use retail sales;]~~

(~~[12]~~***7***) Operating ~~[an]~~ unapproved ***equipment harmful to human health or safety*** ~~[extraction unit]~~;

~~[(13) Selling an amount of cannabis in excess of transaction limits;]~~

(~~[14]~~***8***) Failing to maintain required security alarm ~~[and surveillance systems]~~;

(~~[15]~~***9***) Any intentional variance from approved procedures in a laboratory;

(~~[16]~~***10***) Failing to notify the Board or Board Agents of a loss of possession or control of a cannabis ***establishment*** ~~facility~~ within 24 hours;

(~~[17]~~***11***) Transferring, moving, or disturbing cannabis or cannabis product which has been quarantined by the Board without Board ***Agent*** approval;

~~[(18) Failing to renew the cannabis establishment license on time; or]~~

([~~19~~]*12*) Any violation of NCCR 11.070*;* [~~.~~]
(13) Transferring or taking possession of cannabis that has not passed the analysis required by a cannabis independent testing laboratory without written approval from the Board Agent;
(14) Failing to appear before the Board when notified to appear at any Board meeting without notice to the Board and/or without a reasonable excuse for failure to appear;
(15) Unintentionally failing to comply with a Board order or directive;
(16) Failing to have video surveillance cameras in place as required;
(17) Changing quantities and/or weights of cannabis or cannabis products without Board Agent approval after they have been tested;
(18) Retesting of cannabis or cannabis product without Board Agent approval;
(19) Failure to maintain a laboratory quality assurance/quality control program;
(20) Any undocumented variance in inventory of over 5% and no more than 10% in total inventory;
(21) Failure to tag over 5% and no more than 10% of mature plants and/or packages; or
(22) Failure to comply with NCCR 5.170.

2. Before consideration of the factors described in [~~subsection 1(a)~~]***NCCR 4.030(2)***, the Board will presume that the following are appropriate penalties for violations of the NCCR and Title 56 of NRS:

(a) For a category [~~II~~] ***III*** violation which is the:

(1) First violation in the immediately preceding 3 years, a civil penalty of not more than $[~~25,000~~] ***15,000*** and***/or*** a suspension for not more than 20 days of a license or cannabis establishment agent registration card.

(2) Second violation in the immediately preceding 3 years, a civil penalty of not more than $[~~75~~]***,15***,000 and***/or*** a suspension for not more than 30 days of a license or cannabis establishment agent registration card.

(3) Third or subsequent violation in the immediately preceding 3 years, ***a civil penalty of not more than $20,000 and a suspension for not more than 30 days of a license or cannabis establishment agent registration card.***
(4) Fourth or subsequent violation in the immediately preceding 3 years, revocation of a license or cannabis establishment agent registration card.

4.050 Category [~~III~~] ***IV*** **Violations.**

1. The Board will determine a category [~~III~~] ***IV*** violation of the NCCR and Title 56 of NRS as follows:

(a) Category [~~III~~] ***IV*** violations are violations of a severity that create a potential threat to public health or safety, including, without limitation:

(1) Transporting cannabis in an unauthorized vehicle;

(2) Allowing consumption by any person of alcohol, cannabis (except at a consumption lounge ***or an establishment with a valid liquor license***) or other intoxicants on the premises of the cannabis establishment or in areas adjacent to the premises of the cannabis establishment which are under the licensee's control, including, without limitation, a parking lot;

(3) Failing to keep any required records, including seed-to-sale tracking requirements;

(4) ***Any undocumented variance in inventory of over 2% and not more than 5% in total inventory;***

(5) Failing to follow an approved security plan;

(6) Allowing disorderly activity;
(7) Allowing any activity which violates the laws of this State;
(8) Failing to notify the Board or Board Agents ***in writing*** within ***the times required in these regulations for any reportable incident, or not to exceed*** 24 hours after discovery of a serious incident or criminal activity on the premises of the cannabis establishment;
[~~(9) Unintentionally failing to pay taxes to the Department of Taxation;~~]
([~~10~~]***9***) Selling unauthorized products ***or using unauthorized ingredients***;
(10) Failing to render waste containing cannabis unusable;
[~~(11) Failing to notify the Board or Board Agents of a modification or expansion of the facilities of the cannabis establishment or a change in equipment or menu of the cannabis establishment;~~
~~(12) Violating packaging or labeling requirements including seed-to-sale tracking system requirements~~]
(11) Allowing the use of a video surveillance camera that is non-functioning or non-operational in a cannabis establishment;
(12) Failing to properly use sanitizer as or when required;
(13) Storing or delivering ~~an~~ unapproved cannabis ~~product~~ or a cannabis product outside the seed-to-sale tracking system;
(14) Failing to meet requirements for the disposal of cannabis waste;
(15) Using unauthorized pesticides, soil amendments, fertilizers or other crop production aids;
(16) Exceeding the maximum serving requirements for cannabis products;
(17) Exceeding a reasonable ***transit*** time frame for delivery ***of cannabis or cannabis products*** without approval from the Board or Board Agents;
(18) ~~Transporting or storing cannabis from an unlicensed source, other than patient samples stored at a cannabis interdependent testing laboratory, or diversion of cannabis or cannabis products;~~ ***Any violation of NRS 678C.410(2);***
(19)Picking up, unloading or delivering cannabis at an unauthorized location;
(20) Failing to comply with requirements for hand washing and employee hygiene, including, without limitation, using a bare hand on a cannabis product;
(21) Failing to maintain proper ***time/***temperature [~~of potentially hazardous food or cannabis products;~~] ***control for safety of food or cannabis products;***
(22) Selling or failing to dispose of cannabis, cannabis products or food items that are spoiled or contaminated;
(23) Failing to tag cannabis or a cannabis product as required;
(24) Failing to follow seed-to-sale tracking system requirements while transporting or delivering cannabis or cannabis products***;***
(25) Failing to properly update the licensee's point of contact with the Board ***within 10 days of any such change;***
(26) Failure to maintain quality assurance/quality control program in a laboratory; [~~or~~]
(27) Failure to maintain updated standard operating procedures[~~.~~] ***;***
(28) Allowing sales of any products at a cannabis consumption lounge that are not permitted to be sold at a cannabis consumption lounge;
(29) Allowing the removal of any single-use cannabis products or ready-to-consume cannabis products from a cannabis consumption lounge;
(30) Permitting the use or consumption of cannabis by any person displaying any visible signs of overconsumption at a cannabis consumption lounge;

(31) Failing to develop, implement, and/or maintain a plan to mitigate the risk of impaired driving at a cannabis consumption lounge; [~~or~~]
(32) Failing to maintain a separate room in a cannabis consumption lounge for cannabis smoking, vaping, and inhalation in a cannabis consumption lounge, unless all such activities are prohibited in the cannabis consumption lounge[~~.~~];
(33) Effecting a change in ownership and/or ownership interest, granting or foreclosing on a security interest, profit sharing, or entering into a management agreement without complying with all the requirements of NCCR, notifying the Board, obtaining approval of the Board, and/or abiding by any additional Board guidance and orders regarding transfers of interest, profit sharing, or management agreements;
(34) Failing to renew the cannabis establishment license on time;
(35) Failure to maintain required; certificates, accreditations, or credentials including but not limited to Agent registration card, Certified Food Protection Manager and Restricted Use Pesticide Applicator License;
(36) Failure to tag over 2% and not more than 5% of mature plants and/or packages in total inventory;
(37) Not properly segregating medical patient retail sales from adult use retail sales;
(38) Operating unapproved equipment;
(39) Failing to timely respond to a statement of deficiencies notice or letter or any other administrative notice of a violation;
(40) Failing to timely implement an approved or directed plan of correction;
(41) Violating regulations on collecting or handling samples for laboratory testing or analysis;
(42) Improper storing of cannabis, cannabis products or other foods;
(43) Failing to properly wash, rinse and sanitize product contact surfaces as required;
(44) Failing to maintain hand-washing facilities that are stocked, accessible and limited to hand washing only;
(45) Infestation by pests that are not multigenerational or on contact surfaces;
(46) Failing to tag immature plant batches of up to 150 plants, which do not yet require individual tags;
(47) Failing to notify the Board or Board Agents in writing within 24 hours after the cannabis establishment discovers any cannabis or cannabis product is missing from its physical inventory and unaccounted for after investigation is complete ~~completes its investigation~~;
(48) Tampering with, disengaging, or otherwise disabling any component of a security system without authorization from a Board Agent, except for maintenance or repair purposes; or
(49) Failing to maintain quality control unit in a cannabis establishment, other than distribution.

2. Before consideration of the factors described in [~~subsection 1(a)~~]***NCCR 4.030(2)***, the Board will presume that the following are appropriate penalties for violations of the NCCR and Title 56 of NRS:

(a) For a category [~~III~~] ***IV*** violation which is the:

(1) First violation in the immediately preceding 3 years, a civil penalty of not more than $[~~10,000~~]***5,000***.

(2) Second violation in the immediately preceding 3 years, a civil penalty of not more than [~~$30,000~~] ***$10,000*** [~~and/or a suspension for not more than 10 days of a license or cannabis establishment agent registration card~~].

(3) Third violation in the immediately preceding 3 years, a civil penalty of not more than [~~$90,000~~] ***$20,000*** and/or a suspension for not more than [~~20~~]***10*** days of a license or cannabis establishment agent registration card.

(4) Fourth violation in the immediately preceding 3 years, a civil penalty of not more than [~~$90,000~~] ***$20,000*** and a suspension for not more than [~~60~~] ***20*** days of a license or cannabis establishment agent registration card.

(5) Fifth [~~or subsequent~~]violation in the immediately preceding 3 years, ***a civil penalty of not more than $20,000 and/or*** revocation of a license or cannabis establishment agent registration card.

(6) Sixth violation in the immediately preceding 3 years, a civil penalty of not more than $20,000 and/or revocation of a license or cannabis establishment agent registration card.

(7) Seventh or subsequent violation in the immediately preceding 3 years, revocation of a license or cannabis establishment agent registration card.

4.055 Category ~~I~~V Violations.

1. The Board will determine a category ~~I~~V violation of the NCCR and Title 56 of NRS as follows:

(a) Category ~~I~~V violations create a climate which is conducive to abuses associated with the sale or production of cannabis or cannabis products, including, without limitation:

(1) [~~Failing to display or have in the immediate possession of each cannabis establishment agent a cannabis establishment agent registration card or proof of temporary registration~~] ***Offering for free or no charge or donating cannabis without a purchase;***

(2) Removing, altering or covering a notice of suspension of a license or any other required notice or sign;

(3) Violating advertising requirements;

[~~(4) Displaying products in a manner visible to the general public from a public right of way;~~

~~(5) Failing to respond to an administrative notice of a violation or failing to pay fines;~~]

(4) Failing to notify the Board or Board Agents in writing and obtain approval from Board Agents of a modification or expansion of the facilities of the cannabis establishment or a change in equipment or menu of the cannabis establishment prior to implementation;

(5) Violating packaging or labeling requirements;

[~~(6) Violating restrictions on sampling;~~]

([~~7~~]***6***) Failing to maintain a standardized scale as required;

[~~(8) Improper storing of cannabis, cannabis products or other foods;~~

~~(9) Failing to properly wash, rinse and sanitize product contact surfaces as required;~~

~~(10) Failing to maintain hand-washing facilities that are stocked, accessible and limited to hand washing only;~~

~~(11) Infestation by pests that are not multigenerational or on contact surfaces;~~
~~(12) Failing to properly use sanitizer as required;~~
~~(13) Violating any transportation or delivery requirements not described in another category of violations;~~]
([~~14~~]*7*) Failing to properly ***and/or timely*** respond to a Board or Board Agent's request for documentation, information, video, or other records; [~~or~~]
(8) Any violation of NCCR 11.015(2);
([~~15~~]*9*) Failing to comply with required employee training;
([~~16~~] *10*) Failing to offer required consumer education, support materials, warnings, and/or notices to a cannabis consumption lounge consumer;
([~~17~~]*11*) Failing to comply with any laws or regulations related to on-site food preparation at a cannabis consumption lounge; or
(~~18~~ *12*) Failing to comply with ventilation requirements at a cannabis consumption lounge;
(13) Selling an amount of cannabis in a single transaction in excess of transaction limits;
(14) Failing to follow the cannabis establishment's own standard operating procedures;
(15) Allowing any blockage of the view of a video surveillance camera or failing to have operational video surveillance cameras providing a 360-degree view of all rooms and storage areas containing cannabis or cannabis products;
(16) Failure to properly reconcile disposal of cannabis and cannabis products with the cannabis establishment's seed to sale tracking system; or
(17) Failing to include the names and agent card numbers of cannabis establishment agents involved in harvests of and disposal of cannabis on harvest and disposal logs.

2. Before consideration of the factors described in [~~subsection 1(a)~~]***NCCR 4.030(2)***, the Board will presume that the following are appropriate penalties for violations of the NCCR and Title 56 of NRS:

(a) For a category ~~I~~V violation which is the:

(1) First violation in the immediately preceding 3 years, a civil penalty of not more than [~~$5,000~~] ***$2,500***.

(2) Second violation in the immediately preceding 3 years, a civil penalty of not more than [~~$10,000 and/or a suspension for not more than 7 days of a license or cannabis establishment agent registration card~~] ***$5,000***.

(3) Third violation in the immediately preceding 3 years, a civil penalty of not more than [~~$20,000 and/or a suspension for not more than 10 days of a license or cannabis establishment agent registration card~~]***$10,000*** .

(4) Fourth violation in the immediately preceding 3 years, a civil penalty of not more than [~~$40,000~~] ***$20,000*** and/or a suspension for not more than [~~20~~] *10* days of a license or cannabis establishment agent registration card.

(5) Fifth violation in the immediately preceding 3 years, a civil penalty of not more than [~~$80,000~~] ***$20,000*** and a suspension for not more than [~~30~~]*20* days of a license or cannabis establishment agent registration card.

(6) Sixth [~~or subsequent~~] violation in the immediately preceding 3 years, [~~revocation of a license or cannabis establishment agent registration card.~~] ***a civil penalty of not more than $20,000 and a suspension for not more than 30 days of a license or cannabis establishment agent registration card.***

(7) Seventh violation in the immediately preceding 3 years, a civil penalty of not more than $20,000 and a suspension for not more than 60 days of a license or cannabis establishment registered agent card.
(8) Eighth violation in the immediately preceding 3 years, a civil penalty of not more than $20,000 or revocation of a license or cannabis establishment registered agent card.
(9) Ninth violation in the immediately preceding 3 years, a civil penalty of not more than $20,000 or revocation of a license or cannabis establishment registered agent card.
(10) Tenth or subsequent violation in the immediately preceding 3 years, revocation of a license or cannabis establishment agent registration card.

4.060 Category V*I* Violations.

1. The Board will determine a category V*I* violation of the NCCR and Title 56 of NRS as follows:

(a) Category V*I* violations are inconsistent with the orderly regulation of the sale or production of cannabis or cannabis products, including, without limitation:

(1) ~~[Failing to submit monthly tax or sales reports or payments]~~***Failing to notify the Board or Board Agents in writing of a notice of eviction within 24 hours of the notice***;

(2) Failing to notify the Board or Board Agents of a temporary closure of the cannabis establishment ***in writing*** within 24 hours of the closure;

(3) Failing to post any required signs;

(4) Failing to notify the Board ***in writing*** of a change in the name of the cannabis establishment ***within 10 days of such name change***;

(5) ~~[Making a payment with a check returned for insufficient funds;]~~ ***Displaying cannabis or cannabis products in a manner visible to the general public from outside the cannabis establishment;***

(6) ~~[Failing to comply with any other requirements not described in another category of violations;]~~ ***Failing to timely pay civil penalties or fines;***

(7) Failing to properly ***and/or timely*** submit quarterly inventory reports, monthly sales reports, or other reports required by the Board ***or Board Agents***; ~~[or]~~

(8) ~~[Failure to pay for all costs involved in screening or testing related to quality assurance compliance checks within 30 days.]~~ ***Violating any transportation or delivery requirements not described in another category of violations;***

(9) Operating a cannabis consumption lounge, or cannabis sales facility, outside of its designated hours of operation or failing to properly post the hours of operation of a cannabis consumption lounge~~[,]~~or cannabis sales facility***;***

(10) ~~[Failing to provide required water service at a cannabis consumption lounge; or (11)]~~ Failing to comply with requirements regarding visibility of consumption from the public at a cannabis consumption lounge***;***

(11) Testing lots which weigh more than the legal limit;
(12) Any undocumented variance in inventory of over 0.25% and not more than 2%;
(13) Failure to tag over 0.25% and not more than 2% of mature plants and/or packages in total inventory;
(14) Failure to properly affix tags to plants as required;

(15) Failing to, and/or the inability to, print a properly time-stamped screen shot from any operational video surveillance camera at the request of the Board or Board Agents;
(16) Failing to accept or reject into the seed-to-sale tracking system any cannabis or cannabis product delivery within 24 hours; or
(17) Failing to comply with any requirements of NCCR 6.082 not set forth elsewhere.

2. Before consideration of the factors described in ~~[subsection 1(a)]~~ ***NCCR 4.030(2)***, the Board will presume that the following are appropriate penalties for violations of the NCCR and Title 56 of NRS:

(a) For a category V***I*** violation which is the:

(1) First violation in the immediately preceding 3 years, a warning.

(2) Second violation in the immediately preceding 3 years, a civil penalty of not more than ~~[$2,500]~~ ***$1,500***.

(3) Third violation in the immediately preceding 3 years, a civil penalty of not more than ~~[$5,000 and/or a suspension for not more than 3 days of a license or cannabis establishment agent registration card]~~ ***$3,000***.

(4) Fourth violation in the immediately preceding 3 years, a civil penalty of not more than ~~[$10,000 and/or a suspension for not more than 7 days of a license or cannabis establishment agent registration card]~~ ***$5,000***.

(5) Fifth violation in the immediately preceding 3 years, a civil penalty of not more than ~~[$20,000 and/or a suspension for not more than 10 days of a license or cannabis establishment agent registration card]~~ ***$10,000***.

(6) Sixth or subsequent violations in the immediately preceding 3 years, a civil penalty of not more than ~~[$40,000]~~ ***$20,000 for each such violation*** and/or a suspension for not more than 20 days of a license ***for each such violation*** or cannabis establishment agent registration card.

4.061 Category VII Violations.

1. The Board will determine a category VII violation of the NCCR and Title 56 of NRS as follows:

(a) Category VII violations are inconsistent with the orderly regulation of the sale or production of cannabis or cannabis products, though of a less serious nature than category VI violations, including, without limitation:

(1) Failing to display or have in the immediate possession of each cannabis establishment agent a cannabis establishment agent registration card or proof of temporary registration;

(2) Failing to comply with any other requirements not described in another category of violations;

(3) Failing to timely pay taxes or timely file tax returns;

(4) Failure to pay for all costs involved in Board or Board Agent ordered screening or testing within 30 days of invoice;

(5) Failing to provide required water service at a cannabis consumption lounge;

(6) Failing to provide notice to the Board within 10 working days of the date an employee begins employment and/or ends employment with the cannabis establishment;

(7) Failing to maintain a Visitor Log as required;

(8) Any documented variance exceeding 0.25% total inventory; or

(9) Failing to timely pay investigation costs pursuant to NCCR 6.025.

2. Before consideration of the factors described in NCCR 4.030(2), the Board will presume that the following are appropriate penalties for violations of the NCCR and Title 56 of NRS:

(a) For a category VII violation which is the:

(1) First violation in the immediately preceding 3 years, a formal written warning.

(2) Second violation in the immediately preceding 3 years, a second formal, written warning.

(3) Third violation in the immediately preceding 3 years, a civil penalty of not more than $1,500.

(4) Fourth violation in the immediately preceding 3 years, a civil penalty of not more than $3,000.

(5) Fifth violation in the immediately preceding 3 years, a civil penalty of not more than $5,000.

(6) Sixth violation in the immediately preceding 3 years, a civil penalty of not more than $10,000.

(7) Seventh or subsequent violations in the immediately preceding 3 years, a civil penalty of not more than $20,000 for each such violation and/or a suspension for not more than 10 days of a license for each such violation or cannabis establishment agent registration card.

4.070 Complaint. ***In addition to the requirements of NRS 678A.520(1) (as amended by S.B. 195 Sec. 5, 2023 Leg., 82th Sess. (Nv. 2023))*****,*** [~~I~~]~~t~~he complaint must contain the following information:

1. The date of the violation or, if the date of the violation is unknown, the date that the violation was identified;
2. The address or description of the location where the violation occurred;
3. The section of the NCCR and Title 56 of NRS that was violated and a description of the violation;
4. The amount of the civil penalty that the Board may impose or a description of the action the Board may take for the violation;
5. A description of the payment process, including a description of the time within which and the place to which any civil penalty must be paid if the respondent does not wish to dispute the complaint;
6. An order prohibiting the continuation or repeated occurrence of the violation described in the complaint;
7. A description of the complaint process, including, without limitation, the time within which respondent must serve an answer to the complaint and the place to which the answer must be served; and
8. The name of the Board Agent who performed the investigation.

4.090 Appearance through counsel.

1. Parties to proceedings governed by this regulation may appear personally or through an attorney, except that the parties must personally attend any hearing on the merits unless such attendance has been waived pursuant to NCCR 2.
2. When a party has appeared through an attorney, service of all notices, motions, orders, decisions, and other papers shall thereafter be made upon the attorney.
3. When a party is represented by an attorney, the attorney shall sign all motions, oppositions, notices, requests, and other papers on behalf of the party, including requests for subpoenas.
4. An attorney may withdraw from representing a person upon notice to the person or licensee, and the Board. The notice must include the reason for the requested withdrawal. The attorney must notify the person or license of an opportunity to object to the withdrawal. If the party or licensee objects to the withdrawal, the person or licensee must so notify the Board ***no later than seven days from receipt of the notice.*** The Board may deny the request if there may be an unreasonable delay in the case or the substantial rights of the person or licensee may be prejudiced.
5. If the Board finds that an attorney has violated any provision of this section, the Board may bar the attorney from participating in the case or may impose such other sanctions as the Board deems appropriate.
6. A person or licensee subject to a hearing pursuant to this chapter is responsible for all costs related to the presentation of the defense.

4.095 Early case conference and hearing.

1. Within 10 days after the respondent answers the complaint pursuant to NRS 678A.520 and demands a hearing or if the Board orders a hearing even if the respondent waives his or her right to a hearing, the parties shall hold an early case conference at which the parties and a hearing officer employed by the Board, ~~[or as permitted by NAC 616C.2753,]~~ or a delegated member of the Board, a panel of the Board, or the Board must preside. At the early case conference, the parties shall in good faith:

(a) Set the earliest possible hearing date agreeable to the parties and the hearing officer, a delegated member of the Board, panel of the Board, or the Board, including the estimated duration of the hearing no later than 45 days after receiving the respondent's answer unless an expedited hearing is determined to be appropriate. ***The parties, with the approval of the Chair or Hearing Officer, may agree to extend the 45 day requirement***;

(b) Set dates:

(1) By which all documents must be exchanged;

(2) By which witness lists must be exchanged;

(3) By which all prehearing motions and responses thereto must be filed; and

(4) For any other foreseeable actions that may be required for the matter;

The parties, with approval of the Chair or Hearing Officer, may later agree to continue any of these dates;

(c) Discuss or attempt to resolve all or any portion of the evidentiary or legal issues in the matter;

(d) Discuss the potential for settlement of the matter on terms agreeable to the parties; and

(e) Discuss and deliberate any other issues that may facilitate the timely and fair conduct of the matter.

2. A formal hearing must be held at the time and date set at the early case conference ***(or by the approved stipulation of the parties)*** by:

(a) The Board;

(b) A hearing officer; or

(c) A panel of three members of the Board.

3. The hearing will be conducted as set forth in NRS 678A.540. If the hearing is held before a hearing officer or panel of the Board, the hearing officer or panel shall issue, within 30 days of the last date of the hearing, findings of fact and conclusions of law for the Board's review pursuant to NCCR 4.135(1).

4. For purposes of NRS 678A.550 and the regulations regarding conduct of a hearing, a Board member shall be deemed present at a hearing when said Board member has reviewed the full written or audio transcript of the hearing and all evidence submitted at the hearing.

4.100 Reinstatement of license or cannabis establishment agent registration card: Application; conditions, limitations or restrictions upon reinstatement; denial.

1. If a person applies for reinstatement of a license or cannabis establishment agent registration card that has been revoked pursuant to ~~[this chapter]~~ ***Title 56 of NRS and these regulations***, the person shall:

(a) Submit an application on a form supplied by the Board.

(b) Satisfy all the current requirements for the issuance of an initial license or cannabis establishment agent registration card.

(c) Attest that, in this State or any other jurisdiction:

(1) The person has not, during the period of revocation, violated any state or federal law relating to cannabis, and no criminal or civil action involving such a violation is pending against the person; and

(2) No other regulatory body has, during the period of revocation, taken disciplinary action against the person, and no such disciplinary action is pending against the person.

(d) Satisfy any additional requirements for reinstatement of the license or cannabis establishment agent registration card prescribed by the Board.

2. The Board will consider each application for reinstatement of a license or cannabis establishment agent registration card submitted pursuant to this section. In determining whether to reinstate the license or cannabis establishment agent registration card, the Board will consider the following criteria:

(a) The severity of the act resulting in the revocation of the license or cannabis establishment agent registration card.

(b) The conduct of the person after the revocation of the license or cannabis establishment agent registration card.

(c) The amount of time elapsed since the revocation of the license or cannabis establishment agent registration card.

(d) The veracity of the attestations made by the person pursuant to subsection 1.

(e) The degree of compliance by the person with any additional requirements for reinstatement of the license or cannabis establishment agent registration card prescribed by the Board.

(f) The degree of rehabilitation demonstrated by the person.

3. If the Board reinstates the license or cannabis establishment agent registration card, the Board may place any conditions, limitations or restrictions on the license or cannabis establishment agent registration card as it deems necessary.

4. The Board may deny reinstatement of the license or cannabis establishment agent registration card if the person fails to comply with any provisions of this section.

5. This section shall not be interpreted to give any party or other person a right to reinstatement of the license or cannabis establishment agent registration card.

4.105 Grounds for summary suspension; notice; request for hearing.

1. ~~[If, due to the actions of a cannabis establishment, there could be an impairment of the health and safety of the public, the Executive Director, or the Deputy Director in his absence, will convene an emergency Board meeting telephonically.~~

~~2.~~] Pursuant to ***and in accordance with*** subsection 3 of NRS 233B.127, if the Board finds that the public health, safety or welfare imperatively requires emergency action, the Board may issue an order of summary suspension of the license of a cannabis establishment or a cannabis establishment agent registration card pending proceedings for revocation or other action. An order of summary suspension issued by the Board must contain findings of the exigent circumstances which warrant the issuance of the order of summary suspension, and a suspension under such an order is effective immediately.

~~[3.]~~ ***2.*** The Board ***or its designee*** will give notice to a licensee or person that is subject to an order of summary suspension of the facts or conduct that warrant the order and the deficiencies that must be corrected to lift the order. A cannabis establishment whose license has been suspended pursuant to section ***1*** ~~2~~ shall develop a plan of correction for each deficiency and submit the plan to the Board for approval within 10 business days after receipt of the order of summary suspension. The plan of correction must include specific requirements for corrective action, which must include times within which the deficiencies are to be corrected. A licensee or person that is subject to an order of summary suspension shall not operate until the Board or its designee has confirmed that the deficiencies identified in the order have been corrected.

~~[4.]~~ ***3.*** If the plan submitted pursuant to section 3 is not acceptable to the Board or its designee, the Board may direct the cannabis establishment to resubmit a plan of correction or the Board may develop a directed plan of correction with which the cannabis establishment must comply. The Board's acceptance of a plan of correction does not preclude the Board from assessing fines and/or pursing disciplinary action against the licensee for any violations connected with the suspension.

~~[5.]~~ ***4.*** A licensee or person that is subject to an order of summary suspension may request a hearing regarding the order within 10 business days after the order is issued. A hearing on the summary suspension must be held within 30 days after that request for hearing.

4.110 Discovery: mandatory exchanges.

1. Within 20 calendar days after the service of the answer by the first answering respondent, and thereafter as each respondent answers the complaint, the parties shall confer for the purpose of complying with subsection 3 of this section.

2. Within 5 calendar days after a request for hearing regarding an order of summary suspension, the parties shall confer for the purpose of complying with subsection 3 of this section.

3. At each conference the parties shall:

(a) Exchange copies of all documents and other evidence then reasonably available to a party which are then intended to be offered as evidence in support of the party's case in chief; and

(b) Exchange written lists of persons each party then intends to call as a ~~[material]~~ witness in support of that party's case in chief. Each witness shall be identified by name, if known, position, business address, and a brief description of the purpose for which the witness will be called. If no business address is available, the party shall provide a home address for the witness, or shall make the witness available for service of process. ~~[For the purpose of this paragraph, a "material witness" is a person whose testimony relates to a genuine issue in dispute which might affect the outcome of the proceeding.]~~

4. The investigative file for a case***, or any portion thereof***, is not discoverable unless Board counsel intends to present materials from the investigative file as evidence in support of the case. The investigative file for the case includes all communications, records, affidavits or reports acquired or created as part of the investigation of the case, whether or not acquired through a subpoena related to the investigation of the person. Discovery of the investigative file is limited to solely those documents the Board Counsel intends to use as evidence in support of its case, as disclosed prior to the hearing.

5. A party may not serve any written discovery on another party, inclusive of interrogatories, requests for production, requests for admissions and/or depositions by written questions.

6. ~~[Pursuant to NRS 678A.530(2), a party may take the deposition of a material witness.~~

~~(a) A party who wishes to take a deposition of a material witness must request such a deposition at any early case conference held in the matter or submit a written application at least 30 days before the hearing. The application must:~~

~~(1) Set forth the reason why the deposition is necessary; and~~

~~(2) Be accompanied by the appropriate orders for deposition.~~

~~(b) A material witness is a witness who has percipient knowledge of the alleged misconduct of the licensee. If there is any dispute as to whether a particular witness is material, such dispute shall be submitted to the Chair or hearing officer and they shall rule on whether such witness is material.~~

~~€ The Chair or the hearing officer shall approve or deny the application within 5 days after the receipt of the application.~~

~~(d) If a material witness deposition is allowed it shall be conducted in accordance with the Nevada rules of civil procedure and not last more than one day/seven hours unless good cause is shown.~~

~~€ Depositions of non-material witnesses may be permitted in two very limited circumstances:~~

~~(1) If the potential witnesses resides outside of Nevada; or~~

~~(2) If the witness is not available to testify during the hearing.~~

~~(f) If the parties cannot agree on whether a non-material witness can be deposed, such dispute shall be submitted to the Chair or the hearing officer and they shall rule on this issue, taking into account whether the burden and expense of the proposed deposition outweighs its likely benefit.~~

~~7.~~ ~~]~~It shall be a continuing obligation of the parties to produce documents, witness lists, and other matters governed by this section as such become identified by and available to the parties. A party may amend its responses to the requirements of this section by informing the adverse party that documents previously produced or witnesses previously listed, will not be introduced in that party's case in chief. ***However, there shall be no supplementation of witnesses or documents after the discovery deadline set at the early case conference (or any extension granted regarding same), unless the proffering party can demonstrate good cause for the failure to timely disclose such supplementation. If such good cause is shown, the opposing party shall be granted sufficient time to disclose witnesses and documents that rebut the new evidence proffered.***

4.130 Subpoenas.

1. The executive assistant shall issue subpoenas, including subpoenas duces tecum, upon the request of a party, in accordance with this section.

2. Subpoenas may be issued ~~[only for the following purposes:]~~

(a) ~~[To compel a nonparty witness to appear and give oral testimony at a deposition as provided by NRS 678A.530(2); and~~

~~(b) T~~]*to* compel any person to appear at the hearing on the merits of the case, to give oral testimony alone, or to produce documents or other tangible things.

3. Subpoenas shall be submitted to the executive assistant for issuance on a form approved by the Chair. Concurrently with the submission of the subpoena to the executive assistant, the requesting party shall serve a copy on all other parties to the proceeding, and shall file proof of such service with the Board.

4. Subpoenas will not be issued in blank. A subpoena submitted for issuance must contain the title and number of the case, the name of the person to whom it will be directed, the date, time, and place of the hearing or deposition, and the name and signature of the requesting party or the requesting party's attorney. A subpoena duces tecum must in addition contain a complete description of specific documents or other tangible things that the witness will be required to produce at the hearing.

5. Unless the witness agrees otherwise, a subpoena issued for the purpose provided by subsection 2(b) must be served by the requesting party at least 10 calendar days prior to the hearing or deposition. A subpoena will be issued during the hearing or upon less than 10 days' notice only upon order of the Board for reasonable cause shown by the requesting party.

4.135 Disposition of charges: Adjudication by Board.

1. Prior to the adjudication, at least three members of the Board shall review a full transcript of the hearing or the phonographic recording of the hearing*, as well as all admitted exhibits,* to ensure they have heard all the evidence presented and shall review the findings of fact and conclusions of law submitted after the hearing.

2. At the adjudication, the Board shall consider any findings of fact and conclusions of law submitted after the hearing and shall allow:

(a) Board ~~[a]~~Agent or counsel for the Board to present a disciplinary recommendation and argument;

(b) The respondent or counsel of the respondent to present an argument, if they wish to, in opposition to or support of the disciplinary recommendation; and

€ The Board may limit the time within which the parties and the complainant may make their arguments and statements.

3. At the conclusion of the presentations of the parties, the Board shall deliberate and may by a majority vote impose discipline based upon the evidence, findings of fact and conclusions of law and the presentations of the parties.

4. If the Board finds that a violation has occurred, it shall by order any and all discipline authorized by ~~[this Chapter]~~ *these regulations* and Title 56 of the NRS.

5.Within 30 days after the conclusion of the adjudication by the Board, the Board shall issue a final order, that imposes discipline and incorporates the findings of fact and conclusions of law obtained from the hearing. An order that imposes discipline and the findings of fact and conclusions of law supporting that order are public records.

4.137 Settlement of Disciplinary Actions and/or Contested Cases.

1. Pursuant to S.B. 195 Sec. 2, 2023 Leg., 82th Sess. (Nv. 2023) and NRS 233B.121(5), the parties to any disciplinary action may agree to resolve a disciplinary action or contested case via a settlement agreement at any time. Settlement agreements may be entered into prior to or after commencement of a contested case and/or disciplinary action or the filing of a disciplinary complaint.

2. Should the parties enter into a settlement agreement, that settlement agreement shall not be effective until approved by a majority vote of the Board at an open meeting.

3. If the parties enter into a settlement agreement after a disciplinary action or contested case has commenced, or have agreed to the primary terms of a settlement, the Board, a panel of the Board, or the Board's appointed hearing officer may enter a stay of the proceedings pending the Board's consideration of approval of a final settlement agreement executed by the parties.

4. In any settlement agreement, the parties may stipulate to the civil penalties to be imposed, any other discipline to be imposed (inclusive of revocation or suspension), the mitigating circumstances present and the appropriate weight of the mitigating circumstances, and any other terms and conditions relevant to the disciplinary action or contested case.

5. In considering a settlement agreement, the Board may approve the settlement agreement, reject the settlement agreement, or remand the settlement agreement back to the parties to determine whether settlement may be reached on different terms. If the parties to the settlement agreement can agree to such different terms, an amended settlement agreement may be noticed for a later Board meeting for consideration of approval.

4.140 Declaratory orders and advisory opinions.

1. ***Pursuant to NRS 233B.120,*** any applicant for licensure, licensed cannabis establishment, or holder of registry identification card may obtain a determination or advisory opinion from the Board as to the applicability of any provision of chapters 678A through 678D of NRS or any regulation adopted pursuant thereto by bringing a petition for a declaratory ruling before the Board. No other persons or entities may petition the Board for a declaratory ruling.

2. A declaratory ruling is an extraordinary remedy that will be considered by the Board only when the objective of the petitioner cannot reasonably be achieved by other means and when the ruling would be significant to the regulation of cannabis. The Board will construe any statute or regulation reviewed pursuant to this section in a manner consistent with the declared policy of the State of Nevada.

3. A petition for a declaratory ruling shall be filed with the Executive Director, together with a nonrefundable filing fee in the amount of $500.00.

4. The petition for a declaratory ruling must contain:

(a) The name, business address, ***email***, and telephone number of the petitioner;

(b) A statement of the nature of the interest of the petitioner in obtaining the declaratory ruling;

(c) A statement identifying the specific statute or regulation in question;

(d) A clear and concise statement of the interpretation or position of the petitioner relative to the statute or regulation order in question;

(e) A description of any contrary interpretation, position or practice that gives rise to the petition;

(f) A statement of the facts and law that support the interpretation of the petitioner, along with a table of legal authorities;

(g) A statement showing why the subject matter is appropriate for Board action in the form of a declaratory ruling and why the objective of the petitioner cannot reasonably be achieved by other administrative remedy;

(h) A statement identifying all persons or groups who the petitioner believes will be affected by the declaratory ruling, including the cannabis industry as a whole, and the manner in which the petitioner believes each person will be affected; and

(i) The signature of the petitioner or the petitioner's legal representative.

The Board may summarily dismiss, with or without prejudice, a petition that does not meet all of the requirements set forth in this paragraph.

5. A petitioner may not file a petition for declaratory ruling involving questions or matters that are issues in a disciplinary action or ~~[civil penalty action]~~ ***contested case*** with the Board in which the petitioner is a party or has a financial and/or ownership interest in a party

6. The Board will consider a petition for declaratory ruling at the next scheduled Board meeting, provided that the petition is filed with the Executive Director ~~[15]~~***20*** calendar days prior to that scheduled Board meeting. If the petition is not filed with the Executive Director ~~[15]~~***20*** calendar days prior to next scheduled Board meeting, the petition will be considered at the following scheduled Board meeting. ***The Board may continue these dates for good cause.***

7. In considering a petition for a declaratory ruling at the Board's meeting, the Board, by majority vote of the members, may take any of the following actions:

(a) Dismiss the petition and close the case;

(b) Order a hearing with oral argument on the petition and set a date for said hearing, which may be at a subsequently scheduled Board meeting;

(c) Issue an order permitting any other licensee or applicant to file a brief supporting or opposing the petition. If the Board chooses this option, supporting or opposing briefs shall be due 10 calendar days after the Board meeting during which the petition is considered and any reply briefs shall be due 5 calendar days thereafter. All such briefs must be timely filed and served on the Executive Director and the other parties involved, or will not be considered. Each such brief must be accompanied by a non-refundable filing fee of $250;
(d) After hearing the petition and reviewing any additional briefing (if applicable), issue an order granting, denying ***(with or without prejudice),*** or granting in part and denying in part, the petition.

8. The petitioner may not obtain judicial review of any Board order entered pursuant to this regulation.
9. The petitioner, or any other party filing a brief under subsection 7€, may request a waiver of the filing fee pursuant to a showing of financial hardship.

4.145 Adoption, amendment or repeal of a regulation.

1. ***Pursuant to NRS 233B.100(1),*** any interested ~~[party]~~ ***person*** may petition the Board to request the adoption, amendment or repeal of a ***Cannabis Compliance Board*** regulation ~~[under NCCR pursuant to NRS 678A.460(1)(d)]~~.
2. The Board will construe any such petition pursuant to this section in a manner consistent with the declared policy of the State of Nevada.
3. A petition to the Board to request the adoption, amendment or repeal of a regulation shall be filed with the Executive Director, together with a nonrefundable filing fee in the amount of $500.00.
4. The petition to request the adoption, amendment or repeal of a regulation must contain:
(a) The name, business address, ***email,*** and telephone number of the petitioner;
(b) A statement of the substance or nature of the regulation, amendment or repeal requested;
(c) A statement identifying the specific regulation in question;
(d) A clearly drafted proposed new regulation to be adopted, a clearly drafted amendment to a specific regulation or a detailed statement of what regulation is to be repealed and why, depending on the specific request;
(e) A statement***, with supporting data and evidence when applicable,*** identifying all persons or groups who the petitioner believes will be affected by the adoption, amendment or repeal of a regulation, including the cannabis industry as a whole, and the manner in which the petitioner believes each person will be affected; and
(f) The signature of the petitioner or the petitioner's legal representative.

The Board may summarily dismiss, with or without prejudice, a petition that does not meet all of the requirements set forth in this paragraph.

5. A petitioner may not file a petition for adoption, amendment or repeal of a regulation that involves regulations that are issues in a disciplinary action or ~~[civil penalty action]~~ ***contested case*** with the Board in which the petitioner is a party or has a financial and/or ownership interest in a party.

6. Pursuant to NRS 233B.100(1), within 30 days, the Board shall either deny the petition in writing stating its reasons for denial, or initiate regulation making proceedings. The Board may delegate to the Chair the decision on whether to deny the petition. The Board may set a hearing on the petition within 30 days of its submission at the next regularly scheduled Board meeting. The Board or its counsel may stipulate with the petitioner to waive the 30-day deadline for a decision on the petition. The petition may be denied with or without prejudice for any reason deemed appropriate by the Board or

the Chair, including, but not limited to, failure to adequately comply with the requirements of NRS 233B.100(1) and/or this Regulation, the request in the petition is contrary to Nevada law, the request in the petition is moot or is already addressed in an existing regulation or statute or Board process, the request in the petition is contrary to declared policy of the State of Nevada, the petitioner is not deemed to be an interested person, and/or the petition presents insufficient data and/or information for the Board to make a decision. If the petition is denied without prejudice, the petitioner may file a new or amended petition to attempt to cure any deficiencies.

7. For purposes of this Regulation, an "interested person" is defined to be an applicant for licensure, a cannabis establishment licensee, a person directly affected by Title 56 of the NRS and/or the NCCR, and/or a group or association of such licensees (provided that each such licensee member of the group is identified by name and address), applicants, or persons directly affected by Title 56 of the NRS and/or the NCCR.

~~[6]~~***8. Except as otherwise set forth in subsections 4 and 6***, ~~[I]~~*i*n considering a petition for adoption, amendment or repeal of a regulation at the Board's meeting, the Board, by majority vote of the members, may take any of the following actions:

(a) Dismiss the petition with no action taken;

(b) Refer the petition to the Cannabis Advisory Commission for consideration and recommendations***, if the petitioner has waived the 30-day requirement for a decision***;

(c) Order a hearing with oral argument on the petition and set a date for said hearing, which may be at a subsequently scheduled Board meeting;

(d) Issue an order permitting any other ~~[licensee or applicant]~~ ***interested person*** to file a brief supporting or opposing the petition. If the Board chooses this option, supporting or opposing briefs ~~[shall be due 10 calendar days after the Board meeting during which the petition is considered and any reply briefs shall be due 5 calendar days thereafter.]~~ ***must be filed no later than two days prior to the Board's deadline for a decision.*** All such briefs must be timely filed and served on the Executive Director and the other parties involved, or will not be considered. Each such brief must be accompanied by a non-refundable filing fee of $250;

(e) After hearing the petition and reviewing any additional briefing (if applicable), issue an order granting, denying, or granting in part and denying in part, the petition.

9. Except as otherwise set forth in subsections 4 and 6, prior to considering a petition as set forth in subsection 8, the Board may submit the petition to a Hearing Officer employed by the Board to review the petition and recommend to the Board a course of action to take on the petition. In the Hearing Officer's review of the petition, the Hearing Officer may communicate with and/or solicit comment from the Board's staff and/or counsel representing the Board.

~~[8]~~. ***10.*** The petitioner may not obtain judicial review of any Board order entered pursuant to this regulation.

~~[9.]~~ ***11.*** The petitioner, or any other party filing a brief under subsection ~~[7]~~***8***(d), may request a waiver of the filing fee pursuant to a showing of financial hardship.

4.150 Petition for Exemption from Excluded Felony Offense Restrictions.

1. Pursuant to S.B. 277 Sec. 4.5, 2023 Leg., 82th Sess. (Nv. 2023), a person convicted of an excluded felony offense may submit to the Board a petition for exemption from restrictions imposed pursuant NRS 678B.210(3)(b), 678B.250(3)(b), and/or 678B.340(6)(a) by submitting a petition to the Board which fulfills the requirements set forth in this regulation.

2. The Board will construe any such petition pursuant to this section in a manner consistent with the declared policy of the State of Nevada.

3. The petition must contain:

(a) The name, residence, business address (if applicable), email, and telephone number of the petitioner;

(b) The date of conviction for each excluded felony offense;

(c) The date that probation and/or supervised release ended for each excluded felony offense;

(d) Certified copies of the judgment or judgments of conviction for each excluded felony offense;

(e) An explanation as to why the petitioner believes they will not pose a threat to the health or safety of the public;

(f) An explanation as to why the petitioner believes they will not negatively impact the cannabis industry in this State;

(g) The position, employment, ownership interest, and/or other role petitioner plans to undertake in the cannabis industry in this State, if the petition is granted;

(h) A list of conditions and limitations the petitioner is willing to accept on his or her involvement in the cannabis industry in this State;

(i) The signature of the petitioner or the petitioner's legal representative;

(j) Any other information or documents requested by the Board or Board Agents during their investigation of the petition.

The Board may summarily deny, with or without prejudice, a petition that does not meet all of the requirements set forth in this paragraph.

4. The Board or the Board's Agents may request the criminal history record of the petitioner. To the extent consistent with federal law, if the Board makes such a request of the petitioner, the Board shall require the petitioner to submit his or her criminal history record which includes a report from:

(a) The Central Repository for Nevada Records of Criminal History; and

(b) The Federal Bureau of Investigation.

5. After the petitioner has filed the petition, a Board Agent shall initially evaluate it and undertake any needed investigation. Within 60 days of the filing of the petition said Board Agent will inform petitioner whether any additional documents or information is needed. Petitioner shall provide said additional information or documents to the Board Agent within 45 days of any such request. The Board Agent shall then have 45 days after submittal of all the requested additional information or documents to conclude the evaluation and investigation.

6. Once the Board Agent has completed the investigation, the petition shall be presented to the Board for consideration at an open meeting on notification to the petitioner.

7. At the time of the Board's consideration, the Board may hear from and question the petitioner, and may go into closed session as required by law.

8. After hearing from the petitioner, the Board may grant the petition in its entirety, grant the petition with any terms or conditions as set forth in S.B. 277 Sec. 4.5(4), 2023 Leg., 82th Sess. (Nv. 2023), or deny the petition with or without prejudice. The Board shall issue a final order to petitioner of its decision within 30 days of its decision.
9. The petitioner may not obtain judicial review of any Board order entered pursuant to this regulation.

4.200 Actions Relating to Unlicensed Activity.
1. The CCB may issue a notice of violation and an order to cease unlicensed activity to any person or business who is cultivating, processing, distributing, transporting, or selling or offering to sell cannabis or cannabis product, or engaging in an indirect retail sale of cannabis or cannabis product including but not limited to listing and disseminating in print or online an unlicensed cannabis business and/or delivery app, without obtaining the appropriate license, including any owner of real property where the unlicensed activity took place.
2. In the event that the CCB issues a notice of violation and order to cease unlicensed activity to a person or business identified in Section (1):
(a) that person or business must cease all unlicensed cannabis related activity as described in Section (1) effective immediately upon the notice and order:
(1) being affixed to the physical location where such activity is taking place; or
(2) being delivered by hand or by registered or certified mail to the person or business acting or engaging in the unlicensed activity;
(b) pursuant to NRS 678A.440(11) (as amended by S.B. 328 Sec. 1.6, 2023 Leg., 82nd Sess. (Nv.2023)), NRS 179.1156 to 179.121, inclusive, and NRS 678C.600, the CCB may seize and destroy any cannabis and/or cannabis product found in the possession of a person engaged in the conduct described in Section (1) of this section;
(c) the CCB may affix a copy of such notice of violation and order to cease unlicensed activity on the front window, door, or exterior wall of the location where such activity is taking place. The notice and order shall be within five feet of the front door or other public points of entry, at a vertical height no less than four feet and no more than six feet from the ground or floor. When an establishment does not have a direct entrance from the street, the person shall permit the CCB to post such notice of violation and order to cease and desist unlicensed activity at any point of entry in a place where potential customers or members of the public are likely to see it;
(d) such notice of violation and order to cease unlicensed activity shall not be removed except when authorized by the CCB. Any removal of such notice of violation and/or order to cease and desist unlicensed activity shall constitute a violation of these regulations and shall be punishable by a fine of up to $50,000;
(e) the person or business served with such notice of violation and order to cease unlicensed activity shall permit the CCB to affix one or more warning stickers at or near the front door or other opening to such location where customers enter from the street advising the public that the business is ordered to stop the unlawful activity and of the public health and safety concerns relating to illicit cannabis;

(f) such warning sticker shall not be removed until authorized by the CCB. Any unauthorized removal of the warning sticker shall constitute a violation of these regulations and shall be punishable by a fine of up to $50,000 as well as administrative costs and fees, including attorneys' fees.

3. The CCB may initiate an administrative proceeding to enforce the order to cease the unlicensed activity and order the financial penalty that the CCB assessed for the violation. The proceeding will be subject to NRS 233B, NRS 678A, and NCCR 4.070 – 4.135 inclusive. Any references to "licensee" and "cannabis establishment" in such sections shall be read to apply to persons subject to enforcement pursuant to this section.

(a) If the CCB has cause to believe that a person has engaged or is engaging in an unlicensed activity outlined in Section (1), the CCB via the executive assistant may issue a subpoena to require the testimony of any person or the production of any documents, and may administer an oath or affirmation to any person providing such testimony. The CCB may use any documents, records, or materials produced pursuant to a subpoena issued under this section in the course of a civil or administrative action brought pursuant to NCCR 4.200.

(1) The subpoena must be served upon the person in the manner required for service of process in this State or by certified mail. An employee of the CCB may personally serve the subpoena.

(b) Pursuant to NRS 233B.121(5), NRS 678A ((as amended S.B. 195 Sec. 2, 2023 Leg., 82nd Sess. (Nv2023)) and NCCR 4.137, the parties may enter a stipulation for the resolution of any and all issues at any time. Settlement agreements may be entered into prior to or after commencement of enforcement action identified in Section 3. Should the parties enter into a settlement agreement, that settlement agreement shall not be effective until approved by a majority vote of the Board at an open meeting. A Board-approved settlement agreement shall have the same force and effect as an order issued by the CCB after a hearing.

(c) After the administrative proceeding to enforce an order to cease and desist the unlicensed activity or order the financial penalty, the CCB shall issue a decision based on findings of fact and conclusions of law pursuant to NRS 233B.125 and NRS 678A.590 except as otherwise provided in NRS 233B.121(5). Such decision shall be final and binding when issued.

(d) All parties shall have the right to judicial review of the CCB's decision pursuant to NRS 233B.130 – NRS 233B.150, inclusive and NRS 678A.610.

4. In addition to the penalties outlined in NRS 678A.650 and NRS 452.553, a person identified in Section 1 who does not hold a license and who, in violation of the provisions of this title:

(a) cultivates, processes, distributes, transports, or sells cannabis and/or cannabis product

(b) advertises the sale of cannabis or cannabis products, or

(c) engages in an indirect retail sale of cannabis or cannabis products

➥is liable for a civil penalty of not more than $50,000 to be recovered in an action brought by the CCB.

5. Any money collected as a civil penalty pursuant to Section (4) of this rule must be used to pay the actual cost of prosecution, court costs and costs incurred for the disposal of any hazardous waste in connection with the violation for which the penalty was imposed.

6. Such a civil penalty is not barred by a prior acquittal of the defendant in a criminal action arising out of the same act, transaction or occurrence. A final judgment or decree rendered in favor of the State in any criminal proceeding arising out of the same act, transaction or occurrence estops the defendant in a subsequent civil penalty action from denying the essential allegations of the criminal offense.

7. The Attorney General may bring an action to enjoin a person who engages in any of the conduct described in Section (1) in addition to any action permitted by the CCB outlined in this Rule.

8. In lieu of initiating an administrative proceeding, the CCB may, in its sole determination, issue an administrative fine not to exceed $20,000.00 to any individual undertaking cannabis related activity as described in Section (1) of this section.

Proposed Changes to NCCR Regulation 6

PRODUCTION AND DISTRIBUTION OF CANNABIS

New
~~[Deleted]~~

6.025 Board authorized to collect fee for costs for [~~oversight~~] ***investigation*****; hourly rate**.

1. For the ongoing activities of the Board relating to the [~~oversight~~] ***investigation*** of cannabis establishments ***pursuant to NRS 678B.390***, the Board will collect an assessment from each cannabis establishment for the [~~time and effort~~] ***costs*** attributed to the [~~oversight~~] ***investigation*** of the cannabis establishment at an hourly rate established by the Board. ~~Necessary travel accommodations accrued by Board agents, including airfare and hotel stays,~~ ***An hourly fee at a rate of $111.00 for each hour spent by agents of the Board in conducting the investigation, and costs for the travel expenses and per diem allowances (as assessed at the rate established by the State Board of Examiners for state officers and employees generally) of the agents of the Board conducting the investigation*** will ~~also~~ be billed to the cannabis establishment. [~~The activities where the hourly rate for time and effort will be charged include, but are not limited to:~~

~~(a) Any type of routine inspection;~~
~~(b) Any type of routine audit;~~
~~(c) Hearing preparation and attendance for Board agents;~~
~~(d) Investigations of complaints submitted to the Board by a consumer, or any other outside individual or entity, if said complaint is substantiated;~~
~~(e) Investigations based on any type of requested transfer of interest;~~
~~(f) Investigations based on any type of requested waiver;~~
~~(g) Investigations based on an application for a new cannabis establishment license; and~~
~~(h) Any other type of inspection, audit, or investigation deemed necessary by the Board.~~]

2. [~~The assessment for time and effort will be based upon the hourly rate established for the Board agents as determined by the budget of the Board. Licensees will be notified of any fee changes.~~

~~3. Cannabis establishments and its agents will not be billed for an investigation regarding an application for a registration card. Furthermore, cannabis establishments will not be billed for Petitions filed pursuant to NCCR 4.140 or 4.145.~~

~~4. As used in this section, "substantiated" means supported or established by evidence or proof.~~]

Prior to the commencement of an investigation, the Board shall provide the licensee or applicant an estimate of the anticipated costs of the investigation. A request for any action identified in NRS 678B.390(5) will initiate the Board's obligation to provide such an estimate.

3. The Board is required to provide a licensee or an applicant an itemized list of the costs incurred in the investigation. All such costs shall be due 60 days after receipt of the CCB Invoice. Failure to pay such costs upon the due date is a Category VII violation pursuant to NCCR 4.061.

4. A licensee or an applicant may request from the Board documentation, prepared by the Board or its agents conducting the investigation, relating to the costs of the investigation by sending an email request to ccbtimeandeffort@ccb.nv.gov.

5. A licensee or an applicant may appeal to the Board any itemized cost, or a licensee or an applicant may request a reduction of the total amount charged for the investigation if the total amount charged exceeds the estimate of the anticipated costs provided to the licensee or applicant by 25 percent or more.

6.085 Required security measures, equipment and personnel; location of outdoor cultivation facility must allow for response by local law enforcement.

1. To prevent unauthorized access to cannabis at a cannabis establishment, the cannabis establishment must have:

(a) One single secure entrance of the physical building;

(b)No visible cannabis or cannabis products from outside the establishment.

(c) Security equipment to deter and prevent unauthorized entrance into limited access areas that includes, without limitation:

(1) Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular or private radio signals, or other mechanical or electronic device, and which, for a cannabis cultivation facility which engages in outdoor cultivation, covers the entirety of the cultivation area and the perimeter and exterior area of the cannabis cultivation facility;

(2) Exterior lighting to facilitate surveillance which, for a cannabis cultivation facility which engages in outdoor cultivation:

(I) When the lighting would not interfere with the growing cycle of a crop, covers the entirety of the cultivation area and the perimeter and exterior area of the cannabis cultivation facility; and

(II) When the lighting would interfere with the growing cycle of a crop, covers the perimeter and exterior area of the cannabis cultivation facility;

(3) Electronic monitoring, including, without limitation, each of the following:

(I) At least one call-up monitor that is 55 inches or more;

(II) A printer capable of immediately producing a clear still photo from any video camera image, which photo must be provided to the Board or Board Agents for review upon request;

(III) Video cameras with a recording resolution of at least 1920 x 1080, or the equivalent, at a rate of at least 15 frames per second which provide coverage of all entrances and exits of the building, any room or area that holds a vault and any point-of-sale location, which record 24 hours per day, which are capable of being accessed remotely by a law enforcement agency in real time and which may record motion only. The information necessary to remotely access the camera footage must be entered into the cannabis establishment's Accela portal. A video camera providing coverage of a point-of-sale location must allow for the identification of any person purchasing cannabis. In a cannabis consumption lounge, the entire area that is used by consumers must be covered by video cameras;

(IV) Video cameras with a recording resolution of at least 720 x 480, or the equivalent, at a rate of at least 15 frames per second which provide coverage of all limited access areas not described in sub-subparagraph

(III) and any activity in or adjacent to the establishment, which record 24 hours per day, which are capable of being accessed remotely by a law enforcement agency, the Board, and Board Agents in real time upon request, which may record motion only and which, for a cannabis cultivation facility which engages in outdoor cultivation, cover the entirety of the cultivation area and the perimeter and exterior area of the cannabis cultivation facility. The information necessary to remotely access the camera footage must be entered into the cannabis establishment's portal within the Board's electronic licensing system;

(V) A video camera which is capable of identifying any activity occurring within the cannabis establishment in low light conditions 24 hours per day;

(VI) A method for storing video recordings from the video cameras for at least 30 calendar days in a secure on-site or off-site location or through a service or network that provides on-demand access to the recordings and providing copies of the recordings to the Board and Board Agents for review upon request, on portable, external hard drives or other media as directed by the Board or Board Agents, at the expense of the cannabis establishment, and within a reasonable timeframe as determined by the Board or Board Agents. Adequately sized portable, external drives must be immediately available to store a minimum of seven days (168 Hours) of video from a minimum of seven cameras. External drives must be USB 3.0 or greater and formatted with FAT32 or exFAT and will not be returned to the establishment;

(VII) A failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system;

(VIII) In a cannabis consumption lounge, security personnel are required tomonitor real time security camera footage while the facility is open for business as prescribed by the Board; and

(IX) Sufficient battery backup for video cameras and recording equipment to support at least 5 minutes of recording in the event of a power outage;

(4) Immediate automatic or electronic notification to alert local law enforcement agencies of an unauthorized breach of security at the cannabis establishment in the interior of each building of the cannabis establishment; and

(5) For a cannabis cultivation facility which engages in outdoor cultivation:

(I) An alarm system and video cameras which are monitored 24 hours per day;

(II) An exterior barrier, determined to be appropriate by local law enforcement, which is located around the perimeter of the cannabis cultivation facility and which consists of a solid block wall or chain link fence with a height of at least 8 feet and an additional fence with a height of at least 8 feet located at least 10 feet and not more than 20 feet inside of the solid block wall or chain link fence; and

(III) A secure brick and mortar building which is approved by the appropriate Board Agent as suitable to dry and store cannabis and which meets the security and sanitation requirements for a cannabis cultivation facility which engages in indoor cultivation of cannabis.

(d) Policies and procedures:

(1) That restrict access to the areas of the cannabis establishment that contain cannabis to persons authorized to be in those areas only;

(2) That provide for the identification of persons authorized to be in the areas of the cannabis establishment that contain cannabis;

(3) That prevent loitering, other than consumers already admitted to a cannabis consumption lounge;

(4) For conducting electronic monitoring;

(5) For the use of the automatic or electronic notification to alert local law enforcement agencies of an unauthorized breach of security at the cannabis establishment;

(6) For limiting the amount of money available in any retail areas of the cannabis establishment and for training employees on this practice;

(7) For notifying the public of the minimal amount of money available, which may include, without limitation, the posting of a sign;

(8) For maintaining communication with law enforcement agencies; and

(9) For providing and receiving notifications regarding burglary, attempted burglary, robbery, attempted robbery and other suspicious activity.

2. Each video camera used pursuant to subparagraph (3) of paragraph (c) of subsection 1 must:

(a) Include a date and time generator which possesses the capability to display the date and time of recorded events on the recording in a manner that does not significantly obstruct the recorded view; and

(b)Be installed in a manner that will prevent the video camera from being readily obstructed, tampered with or disabled.

3. A cannabis establishment shall make a reasonable effort to repair any malfunction of security equipment within 72 hours after the malfunction is discovered. A cannabis establishment shall notify the Board and local law enforcement ***if requested by local law enforcement agency,*** within 24 hours after a malfunction is discovered and provide a plan of correction. Failure to correct a malfunction within 72 hours after the malfunction is discovered is a violation of this section.

4. If a video camera used pursuant to subparagraph (3) of paragraph (c) of subsection 1 malfunctions, the cannabis establishment shall immediately provide alternative video camera coverage or use other security measures, such as assigning additional supervisory or security personnel, to provide for the security of the cannabis establishment. If the cannabis establishment uses other security measures, the cannabis establishment must immediately notify the Executive Director, and the Executive Director will determine whether the other security measures are adequate.

5. Each cannabis establishment shall maintain a log that documents each malfunction and repair of the security equipment of the cannabis establishment pursuant to subsections 3 and 4. The log must state the date, time and nature of each malfunction, the efforts taken to repair the malfunction and the date of each effort, the reason for any delay in repairing the malfunction, the date the malfunction is repaired and, if applicable, any alternative security measures that were taken. The log must also list, by date and time, all communications with the Board, Board Agents or Executive Director concerning each malfunction and corrective action. The cannabis establishment shall maintain the log for at least 1 year after the date of last entry in the log.

6. Each cannabis establishment must employ a security manager or director who must be responsible for:

(a) Conducting a semiannual audit of security measures to ensure compliance with the state procedures of the cannabis establishment and identify potential security issues;

(b) Training employees on security measures, emergency response and robbery prevention and response before starting work and on an annual basis; and

(c) Evaluating the credentials of any third party who intends to provide security to the cannabis establishment before the third party is hired by or enters into a contract with the cannabis establishment.

7. Each cannabis establishment shall ensure that the security manager or director of the cannabis establishment, at least one employee of the cannabis establishment or the employees of any third party who provides security to the cannabis establishment has completed or will complete within three months of being hired, to be proven by written attestation from the employee and the training officer, the following training:

(a) Training in theft prevention or a related subject;

(b) Training in emergency response or a related subject;

(c) Training in the appropriate use of force or a related subject that covers when the use of force is and is not necessary;

(d) Training in the use and administration of first aid, including cardiopulmonary resuscitation;

(e) Training in the protection of a crime scene or a related subject;

(f) Training in the control of access to protected areas of a cannabis establishment or a related subject;

(g) Not less than 8 hours of on-site training in providing security services; and

(h) Not less than 8 hours of classroom training in providing security services.

8. A cannabis cultivation facility which engages in the outdoor cultivation of cannabis must be located in such a manner as to allow local law enforcement to respond to the cannabis cultivation facility within 15 minutes after being contacted unless the local law enforcement agency determines some other response time is acceptable.

9. Cannabis establishments must ensure that armed security officers do not violate the provisions of NRS 202.257 (possessing a firearm while under the influence of a controlled substance). In addition, a cannabis consumption lounge shall prohibit consumers from bringing firearms into a consumption lounge, including posting of signs providing notice of same.

10. A cannabis establishment shall operate the business in a decent, orderly, and respectable manner. A licensee shall not knowingly permit any activity or acts of disorderly conduct, nor shall a licensee permit rowdiness, undue noise, or other disturbances or activity offensive to a reasonable person, neighboring business, or to the residents of the neighborhood in which the business is located.

11. If an emergency requires law enforcement, firefighters, emergency medical service providers, Board Agents or other public safety personnel to enter the premises of the business, the cannabis establishment is responsible for ensuring that all consumption of inhalable cannabis, if allowed, and other activities if requested, cease until such personnel have completed their investigation or services and have left the premises.

12. A cannabis establishment must report directly to the Board any criminal activity requiring an in-person response from law enforcement within 24 hours after an owner or employee of the business learns of the event.

13. If the Board learns of an increase in criminal activity at or near the location of a particular cannabis establishment, the Board may require the licensee to create an appropriate risk mitigation plan and submit to the Board.
14. Employees are prohibited from consuming cannabis while on duty and at work. The cannabis establishment shall create appropriate procedures to ensure employees do not show up to work or remain at work intoxicated.

Proposed Changes to NCCR Regulation 5
LICENSING, BACKGROUND CHECKS, AND REGISTRATION CARDS

New
~~[Deleted]~~

5.075 Authority of Board and Executive Director relating to inspections and investigations, summoning of witnesses and issuance of subpoenas, administration of oaths and administration of provisions of chapter.

1. Submission of an application for a license for a cannabis establishment constitutes permission for entry to and reasonable inspection of the cannabis establishment by the Board and Board Agents, with or without notice. An inspector conducting an inspection pursuant to this section does not need to be accompanied during the inspection.
2. The Executive Director may, upon receipt of a complaint against a cannabis establishment, except for a complaint concerning the cost of services, a complaint concerning the efficacy of cannabis or a complaint related to consumer service issues, conduct an investigation during the operating hours of the cannabis establishment, with or without notice, into the premises, facilities, qualifications of personnel, methods of operation, policies, procedures and records of that cannabis establishment or any other cannabis establishment which may have information pertinent to the complaint.
3. Board Agents may enter and inspect any building or premises at any time, with or without notice, to:
    (a) Secure compliance with any provision of the NCCR or Title 56 of NRS;
    (b) Prevent a violation of any provision of the NCCR or Title 56 of NRS; or
    (c) Conduct an unannounced inspection of a cannabis establishment in response to an allegation of noncompliance with the NCCR or Title 56 of NRS.
4. The Board may:
    (a) Summon witnesses to appear and testify on any subject material to its responsibilities under this chapter or Title 56 of NRS. No property owner and no officer, director, superintendent, manager or agent of any company or corporation, whose property is wholly in one county, shall be required to appear, without his or her consent, at a place other than the county seat or at the nearest town to his or her place of residence or the principal place of business of such company or corporation. Such summons may be served by personal service by the Executive Director or his or her agent or by the sheriff of the county.
    (b) Except as otherwise provided in this paragraph, issue subpoenas to compel the attendance of witnesses and the production of books and papers and may seek to enforce the subpoenas by petition to any court of competent jurisdiction in the manner provided by law. The Board will not issue a subpoena to compel the production of books and papers that contain individually identifiable health information.
5. Any member of the Board, the Executive Director or any officer of the Board designated by the Board or Executive Director may administer oaths to witnesses.

6. The Board and Board Agents may:

(a) Inspect and examine all premises wherein cannabis is manufactured, sold or distributed;

(b) Inspect all equipment and supplies in, upon or about such premises;

(c) Summarily seize and remove from such premises any cannabis or cannabis products and impound any equipment, supplies, documents or records for the purpose of examination and inspection;

(d) Demand access to and inspect, examine, photocopy and audit all papers, books and records of any applicant or licensee, on his or her premises, or elsewhere as practicable, and in the presence of the applicant or licensee, or his or her agent, relating to the gross income produced by any cannabis establishment, and require verification of income, and all other matters affecting the enforcement of the policy or any of the provisions of this chapter or any chapter of Title 56 of NRS; and

(e) Demand access to and inspect, examine, photocopy and audit all papers, books and records of any affiliate of a licensee whom the Board knows or reasonably suspects is involved in the financing, operation or management of the licensee. The inspection, examination, photocopying and audit may take place on the premises of the affiliate or another location, as practicable, and in the presence of the affiliate or its agent.

7. Board Agents will enter and inspect [~~at least annually,~~] with or without notice, each building or the premises of a cannabis establishment to ensure compliance with the provisions of this chapter and Title 56 of NRS. ***All cannabis establishments may be inspected at least annually except that cannabis independent testing laboratories may be inspected at least biennially, with interim follow-up activities at least annually.*** Nothing in this subsection shall be construed to prohibit an appropriate local administrative authority from conducting an inspection of the facilities or operations of a cannabis establishment as provided by the ordinance of a local government.

8. Board Agents will enter and inspect, with or without notice, any building or premises operated by a cannabis establishment within 72 hours after the Board is notified that the cannabis establishment is operating without a license for the cannabis establishment.

9. Board Agents will inspect the medical cannabis establishment and the cannabis establishment of a dual licensee at the same time using the same inspection team to ensure consistency and efficiency. Board Agents will conduct such an inspection in a manner which is not unduly burdensome for the dual licensee.

10. The Board or Board Agents may consult with any person or entity, as needed, in any of the Board's audits, inspections, and/or investigations. This includes, but is not limited to, allowing such persons or staff from said entities to accompany Board Agents during inspections, and/or investigations.

11. The Board will administer the provisions of the NCCR and Title 56 of NRS for the protection of the public and in the public interest in accordance with the policy of this State.

12. As used in this section, "individually identifiable health information" means information which identifies a natural person, or from which the identity of a natural person may reasonably be ascertained, and which relates to:

(a) The past, present or future physical or mental health or condition of the person or

(b) The provision of health care to the person.

Proposed Changes to NCCR Regulation 7
CANNABIS SALES FACILITY

New
~~[Deleted]~~

7.035 Storage and location of products; disclosure of cannabis testing facility performing quality assurance tests upon request of consumer; approved sources of products for sale; maintenance and availability of certificate of analysis; exemption for industrial hemp.

1. A cannabis sales facility must store all usable cannabis, concentrated cannabis and cannabis products behind a counter or other barrier to ensure a consumer does not have direct access to the cannabis, concentrated cannabis or cannabis products.
2. Upon the request of a consumer, a cannabis sales facility must disclose the name of the cannabis testing facility which performed the required quality assurance tests for the cannabis sales facility and ***provide a copy of*** the corresponding certificate of analysis ***and soil amendment to the consumer.***
3. A cannabis sales facility may only sell usable cannabis obtained from a cannabis cultivation facility in this State.
4. Except as otherwise provided in subsection 6, a cannabis sales facility may only sell concentrated cannabis and cannabis products obtained from a cannabis product manufacturing facility in this State.
5. ~~[Except as otherwise provided in subsection 6, a]~~ ***A*** cannabis sales facility may not sell a product other than usable cannabis, concentrated cannabis or cannabis products which contain any level of THC or CBD without the approval of the appropriate Board Agent. Each cannabis sales facility shall maintain a file which contains a certificate of analysis for any such approved product at the cannabis sales facility and shall make the file available for review upon request.
6. The provisions of subsection 4 ***do***~~[es]~~ not apply to industrial hemp, as defined in NRS 557.~~[040]~~***160,*** which is certified and registered with the State Department of Agriculture.

Proposed Changes to NCCR Regulation 11
CANNABIS INDEPENDENT TESTING LABORATORY

New
~~[Deleted]~~

11.010 Employment, qualifications and duties of scientific director; inspection of testing laboratory upon appointment of new director.

1. Each cannabis independent testing laboratory must employ a scientific director who must ***reside within 200 miles of the laboratory, and shall be*** responsible for:

(a) Establishing and maintaining a quality control and quality assurance program that ensures the quality of the cannabis independent testing laboratory's services, and that is capable of identifying any failure of quality when it occurs;

(b) Ensuring safety and hazardous substance control in the laboratory;

~~[(b)]~~ ***(c)*** Supervising all staff of the cannabis independent testing laboratory; ~~[and]~~

(d) Reviewing all new technical policies and procedures, as well as substantial changes to existing technical policies and procedures, prior to implementation. These reviews must be documented and may not be delegated;

(e) Ensuring technical policies and procedures are reviewed at least biennially thereafter, with documentation of this review. This review may be delegated to a knowledgeable person, and must ensure technical policies and procedures are complete, current, and scientifically valid and relevant; and

~~[(c)]~~ ***(f)*** Actively participating in the operation of the cannabis independent testing laboratory to the extent necessary to assure compliance with the NCCRs and Title 56 of NRS.

2. The scientific director of a cannabis independent testing laboratory must have earned:

(a) A doctorate degree in science from an accredited college or university and have at least 2 years of post-degree laboratory experience;

(b) A master's degree in science from an accredited college or university and have at least 4 years of post-degree laboratory experience; or

(c) A bachelor's degree in science from an accredited college or university and have at least 6 years of post-degree laboratory experience.

3. If a scientific director is no longer employed by a cannabis independent testing laboratory, the cannabis independent testing laboratory shall not be permitted to conduct any testing. An interim director that meets the minimum qualifications may be appointed for no more than 90 days ***unless an extension is granted by the appropriate Board Agent***.

4. A cannabis independent testing laboratory shall ~~[immediately]~~ inform the Board **within 3** ***business days*** upon the appointment of a new scientific director ***or interim director.***

5. A scientific director shall be available to the personnel of a testing laboratory, in person or by telephonic or other electronic means, for any necessary consultation.

6. The scientific director must be on the premises of the testing laboratory at least ~~[5]~~ ***10*** workdays each month. ***If circumstances temporarily prevent the scientific director from meeting this requirement, the laboratory shall appoint an interim director who meets the minimum qualifications for the necessary length of time, not to exceed 90 days, unless an extension is granted by the appropriate Board Agent.***

(Amended: 8/2021)

11.015 Requirements for testing laboratory to handle, test or analyze cannabis.

1. A cannabis independent testing laboratory shall not handle, test or analyze cannabis unless:
   (a) The cannabis independent testing laboratory has been issued a license;
   (b) The cannabis independent testing laboratory is independent from all other persons involved in the cannabis industry in Nevada; and
   (c) No person with a direct or indirect interest in the cannabis independent testing laboratory has a direct or indirect financial interest in:
      (1) A cannabis sales facility;
      (2) A cannabis production facility;
      (3) A cannabis cultivation facility;
      (4) A cannabis distributor;
      (5) A provider of health care who provides or has provided written documentation for the issuance of registry identification cards or letters of approval;
      (6) Any other entity that may benefit from the cultivation, manufacture, dispensing, sale, purchase or use of cannabis or cannabis products, or
      (7) A cannabis consumption lounge.
2. A cannabis independent testing laboratory shall implement business practices which are structured and managed so as to safeguard impartiality in testing including:
   (a) A testing laboratory may not offer a different fee schedule or waive payment in the event of failing or otherwise undesirable test results; and
   (b) Refunds, rebates or any other return of payment in the form of alternate compensation is not permitted for the reason of failing or otherwise undesirable test results.
3. A cannabis independent testing laboratory is not required to use a cannabis distributor to collect or move samples for testing.
4. A cannabis independent testing laboratory shall implement a safety program which follows all applicable requirements of Laboratory Safety Guidance published by the Occupational Safety and Health Administration of the United States Department of Labor.

(Amended: 7/2022)

11.020 Agreement to become accredited within 1 year after licensure; provision of annual inspection report to Board; inspection by accrediting organization is not substitute for inspection by Board.

1. Each cannabis independent testing laboratory must agree to become accredited pursuant to standard ISO/IEC 17025 of the International Organization for Standardization within 1 year after licensure. The scope of accreditation must cover all analytes pursuant to NCCR 11.050.
2. Each cannabis independent testing laboratory that claims to be accredited must provide the Board with copies of each annual inspection report from the accrediting organization, including, without limitation, any deficiencies identified in and any corrections made in response to the report. ***The final inspection report and accreditation certificate must be provided to the Board within 2 business days of receipt.***
3. Inspection by an accrediting organization is not a substitute for inspection by the Board or Board Agents.

11.025 Adherence to general laboratory standards, practices, procedures and programs; inspection by Board or authorized third party; adoption of publications by reference.

1. Each cannabis independent testing laboratory must:

~~[(a) Follow the most current version of the Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control monograph published by the American Herbal Pharmacopoeia.~~

~~(a) Follow the Recommendations for Regulators–Cannabis Operations published by the American Herbal Products Association.~~

~~(c)]~~ ***(a)*** Be accredited pursuant to standard ISO/IEC 17025 of the International Organization for Standardization by an impartial organization that operates in conformance with standard ISO/IEC 17011 of the International Organization for Standardization and is a signatory to the Mutual Recognition Arrangement of the International Laboratory Accreditation Cooperation.

~~[(d)]~~ ***(b)*** ~~[Follow]~~ ***Adhere to*** the Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, ~~[and]~~ Pharmaceuticals***, and Cannabis*** — An Aid to the Interpretation of ISO/IEC 17025:~~[2005 (2015)]~~ ***2017, A Revision of the ALACC Criteria: February 2024,*** published by AOAC International.

(c) Adhere to ASTM D8282: "Standard Practice for Laboratory Test Method Validation and Method Development", published by the American Society for Testing and Materials (ASTM).

(d) Adhere to ASTM D8347 21a: "Standard Guide for Requirements for Analytical Laboratory Related Professions Within the Cannabis and Hemp Industries", published by the American Society for Testing and Materials (ASTM).

(e) Adhere to ASTM D8244-20: "Standard Guide for Analytical Operations Supporting the Cannabis Industry", published by the American Society for Testing and Materials (ASTM).

(f) Adhere to ASTM D8334/D8334M-20 Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory, published by the American Society for Testing and Materials (ASTM).

(g) Should any conflicts between references be identified, the Board shall issue guidance.

2. Each cannabis independent testing laboratory shall demonstrate proficiency in testing samples using the analytical methods approved by the Board or the appropriate Board Agent by participating in the approved proficiency testing program for all required analytes within 6 months after the date upon which the cannabis independent testing laboratory is issued a license.

3. The Board may require an independent third party to inspect and/or monitor the analytical testing methodologies and technical competence of the cannabis independent testing laboratory on an ongoing basis.

4. Each cannabis independent testing laboratory shall:

(a) Adopt and follow minimum good laboratory practices which must, at a minimum, satisfy the OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring published by the Organisation for Economic Co-operation and Development.

(b) Become certified by the International Organization for Standardization and agree to have the inspections and reports of the International Organization for Standardization made available to the Board or Board Agents.

(c) Maintain internal standard operating procedures. A copy of these procedures shall be provided promptly to the Board or Board Agents upon request.

(d) Maintain a quality control and quality assurance program. ***The quality assurance program must include a written ethics policy, provide training to all laboratory staff on the ethics policy, and require all laboratory staff to sign an attestation statement that they will adhere to the ethics policy.***

5. The Board Agents or an independent third party authorized by the Board may conduct an inspection of the practices, procedures and programs adopted, followed and maintained pursuant to subsection 4 and inspect all records of the cannabis independent testing laboratory.

6. A cannabis independent testing laboratory must use, when available ***and approved by the appropriate Board Agent***, testing methods that have undergone validation by the Official Methods of Analysis of AOAC International, ***or*** the Performance Tested Methods Program of the Research Institute of AOAC International~~,~~. ***If these are not available, the cannabis independent testing laboratory may use methodologies from*** the Bacteriological Analytical Manual of the Food and Drug Administration, the International Organization for Standardization, the United States Pharmacopeia, the Microbiology Laboratory Guidebook of the Food Safety and Inspection Service of the United States Department of Agriculture, ***the Elemental Analysis Manual for Food and Related Products of the Food and Drug Administrations, the Pesticide Analytical Manual of the Food and Drug Administration,*** or an equivalent third-party validation study approved by the Board. If no such testing method is available, a cannabis independent testing laboratory may use an alternative testing method or a testing method developed by the cannabis independent testing laboratory upon demonstrating the validity of the testing method ***in cannabis matrices and*** receiving the approval of the ***appropriate*** Board ***Agent***.

(a) As fit-for-purpose and/or cannabis-specific standard methods are published by standardizing entities, Board Agents will review these for approval, and additional guidance for implementation will be issued as needed.

7. All quality assurance tests pursuant to NCCR 11.050 ***shall meet the AOAC Cannabis Standard Method Performance Requirements (SMPRs) for the adopted reference method, at a minimum, and*** shall be validated or verified ***according to, as applicable:*** [~~by the cannabis independent testing laboratory observing the guidelines of the most recent version of standard~~]

(a) ASTM D8282: "Standard Practice for Laboratory Test Method Validation and Method Development", published by the American Society for Testing and Materials (ASTM)**.** [~~and available at www.astm.org. , or any subsequent standard as approved by the appropriate Board Agent~~.]

(b) AOAC - Appendix J: Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces, 2012;

(c) AOAC - Appendix K: Guidelines for Dietary Supplements and Botanicals, 2013;

(d) Standard ISO/IEC 16140-3 "Microbiology of the Food Chain- Method Validation-Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory"; or,

(e) Any subsequent standard as approved by the appropriate Board Agent.

8. The Board hereby adopts by reference:

(a) Recommendations for Regulators — Cannabis Operations published by the American Herbal Products Association.

~~[(a)]~~ ***(b)*** The Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control monograph published by the American Herbal Pharmacopoeia. A copy of that publication may be obtained from the American Herbal Pharmacopoeia, P.O. Box 66809, Scotts Valley, California 95067[~~, or at the Internet address http://www.herbal-ahp.org/~~;

~~(b)]~~***(c)*** The ***current version of the*** OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring published by the Organisation for Economic Co-operation and Development~~[A copy of that publication may be obtained free of charge from the Organisation for Economic Co-operation and Development at the Internet address http://www.oecd.org/env/ehs/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm~~;

~~(c)]~~ ***(d)*** Standard ISO/IEC 17025 published by the International Organization for Standardization~~. [A copy of that publication may be obtained from the American National Standards Institute at the Internet address https://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+17025%3a2005 *https://webstore.ansi.org/Standards/ISO/isoiec170252017*~~;

~~(d)~~]***(e)*** The Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals — An Aid to the Interpretation of ISO/IEC 17025:[~~2005 (2015)~~]***2017*** published by AOAC International~~. [A copy of that publication may be obtained from AOAC International at the Internet address https://www.aoac.org/aoac-accreditation-guidelines-for-laboratories-alacc/]~~;

(f)WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020 (WHO technical report series; no. 1025). Annex 4: Good Chromatography Practices;

(g)The OECD Guidance Document for Single Laboratory Validation of Quantitative Analytical Methods - Guidance Used in Support of Pre-And-Post-Registration Data Requirements for Plant Protection and Biocidal Products published by the Organisation for Economic Co-operation and Development; and

(h) Upon its publication, the Board may adopt the Cannabis Regulators Association (CANNRA) Laboratory Testing and Standardization Guidance as a reference.

11.030 Establishment of policies for adequate chain of custody and requirements for samples of products provided to testing laboratory. Each cannabis independent testing laboratory must establish ***and follow*** policies for an adequate chain of custody and sample identification requirements for samples of products provided to the cannabis independent testing laboratory for testing or research purposes, including, without limitation, policies and requirements for:

1. Issuing instructions for the minimum sample and storage requirements;

2. Ensuring positive identification of the cannabis or cannabis product by verifying the accuracy of the seed-to-sale tracking information present on the source package immediately prior to sample collection. Laboratory staff must verify the seed-to-sale tracking information matches that of the transfer manifest and laboratory Chain of Custody.

~~[2.]~~ ***3.*** Documenting the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the sample ***on the laboratory chain of custody document and/or the seed-to-sale transfer manifest*****;**

~~[3.]~~ ***4.*** Documenting the ~~condition~~ ***description*** and amount of the sample ~~[provided]~~ at the time of ***collection or*** receipt ***on the laboratory chain of custody document and/or the seed-to-sale transfer manifest*****;**

~~[4.]~~ ***5.*** Documentation of any pertinent sample identifiers, including but not limited to product type, product name, strain name, seed-to-sale tracking number, batch/lot number and production run number as appropriate;

~~[5.]~~ ***6.*** Documenting all persons handling the original samples, aliquots and extracts;

~~[6.]~~ ***7.*** Providing adequate identification on sample containers throughout all phases of testing, including, but not limited to aliquots, dilutions, tubes, slides, culture plates, extracts, data files, images, and other secondary samples created during the processing or testing of a sample. The sample identifier(s) on any sample container must be indelible, legible, and able to withstand all stages of processing and conditions of storage;

~~[7.]~~ ***8.*** Documenting all transfers of samples, aliquots and extracts referred to another cannabis independent testing laboratory for additional testing or whenever requested by a client;

~~[8.]~~ ***9.*** Maintaining a current list of authorized cannabis establishment agents and restricting entry
to the laboratory to only those authorized;

~~[9].~~ ***10.*** Securing the cannabis independent testing laboratory during nonworking hours;

~~[10.]~~ ***11.*** Securing short- and long-term storage areas when not in use;

~~[11.]~~ ***12.*** Utilizing a secured area to log-in and aliquot samples;

~~[12.]~~ ***13.*** Ensuring samples are stored appropriately; ~~[and]~~

~~[13.]~~ ***14.*** Documenting the disposal of samples, aliquots and extracts~~.~~ ***and***

~~[14.]~~***15. Follow, at a minimum, the chain of custody and sample identification requirements of ASTM D8334/D8334M-20 Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses, for all cannabis products.***

***

11.045 Limited testing for research and development purposes.

1. A cannabis cultivation facility or a cannabis production facility may conduct operations and request limited laboratory testing by a cannabis independent testing laboratory for research and development purposes.

2. A cannabis cultivation facility or cannabis production facility described in subsection 1 shall:

(a) Notify***, and receive approval from,*** the appropriate Board Agent of its intent to conduct research and development on a form prescribed by the Board by electronic mail before sending a sample to a cannabis independent testing laboratory;

~~[(b) Receive approval from the appropriate Board Agent for the requested research and development studies.~~

~~(c)]~~ ***(b)*** Quarantine each batch, lot or production run in a separate quarantine area and label each batch, lot or production run with a distinctive label containing "R&D QUARANTINE" as a header and footer in ***at least*** 20-point white font and a red background;

~~[(d)]~~ ***(c)*** Account for all cannabis subject to quarantine pursuant to paragraph (b) in the seed-to-sale tracking system;

~~[(e)]~~ ***(d)*** Limit all research and development operations to clearly segregated and designated areas or rooms marked "R&D CULTIVATION AREA" or "R&D PRODUCTION AREA" on ***at least*** 8 1/2 by 11-inch signs with a red background and white lettering, posted at the entrance to the area or room and along the walls of the area or room, with a minimum of one sign for every 300 square feet of the area or room; and

~~[(f)]~~ ***(e)*** Perform research and development operations in a grow room only if the plants used for such operations are designated and separated from other plants.

(f) The cannabis cultivation facility or cannabis production facility must provide the research and development (R&D) approval form to the cannabis independent testing laboratory that will be performing the R&D testing laboratory prior to laboratory sample collection.

3. A cannabis cultivation facility or cannabis production facility operating as described in subsection 1 may request limited testing protocols from a cannabis independent testing laboratory for research and development purposes. A cannabis independent testing laboratory shall not perform any laboratory tests on research and development samples which were not specifically indicated as part of the approved study.

(a) The Board may draft a policy allowing licensees to apply for a variance on testing requirements under certain conditions for R&D purposes.

4. A cannabis independent testing laboratory that performs testing for a cannabis cultivation facility or cannabis production facility described in subsection 1 shall report the results of the testing to the cannabis establishment and to the Board ~~[by electronic mail]~~ ***in a manner prescribed by the Board***. The cannabis independent testing laboratory shall clearly mark the test results with "R&D TESTING ONLY -- NOT FOR RESALE" on the top of each page of the report in 20-point white font and a red background.

5. A batch, lot or production run produced for research and development purposes pursuant to this section which fails quality assurance testing need not be destroyed.

6. A batch, lot or production run originally produced for research and development purposes pursuant to this section may not be sold to a cannabis sales facility until the batch, lot or production run has undergone and passed all testing required by NCCR 6.100. ***The cultivation or production facility must utilize the same cannabis independent testing laboratory who performed the limited testing on a lot or production run in accordance with subsection 3 to perform the final testing of that lot or production run.***

7. A batch, lot or production run which fails quality assurance testing under research and development provisions may not be remediated without Board approval.

11.050 Required quality assurance tests; submission of wet cannabis for testing.

1. Each cannabis independent testing laboratory must use the sampling protocols and the general body of required quality assurance tests for usable cannabis, as received, concentrated cannabis and cannabis products set forth in this section. Such tests may include moisture content, potency analysis, foreign matter inspection, microbial screening, pesticide and other chemical residue and metals screening and residual solvents levels. A cannabis independent testing laboratory may request permission from the appropriate Board Agent to obtain additional sample material for the purposes of completing required quality assurance tests but may not use such material for the purposes of resampling or repeating quality assurance tests. A cannabis independent testing laboratory may retrieve samples from the premises of another cannabis establishment and transport the samples directly to the cannabis independent testing laboratory. A cannabis independent testing laboratory transporting samples may make multiple stops if:

(a) Each stop is for the sole purpose of retrieving a sample from a cannabis establishment; and

(b) All samples remain secured at all times.

///

///

///

///

///

///

2. The tests required pursuant to subsection 1 by a cannabis independent testing laboratory are as follows:

Product	Tests Required	Action Levels
Usable cannabis, infused pre- and crude collected resins, received, excluding wet cannabis	1. Moisture content 2. Potency analysis 3. Terpene analysis 4. Foreign matter inspection 5. Mycotoxin screening 6. Heavy metal screening 7. Pesticide residue analysis 8. Herbicide screening 9. Growth regulator screening 10. Total yeast and mold 11. Total Enterobacteriaceae 12. Salmonella 13. Pathogenic E. coli 14. Aspergillus fumigatus 15. Aspergillus flavus 16. Aspergillus terreus 17. Aspergillus niger ~~18. Total coliform~~	1. < 15% 2. N/A 3. N/A 4. None detected 5. < 20 ug/kg for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 ug/kg for Ochratoxin A 6. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm 7. See ~~NAC 555.650~~ ***NCCR 11.065*** 8. See ~~NAC 555.650~~ ***NCCR 11.065*** 9. See ~~NAC 555.650~~ ***NCCR 11.065*** 10. < 10,000 colony forming units per gram 11. < 1,000 colony forming units per gram 12. None detected per gram 13. None detected per gram 14. None detected per gram 15. None detected per gram 16. None detected per gram 17. None detected per gram ~~18. < 1,000 colony forming units per gram~~
Usable cannabis, as received, which is destined for extraction	***1. Foreign matter inspection*** ***2. Mycotoxin screening*** ***3. Heavy metal screening*** ***4. Pesticide residue analysis*** ***5. Herbicide screening*** ***6. Growth regulator screening*** ***7. Total Enterobacteriaceae*** ***8. Salmonella*** ***9. Pathogenic E. coli***	***1. None detected*** ***2. < 20 µg/kg for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 µg/kg for Ochratoxin A*** ***3. Arsenic: < 2ppm Cadmium: <0.82 ppm Lead: 1.2 ppm Mercury: < 0.4 ppm*** ***4. See NCCR 11.065*** ***5. See NCCR 11.065*** ***6. See NCCR 11.065*** ***7. < 1,000 colony forming units per gram*** ***8. None detected per gram*** ***9. None detected per gram***

Product	Tests Required	Action Levels
Wet cannabis, as received, which is destined for extraction	~~1.Potency analysis~~ ~~2.Terpene analysis~~ ~~3.~~*1.* Foreign matter inspection ~~4.~~*2.* Mycotoxin screening ~~5.~~*3.* Heavy metal screening ~~6.~~*4.* Pesticide residue analysis ~~7.~~*5.* Herbicide screening ~~8.~~*6.* Growth regulator screening ~~9.Total yeast and mold~~ ~~10.~~*7.* Total Enterobacteriaceae ~~11.~~*8.* Salmonella ~~12.~~*9.* Pathogenic E. coli ~~13.Aspergillus fumigatus~~ ~~14.Aspergillus flavus~~ ~~15.Aspergillus terreus~~ ~~16.Aspergillus niger~~ ~~17.Total coliform~~	~~1.N/A~~ ~~2.N/A~~ ~~3.~~ *1.* None detected ~~4.~~ *2.* < 20 µg/kg for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 µg/kg for Ochratoxin A ~~5.~~ *3.* Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm ~~6.~~ *4.* See NCCR 11.065 ~~7.~~ *5.* See NCCR 11.065 ~~8.~~ *6.* See NCCR 11.065 ~~9.< 10,000 colony forming units per gram~~ ~~10.~~ *7.* < 1,000 colony forming units per gram ~~11.~~ *8.* None detected per gram ~~12.~~ *9.* None detected per gram ~~13.None detected per gram~~ ~~14.None detected per gram~~ ~~15.None detected per gram~~ ~~16.None detected per gram~~ ~~17.< 1,000 colony forming units per gram~~
Extract of cannabis (nonsolvent) like hashish, bubble hash, infused dairy butter, mixtures of extracted products or oils or fats derived from natural sources, including concentrated cannabis extracted with ethanol or CO2	1. Potency analysis 2. Foreign matter inspection 3. Mycotoxin screening 4. Heavy metal screening 5. Pesticide residue analysis 6. Total yeast and mold 7. Total Enterobacteriaceae 8. Salmonella 9. Pathogenic E. coli 10.Aspergillus fumigatus 11.Aspergillus flavus 12.Aspergillus terreus 13.Aspergillus niger	1. N/A 2. None detected 3. < 20 µg/kg for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 µg/kg for Ochratoxin A 4. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm 5. See NCCR 11.065 6. < 1,000 colony forming units per gram 7. <100 colony forming units per gram 8. None detected per gram 9. None detected per gram 10. None detected per gram 11. None detected per gram 12. None detected per gram 13. None detected per gram

Product	Tests Required	Action Levels
Extract of cannabis (solvent-based) made with any approved solvent, Including concentrated cannabis extracted by means other than with ethanol or CO2	1. Potency analysis 2. Foreign matter inspection 3. Residual solvent test 4. Mycotoxin screening 5. Heavy metal screening 6. Pesticide residue analysis 7. Total yeast and mold 8. Total Enterobacteriaceae 9. Salmonella 10.Pathogenic E. coli 11.Aspergillus fumigatus 12.Aspergillus flavus 13.Aspergillus terreus 14.Aspergillus niger	1. N/A 2. None detected 3. < 500 ppm 4. < 20 µg/kg for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 µg/kg for Ochratoxin A 5. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm 6. See NCCR 11.065 7. < 1,000 colony forming units per gram 8. < 100 colony forming units per gram 9. None detected per gram 10.None detected per gram 11.None detected per gram 12.None detected per gram 13.None detected per gram 14.None detected per gram
Edible cannabis product, including a product which contains concentrated cannabis	1. Potency analysis 2. Foreign matter inspection 3. Total Enterobacteriaceae 4. Salmonella 5. Pathogenic E. coli 6. Total aerobic count 7. Water activity or pH	1. N/A 2. None detected 3. < 1,000 colony forming units per gram 4. None detected per gram 5. None detected per gram 6. < 100,000 colony forming units per gram 7. Water activity < 0.86 or pH < 4.6
Liquid cannabis product, including, without limitation, soda or tonic, including a product which contains concentrated cannabis	1. Potency analysis 2. Foreign matter inspection 3. Total Enterobacteriaceae 4. Salmonella 5. Pathogenic E. coli 6. Total aerobic count 7. Water activity or pH	1. N/A 2. None detected 3. < 1,000 colony forming units per gram 4. None detected per gram 5. None detected per gram 6. < 100,000 colony forming units per gram 7. Water activity < 0.86 or pH < 4.6
Topical cannabis product, including a product which contains concentrated cannabis	1. Potency analysis	1. N/A

3. A sample of usable cannabis must be at least [~~10~~] ***20 grams***. A sample of a production run must be the lesser of 1 percent of the total product weight of the production run or 25 units of product, but not less than 5 grams of the production run. Before testing, all samples must be homogenized by the testing laboratory using a homogenization process which has been approved by the appropriate Board Agent and in a manner that prevents contamination of test samples or analytical portions.
4. The analytical portion that is used for the purposes of [~~any~~] ***each*** microbial test must be a minimum of one gram, unless otherwise approved by the Board.
5. A cannabis establishment shall not submit wet cannabis to a cannabis independent testing laboratory for testing unless the wet cannabis is destined for extraction and weighed within 2 hours after harvest. The plant must not undergo any further processing, including, without limitation, drying the plant and subsequently selling separately the cannabis bud and cannabis trim from the plant, before being weighed.
6. As used in this section, "as received" means the unaltered state in which a sample was collected, without any processing or conditioning, which accounts for all mass, including moisture content. A cannabis independent testing laboratory shall not report the results of usable cannabis on a dry weight basis.
7. A cannabis independent testing laboratory shall [~~provide~~] ***make available*** the final certificate of analysis to the Board ***upon request,*** [~~and to the cannabis establishment from which the sample was collected~~] within 2 business days [~~after obtaining the results~~] ***unless an extension is granted by the Board Agent.***
8. The certificate of analysis shall include a photo of the product, as received.
9. The certificate of analysis shall include the statement, in 8-point font, "The test results listed in this COA may not reflect the current state of the product if more than one year old, due to product changes during storage."

11.053 Requirements for testing methods and quality control.
1. Board Agent(s) may establish and publish a policy on testing methods and quality control requirements including, but not limited to, calibration requirements, quality control, and limits of detection (LOD)/limits of quantitation (LOQ). These requirements may be periodically reviewed, and if updated, policy shall be published.

11.060 Performance of testing to verify homogeneity of potency of edible cannabis products.
1. Except as otherwise provided in subsection 2, a cannabis independent testing laboratory shall perform testing to verify the homogeneity of the potency of an edible cannabis product by testing multiple samples from a single production run.
2. A cannabis independent testing laboratory that tests an edible cannabis product which has previously had the homogeneity of the potency of the edible cannabis product verified by a cannabis independent testing laboratory and which has not undergone a change in recipe may verify the homogeneity of the edible cannabis product by testing one or more single units or servings from a production run of the edible cannabis product.
3. The cannabis independent testing laboratory will verify the homogeneity of the potency of the edible cannabis product only if:
(a) The concentration of THC [~~and weight~~] of each sample is within 15 percent above or below the intended concentration of THC [~~and weight;~~] and
(b) ~~[No combination of samples which comprise 10 percent or less of the cannabis product contain 20 percent or more of the total THC in the cannabis product.]~~ ***The concentration of THC of each sample must not exceed the intended THC limits for sale in NCCR 9.045 section 2.***

11.065 Use of approved pesticides by cannabis establishment; performance of pesticide residue analysis by testing laboratory.

1. A cannabis establishment shall only use a pesticide in the cultivation or production of cannabis or cannabis products if the pesticide appears on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550.

2. When performing pesticide residue analysis pursuant to NCCR 11.050, a cannabis independent testing laboratory shall analyze for the pesticides which occur on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550 at the detection levels specified by the State Department of Agriculture and for any other substances required by the Board. If:

(a) A pesticide which occurs on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550 is detected at a level which exceeds the level specified by the State Department of Agriculture; or

(b) A pesticide which does not occur on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550 is detected in any amount which is positively [~~verified~~] ***identified by the cannabis independent testing laboratory equal to, or greater than, the limit of detection established by the laboratory,*** the pesticide residue analysis is failed.

(c) Limits of detection must be defined for every pesticide analyzed by the laboratory and must be lower than the limits of quantitation.

3. ***The Board shall publish a policy on minimum Limits of Detection (LOD) for pesticides.***

11.070 Testing: Selection of representative samples and random samples; segregation period for entire lot; duties of testing laboratory; disposal of lot if sample fails test; release of lot if sample passes test; filing of electronic copy of certificate of analysis for tests performed by testing laboratory; grounds for disciplinary action for failure to comply.

1. Immediately before packaging:

(a) Usable cannabis for sale to a cannabis sales facility, cannabis production facility or another cannabis cultivation facility, a cannabis cultivation facility shall segregate all harvested cannabis into homogenized lots of flower and trim, respectively, and allow a cannabis independent testing laboratory to select a homogenous representative sample for testing from each lot the cannabis cultivation facility has segregated. The cannabis testing laboratory which performs the test must collect the samples. If the cannabis cultivation facility has segregated the lot of harvested cannabis into packages or container sizes smaller than the entire lot, the cannabis cultivation facility must present all packages comprising the lot to the cannabis independent testing laboratory, and the testing laboratory must sample and test each package containing harvested cannabis from the lot.

(b) Concentrated cannabis or cannabis products, a cannabis production facility shall ***segregate concentrated cannabis or cannabis products into production runs and*** allow a cannabis independent testing laboratory to ***randomly*** select a ~~[random]~~ ***homogeneous representative*** sample ***for testing*** from each ~~[lot or]~~ production run ~~[for testing by the cannabis independent testing laboratory.]~~ The cannabis independent testing laboratory performing the testing must collect the samples. ***If a production run of concentrated cannabis or cannabis products is stored in multiple containers, the cannabis production facility must present all containers comprising the production run to the cannabis independent testing laboratory, and the testing laboratory must sample and test each container which comprises the production run.***

(1) The cannabis independent testing laboratory must follow ASTM D8334/D8334M-20 Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses, including, but not limited to, the aseptic sampling procedures described below when collecting samples for testing.

(2)The laboratory must use aseptic sampling techniques when collecting all cannabis category types, and adhere to the steps described below, at a minimum:

(I) Fit-for-purpose sampling equipment such as tongs, spatulas, calipers, or sample corers must be used for sampling cannabis and cannabis products. The sampling equipment must be aseptically cleaned between the sampling of different lots or production runs (or more times, if determined necessary by the sample collector) using ethanol, minimum 70%, or equivalent.

(II)The sample collector will wear new aseptic gloves before sampling a different harvest batch or production run (or more frequently, if determined necessary by the sample collector).

(III) The sample aliquot(s) shall be taken from multiple areas of each container (i.e., the upper, middle, and lower sections), such that the samples taken are representative of the entire lot or production run. In

the case of large bales or bags, samples must be taken from a depth of at least 10 cm [3.9 in.].

(IV) The sample collector shall take extreme care if sampling from multiple sites in one day to ensure contaminants (such as microorganisms, insects, residues, etc.), pathogens, or other organisms or substances are not transferred between facilities.

(V) The field balance used for sampling must meet the following requirements, at minimum:

(a) Must be capable of weighing 65 % of specimen weight or 0.1 g [0.000220462 lb], whichever is less.

(b) Must be calibrated to include the range of specimen weight.

(3) Facility must provide adequately convenient access to a handwashing sink for the laboratory sampler to fulfill required handwashing and glove changing requirements for preventing contamination during sampling, while also maintaining adequate camera coverage of all sampling activities.

(c) The facility shall notify the laboratory prior to sample collection if the batch or lot to be sampled is remediated.

~~[(c)]~~ ***(d)*** The cannabis independent testing laboratory selecting a sample shall seal the sample within the package to ensure sample integrity. The sample shall be collected in a tamper resistant package or in a package that is sealed with tamper resistant tape immediately after the sample is placed in the package.

~~[(d)]~~ ***(e)*** The cannabis independent testing laboratory shall ensure the seed-to-sale identification tag is affixed to the sample package. The batch, lot or production run number and the weight or quantity of the sample shall be documented on the sample package and on the chain of custody.

2. A cannabis independent testing laboratory that collects a sample pursuant to this section shall test the sample as provided in NCCR 11.050.

3. From the time that a lot or production run has been homogenized for sample testing and eventual packaging and sale to a cannabis sales facility, cannabis production facility or, if applicable, another cannabis cultivation facility, the cannabis establishment which provided the sample shall segregate and withhold from use the entire lot or production run, except the samples that have been removed by the cannabis independent testing laboratory for testing, until the cannabis independent testing laboratory provides the certificate of analysis from its tests and analysis. During this period of segregation, the cannabis establishment which provided the sample shall maintain the lot or production run in a secure, clearly designated, cool and dry location so as to prevent the cannabis from becoming contaminated or losing its efficacy. Under no circumstances shall the cannabis establishment which provided the sample sell the cannabis or cannabis products, as applicable, to a cannabis sales facility, cannabis production facility or, if applicable, another cannabis cultivation facility before the time that the cannabis independent testing laboratory has completed its testing and analysis and provided the certificate of analysis to the cannabis establishment which provided the sample.

~~[4. Except as otherwise provided in subsection 5, a cannabis independent testing laboratory shall immediately return or dispose of any sample received pursuant to this section upon the completion of any testing, use or research. If a cannabis independent testing laboratory disposes of a sample received pursuant to this section, the cannabis independent testing laboratory shall document the disposal of the sample using its seed-to-sale tracking system pursuant to NCCR 6.080 and 6.082.~~

~~[5.]~~ ***4.*** A cannabis independent testing laboratory shall keep any samples which fails testing, or which is collected by the Board for confirmation testing 30 days after failure or collection testing. A sample which is kept pursuant to this subsection must be stored in a manner approved by the appropriate Board Agent. A cannabis independent testing laboratory shall dispose of a sample kept pursuant to this subsection after 30 days have elapsed after failure or collection***, and shall document the disposal of the sample using its seed-to-sale tracking system pursuant to NCCR 6.080 and 6.082.***

~~[6.]~~ ***5.*** Except as otherwise provided in NCCR 11.075, if a sample provided to a cannabis independent testing laboratory pursuant to this section does not pass the testing required by NCCR 11.050, the cannabis establishment which provided the sample shall dispose of the entire lot or production run from which the sample was taken and document the disposal of the sample using its inventory control system pursuant to NCCR 6.080 and 6.082.

~~[7.]~~ ***6.*** If a sample provided to a cannabis independent testing laboratory pursuant to this section passes the testing required by NCCR 11.050, the cannabis independent testing laboratory shall release the entire lot or production run for immediate manufacturing, packaging and labeling for sale to a cannabis sales facility, a cannabis production facility or, if applicable, another cannabis cultivation facility.

~~[8.]~~ ***7.*** A cannabis establishment shall not use more than one cannabis independent testing laboratory to test the same lot or production run of cannabis without the approval of the appropriate Board Agent.

~~[9.]~~ ***8.*** A cannabis independent testing laboratory shall file with the Board, in a manner prescribed by the Board, an electronic copy of the certificate of analysis for all tests performed by the cannabis independent testing laboratory, regardless of the outcome of the test, including all testing required by NCCR 11.050 to 11.065, inclusive~~.~~ ~~[at the same time that it transmits those results to the facility which provided the sample.]~~ ***The cannabis independent testing laboratory shall not provide preliminary test results to a cannabis cultivation facility or cannabis production facility, including any of their employees or representatives, prior to submitting the Certificate of Analysis to the Board.*** ~~[The cannabis independent testing laboratory shall transmit an electronic copy of the certificate of analysis for each test to the Board by electronic mail at:~~

~~(a) If the test was passed, cannabislabpass@ccb.nv.gov; or~~

~~(b) If the test was failed, cannabislabfail@ccb.nv.gov.~~

~~10]~~***9.*** ~~[An electronic mail message transmitted pursuant to subsection 9 must be formatted as follows:]~~***Certificates of Analysis must be reported as follows:***

(a) ~~[The subject line of the electronic mail message must be the name of the cannabis establishment from which the sample was collected.]~~ ***Test results and Certificate of Analysis must be uploaded to the seed-to-sale system in accordance with policy issued by the Board.***

(b) The name of the electronic file containing the certificate of analysis must be:

(1) Except as otherwise provided in subparagraph (2) or (3), the ~~[Facility]~~ ***cannabis establishment*** ID assigned by the Board to the cannabis independent testing laboratory, followed by an underscore, followed by the ~~[four digit identifier]~~ ***cannabis establishment ID*** assigned by the Board to the cannabis establishment from which the sample was collected, followed by ***an underscore, followed by the identification number assigned to the test sample within the seed-to-sale tracking system. Followed by an underscore, followed by the product name assigned to the test sample within the seed-to-sale tracking system.*** :

~~(I) [If the sample was from a production run, the production run number; or~~

~~(II) If the sample was not from a production run, the batch number, followed by an underscore, followed by the lot number.]~~

(2) If the certificate of analysis is from a retesting of a previously failed sample, an underscore followed by the word "Retest" must be appended to the end of the name of the electronic file.

(3) If the certificate of analysis has been amended, an underscore followed by the word "Amended" must be appended to the end of the name of the electronic file.

(c) If the certificate of analysis has been amended, the electronic copy of the certificate of analysis must state "Amended" in 20-point bold red font at the center of the top of the first page of the report and must contain a statement of the reason for the amendment that clearly and completely describes the change in 10-point ***red*** font.

(d) If the Certificate of Analysis is from a retesting of a previously failed sample, the electronic copy of the certificate of analysis must state "Retest" in 20-point bold red font at the center of the top of the first page of the report.

(1) The cultivation or production facility must provide the retest approval issued by Board Agents to the laboratory, as well as the list of samples pertaining to that retest approval to the laboratory prior to sample collection.

~~[11.]~~ ***10.*** The Board will take immediate disciplinary action against any cannabis establishment which fails to comply with the provisions of this section or falsifies records related to this section, including, without limitation, revoking the license of the cannabis establishment.

~~[12.]~~ ***11.*** A cannabis independent testing laboratory may subcontract its testing of cannabis or cannabis products only to another cannabis independent testing laboratory. ***The name and cannabis establishment ID of the cannabis testing laboratory which performed the subcontracted testing must be indicated on the final Certificate of Analysis in at least 8-point font.***

~~[13~~.] ***12.*** The Board may publish on their website all Certificates of Analysis issued to them in the preceding time.

(Amended: 8/2021)

11.075 Testing: Authorized use of cannabis upon failure of microbial screening; automatic failure to pass; request for retest; retest for pesticide residue must be performed by State Department of Agriculture; effect of passing or failing retest.

1. Upon approval of the appropriate Board Agent, a lot or production run of cannabis that fails a residual solvent, pH, water activity (aw), homogeneity, or microbial screening test may be remediated or used to make an extract. After processing, the remediated lot or extract must pass all required quality assurance tests. Processes for treatment or remediation of cannabis must be pre-approved by the appropriate board agent.

(a) The cannabis establishment must maintain documentation of post-harvest treatment or remediated lots, including the date and method of treatment or remediation. All post-harvest treatment or remediation processes must be pre-approved by the appropriate Board agent.

2. If a sample from a cannabis production facility fails a quality assurance test, the entire production run from which the sample was taken automatically fails the quality assurance test.

3. At the request of a cannabis cultivation facility or a cannabis production facility, the appropriate Board Agent may, on a case-by-case basis, authorize a retest to validate the results of a failed test. The cannabis cultivation facility or cannabis production facility is responsible for all costs involved in a retest performed pursuant to this section.

4. A cannabis cultivation facility or a cannabis production facility may not request a retest pursuant to this section if the lot or production run has undergone any type of remediation since the time samples were initially taken for testing. ***A cannabis independent testing laboratory may not retest a lot, production run or test sample of cannabis or cannabis products or implement internal retesting procedures for cannabis or cannabis products, without approval by the appropriate Board Agent.***

5. A cannabis cultivation facility or a cannabis production facility shall submit a request for retesting to the appropriate Board Agent in writing and on a form designated by the Board.

6. If the appropriate Board Agent grants a request for retesting, the Board Agent will select the cannabis independent testing laboratory that will perform the retest.

7. Except as otherwise provided in this subsection, a cannabis cultivation facility or a cannabis production facility may submit a request for retesting of not more than 50 lots or production runs each calendar year. For any subsequent failure of a quality assurance test in a calendar year, the facility shall request permission from the Board for an additional 50 tests, destroy the lot or the entire production run, or request to send the lot or production run to extraction or remediation. The Board may extend authority to the Executive Director of the CCB to approve such requests. If the additional 50 retests are approved, a cannabis cultivation facility or a cannabis production facility must obtain the results of two retests in the category which failed, from two different cannabis independent testing laboratories. For the retested lot or production run to be approved for sale, both retests must provide passing results. If both retests provide passing results, the certificate of analysis with the higher quantifiable results will be recorded. If it is not clear which certificate has higher results, the appropriate board agent will select the one to be recorded. No more than one such request for additional tests is permitted within a calendar year. A lot which only fails a quality assurance test for moisture content must not be counted for the purpose of this subsection.

(a) To request permission from the Board for an additional 50 tests, a cannabis cultivation facility or a cannabis production facility must file a petition with the Board which must include the following:

(1) Request for the additional 50 tests;

(2) List the prior 50 lots or production runs that failed, what they failed for, and which cannabis independent testing laboratory performed the test; and

(3) List whether the prior 50 lots or production runs passed pursuant to a retest, and which cannabis independent testing laboratories performed the retests.

8. A failed quality assurance test for pesticide residue must be retested by the State Department of Agriculture unless otherwise approved by the Board or appropriate Board Agent.

9. If a sample passes the same quality assurance test upon retesting, the cannabis cultivation facility or cannabis production facility need not destroy the lot or production run and may sell the lot or production run to a cannabis cultivation facility, cannabis sales facility or cannabis production facility, as applicable.

10. If a sample fails the same quality assurance test upon retesting, the Board Agent denies a request for retesting or a cannabis cultivation facility or a cannabis production facility does not request retesting after a sample fails a quality assurance test, the facility shall destroy the entire lot or production run from which the sample was taken.

(Amended: 8/2021)

11.085 Random quality assurance compliance checks; costs for screening or testing.

1. Upon the request of the Board, a cannabis facility must provide a cannabis independent testing laboratory designated by the Board with a sample of cannabis or a cannabis product in an amount determined by the cannabis independent testing laboratory to be sufficient for random quality assurance compliance checks in a secure manner such that the cannabis independent testing laboratory can confirm that it has received and is testing the correct sample.

2. The cannabis independent testing laboratory that receives a sample pursuant to subsection 1 shall, as directed by the Board:

(a) Screen the sample for pesticides, chemical residues, herbicides, growth regulators and unsafe levels of metals;

(b) Perform any other quality assurance test deemed necessary by the Board; and

(c) Report its results to the Board.

3. ***The responsibility*** ~~cannabis cultivation facility or cannabis production facility is responsible~~ for all costs involved in screening or testing performed pursuant to this section. ***shall be borne in accordance with the following:***

(a) If the testing is performed as a consequence of an investigation of a cannabis cultivation facility, the costs shall be borne by the cannabis cultivation facility even if the investigation does not lead to a substantiated violation of the law;

(b) If the testing is performed as a consequence of an investigation of a cannabis production facility, the costs shall be borne by the cannabis production facility even if the investigation does not lead to a substantiated violation of the law; or

(c) If the testing is performed as a consequence of an investigation of a cannabis independent testing laboratory, the costs shall be borne by the cannabis independent testing laboratory being investigated even if the investigation does not lead to a substantiated violation of the law.

4. A cannabis cultivation facility, cannabis production facility, or cannabis independent testing laboratory who is responsible for costs of testing pursuant to subsection 3 must remit payment for the costs to the cannabis independent testing laboratory that performed the testing within 30 days of receipt of the invoice.

Public Notice

The public is hereby noticed that items on this agenda are stacked. Items may be taken out of order, two or more agenda items may be combined for consideration, and/or at any time an agenda item may be removed from the agenda or discussion delayed.

The Cannabis Compliance Board (CCB) will take public comment on any matters within its jurisdiction, control, or advisory power. The Board is not permitted to deliberate or take action on any items raised during the public comment period until the matter itself has been specifically included on an agenda as an item upon which action may be taken by the Board. Comments by the public may be limited to three minutes as a reasonable time, place, and manner restriction, but may not be limited upon viewpoint. If a member of the public is unable to attend the meeting in person and would like to provide public comment during the meeting through remote appearance, they can submit a request via email before the scheduled meeting to regulations@ccb.nv.gov to receive instructions to join the meeting remotely. The CCB is not responsible for technical difficulties a member of the public may experience in connecting to the meeting remotely. Comments by the public may be emailed to regulations@ccb.nv.gov by 5:00 p.m. the day before the scheduled meeting and include the commenter's full name. Content may be redacted due to inappropriate language. All written public comments shall, in their entirety, be included as part of the public record. Prior to the commencement and conclusion of a contested case or a quasi-judicial proceeding that may affect the due process rights of an individual, the Board may refuse to consider public comment regarding the matter pursuant to NRS 678A.560 and NCCR 4.080. In the event technical difficulties prevent these proceedings from being broadcast, the CCB, at its discretion, may conduct the meeting without the proceedings being broadcast.

We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements for the meeting are necessary, please notify the Cannabis Compliance Board via email at regulations@ccb.nv.gov, in writing at Cannabis Compliance Board, 700 E. Warm Springs Rd., Suite 100, Las Vegas, Nevada 89119 or by calling 702-486-8241 as soon as possible.

This agenda has been emailed for posting at the following locations: Cannabis Compliance Board 700 E. Warm Springs Rd., Suite 100, Las Vegas, Nevada; Cannabis Compliance Board 3850 Arrowhead Dr., Carson City, Nevada; The Legislative Building – Capitol Complex, Carson City; The Nevada State Library 100 Stewart Street, Carson City; on the official website of the State of Nevada at https://notice.nv.gov, pursuant to NRS 232.2175; on the Legislative website at https://www.leg.state.nv.us/, on the Cannabis Compliance Board's website at https://ccb.nv.gov and to the Interested Parties mailing list maintained by the agency.

In the event there are supporting materials available for items on this agenda, such materials will be produced upon request pursuant to NRS 241.020(7) and (8) by submitting a request via email to regulations@ccb.nv.gov or via mail at 700 E. Warm Springs Rd., Suite 100, Las Vegas, Nevada, 89119. Supporting materials may also be available at the Cannabis Compliance Board's website at https://ccb.nv.gov/public-meetings/

BOTEC
Analysis Corporation

Sampling Cannabis for Analytical Purposes

Michelle Sexton, Steep Hill Lab
Jeremy Ziskind, BOTEC Analysis

BOTEC Analysis Corp.
I-502 Project #430-1e
Nov. 15, 2013

BACK OF THE ENVELOPE CALCULATIONS

Table of Contents

Overview ____ 3
Sampling ____ 3
Sampling of Raw Plant Material ____ 3
Sampling Unit ____ 4
Test Specimen ____ 4
Homogenization of the raw sample ____ 4
Grinding ____ 5
Quartering ____ 5
Obtaining a representative sample for analysis ____ 5
Sampling of extracts or finished products ____ 8
Sampling Unit ____ 8
Test Specimen ____ 8
Homogenization of the pooled sample ____ 8
Quartering ____ 8
Representative sample for analysis ____ 9
Varietal Registration ____ 12
Testing Facility ____ 12
Heterogeneity ____ 13
Typical Heterogeneity ____ 13
Heterogeneity across strains ____ 13
Heterogeneity across production methods ____ 17
UV lighting as a factor in THC content ____ *18*
Degrees of plant/crop heterogeneity ____ 19
Tensions in Testing Procedures ____ 21
Financial Feasibility for Raw Plant Material ____ 22
Financial Feasibility for Extracts and Infused Products ____ 23
Conclusion ____ 24

Overview

This paper discusses the practice and regulatory implications of sampling cannabis for potency and purity tests. It proceeds in three parts: first, by discussing proper procedures by which a small, representative test sample can be taken from a larger lot of cannabis; second, by discussing the natural levels of heterogeneity in the cannabis plant; and finally, by discussing the cost burdens of different sampling regulations, including the size of a lot.

Initiative 502 established a program for chemically testing regulated cannabis, in order to protect consumers from unhealthy product and inform them of a product's potency and purity. Such a program will require a policy on sampling methodology. Sampling is an integral aspect of cannabis testing, and if done dishonestly or improperly, it may skew the results of an otherwise reliable testing process. Of particular regulatory importance is to prohibit producers or testers from manipulating sampling procedures in order to exaggerate a product's reported potency or purity, and consequent retail value. Another important decision is the appropriate size of the sampling lot. Both of these policy decisions are important in order to establish a high standard for industry practice and to prevent intentional manipulation of results.

In the regulations proposed by the WSLCB on July 3rd, 2013, the unit of usable cannabis from which a sample is pulled is referred to as a lot. A lot of flower must come from one or more plants of the same strain and weigh no more than five pounds[WAC 314-55-010(9)]. The unit of extract or infused cannabis product from which a testing sample is pulled is referred to as a "batch." A grower's yield or harvest, typically pulled from a set of plants of the same strain grown under the same conditions, is broken up into lots, and those lots are submitted for testing. It can be assumed that growers will create lots as large as they are allowed, and that they will want to lose as little product to testing as possible and minimize their testing costs.

In determining a requisite sampling lot size, the Washington State Liquor Control Board (WSLCB) faces an inherent trade-off between accuracy (or representativeness) in testing results and regulatory cost. On one hand, a larger lot size eases the burden on the cannabis industry by requiring fewer tests, since each lot must be individually divided into a sample and run through the required tests. Moreover, since sampled material cannot be sold, a larger lot size decreases the dead loss of unsellable cannabis. On the other hand, if there is a large amount of variation within an individual lot, a sample from within that lot might have drastically different properties than another part of that lot. This is the problem introduced by the heterogeneity of cannabis, in part because grinding the product into a homogenous mixture decreases its retail value, and in part because of the biological properties of the plant.

Cannabis plants exhibit heterogeneity in two regards: across different parts within the same plant and across different plants within the same strain. Cannabis plants have been subject to decades (if not centuries) of intense domestication, both through breeding and cloning, creating a wide variety of strains each with their own biological peculiarities. Through a combination of conventional wisdom among growers and scientific studies, we

know that some strains can be cloned with higher levels of similarity than others. This characteristic would reduce the level of variety from one plant to another, provided both are members of the same strain. Another type of heterogeneity, intra-plant, is important to sampling procedures. This paper will review the mixed literature on levels of heterogeneity in cannabis plants and identify policies appropriate to deal with those levels of natural heterogeneity.

As the I-502 market develops, and more growers demonstrate their capacities to produce and reproduce strains with consistent cannabinoid profiles, the WSLCB may consider developing a varietal registry of different cannabis strains. Such a registry could establish expected potency levels and variances for particular strains. This information could be used both to verify the accuracy of a particular test result and to distinguish those varieties with the most severe levels of variance. A possible cost-saving measure would be to allow larger lot sizes or more relaxed testing regulations for those strains known to exhibit lower levels of variation. Such research could also facilitate the distinction between one strain and another, as defined in WAC 34-55-102(10) of the CR-102 for cannabis producer licenses and requirements.

This paper makes two assumptions about the procedures of testing laboratories. First, we assume a high degree of competence from laboratories, and of the accuracy, robustness, and reproducibility of their methodologies. It is imperative that any laboratory providing testing be able to demonstrate at least 95% accuracy of the testing methodology by passing a blind proficiency test of random samples. Second, it is assumed that a chain-of-custody plan will be followed, such that no contamination will be introduced in the lab. Sterile handling in a biosafety hood (Class II, Type A bio-safety cabinet) is necessary for testing for microbiological contamination. Each facility should have a sample processing room and secure storage room. At the point of sample reception, a log should note the time of arrival, the recipient, the sender, and the lot and, when applicable, the batch number (USDA 2013).

Sampling of Raw Plant Material

Sampling

Sampling is the selection of a subset within a whole, in order to estimate characteristics of the whole. In the case of cannabis, this is harder than it may appear at first blush. First, cannabis naturally varies in chemical potency, both within a single plant and between one plant and another (and between strains); secondly, cannabis is commonly marketed as intact flower buds. For this reason, cannabis cannot be homogenized without permanently damaging the un-sampled product. Alcoholic beverages, for instance, do not face this second problem. Even if a company's brewing or distilling process produces some vats with 6% alcohol and others with 7% alcohol, simply mixing the two vats together can standardize the product. Similarly, tobacco is generally baled, and cores are taken for quality analysis without damage to the bulk material. Performing the same procedure with cannabis would require grinding the entire crop into small bits, thereby reducing its aesthetic appeal and retail value. Since the heterogeneity in cannabis potency cannot easily be mixed away, this puts the onus on other ways for verifying that a sample is representative of its whole.

Since the psychoactive chemicals of cannabis are unevenly and non-randomly distributed throughout the plant, there exists an opportunity for producers to manipulate the sampling process in order to produce a sample that exaggerates their crops' potency. THC content is commonly regarded to vary from the top to the bottom of the plant, or by the proximity to the light source. In the case of outdoor production, it is widely believed that flowers from the bottom of a plant receive less sunlight than those at the top of the plant; this is also purported to be true for indoor production, but the effect might be mitigated by carefully placing high-intensity lamps so that they shine more uniformly on all flowers in the plant. In either case, flowers that receive less exposure to light are likely to have lower cannabinoid and terpenoid content. Since a cannabis producer is typically aware which parts of the plant are most well lit, he often knows where to find the most potent flowers from the cannabis plant – typically, those at the top. Potentially, this represents a crucial information asymmetry between the producer and the testing agency. A producer may manipulate his crop's potency ratings by deliberately selecting his plant's most potent flowers and submitting them to the testing agency as representative of the entire plant's (or crop's) inflorescence.

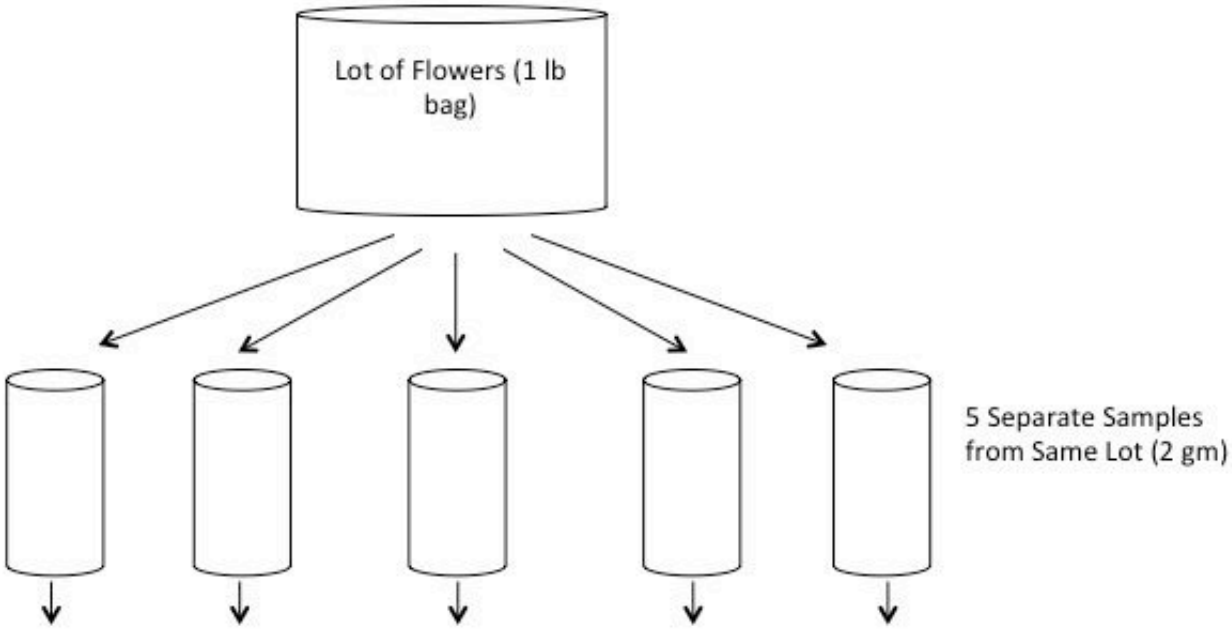
There are several options to address this vulnerability, depending in part on whether samples are taken at the time of harvest or only after the harvest is dried. If samples are taken at the time of harvest, cannabis should be gathered in groups according to their exposure to light. This could be achieved by adhering to height standards (such as one sample taken at x feet and another at y feet) or distance in lumens away from the light source. These samples would need to be cured or dried prior to analysis. In this case, a trained field inspector (as recommended by the USDA-Animal and Plant Inspection Service Plant Protection and Quarantine APHIS-PPQ) could sample at the time of harvest, selecting flowering tops taken from different parts of the plant. Health Canada has prescribed a procedure for industrial hemp that could be adapted to this purpose (Canada 2008). If plants were trellised, then a height variable would not be necessary. Each plant to be sampled needs to be readily accessible from all sides of the plant, and in its original growing location. Official samples should be brought to the testing location by the inspector.

Another option is to allow producers to lot cannabis according to their own methods, but then have testing agencies select a random sample from within those lots. In this case, growers would first dry and lot their own harvests. The agencies would then randomly sample the lots using established methodologies. In this scenario, growers might choose to lot their harvest based on flower size, light exposure, or other strategic considerations. If a lot is smaller than two kg or under the five lb. lot definition, then whatever is 20% of the lot can be used for sampling, as long as the final sample taken for cannabinoid analysis is at least 2.5 g. The rest of the plant material can be returned to the grower (except for additional material needed for microbiological testing) when performed on a separate sample. Allowing growers to perform their own semi-quantitative testing at this level could represent a cost savings to the grower. A semi-quantitative methodology might be high performance thin layer chromatography or infrared technology.

In either case, it is important that growers cannot knowingly provide testing agencies with samples that are unrepresentative of the lot. In the first case, this is accomplished by

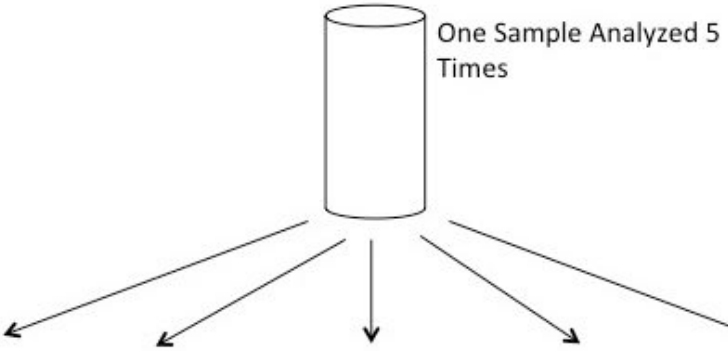
preventing growers from being able to select the sample; in the second case, this is accomplished by sampling from a larger lot than is normal. Regardless of the sampling protocol, any laboratory or method used must demonstrate precision (Figure 1), intra-assay accuracy (Figure 2), and reproducibility over time (Figure 3). These data were generated and compiled using cannabis samples in California as part of an internal single-lab validation methodology by Integrated Analytical Systems, a bio-analytical company in Berkeley, California

Figure 1: Method Precision



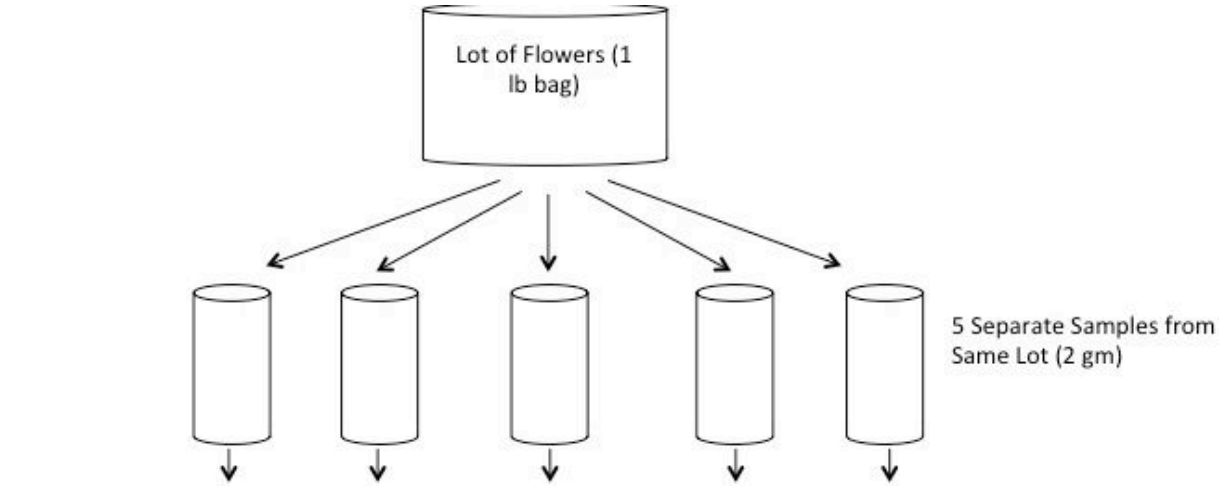
Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Relative Variability
7.59% THC	8.44% THC	7.85% THC	8.32% THC	7.59% THC	***±5.1%***

Figure 2: Method Accuracy



Analysis 1	Analysis 2	Analysis 3	Analysis 4	Analysis 5	Relative Variability
7.81%	8.06%	8.02%	7.88%	7.91%	±2.3%

Figure 3: Method Reproducibility Over Time



Day of Analysis	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	
Day 1	9.11% THC	8.42% THC	8.62% THC	8.01% THC	8.56% THC	
Day 60	9.03% THC	8.62% THC	8.40% THC	7.73% THC	8.69% THC	
Difference	0.9%	2.4%	2.7%	3.5%	1.5%	**±2.2%**

Sample preparation for useable cannabis

Established methodologies exist for preparing a sample of useable cannabis for testing. These methods vary slightly based on the intent of the test (e.g. detecting pesticides, or potency, or microbiotics). However, for the most part a simple and common protocol should be used for this process.

Selecting the sample

Cannabis inflorescence (fruiting tops or flowers) or "trim" is sampled when performing testing for potency and/or microbiotics. The "fan leaves" of the plant are used for pesticide testing. Broad leaf should be collected from each plant in the lot. This sampling could be done at another time prior to harvest.

A test specimen will be comprised of inflorescence taken from a lot of plants, and a representative sample of 10 grams per kilogram (or 2% of the total lot) or trim from the flowers (10 grams per kilogram or 2%). A "lot" of plants can be distinguished by count, by lumens, or defined by the space receiving approximately the same conditions with regard to light, moisture, nutrition, CO_2 and temperature recommended to be 20 plants (Mechtler et al. 2004).

Homogenization of the raw sample

The plant sample must be made homogeneous for test results to be representative. Homogenization requires the sample be broken down to a form that can be mixed effectively, comparable to the process of turning wheat into flour.

First, the sample should be ground to a size of around 0.5 cm in size and thoroughly mixed. There is some disagreement about grinding a sample because trichomes can be lost in the process, but without grinding a sample cannot be as homogeneous. To minimize the leaching of resins, grinders made of silanized glass or stainless steel are recommended over wood and plastic. Regardless of the material, every element of the grinder must be thoroughly cleaned with solvent rinses between samples.

Once grinding is completed, the next step is quartering. Quartering ensures that every part of the sample is sufficiently mixed to have an equal chance of being selected for testing. The ground sample is gathered into an even and square-shaped heap. Next, it is divided diagonally into four equal parts. The two opposite parts are then taken and carefully mixed. This portion is now placed in another square shape and divided diagonally. Two opposite parts are taken and carefully mixed. This 2.5-gram sample can be used for the analysis of cannabinoids, terpenoids, or other phytochemicals.

The remainder of the sample can be used for microbiological testing. Sampling methods could be further refined and validated through a series of experiments that the WSLCB should conduct to determine the relative variance of different sampling methodologies for cannabis crops. This data can then be made available to the entire industry, and may serve to refine the regulatory process.

Obtaining a representative sample for analysis

A two-gram sample of flower or trim should allow for a confidence of approximately 12% relative variability (or five grams for a relative error of approximately 5%; see Table 1 and Figure 4). In developing the laboratory protocol, a five-gram representative sample is needed for the least variability. However, as the data below reflect, 2.5 grams would allow for an acceptable variation across a single sample. Analytical performance standards for hemp are described in Table 2 (Canada 2008).

Table 1

Sample Weight	Variability
1 gram	±9.9%
*2 grams**	*±5.1%*
3 grams	±4.3%
5 grams	±1.5%

* recommended weight to submit for testing

Figure 4

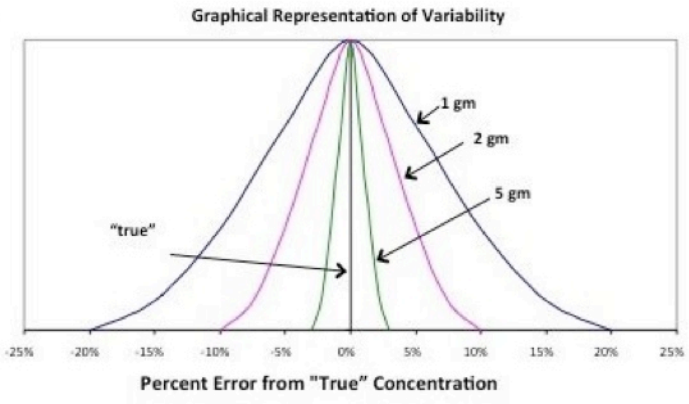


Table 2: Analytical performance standards for hemp, and parameters for THC analysis: the limit of detection (LOD), limit of quantification (LOQ), and acceptable linear range for reference standards. These values may be adopted and required of labs that want to be certified to test cannabis in Washington State.

Parameters	Concentration of THC in industrial help, other than its derivatives or products containing those derivatives	Concentration of THC in derivatives of industrial hemp, or products containing those derivatives

Minimum limit of detection	0.1% (w/w)	4.0 µg/g
Minimum limit of quantification	0.1% (w/w)	4.0 µg/g
Intra-assay precision	C.V. (coefficient of variation) ≤ 10% at 0.3% (n=8)	C.V. (coefficient of variation) ≤ 10% at 10.0 µg/g (n=8)
Linear range	$r^2 \leq 0.98$ in the range of 0.1% to 1.0% (w/w)	$r^2 \leq 0.98$ in the range of 4.0 µg/g to 30.0 µg/g (w/w)

Sample preparation for extracts and cannabis-infused products

The global market for botanical and plant-derived drugs is expected to increase from $19.5 billion in 2008 to $32.9 billion in 2013. Finished products made from medicinal and aromatic plants are increasingly prescribed and bought over the counter. An extract is obtained as a solution by treating plants (or parts of them) with a solvent, which can then be further concentrated through evaporation, distillation, or some other process (WHO 2004). Liquids intended for oral consumption should be uniform, and finished products need to be handled in clean facilities and assayed for residual solvent and/or labeled with final ethanol or glycerol concentration. Mixed batches can be used for solvent extraction and a homogeneous sample needs to be submitted for final analytical determination of active ingredients. An herbal drug product may be a solid extract, a soft extract (partially evaporated), or a liquid extract (1:1).

Selecting the Sample

The sampling unit is a batch of extract (there may be more than one per lot) including tinctures and fatty oils of herbal materials. Extract lots are produced either by extraction, fractionation, purification, concentration, or other physical or biological processes. The final volume is the lot size, while "individual units" are the containers of product eventually sold from this lot. Extractions are preparations made by steeping or heating herbal materials in alcohol, glycerin and/or honey, or in other materials (WHO 2007). The size of the sampling unit should be scaled to be representative of the size of the lot of extract, and the sample size will determine an acceptable quality level. Resins and solid extracts should be sampled by weight, and liquids by volume.

Testing agencies should adequately homogenize each batch and take representative samples from three separate areas of the container (WHO 1998). The amount of the representative sample may be determined by the volume of the batch, again extracting a predetermined percent of the total volume. In the case of resinous material, it may need to be warmed on a heater/stirring device. This is now a "pooled" sample.

Homogenization of the pooled sample

Homogenization of the sample should occur by stirring or vortexing and may require heating of the sample. After homogenization, the sample should be quartered.

The process of quartering samples of a finished product is similar to quartering samples of dried flower. A sample is placed in a single container, and then divided into four equal volumes. Two parts are then combined and vortexed. This portion is now divided in half. Two opposite parts are taken and mixed. This representative sample can be used for the analytics of cannabinoids, terpenoids, or other phytochemicals.

The remainder of the sample can be used for microbiological or residuals testing. Sampling methods should be further refined and validated through a series of experiments that the WSLCB could conduct to determine the relative variance of different sampling methodologies for cannabis derived products. These data can then be made available to the entire industry, and provide guidance for the regulatory process.

Acceptance Sampling

Acceptance sampling could prove a viable alternative to the sampling methods described above. Acceptance sampling was originally applied by the U.S. military for the testing of bullets during World War II. If every bullet were to be tested in advance, no bullets would be left to ship. If, on the other hand, none were tested, malfunctions were likely to occur in the field of battle (Bheda 2010). Acceptable Quality Level (AQL) is a statistical measurement of the maximum number of defective goods considered acceptable in a particular sample size. If the AQL is not reached for a particular sampling of goods, manufacturers will review the various parameters in the production process to determine the areas causing the defects.

The AQL will vary from product to product. For example, medical products are more likely to have a more stringent AQL because defective products can result in serious health risks. Companies have to weigh the added cost associated with the stringent testing and potentially higher spoilage due to a lower defect acceptance with the potential cost of a product recall. Industry AQL charts could provide WSLCB with AQL protocol for botanical products made from cannabis extracts.

The lot size, on the y-axis, is based on how many individual units will be on the market from a particular lot. Unit size is not defined by the chart, but by individual manufacturers. For instance, a CO_2 cartridge manufacturer's unit would be a single cartridge, a baker's unit may be an individual cookie, and a farmer's unit might be a gram or an ounce. The AQL (the x axis) is the level of acceptance for the number of units that fall outside of quality parameters (how many). The numbers within the body of the chart are sample sizes. When working with a lot size of 2500 units at a 0.065% AQL, one would want a sample size of 200 units from each lot to ensure this level of confidence. As the AQL is reduced, confidence increases in the probability of units meeting quality parameters. Following our example, a 2500 unit lot with an AQL of 0.065% (with zero units falling out of specs in a sample of 200) has a statistical probability of producing two defective units. By contrast, a lot of 2500 units with an AQL of 1% (with zero units falling out of specs in a sample of 42) has a statistical probability of producing 25 defective units.

In order to implement this strategy for cannabis products, it would be necessary to convert what is currently a continuous variable (% concentration) to a discrete binary variable. Setting a threshold for acceptable quality or concentration of product would accomplish this.

Acceptance sampling protocol for the cannabis industry could take many forms. The practice is easily applied to products with obvious definitions of a unit, such as extracts or edibles because their contents have been homogenized. It will not be as clear how appropriate acceptance sampling could be for raw flower until more is understood about the heterogeneity of the crop. Theoretically a lot of flower would be broken up into predetermined units of sale and a certain number of those units selected for testing. Qualifications to deem a unit defective could be a certain level of contaminants or a cannabinoid profile that is too different from the goal for that strain.

Varietal Registration and State-led Research Efforts

For obvious historical reasons, the science and practice of cannabis cultivation and testing are not as well established or well documented as in other fields. Cannabis production and testing has historically been performed in secrecy, and private companies have been reluctant to construct and share large databases. This lack of shared knowledge constrains both the cannabis industry and regulators. Establishing an informational database or a center for research would deliver some benefit to the State of Washington, if it were to decide to spearhead such an effort.

One model of a shared informational database is a germplasm bank or a varietal registration, also known as a chemotaxonomic classification system and an associated seed repository, intended to illuminate the characteristics of different cannabis strains. Registration could occur upon a grower's demonstrated ability to reproduce a strain with a high degree of homogeneity. Such a strain could then, in effect, be trademarked without ownership rights and registered with the State as a "varietal." This public database could be useful to both entrepreneurs in the private sector and regulators in the public sector. Over time, if a strain's ability to retain phenotype is relatively strong, regulators may opt to relax testing requirements for a certain varietal, defraying testing costs in the long term. This registration could also help regulators to distinguish between different strains ("…a pure breed or hybrid variety of Cannabis reflecting similar or identical combinations of properties such as appearance, taste, color, smell, cannabinoid profile, and potency"). The issue of chemical fingerprinting is further discussed in the BOTEC paper, "1c. Testing for Psychoactives."

More ambitiously, Washington could also opt to establish a research center within an existing state laboratory. Such a program could investigate many different aspects of the cannabis plant, including product consistency, identifying new varietals, fingerprinting cultivars, participating in the development of medically relevant strains, and determining whether there actually are ailment- or symptom-specific components. Such an effort could contribute to arguments to designate Washington as a "Protected Geographical Indication" or a "Protected Designation of Origin." To date, such research has been blocked by federal regulations, although it is often taken for granted in other areas of agriculture.

However, Washington might pay all the costs of such an effort and reap only a small portion of the benefits. Although Washington, along with Colorado, has recently become a major player in the cannabis industry, this celebrity status might not last. Other states might legalize as soon as 2014 or 2016 – notably California – and they may do so with more business-friendly regulations, not to mention warmer and drier climates. Initiative 502 may have given Washington's cannabis industry a head start, but other states will soon join the race. Leading a research effort might help Washington maintain that head start, but should not be expected to guarantee Washington's spot as an industry leader in the long term.

Heterogeneity

In this section we review studies concerned with the heterogeneity of cannabis across growing conditions and varietal strains. Cannabis is an inherently variable plant, with strong genetic and environmental contributions to variance in quality (Zamengo et al. 2013). In the interest of having products in the marketplace that are as predictable as possible (but still appropriately labeled), research and a list of needs should be required.

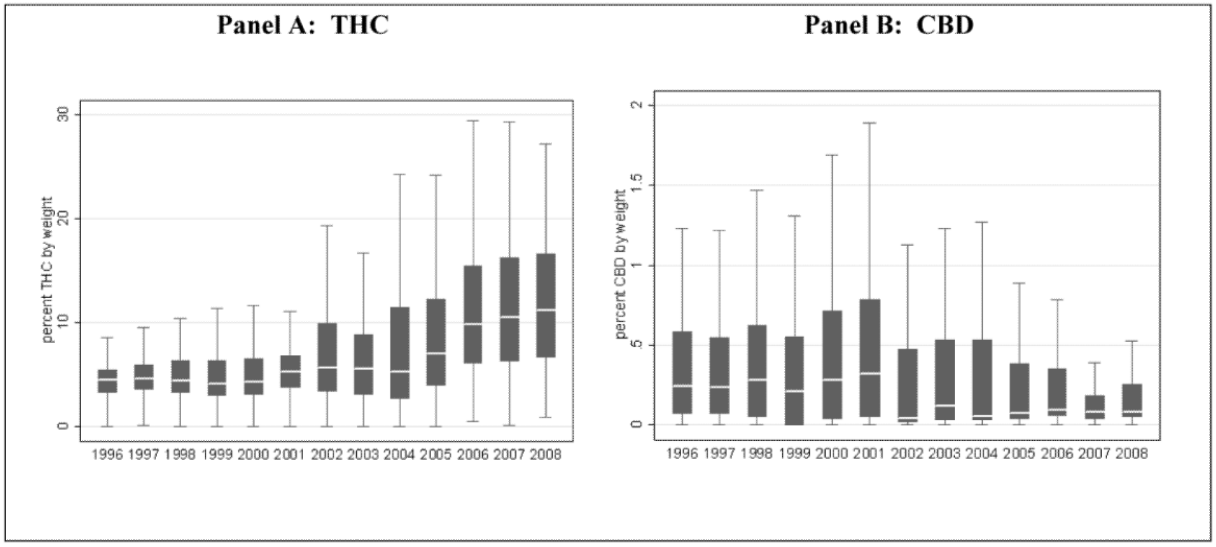
The contents of a lot should be as homogeneous as possible. Gathering lots using the criteria described—products of the same strain, flowers from consistent areas of the plant, similar bud size, etc.—relies largely on growing techniques that have been commonly accepted, but hardly corroborated by scientific protocol. This lack of information reveals vulnerability in sample testing. How effective could testing be if we cannot put forth an acceptable range of its representativeness? Under the regulations put forth by the WSLCB, a lot must consist of flower taken from plants of the same strain. However, there is little literature to tell us that plants of the same strain grown under identical conditions can be assumed homogenous, or to what extent they differ. To know how representative a sample is, we must know the extent of heterogeneity occurring in cannabis plants when grown in identical conditions.

There is a compelling need to learn much more about how growing conditions affect the phenotype and chemotype of the cannabis plant. To set forth a range of acceptable variation in a product, it is important to understand the extent of natural variation. Industry consensus is that the quality and quantity of light will affect THC production. Increasing lumens, particularly of specific wavelengths, may potentially increase THC production, but studies that suggest that cannabinoid content is more controlled by genetics (Fournier et al 1987) than by other factors such as the quality or quantity of light a plant receives. Because cannabinoids are secondary metabolites (chemicals produced by the plant in response to stress), some suggest that light "stress" could increase their production. However, these secondary metabolites may have unknown roles and are not fully understood. There are many other variations in growing techniques, such as addition of CO_2 to the growing environment, nutrient mixtures, soil mixtures, humidity levels, pH balance of the soil, hydroponics, and water administration, that will dictate plant metabolism.

The genetic profile of cannabis has changed over the last several decades, as evidenced by analysis of cannabinoids in seized samples (Burgdorf et al. 2011; Mehmedic et al. 2010)

[See Figure 5]. This change in genetic stock is reflected in the relative changes in total THC content and also the ratio of THC to CBD.

Figure 5: Variability in THC/CBD in seized crops over time. Median, 25th and 75th percentiles of cannabis seized in California for 4,561 plants from 1998 to 2006.



Typical Heterogeneity

Cannabis is an inherently variable plant, with strong genetic and environmental contributions to variance in quality factors. Given the interest in ensuring products in the marketplace are of known content and appropriately labeled, there is a need for research into the determinants of plant characteristics.

An analysis of hemp samples in Germany, Poland, France, and Hungary was undertaken to estimate the sample size needed for "routine control tasks" (Mechtler et al. 2004). One study found no association between plant size and THC content. They also found great consistency in hemp crops over years and consistent "intra-plant" levels of THC with as many as 30 samples from a single plant.

However, another study concluded that a varietally homogeneous hemp field might contain a significant number of plants behaving irregularly with respect to THC values. Further, the number of plants sampled for routine analysis was fixed by European Union (EU) regulations at 50 plants (regulation number (VO (EG) 1177/2000).

Few publications have explored this topic with regards to regulated indoor growth of cannabis. Growers often cultivate what is known as a genet: a "clonal colony" in which all of the individuals (ramets) have originated vegetatively from a single ancestor. One advantage of indoor production is an enhanced ability to carefully control soil nutrients and light, factors that can contribute greatly to variations in growth, biomass, morphology, and physiology of clones (Wang et al. 2012). Under these conditions, producers can provide

consistent treatment from one plant to another, and often to different parts of the same plant (for instance by the uniform position of lights). However, it is unknown what effect these conditions have on reducing the variance in plant chemotypes, or their psychoactive chemical content. For instance, two different plants cloned from the same "mother" might grow differently even if they are exposed to the exact same conditions. It may be in Washington State's interest to commission or encourage such experiments, perhaps as part of a larger effort to form a varietal registry.

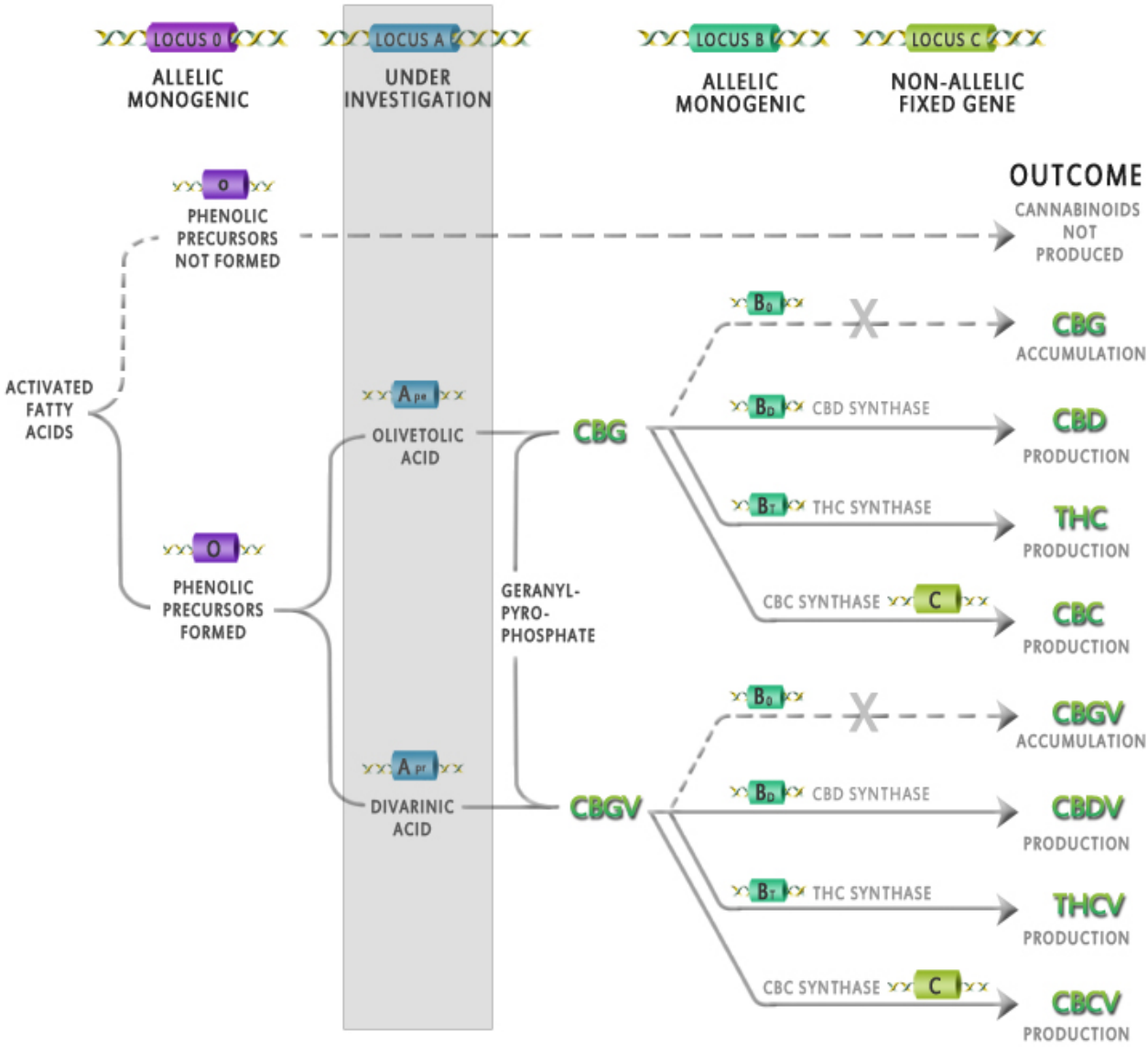
Heterogeneity across strains

Small and Beckstead (1973) were the first to survey cannabis accessions for cannabinoid variability. The University of Mississippi concluded that, phenotypically, cannabis might be a single species that has not stabilized and has many variations (Doorenbos et al. 1971). The researchers prepared fields and planted seed from several varieties, noting that environment and climate, not heredity, are the most important determinants of cannabinoid content. They also found a great deal of inter-plant variability in THC content, and report an interesting anecdote.

A cannabis plant alleged to have been grown in a closet with a tungsten light bulb was delivered to their facility. The authors described it as leggy, with greenish-yellow leaves, and yet the cannabis harvested analyzed for Δ^9-THC at 6.8%, CBD: 0.26%, CBN: 0.28%. At this time, 6.8% THC was well above any of the outdoor plants with regard to THC production. In other words, this neglected specimen was remarkably successful at producing psychoactive cannabinoids, even though it may have been exposed to inferior soil and lighting conditions. This observation is instructive with regard to visible and ultraviolet lighting in indoor growing facilities. Clearly, a "stressed" plant produced a relatively greater amount of THC than any of the other varieties cultivated outdoors. While this report gave some information on heterogeneity across strains, unlike more contemporary farmers the researchers were not growing clones from a single plant.

In 2003, GW Pharmaceutical published a paper in *Genetics* which stated: "there is little doubt that environmental factors have a strong influence in modulating the amount of cannabinoids present in the different parts of the plants at different growth stages." However, they report that cannabinoid profiles in general are under strong genetic control (the THC to CBD ratio, specifically) and that plants typically demonstrate high degrees of polymorphisms (or spontaneous genetic mutations) - up to 80% measured in fiber-type plants - which can account for variability (de Meijer et al. 2003). For plants that were double inbred clones (S_2's: female lines with "pure fixed" chemotype), major cannabinoids ranged from between 84-98% of total cannabinoid fractions.

Figure 5: GW Pharmaceuticals shows how cannabinoid content is under genetic control and uses genetic manipulation to precisely control cannabinoid production.



Below, we compiled THC content data taken from the website of a Seattle-based medical cannabis facility. We randomly chose several strains: "Blue Dream" (n=20), "Blueberry" (n=8), "Jack Herer" (n=9) and "Harlequin" (n=9) for purposes of resale. Figure 6 shows THC concentration by weight, and summary statistics are given in Table 3. Assuming that the samples were tested accurately, these strains appear to have different rates of variability. The data, though very limited, suggest an approximate 25-30% variability in Blue Dream, 25% for Blueberry, 60% for Jack Herer, and 40% for Harlequin. (Due to a small sample size, these figures might not accurately represent characteristics of these strains in the larger market.)

Table 3: Statistics on Δ^9-THC content for four commercial *Cannabis* varieties, from the *Analytical 360* website, a medical cannabis laboratory in Seattle. The sampling and testing

methodology is unreported. Data in this table summarizes the data presented in Figure 6. These data do not necessarily represent typical characteristics of these strains.

	Blue Dream	Blueberry	Jack Herer	Harlequin
Number of observations	21	8	9	9
Minimum	6.560	10.05	5.130	3.710
25% Percentile	14.05	13.16	14.56	4.385
Median	17.05	15.36	16.11	4.930
75% Percentile	18.20	17.47	16.87	5.670
Maximum	21.61	20.67	17.91	7.110
Mean	15.99	15.27	14.80	5.069
Std. Deviation	3.657	3.206	3.816	1.015
Std. Error	0.7980	1.134	1.272	0.3385

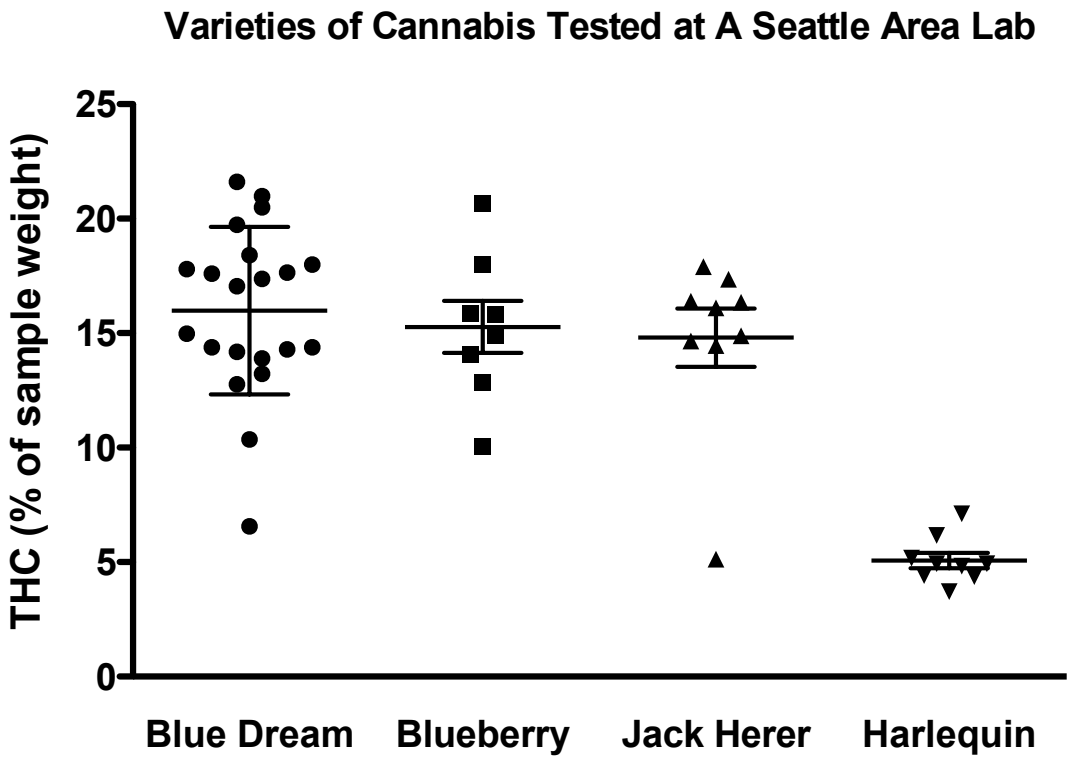


Figure 6**:** A graphical representation of the individual data from Table 3, showing the mean and the standard deviation across randomly chosen strains.

These data suggest that there is significant variation in THC potency within some strains but not others. There are also some cases of irregularity or outliers in each strain set. These data provide information on the lack of homogeneity across a strain. In some cases, there may be an error of categorization: a sample of Harlequin might have been mislabeled as Blue Dream. There may also be a significant genetic drift or disparity within the genotype of cannabis considered to be a single variety. Further, it is unknown whether there is similar variability in the terpenoid profile, which also contributes to the user experience.

Heterogeneity across production methods

The cultivation of cannabis has accelerated over the last 25 years, and is grown all over the world for a variety of uses and in a variety of ways. Globally, these operations can be grouped into three categories: historic/traditional production, cultivation in the developing world for the developing world, and production in the developed world—primarily outdoor but increasingly indoor operations (Decorte et al. 2011). The increased demand for cannabis since the 1960s has provided economic incentives for optimization of growing conditions for the highest yield and maximum potency. Given the range of approaches, it may be difficult to distinguish good from bad growing, but there is no doubt that plants are highly environmentally adaptable and that just like the market and the growers, there is a

lot of heterogeneity. Even when conditions are intended to be identical, there will still be variation across a crop.

Cropping methods and breeding strategies also affect the potency of cannabis (Burgdorf et al. 2011; Pijlman et al. 2005). Over the last four decades, the concentration of THC and other cannabinoids has increased, which baffled Mehmedic and coworkers as they found the "potencies inconceivable" and attributed their high measurements to "scientific and statistical shortcomings" (Mehmedic et al. 2010). There is little doubt that the potency increase is associated with both genetic selection and increasing sophistication of horticultural practices, including lighting, fertilization, addition of carbon dioxide, control of light intensity and photoperiod, temperature control, watering, balancing the pH of the soil, hydroponic growing, "supercropping", plant spacing and trellising, and growing media (Chandra et al. 2008).

UV lighting as a factor in THC content

Ultraviolet radiation plays a role in enhancing THC levels in cannabis. Lydon et al. (1987) showed that THC content could be increased with UV-B irradiation (280-320 nm). However, indoor growing facilities currently favor high-pressure sodium lamps (emitting at around 546-620 nm) and metal halide lights (400-700nm). Seven varieties of cannabis were seeded and grown under conditions common to commercial practice to determine whether the level of electrical power is a useful estimate for final yield, and to determine whether the observation of increased potency could be attributed to lighting regimes (Potter & Duncombe 2012). Conditions were controlled with regard to day length, temperature, and CO_2 level. Zones of light with regard to electrical power consumption were varied and kept at a constant distance from the plant canopy as they grew for eight weeks. Flowers were then harvested, dried, and analyzed. Flower to leaf ratio significantly increased as a function of electrical power with an average yield of 470g/m^2. The authors did not report a significant difference in THC content based on this sodium lighting intensity however, and suggest that the increase in THC is based more on the breeding (genetics).

Table 4: The effect of light power density on Δ^9-THC potency.

Electrical Power Per Unit Area W/m^2	Variety							
	Early Pearl	G1	Wappa	White Berry	Super Skunk	Hindu Kush	White Widow	Mean*
270	9.54	10.49	19.28	11.04	18.89	12.22	17.78	14.46
400	9.43	11.07	19.05	10.45	19.37	12.72	17.53	14.38
600	9.54	11.36	17.77	11.02	19.08	13.26	17.43	14.49

*There was no observed increase in mean potency—linear regression, $p > 0.05$.
THC, $\triangle^9$-tetrahydrocannabinol.

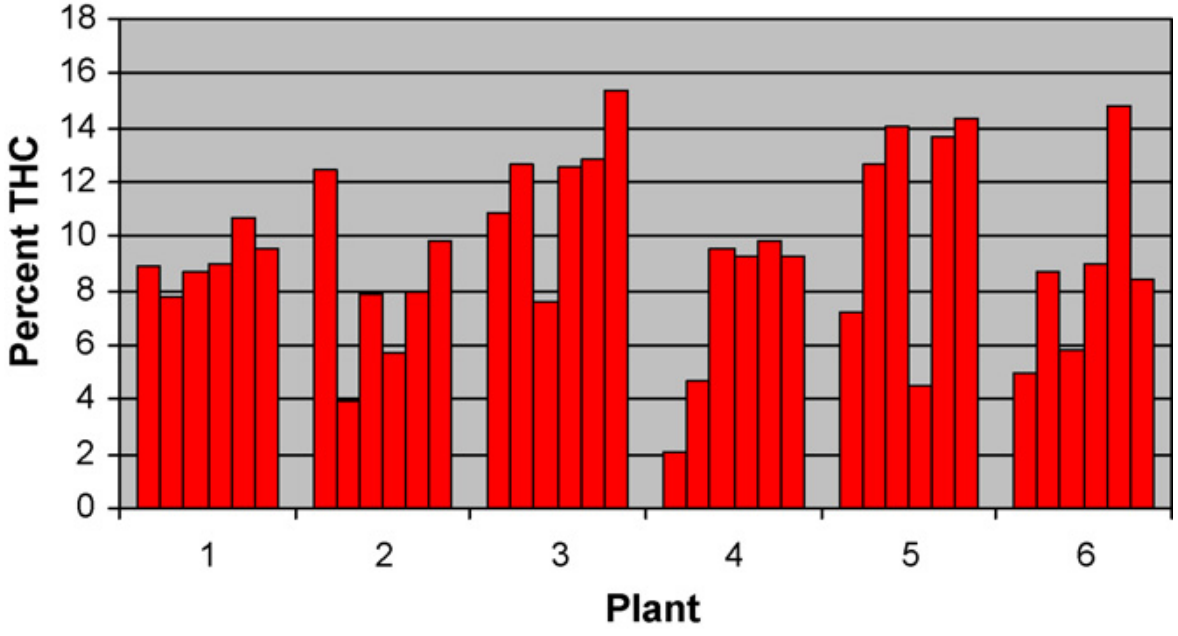
Indoor growers often use a variety of lighting sources (including metal halide and LED) that provide greater spectrum of lighting, and measure lumens (not wattage) to predict vegetative growth. Whether and how specific wavelengths and intensities factor in THC

potency remains unknown. These are much needed experiments that could benefit the industry by maximizing product consistency and quality control.

Degrees of plant/crop heterogeneity

Indoor cultivation offers an advantage to the grower by allowing greater control over plant environment, and gives the ability to grow continuously without seasonal limitation. The setups vary widely with regard to sophistication. Typically, larger scale operations require higher levels of sophistication. It is assumed that more sophisticated operations are better able to regulate growth. However, variables such as nighttime temperature (if using outdoor ventilation), moisture and nutrient supply (if not automated), and equipment failures (fans, heaters, and coolers) can all contribute to outcome variability. In order to ascertain variability in yield and potency for criminal sentencing purposes in New Zealand, an initial study of crops of six plants in each of three "grows" were cultivated under controlled, indoor hydroponic conditions (Knight et al. 2010). Since environmental and nutritional factors were controlled, the study found that plant variety had a major influence on THC levels. A much wider study would be required to determine whether there is considerable variation in THC levels in a subspecies. Variability was determined by the authors to be due to flowers not all being at an equal stage of ripeness, and they recommend multiple analyses. A limitation of the study with regards to results from "grow 2" and "grow 3" were that they encountered serious problems, e.g., nutrient burn and spider mites, yet also found considerable variation both inter- and intra-plant. Individual data for the figure below was not provided, so the actual relative variability amongst this set of six clones is unknown (Figure 7).

Figure 7: THC results for six random samples from each plant in Grow 2, (clones) of the Knight study.



Overall, it can be assumed than even when growing the same variety under the same conditions there may be a substantial degree of cannabinoid variability. Based on the limited data available, it is best to label cannabis potency as a range - not a definite value, - for a given variety. Many laboratories currently report potency to two decimal points, allowing the consumer to misperceive precision for accuracy. This practice is misleading, and misrepresents the accuracy of testing protocols. Typically, that amount of specificity is warranted when results are based on multiple samples (n=3 in research). For single samples, decimal points should be dropped when reporting test results even if a lab has demonstrated a high degree of proficiency, as the inter and intra-plant variability warrant reporting potency in a range. Based on these data, a suggested range that may be reliable is around 2%. As the skill level of growers is refined, and with experimental data demonstrating a lower relative variation, this could be reduced to 1%. A state-sanctioned laboratory to conduct such experiments is needed.

Tensions in Testing Procedures

Many of the sampling policies described in this paper have significant implications on the price of testing. (To be clear, by price of testing we mean the costs levied on the producer, processor, and testing laboratory, as a result of specific policies regarding sampling methodology.) Since these regulations pertain only to the I-502 market, and not to the medical or black markets, minimizing the cost burden of testing and sampling-related policies is important to strengthening I-502's ability to complete with these markets on price. Moreover, and for the same reason, even the most relaxed and least imposing testing and sampling policies discussed in this document will represent a cost increase over the current levels of testing expenditure as enjoyed even recently by the medical and gray markets. (However, these quality assurance regulations may also produce value, if consumers are willing to pay higher prices for cannabis with these assurances of potency and purity.)

The definition of a lot may have to evolve over time as the economy of scale evolves with the market. If it is projected that only large producers will be able to remain in the marketplace, then lot sizes will become much larger than what the existing framework may allow.

The suggested amount for a lot of plant material is not more than five pounds, based upon the approximate flower yield from an indoor grow facility using tables, or a 25 foot greenhouse row with mature plants spaced six feet apart (average yield estimated at 500 grams of flower per plant; Potter et al. 2012). The size of the greenhouse or area in which a particular variety is grown should determine what makes up the lot. A lot can be part of a larger unit that is a complete harvest. For instance, a harvest may include one lot or ten lots.

The decision on a maximum lot size entails a specific trade-off between cost and representativeness of the sample. As allowed lot sizes increase, producers and processors may separate products into a lesser number of individual lots, and testing laboratories may run fewer tests. Depending on required lot sizes, and based on the estimates of lot sizes in this document, a producer who produces a ton of plant material a year might have to pay as

much as $65,000 a year for the required testing (excluding the possibility of bulk discounts). This would represent approximately 4% of gross income. (See Table 5).

Another option to reduce the cost burden of these policies would be to allow growers to access semi-quantitative methods for potency results, and provide this along with pesticide testing data as part of the grower's certificate of analysis. Then, producer-processors would absorb some of the costs for quantitative potency and microbiology testing of product that will be distributed for retail sale. For instance, HPTLC or infrared (IR) can be used to estimate potency and help growers conduct their own experiments with growing methodologies and harvest times. A semi-quantitative result can qualify for a certificate of analysis for the producer/processor. At the next stage of packaging and finishing the product, the quantitative analysis could occur (HPLC, GC).

Finally, we might expect some decrease in the cost of testing as the volume of demand for testing increases. For instance, a common blood test for total cholesterol has a retail price of five dollars in California, yet preparing a blood sample is more time-consuming and expensive than preparing a cannabis sample. One important factor that distinguished the cholesterol test from the cannabis test is the volume of sales activity to the vendor. As demand for testing increases, testing companies will be able to make more efficient use of capital and overhead, and thus costs for testing may sink across the board.

Financial Feasibility for Raw Plant Material

Twenty grams per kilogram from the producer equates to a net loss of an estimated 60 dollars in sales for the grower, or about 1% of the total lot price. With large-scale growing facilities, a 2% sample represents a cost of about $100, and at this time with the grower performing all of the required tests, another $200. $300 per kilo of plant material over a year, if producing a ton would cost the grower about $125,000 a year. If the lot size is increased to 5kg, costs would be reduced, but it will be necessary for laboratories to decrease the cost of running the test by improving high-throughput procedures. Estimates are provided in Table 5.

Table 5: Comparing the cost of testing cannabis flowers with respect to size of the grow facility.

Lot (Kilos per year)	**# of 2 kilo batches**	**Sample cost per lot (@$3 per gram)**	**Test Cost per batch**	**Cost per harvest**	**Cost per Year**
15.6	7.8	$468	$1560	$8,112	$64,896
9.36	4.68	$280	$1,216	$4,864	$38,937
4.68	2.34	$140	$608	$2,432	$19,468
2.34	1.17	$70	$304	$1,216	$9,734

The above table calculates cost for a producer with eight harvests a year (twice-annual production for each of four varieties, operating at different scales of production. Each test that must be carried out has two cost components: price of testing and value of the destroyed sample. The price of each individual test (including cannabinoids, pesticides, heavy metals, and microbiology) is assumed to be $50. Each test requires homogenizing 20 grams of product; in the testing process, seven grams are rendered unusable and the remainder may be returned to the producer in a homogenized state. The table assumes that the value of each gram of cannabis to the producer is $3 per gram, and that homogenized cannabis loses half of its value. (By these calculations, each test costs the producer a combined $40.50 in inventory.) Based on these numbers, the total cost of testing is 4% of the total potential gross receipts at $3 per gram.

Financial Feasibility for Extracts and Infused Products

It is more difficult to project costs of sampling extracts or cannabis-infused products. These are currently being produced in a variety of ways, from very expensive supercritical CO_2 extraction to simple tincturing with ethanol. Moreover, extractions are performed on widely different scales, from quart jar operations in home kitchens to larger lots in professional facilities. The amount of starting material and volume produced will vary greatly across these methods. Retail price also varies based on the cost of the materials involved in producing the product. A great deal more research should be done to determine representative sample sizes and cost projections for testing these products. More concentrated resins may need a smaller representative sample than a more dilute tincture. As discussed earlier, a representative sample from a lot may be 2% of the total or an AQL protocol can be developed that is based on lot size. Without knowing the exact costs of producing the various types of products, it is difficult to estimate the testing costs and feasibility.

A pound of raw material may yield about 50 g of a semi-solid extract using CO_2 extraction. For a tincture using glycerine or ethanol extract, the starting material will dictate the size of the lot. Standard statistical sampling was described in the sampling section.

<u>Conclusion</u>

There are many factors that can affect the cannabinoid profile and potency of cannabis. Controlling for the stain or genetic make up of a plant is often considered the most effective way to ensure a homogeneous crop. Though the WSLCB regulations require that a lot of cannabis be of the same strain, in this paper we have seen that other factors such as lighting quality and nutrients may play a major role in the potency of the plant. Informing the consumer about the strain of cannabis they are purchasing may not give them as much information about the psychoactive content of the product as could be hoped. Continuous testing of harvests is required to truly inform the customer.

Just like any other industry, standardized statistical sampling methods for the Washington cannabis industry are needed to ensure customer safety and to support a supply chain to produce products of unrivaled standards, purity, and quality. Cannabis is a highly variable

crop, and lot size must be small enough to recognize the unique makeup of a particular harvest. The extent of variability in cannabis is not infinite and at a certain point there are diminishing returns of reducing lot size. Required methods for gathering lots and retrieving samples must attempt to reduce variability and any opportunity for the results to be manipulated while at once keeping down the cost of testing.

The various methodologies and constraints of sampling methodologies have been explained herein. It is expected that some of these may change with the development of technology and the dissemination of knowledge across industry. The future trajectory of these developments has an element of unknowability, and there may come a time when they may merit a separate response from regulating agencies. In the meantime, additional research may be productive to the mission of ensuring the quality, consistency, and accurate labeling of cannabis products.

References:

Bheda, R. (2010). What is acceptable quality level? : Rajesh Bheda Consulting. Available from: http://rajeshbheda.com/pdf/rbc-article9.pdf.

Burgdorf, J.R., Kilmer, B., & Pacula, R.L. (2011). Heterogeneity in the composition of marijuana seized in California. *Drug Alcohol Depend, 117*, 59–61.

BBC Research, "Global Market For Botanical And Plant-Derived Drugs Worth $32.9 Billion In 2013", BCC Research LLC

Canada, H. (2008). Industrial Hemp Technical Manual. B. o. D. Surveillance. Canada, Therapeutic Products Directorate.

Chandra S., Lata, H., Khan, I.A., & Elsohly, M.A. (2008). Photosynthetic response of *Cannabis sativa* L. to variations in photosynthetic photon flux densities, temperature and CO_2 conditions. *Physiol Mol Biol Plant,s 14*, 299–306

de Meijer, E.P., Bagatta, M., Carboni, A., Crucitti, P., Moliterni, V.M., Ranalli, P., & Mandolino, G. (2003). The inheritance of chemical phenotype in *Cannabis sativa* L. *Genetics, 163*,335–46.

Decorte, T., Potter, G., & Bouchard, M. (2011). *World Wide Weed: Global Trends in Cannabis Cultivation and its' contro*l. Ashgate Publishers, Farnham, Surrey UK. 314 pp.

Doorenbos, N.J., Fettermsn, P.S., Quimby, M.W. & Turner, C.E. (1971). Cultivation, extraction and analysis of *Cannabis sativa* L. *Annals of the New York Academy of Sciences, 191*, 3–14.

Knight, G., Hansen, S., Connor, M., Poulsen, H., McGovern, C. & Stacey, J. (2010). The results of an experimental indoor hydroponic Cannabis growing study, using the 'Screen of Green' (ScrOG) method – Yield, tetrahydrocannabinol (THC) and DNA analysis. *Forensic Science International, 202*,36–44.

Lydon, J., Teramura, A.H. & Coffman, C.B. (1987). UV-B radiation effects on photosynthesis, growth and cannabinoid production of two *Cannabis sativa* chemotypes. *Photochemistry and Photobiology, 46*(2),201–206.

Mechtler, K.B., Bailer, J. & de Hueber, K. (2004). Variations of Δ^9-THC content in single plants of hemp varieties. *Industrial Crops and Products*, *19*(1), 19–24.

Mehmedic, Z., Chandra, S., Slade, D., Denham, H., Foster, S., Patel, A.S., Ross, S.A., Khan, I.A., ElSohly, M.A. (2010). Potency trends of Δ^9-THC and other cannabinoids in confiscated cannabis preparations from 1993 to 2008. *Journal of Forensic Sciences 55*, 1209–1217.

Pijlman, F.T., Rigter, S.M., Hoek, J., Goldschmidt, H.M. & Niesink, R.J. (2005). Strong increase in total Δ-THC in cannabis preparations sold in Dutch coffee shops. *Addiction Biology 10*171–180.

Potter, D.J. & Duncombe, P. (2012). The effect of electrical lighting power and irradiance on indoor-grown cannabis potency and yield. *Journal of Forensic Sciences 57*, 618–622.

Small, E. & Beckstead, H.D. (1973). Common cannabinoid phenotypes in 350 stocks of Cannabis. *Lloydia 36*, 144-65.

USDA (2013). *Plant Health*. Available from: http://www.aphis.usda.gov/plant_health /cphst/index.shtml.

Wang, P., Lei, J.P., Li, M.H. & Yu, F.H. (2012). Spatial heterogeneity in light supply affects intraspecific competition of a stoloniferous clonal plant. *PLoS One* 7:e39105.

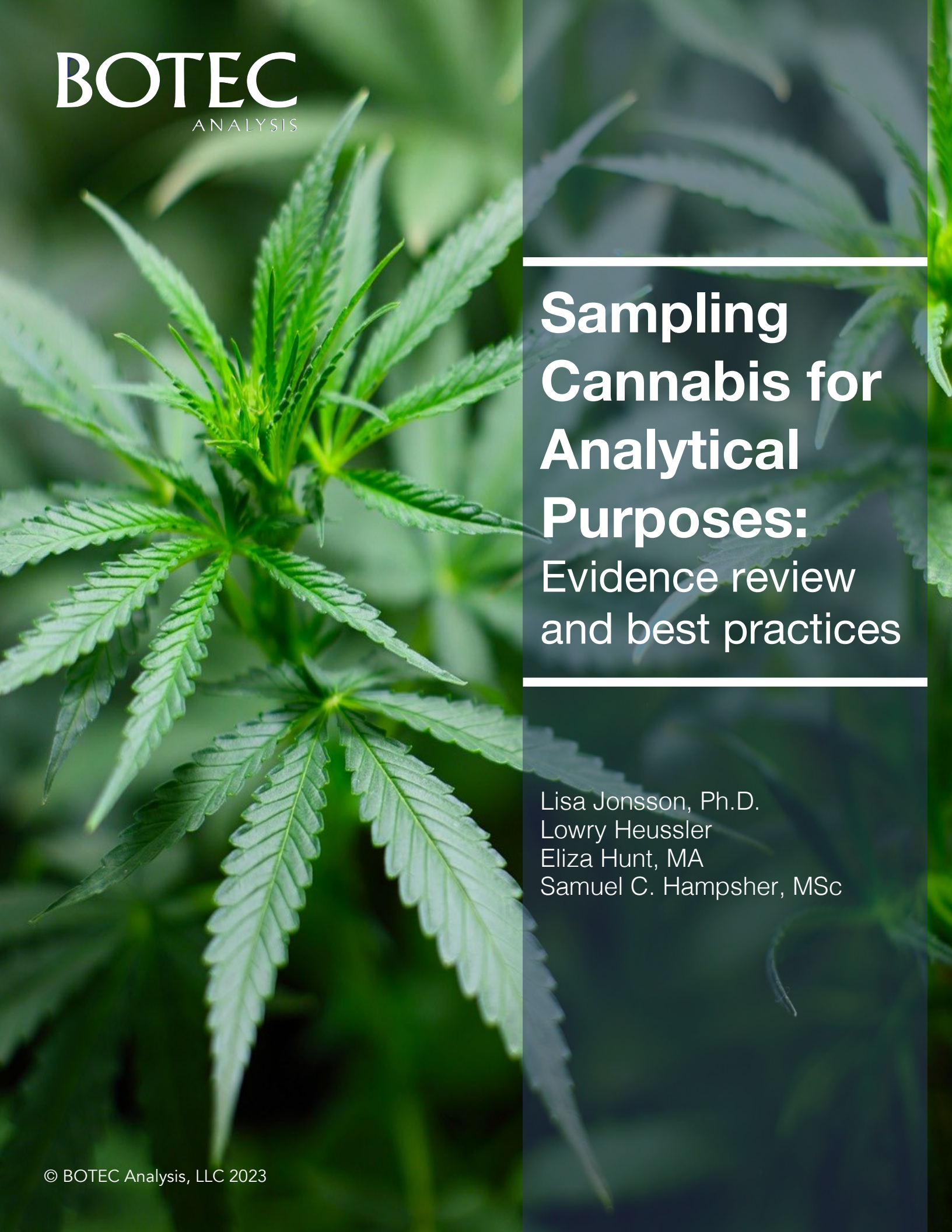
WHO (1998). Quality Control Methods for Medicinal Plant Materials. World Health Organization, England, 214 pp. Available from: http://whqlibdoc.who.int /publications/1998/9241545100.pdf.

WHO (2004). *Concerning the Data Requirements for Active Substances of Plant Protection Products Made From Plants or Plant Extracts*. Directorate-General HACP: European Commission, Health & Consumer Protection Directorate-General. Available from: http://ec.europa.eu/food/plant/protection/evaluation/plant_extracts.pdf.

WHO (2007). The manufacture of herbal medicines. In: *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials*. World Health Organization, India, pp 254-275. Available from: http://www.who.int/medicines /areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf.

WHO (2011). Prequalification of quality control laboratories. Procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies. WHO Technical Report Series, No. 961, Annex 12, pp 393–402. World Health Organization. Available from: http://apps.who.int/medicinedocs /documents/s18680en/s18680en.pdf.

Zamengo, L., G. Frison, et al. (2013). "Variability of cannabis potency in the Venice area (Italy): A survey over the period 2010-2012." Drug Test Anal



BOTEC ANALYSIS

Sampling Cannabis for Analytical Purposes:

Evidence review and best practices

Lisa Jonsson, Ph.D.
Lowry Heussler
Eliza Hunt, MA
Samuel C. Hampsher, MSc

Sampling Cannabis for Analytical Purposes:

Evidence review and best practices

Lisa Jonsson, Ph.D.
Lowry Heussler
Eliza Hunt, MA
Samuel C. Hampsher, MSc

BOTEC
ANALYSIS

www.botecanalysis.com

Table of Contents

Table of Contents ..... *iii*

List of Figures ..... *iv*

List of Tables ..... *iv*

Overview *5*

Importance of testing *6*

Understanding Cannabis Heterogeneity 9

Typical Heterogeneity 9

Heterogeneity across strains 10

Heterogeneity across production methods 11

UV lighting as a factor in THC content 11

Degrees of plant/crop heterogeneity 12

Sampling Theory *14*

Sampling of Raw Plant Material 15

The importance of the lot size in collecting a representative sample 19

The importance of sample size in statistical error 19

Preparation of Analytical Samples 21

Homogenization of the raw sample 21

Sampling Extracts and Cannabis-derived Products 22

Special considerations for edibles and drinks 23

Analytical sampling of cannabis-derived products 23

Tensions in Testing Procedures and the broader context for adult-use cannabis. *24*

Limitations *28*

Conclusion & recommendations *29*

References *30*

List of Figures

FIGURE 1: METHOD PRECISION 17
FIGURE 2: METHOD ACCURACY 18
FIGURE 3: METHOD REPRODUCIBILITY OVER TIME 18
FIGURE 4: GRAPHICAL REPRESENTATION OF VARIABILITY 20

List of Tables

TABLE 1: TERMS AND DEFINITIONS 14
TABLE 2: ANALYTICAL PERFORMANCE STANDARDS FOR HEMP, AND PARAMETERS FOR THC ANALYSIS: THE LIMIT OF DETECTION (LOD), LIMIT OF QUANTIFICATION (LOQ), AND ACCEPTABLE LINEAR RANGE FOR REFERENCE STANDARDS 20

Overview

The cannabis industry and regulations have changed dramatically since 2013 when BOTEC released "Sampling Cannabis for Analytical Purposes." At the time, only Washington and Colorado had legalized it. As of 2023, only 6 states maintain complete prohibition, 23 have full legalization, and the remaining 21 have loosened cannabis laws without fully legalizing a market for adult use. Since cannabis remains a Schedule I drug, the federal government cannot set testing protocols, leaving us with a patchwork of cannabis testing methods and standards across the country.

In 2013, BOTEC noted that regulating testing lot size requires striking a balance between cost and representativeness of the sample. As allowed lot sizes increase, so does the danger of selling contaminated products or mislabeling potency. Our initial calculations took into consideration production costs in a nascent market and what was then known about quantified risks. We also observed that lot sizes might change as the economy of scale evolved with the market, and if large producers (sometimes called Big Marijuana) squeezed out small businesses, lot sizes could become much larger. Ten years later, the industry is much larger, states are seeing value in the preservation of small businesses, and research does not show a scientific basis for changing the 5-pound lot size.

Ensuring a reliable system of purity and potency requires regulation covering a complex set of processes from lab management and certification to testing methodology and equipment. Sampling methodology is not a hot topic even though it establishes the floor for product testing and labeling. This update to BOTEC's initial work reviews the growing body of literature on sampling protocols for cannabis, emerging best practices in sampling, and continued challenges for cannabis testing.

In general, the U.S. government has been so effective in the area of product safety regulation that consumers pay little attention to the topic. By contrast, recreational users of illicit drugs had no illusions of governmental protection. They were already operating outside the law. Without top-down federal oversight, legalization requires each state to create a testing system that transforms cannabis from a risky underworld venture into a consumer experience akin to a trip to the liquor store.

> "Public health is indivisible from long-term commercial viability."
>
> – New Frontier Data

Cannabis product manufacturers care about testing because the results are critical to product differentiation. Consumer confidence in legal cannabis relies on analytical testing.[1] If consumers lose faith in testing or don't trust labeling standards it undermines the legal market.

[1] Fataar, F., Goodman, S., Wadsworth, E., & Hammond, D. (2021). Consumer perceptions of 'legal' and 'illegal' cannabis in U.S. states with legal cannabis sales. Addictive behaviors, 112, 106563.

Product safety was high among arguments for the legalization of cannabis, especially for medically vulnerable consumers like cancer patients and others with compromised immune systems who consume cannabis regularly, thus increasing exposure to impurities. Cannabis businesses are aware of their own liability to consumers for product failures and rely on adherence to the state testing regimen for the front-line defense.[2] Still, not every state with full legalization has been quick to implement comprehensive lab testing regulations despite the need.[3]

Importance of testing

Failure to detect contaminated cannabis can harm consumers by exposing them to molds, bacteria, pesticides and heavy metals. In Michigan in 2021, 18 medical complaints were filed following ingestion of laboratory-tested cannabis products, with a subsequent recall revealing the products to contain traces of aspergillus, *e. coli* and salmonella.[4] In this case, medical complications ranged from light allergic reactions to hospitalizations. Other cases of aspergillus-infected marijuana, however, have led to fatal chronic pulmonary aspergillosis.[5] Salmonella infections due to contaminated cannabis date back to at least 1982, when the New York Times covered a story in which more than half of 101 patients were hospitalized after ingesting the tainted marijuana or being exposed to its by-products. The NYT reported, "Not only did marijuana smokers get the infection, but also children and other people who lived with them."[6]

Pesticides used during the growing and cultivation processes of cannabis are another threat to consumer safety, as pesticides themselves, their reaction to combustion, and their combination with cannabis and cannabis-derived products. A 2021 review[7] of the implications of pesticide residue to medical use of marijuana in neurological diseases revealed that the same set of signaling pathways impacted by cannabis and pesticides are linked to epilepsy, seizures, and

---

[2] Kerschner, D. et al. (2021). "Product Liability Risks Cannabis Companies Must Consider," Cannabis Law 360, available at https://www.arnoldporter.com/en/perspectives/publications/2021/12/product-liability-risks-cannabis-companies.

[3] Washington State Liquor and Cannabis Board, March 2, 2022, CR103 Memorandum Regarding WAC 314-55-101.

[4] Michelson, A (2022). "Medical weed recalled after tests reveal traces of E. coli and salmonella," Insider, available at: link, accessed February 13, 2023.

[5] Gargani Y, Bishop P, Denning DW (2011). "Too many mouldy joints - marijuana and chronic pulmonary aspergillosis," Mediterranean Journal of Hematology, available at: https://www.mjhid.org/index.php/mjhid/article/view/2011.005.

[6] Taylor, DN (1982). "Marijuana Linked to Salmonellosis," The New York Times, available at: link, , accessed February 13, 2023.

[7] Pinkhasova DV, Jameson LE, Conrow KD, Simeone MP, Davis AP, Wiegers TC, Mattingly CJ, Leung MCK (2021). "Regulatory Status of Pesticide Residues in Cannabis: Implications to Medical Use in Neurological Diseases," Current Research in Toxicology, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8296824/

other neurotoxic consequences. For instance, exposure to cannabis, carbamate insecticides, and organophosphate insecticides can all be connected to mitochondrial toxicity and oxidative stress.

Exposure to heavy metals (HMs) is of great concern as regards human ingestion of cannabis or cannabis derived products. Cannabis species have been leveraged for phytoremediation due to several characteristics of the plant that lends them to efficiently bioaccumulate heavy metals including mercury, lead, chromium, cadmium, and arsenic.[8] High tolerance to climate stress, weedy propensities and phenotypic plasticity traits are among a few of those traits which also allow the plant to be resilient and reproductive.[9] Ingestion or exposure to these metals can be highly hazardous to a consumer, as detailed in Box 1 below.

Box:1 Dangers of Heavy Metal Ingestion

Ingesting more than 0.01ppm of **mercury** can result in damaging the kidneys, brain, nervous system and lungs in a developing fetus. In an adult, ingestion can cause gastrointestinal problems (vomiting, nausea, diarrhea) skin rashes, high blood pressure, depression, tremors, headache, fatigue, hair loss and erethism.

Ingestion of more than 0.02ppm of **arsenic** can damage blood vessels, gastrointestinal tissue, heart and brain. Other associated harms are pulmonary disease, neurological problems, peripheral vascular disease, diabetes, mellitus, hypertension and cardiovascular disease. As a carcinogen, arsenic ingestion has also been linked with dermatological, urinary, pulmonary, liver, colon and kidney cancers,

Lead ingestion of over 0.1 ppm can affect gastrointestinal tract and central nervous system. It has also been linked with headache, loss of appetite, abdominal pain, fatigue, hallucinations, vertigo, renal dysfunction, hypertension and arthritis. If ingested during pregnancy, it can result in birth defects, autism, psychosis, allergies, paralysis, weight loss, dyslexia, hyperactivity, muscular weakness, kidney and brain damage.

More than 0.06ppm of **cadmium** consumption can lead to bone and lung damage, respiratory and stomach irritation (vomiting & diarrhea). Further conditions include osteoporosis, "Itai-itai" disease, renal dysfunction and kidney disease, testicular degeneration and prostate cancer.

[8] Bengyella L, Kuddus M, Mukherjee P, Fonmboh DJ & Kaminski JE (2022). Global impact of trace non-essential heavy metal contaminants in industrial cannabis bioeconomy, Toxin Reviews, 41:4,1215-1225, available at: https://pennstate.pure.elsevier.com/en/publications/global-impact-of-trace-non-essential-heavy-metal-contaminants-in-

[9] Ibid.

Ingesting over 0.05ppm of **chromium** can result in allergic reactions, cardiovascular, respiratory, hematological, gastrointestinal, renal, hepatic, and neurological disorders, stomach tumors. It can further lead to the formation of DNA adducts and chromosomal aberrations.[10]

Source: Bengyella et al. (2022).

Most states that have legalized cannabis consumption require potency and purity testing prior to commercial sale. Prior to legalization, the U.S. had limited cannabis testing capability. Testing was largely confined to the criminal justice arena, where the key investigative question was confirmation that a substance was cannabis. Faced with the need to ensure product safety, analytical testing has had to evolve quickly. Today, most legalizing states require testing for potency, terpene content, heavy metals, residual solvents, microbes, pesticides, and mycotoxins. With the explosions of new product types such as topicals, lubricants, suppositories, nasal sprays, and metered-dose inhalers, testing procedures have had to adapt quickly.

Sampling is the foundation of product testing. The entire system relies on the assumption that the tested sample is functionally identical to the larger quantity that will be labeled and offered for sale. In general, the process begins when a grower harvests material from a set of plants from the same batch, grown under the same conditions.[11] The harvested product, presumptively homogenous, is broken up into lots for testing. So long as the independent lab pulls the sample from each lot, as is the case in Nevada (11.070 NCCR), the grower has the incentive to make the lot as homogenous as possible. Since the grower pays for testing and incurs the loss of the material destroyed in testing, lots submitted for testing will be as large as allowed.

Choosing a maximum lot size requires a trade-off between the certainty of homogeneity and cost. Larger lot sizes reduce the number of tests that a producer will have to pay for but decrease assurance that the tested sample is the same as the rest of the lot. Furthermore, a testing failure due to the presence of contaminants in a large lot that is not sufficiently homogenous will require the destruction of more cannabis, not all of which might be contaminated. And of course, if the lot contains contaminants that are not present in the sample drawn by the lab, contaminated cannabis ends up on the store shelves. The result of potency testing will not cause mandatory destruction of the lot but is important for profit and prevention of overdose.

[10] Louis Bengyella, Mohammed Kuddus, Piyali Mukherjee, Dobgima J. Fonmboh & John E. Kaminski (2022). Global impact of trace non-essential heavy metal contaminants in industrial cannabis bioeconomy, Toxin Reviews, 41:4,1215-1225

[11] Nevada's seed-to-sale tracking system ensures that batches are identified from the point or origin. See, generally, 6.080 NCCR.

Understanding Cannabis Heterogeneity

Cannabis is an "extremely inhomogeneous material,"[12] and both genetic and environmental factors directly affect its chemical composition.[13] A single cannabis plant will produce usable cannabis that is chemically heterogeneous in terms of potency and cannabinoid content, based largely on the part of the plant from which it is harvested. Individual plants, even those within the same strain,[14] will differ from each other. Understanding the sources of heterogeneity is key for accurate analytical testing of raw plant material. Because the contents of a testing lot should be as homogeneous as possible, the plant's natural heterogeneity poses a challenge for testing. Sampling methodologies and standards help minimize potential inaccuracy and error that stems from this heterogeneity. Potency and cannabinoid levels are dependent on the strain of cannabis, as well as the propagation method, the conditions under which the plant is grown, the part of the plant from which material is gathered, and the growth stage at harvest, but even when these variables are minimized, homogeneity is not likely. This section reviews the scientific literature on the chemical heterogeneity of cannabis plants.

Currently, industry producers are competing to differentiate themselves through proprietary strains and consistent products. However, the available research does not suggest that plants of the same strain grown under identical conditions generate homogenous cannabis inflorescence (or buds). Research in this field has been slow due to the Schedule 1 status of cannabis. Therefore, much of the existing research in 2013 has not changed, and much of the research that does exist was performed on industrial hemp.

Typical Heterogeneity

Growers often cultivate what is known as a genet: a "clonal colony" in which all the individuals (ramets) originated vegetatively from a single ancestor. Indoor production affords an enhanced ability to control soil nutrients and light, factors that can contribute greatly to variations in growth, biomass, morphology, and physiology of clones.[15] Under these conditions, producers can provide consistent treatment from one plant to another, and often to different parts of the same plant (for instance by positioning lights). However, even within a population of "siblings" growing under

---

[12] Potter, D. J. (2014). A review of the cultivation and processing of cannabis (Cannabis sativa L.) for production of prescription medicines in the UK. *Drug testing and analysis*, 6(1-2), 31-38.

[13] Zamengo, L., G. Frison, et al. (2013), "Variability of cannabis potency in the Venice area (Italy): A survey over the period 2010-2012." https://pubmed.ncbi.nlm.nih.gov/23868754/

[14] Nevada cannabis regulations ensure homogeneity by requiring the grower to identify batches of material, i.e. harvested on or before an identified date, from plants grown from seeds from the same strain. NCCR 1.060. Batches are then divided into lots weighing 5 pounds or less, from which the lab will draw a sample for testing. Test results will apply to each lot. NCCR 1.125.

[15] Wang, P., Lei, J.P., Li, M.H. & Yu, F.H. (2012). Spatial heterogeneity in light supply affects intraspecific competition of a stoloniferous clonal plant. *PLoS One* 7:e39105.

the same conditions, there is wide variation in the synthesis of metabolites (e.g. water, nutrients) such that some variation will remain.[16]

Heterogeneity across strains

In 2013, BOTEC summarized the state of research on cannabinoid variability and strains. Given that cannabis remains a schedule one drug, peer reviewed research has been slow to take off. Small and Beckstead (1973) were the first to survey cannabis accessions for cannabinoid variability.[17] A University of Mississippi study concluded that, phenotypically, cannabis might be a single species that has not stabilized and has many variations.[18] The researchers prepared fields and planted seed from several varieties, analyzed the harvest, and found that that environment and climate, not heredity, were the most important determinants of cannabinoid content.[19] The researchers also discovered a great deal of variability in THC content of different plants. Noting that THC (and other cannabinoids) are secondary metabolites produced by the plant in response to stress, researchers theorized that cannabinoids might be increased by stress, and if so, whether indoor lighting could be a source of that useful stress. Still, fifty years later, the causes of secondary metabolite generation are not well understood.

In 2003, GW Pharmaceutical published a paper in *Genetics* also concluding that environmental factors have a strong influence in modulating cannabinoids content in different parts of the plants at different growth stages. The same paper also reports that cannabinoid profiles in general are under strong genetic control (the THC to CBD ratio, specifically) and that plants typically demonstrate high degrees of polymorphisms (spontaneous genetic mutations) which can account for variability.[20] Other more recent studies concur that potency and cannabinoid concentrates are related to genome, but not solely.[21]

---

[16] Potter, D. J. (2014). A review of the cultivation and processing of cannabis (Cannabis sativa L.) for production of prescription medicines in the UK. Drug testing and analysis, 6(1-2), 31-38.

[17] Small, E. & Beckstead, H.D. (1973). Common cannabinoid phenotypes in 350 stocks of Cannabis. Lloydia 36, 144-65, available at: https://pubmed.ncbi.nlm.nih.gov/4744553/

[18] Doorenbos, N.J., Fettermsn, P.S., Quimby, M.W. & Turner, C.E. (1971). Cultivation, extraction and analysis of Cannabis sativa L. Annals of the New York Academy of Sciences, 191, 3–14, available at: https://nyaspubs.onlinelibrary.wiley.com/journal/17496632

[19] While this report gave some information on heterogeneity across strains, the research was limited since the studied plants were not clones.

[20] de Meijer, E.P., Bagatta, M., Carboni, A., Crucitti, P., Moliterni, V.M., Ranalli, P., & Mandolino, G. (2003). The inheritance of chemical phenotype in Cannabis sativa L. *Genetics*, 163,335–46, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1462421/

[21] De Prato, L., Ansari, O., Hardy, G. E. S. J., Howieson, J., O'Hara, G., & Ruthrof, K. X. (2022). The cannabinoid profile and growth of hemp (Cannabis sativa L.) is influenced by tropical daylengths and temperatures, genotype and nitrogen nutrition. *Industrial Crops and Products*, 178, 114605; Sandhu, S. S., Chiluwal, A., Brym, Z. T., Irey, M., McCray, J. M., Odero, D. C., & Sandhu, H. S. (2022). Evaluating Growth,

While potency and cannabinoid levels may be heavily influenced by the strain, a study in 2019 by Schwabe and McGlauhlin trying to identify genetic profiles of Sativa, Indica and Hybrid concluded that significant genetic differences exist within samples of the same strain. There was no support for dividing the samples into two genetic groups, the groups did not correspond to commonly reported Sativa, Hybrid, or Indica types. At this stage of industry development, strain name is not reliable enough to predict potency or cannabinoid variability. Again, because cannabis remains a schedule one substance, there is no propriety protection for a stains genetic profile. Cultivators cannot impose, nor do they have to adhere to, any genetic definition of a strain. One grower's Blue Dream may be another's OG Kush. Some cultivators are currently registering their strain genome with companies like StrainSecure® in hope of someday gaining the intellectual rights to that specific genome.

Heterogeneity across production methods

The cultivation of cannabis has accelerated since legalization and continues to evolve rapidly. Licensed cultivators have scaled indoor and green house cultivation new a level. The legal market so far has provided economic incentives for optimization of growing conditions for the highest yield and maximum potency. Cropping methods and breeding strategies affect the potency of cannabis.[22] Cultivators are able to influence the potency and other cannabinoids through both genetic selection and increasing sophistication of horticultural practices, including lighting, fertilization, addition of carbon dioxide, control of light intensity and photoperiod, temperature control, watering, balancing the pH of the soil, hydroponic growing, "super-cropping," plant spacing and trellising.[23] De Prato et al. (2022) highlight the importance of temperature, daylength, and nitrogen for growth, time to flowering on cannabinoid concentrations. Given the range of approaches, it is not easy to distinguish good from bad growing, but there is no doubt that plants are highly environmentally adaptable and that just like the market and the growers, there is a lot of heterogeneity. Even when conditions are intended to be identical, there will still be variation across a crop.

UV lighting as a factor in THC content

Ultraviolet radiation plays a role in enhancing THC levels in cannabis. Lydon et al. (1987) showed that THC content could be increased with UV-B irradiation (280-320 nm). However, indoor

---

Biomass and Cannabinoid Profiles of Floral Hemp Varieties under Different Planting Dates in Organic Soils of Florida. *Agronomy*, 12(11), 2845.

[22] Burgdorf, J.R., Kilmer, B., & Pacula, R.L. (2011). Heterogeneity in the composition of marijuana seized in California. Drug Alcohol Depend, 117, 59–61, available at: https://pubmed.ncbi.nlm.nih.gov/21288662/; Pijlman, F.T., Rigter, S.M., Hoek, J., Goldschmidt, H.M. & Niesink, R.J. (2005). Strong increase in total Δ-THC in cannabis preparations sold in Dutch coffee shops. Addiction Biology 10171–180, available at: https://pubmed.ncbi.nlm.nih.gov/16191670/

[23] Chandra S., Lata, H., Khan, I.A., & Elsohly, M.A. (2008). Photosynthetic response of Cannabis sativa L. to variations in photosynthetic photon flux densities, temperature and CO2 conditions. Physiol Mol Biol Plants 14, 299–306, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3550641/

growing facilities have favored high-pressure sodium lamps (emitting at around 546-620 nm) and metal halide lights (400-700nm). Seven varieties of cannabis were seeded and grown under conditions common to commercial practice to determine whether the level of electrical power is a useful estimate for final yield and to determine whether the observation of increased potency could be attributed to lighting regimes.[24] Day length, temperature, and CO_2 level were controlled. Zones of light with varied intensity were kept at a constant distance from the plant canopy as they grew for eight weeks. Flowers were then harvested, dried, and analyzed. The flower-to-leaf ratio significantly increased as a function of electrical power with an average yield of 470g/m^2. The authors did not report a significant difference in THC content based on this sodium lighting intensity however and suggest that the increase in THC is based more on the breeding (genetics).

Degrees of plant/crop heterogeneity

Indoor cultivation offers an advantage to the grower by allowing greater control over the plant environment and gives the ability to grow continuously without seasonal limitations. Sophistication varies greatly. Typically, larger-scale operations require higher levels of sophistication. It is assumed that more sophisticated operations are better able to regulate growth. However, variables such as nighttime temperature (if using outdoor ventilation), moisture and nutrient supply (if not automated), and equipment failures (fans, heaters, and coolers) can all contribute to outcome variability. A recent study showed that in addition to growing conditions when inflorescence is harvested can also impact the potency and other cannabinoid concentrations.[25] In order to ascertain variability in yield and potency for criminal sentencing purposes in New Zealand, an initial study of crops of six plants in each of three "grows" were cultivated under controlled, indoor hydroponic conditions.[26] Since environmental and nutritional factors were controlled, the study found that plant variety had a major influence on THC levels. Variability across the plants was present and determined by the authors to be due to flowers not all being at an equal stage of ripeness, and they recommend multiple analyses.

Overall, a substantial degree of cannabinoid variability can be assumed even when growing the same variety under the same conditions. Based on the limited accuracy of current testing methods, it is best to label cannabis potency as a range – not a definite value, - for a given variety. Many laboratories currently report potency to two decimal points, allowing the consumer to misperceive precision for accuracy. This practice is misleading and misrepresents the accuracy of testing protocols. Typically, that amount of specificity is warranted when results are based on

---

[24] Potter, D.J. & Duncombe, P. (2012). The effect of electrical lighting power and irradiance on indoor-grown cannabis potency and yield. Journal of Forensic Sciences 57, 618–622.

[25] Potter, D. J. (2014). A review of the cultivation and processing of cannabis (Cannabis sativa L.) for production of prescription medicines in the UK. Drug testing and analysis, 6(1-2), 31-38.

[26] Knight, G et al. (2010). The results of an experimental indoor hydroponic Cannabis growing study, using the 'Screen of Green' (ScrOG) method-Yield, tetrahydrocannabinol (THC) and DNA analysis. *Forensic science international*. 202. 36-44. DOI: 10.1016/j.forsciint.2010.04.022.

multiple samples (n=3 in research). For single samples, decimal points should be dropped when reporting test results even if a lab has demonstrated a high degree of proficiency, as the inter and intra-plant variability warrant reporting potency in a range. Based on these data, a suggested range that may be reliable is around 2%. As the skill level of growers is refined, and with experimental data demonstrating a lower relative variation, this could be reduced to 1%. A state-sanctioned laboratory to conduct such experiments is needed.

Sampling Theory

Since analytical testing is destructive by nature, it is not possible to test everything that is sold. Therefore, representative sampling is required. The goal of representative sampling is to select a subset of the whole in order to estimate the characteristics of the whole. Sampling method can significantly bias the final test result.[27] Collecting a representative sample requires controlling for imprecision and bias.[28] Controlling for imprecision means collecting an appropriate size and number of samples to address the compositional and distributional variation of THC and other cannabinoids.[29] Bias is controlled when sampling methodologies ensure an equal probability that any part of a lot could be sampled. This is referred to as probability sampling. Probability sampling is usually performed as a simple random or stratified sampling. Simple random sampling means that every part of the whole has an equal chance of being selected. Stratified sampling requires the container to be subdivided into smaller subsections, then samples are taken from randomly selected strata. Probability sampling applies to both plant material and finished products.

For dried flower, many states specify the minimum percentage of bulk that must be tested, ranging from 0.35% to 1.0% by weight.[30] The size of the bulk from which the samples are taken is usually regulated, this is frequently referred to as the batch or lot size, it is some subset of a total harvest or production run. This is sometimes referred to as the decision unit. Additionally, most state regulations establish the minimum number of samples that must be collected base on the lot or batch size. The size of the lab sample is also regulated because tests can be inaccurate if an insufficient amount of material is tested. In the following sections, we discuss the sampling of different types of matrices or product types. A smaller lot size is important for controlling for distributional heterogeneity. Table 1 below provides some definitions of the different types of samples and stratifications and their relationship to one another.

Table 1: Terms and definitions

Descriptor	Definition
Harvest	Useable cannabis material taken from plants at roughly the same time. "Harvest" may include plants from different strains, grown under various conditions and taken from different parts of the plant.
Batch	A sub-unit of a harvest, Nevada uses the term to describe the usable flower and trim from plants of the same strain.

[27] Opie, Shaun R. *Cannabis Laboratory Fundamentals*. Springer International Publishing, 2021.

[28] Thiex, N., C. Ramsey, R. Bhikha, J. Cook, A. Crawford, D. Danielson, Q. Graves et al (2015). "Guidance on obtaining defensible samples." GOODSamples: Sampling and Sample Handling Working Group.

[29] Ibid.

[30] BOTEC analysis of open-source state regulations available as of 13 February 2023.

Lot	In Nevada, a cannabis batch is divided into lots of 5 pounds or less for testing. Results apply only to what remains of the 5-pound lot after the testing sample is removed.
Lab sample	The is a sample drawn from the lot for analytical testing by the lab.
Analytical Sample	Homogenized cannabis from a lab sample from which the test portion is derived.
Test Portion	Sample used in analytical tests.

Since cannabis and cannabis-derived products can become contaminated or moldy at any point in the production process, testing must be done at various points in the production cycle. This type of repeat testing protects manufacturers who need to be sure that the cannabis or concentrates they buy comply with health and safety standards. Without test results from purchased material, a manufacturer has no way of knowing whether a downstream product failure has resulted from presence of an analyte at the time of purchase. Testing cannabis prior to manufacturing is critical to prevent contamination of the supply chain and costly litigation.

The cannabis market has exploded with new product types, many never conceived of when testing regulations were first drafted. Today, labs could be asked to test anything from pills, oral spray, topicals, drinks, food, oils for cooking, oils/extracts for vaporizing, patches, eye drops, suppositories, IV injections, and dried flower for smoking. Each of these matrices, or product types, requires its own testing procedure. Additionally, today testing has expanded beyond just THC potency to include testing for numerous cannabinoids, pesticides, heavy metals, solvents and microbiological contaminates. This is beyond the scope of this paper, but sampling most of these products requires the same statistical procedures. This paper primarily focuses on sampling of dried flower for smoking or vaporizing (the most popular consumption methods) and includes a brief discussion on sampling down-stream cannabis products.

Sampling of Raw Plant Material

Representative sampling of raw plant material is challenging. Cannabis is commonly sold as intact flower buds which have natural variations in chemical potency. For this reason, cannabis flower is not homogenized prior to sale. Since the variation in cannabis potency cannot easily be mixed away in packaged products of dried flower, sampling procedures are critical for ensuring that a sample is representative of its whole.

Since the psychoactive chemicals of cannabis are unevenly and non-randomly distributed throughout the plant, producers can manipulate the sampling process to produce a sample that exaggerates potency. THC content is commonly regarded to vary from the top to the bottom of the plant, or by the proximity to the light source. In outdoor farming, flowers from the bottom of a plant receive less sunlight than those at the top of the plant, but indoor growers can strategically

place high-intensity lamps to equalize light exposure. Still, flowers that receive less exposure to light are likely to have lower cannabinoid and terpenoid content.

A cannabis producer knows which parts of the plant get the most light and can select the most potent flowers for testing. This step is a point of crucial information asymmetry between the producer and the testing agency. A producer may manipulate his crop's potency ratings by deliberately selecting his plant's most potent flowers and submitting them to the testing agency as a representative of inflorescence.

There are several options to mitigate this vulnerability. Lots should be limited to inflorescence categories: 1) strain, 2) bud size, 3) time of harvesting and curing, and 4) buds that received similar amounts of light, moisture, nutrition, CO2 and temperature. Uniformity can be promoted by adhering to height standards (such as one sample taken at x feet and another at y feet) or distance in lumens away from the light source. These samples would need to be cured or dried prior to analysis. If plants are trellised, then a height variable is not necessary. Each plant to be sampled needs to be readily accessible from all sides, and in its original growing location. Official samples should be brought to the testing location by an inspector or lab representative (as recommended by the USDA-Animal and Plant Inspection Service Plant Protection and Quarantine APHIS-PPQ). Health Canada has prescribed a procedure for industrial hemp that could be adapted to this purpose (Canada 2008).

Many state regulations allow or require the producers to assemble lots from cannabis buds grown under similar conditions (e.g. similar light, moisture, nutrition, CO2, and temperature). Standard practice is for growers create lots from their own harvests, and then bring them to a testing lab where lab personnel randomly select the samples. Sampling procedures are the linchpin of the entire testing regimen, so important to the testing process that some states require that a licensed distributor be present during sampling and certify compliance. California requires filming of the sampling procedure. While the testing lab is responsible for establishing an internal protocol for taking test samples, state regulations should establish guidelines for sampling, such as requiring a specified percentage of the lot mass to be drawn for testing. Often states prescribe the minimum number of samples required based on lot size to help ensure samples are representative of the lot. The rest of the plant material can be returned to the grower (except for additional material needed for microbiological testing) when performed on a separate sample.

Regulations should prevent growers from providing testing labs with samples that are unrepresentative of the lot and from gaming the sampling protocols to manipulate the result. In the first case, this is accomplished by having the lab select the sample; gaming is thwarted by sampling from lots of smaller size. Larger lot sizes make it less likely that the lab result shown on the package accurately represents the contents. Regardless of the sampling protocol, any laboratory or method used must demonstrate precision (Figure 1), intra- assay accuracy

Figure 2), and reproducibility over time (Figure 3). These figures are based on an internal single-lab validation methodology from Integrated Analytical Systems, a bio-analytical company in Berkeley, California.

Figure 1: Method Precision

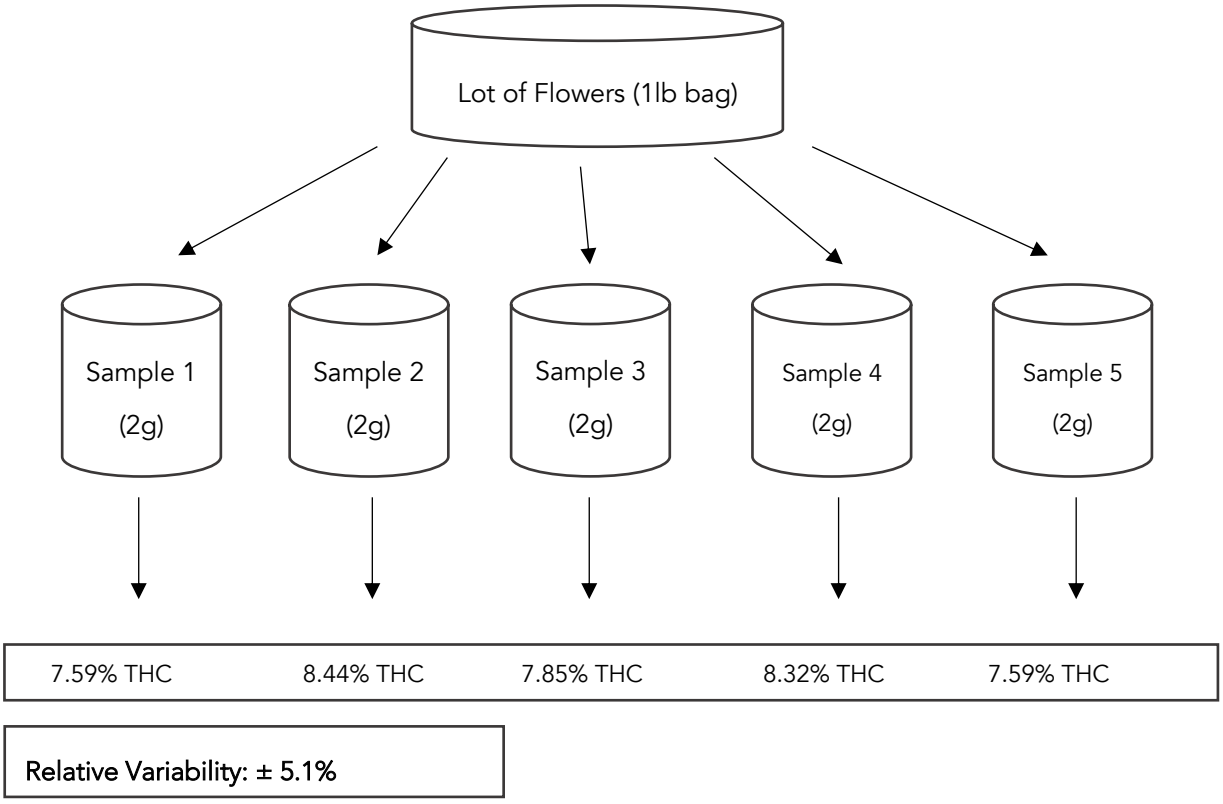
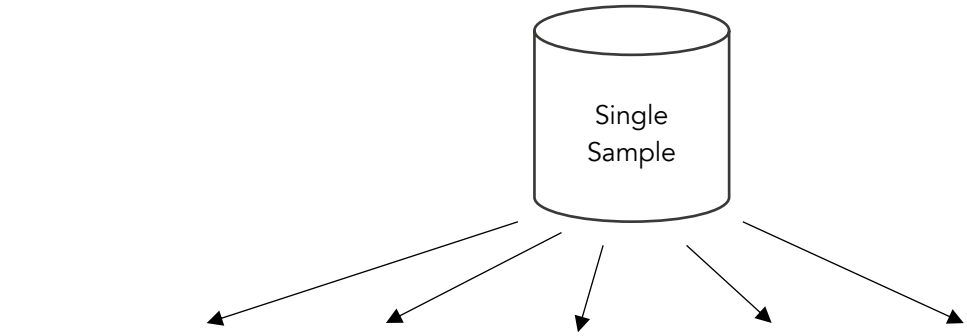


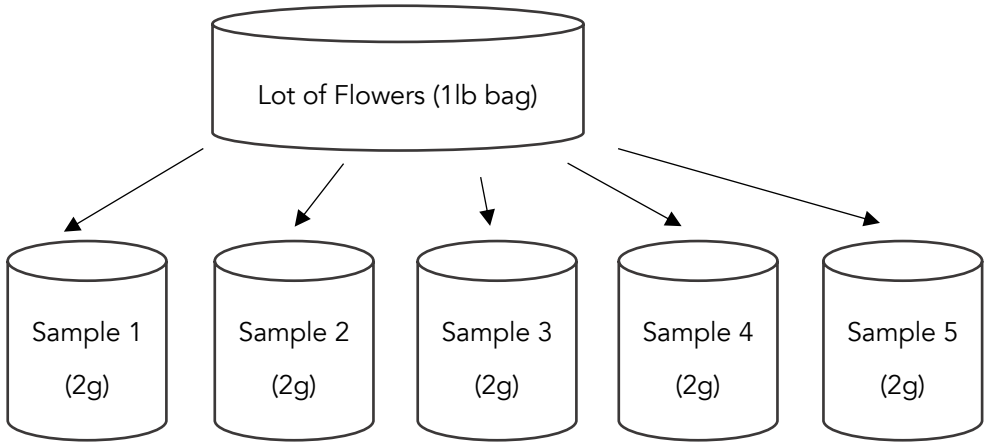
Figure 2: Method Accuracy



Analysis 1	Analysis 2	Analysis 3	Analysis 4	Analysis 5
7.81%	8.06%	8.02%	7.88%	7.91%

Relative Variability: ± 2.3%

Figure 3: Method Reproducibility Over Time



Day of Analysis	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Day 1	9.11%	8.42%	8.62%	8.01%	8.56%
Day 60	9.03%	8.62%	8.40%	7.73%	8.62%
Difference	0.9%	2.4%	2.7%	3.5%	1.5%

Relative Variability: ± 2.2%

The importance of the lot size in collecting a representative sample

Because cannabis is sold as intact buds the sampling protocols must control for a high degree of distributional heterogeneity. The heterogeneity (variation in THC between the buds), cannot be mixed away. For this reason, the lot needs to be sufficiently small to collect a representative sample. The larger the lot size from which the sample is collected, the larger the grouping and segregation error (GSE) becomes.

The importance of sample size in statistical error

Each lab sample will be comprised of inflorescence taken from a single lot of plants. The size of the sample used in testing will affect the confidence of the results. The literature suggests that for a sample to be representative, between 0.5% and 1.0% of the lot mass should be collected. A two-gram sample per 1,000 grams of flower or trim should allow for a confidence of approximately 12% relative variability (or five grams for a relative error of approximately 5%. (See Table 2 and Figure 4).

In developing the laboratory protocol, a five-gram representative sample is needed for the least variability. However, as the data below reflect, 2.5 grams would allow for an acceptable variation across a single sample. Analytical performance standards for hemp are described in Table 2.[31]

[31] Canada, H. (2008). Industrial Hemp Technical Manual. B. o. D. Surveillance. Canada, Therapeutic Products Directorate.

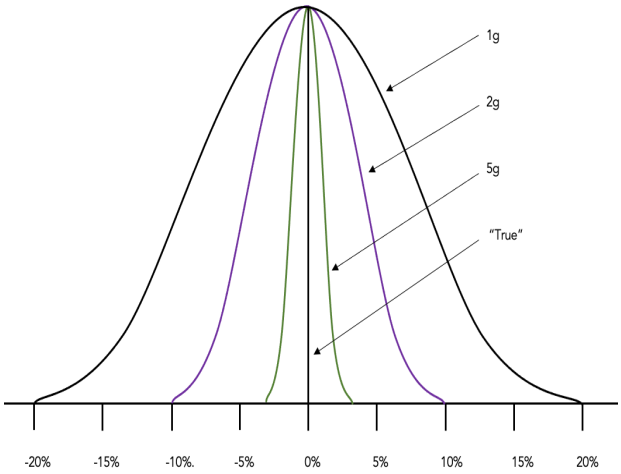
Table 2

Table 2: Analytical performance standards for hemp, and parameters for THC analysis: the limit of detection (LOD), limit of quantification (LOQ), and acceptable linear range for reference standards.

Sample Weight	Variability
1g	± 9.9%
2g	± 5.1%
3g	± 4.3%
5g	± 1.5%

* Recommended weight to submit for testing.

Figure 4: Graphical representation of variability



Preparation of Analytical Samples

Established methodologies exist for preparing a sample of useable cannabis for testing. These methods vary based on the intent of the test (e.g. detecting pesticides, or potency, or micro biotics). There is no standard protocol across states, though some states may regulate the process.

Homogenization of the raw sample

Once the lab samples are collected from the cultivator, the sample must be prepared for analysis. Fundamental sample error (FSE) still poses a threat to the validity of testing results during the preparation of the analytical samples. Each laboratory sample will be subdivided for various tests (heavy metals, solvents, pesticides, microbes), and selection of each test portion presents a new risk that the sample is not representative of the lot. To control FSE at this stage, best practice is to homogenize the lab sample before collection of any test portions. Homogenization averages the THC from the samples. First, the collected samples must be comminuted, or pulverized, to break the sample down into uniform size particles that can be mixed effectively and used in a test portion; this is comparable to the process of turning wheat into flour. There are challenges, however, to comminuting cannabis.

Since 2013, lab testing and sample preparation has made considerable progress. Grinding is the simplest method but may not be the best for cannabis flowers, which are fibrous, and resin filled. Grinding produces heat that can cause melting and activation of oily resins that clog or otherwise stick to the grinding mechanism causing a loss of trichomes and evaporation of volatile metal compounds.[32] High-speed pulverating yields lower phytocannabinoids than manual grinding.[33] Pulverization of dried plant material may be done by mortar and pestle, metal spoon, or glass rod, by cutting the plant material or using a blender. To reduce the force and heat produced by grinding, cannabis samples can be cryo-milled, meaning that the cannabis is essentially frozen before grinding. Lowering the temperature of the cannabis sample causes it to become brittle making comminuting easy and less prone to the problems caused by heat exposure. Cryogenic pulverization is considered a best practice for the preservation of volatile compounds (Atkins, 2019).

There is also some debate about potential sample contamination depending on the type of grinders and sieves. If plastics are used more material is "lost" due to adhesion to the plastic container. [34] The macerated cannabis can then be put through a sieve to ensure appropriate and

---

[32] Opie, Shaun R., ed. (2021). Cannabis laboratory fundamentals. *Springer International Publishing*, available at: https://link.springer.com/book/10.1007/978-3-030-62716-4

[33] Stefkov G, Cvetkovikj Karanfilova I, Stoilkovska Gjorgievska V, Trajkovska A, Geskovski N, Karapandzova M,Kulevanova S. (2022). Analytical Techniques for Phytocannabinoid Profiling of Cannabis and Cannabis-Based Products—A Comprehensive Review. Molecules, Volume 27, page 975. Available at: https://pubmed.ncbi.nlm.nih.gov/35164240/

[34] Ibid.

uniform particle size for the analysis being carried out. Sieving is a critical step in creating homogenous samples. If sieving is not utilized, then a laboratory must show the sample is homogeneous within the accepted tolerance.[35] Once the cannabis is homogenized, a test portion can be prepared. This typically involves dissolving the cannabis into a solution.

Sampling Extracts and Cannabis-derived Products

Downstream cannabis products are mostly made from cannabis extracts made by treating plant material with a solvent, which can then be further concentrated through evaporation, distillation, or some other process (WHO 2004). Concentrates (e.g. dabs and waxes) are purified products that have been processed for specific compounds, primarily cannabinoids and terpenes, and usually consumed through vaporizing or heating. Edibles are produced by adding extracts to virtually any form of food or drink. Topicals, such as lotions and balms, are made from extracts. Pre-rolls (cannabis inflorescence that is ground and rolled for smoking prior to sale) are also downstream products requiring additional testing. Pre-rolls may be infused with extracts to boost potency.

Most states require initial testing of the cannabis inflorescence, and then additional testing of the final product. Solvents used in extracting can be carried into the final product, and some of them are harmful. It is therefore important to test extracts to ensure that any remaining solvents are safe for human consumption. Additionally, testing of extracts, concentrates, and other down-products is best practice to avoid contamination of the supply chain and ensure consumer safety.

Both the purpose and process for sampling downstream products are the same as initial testing, but the protocols for the collection of the lab sample are far simpler. Sampling should collect a minimally necessary amount that represents the chemistry of the bulk material.[36] The sampling unit for cannabis-derived products is a "batch," created from a production run of a single product that uses the same recipe and base incidents, including the same lot(s) of cannabis or cannabis extract. Sampling and testing should be completed after each production run. "Individual units" are the containers of product eventually sold from the batch. Unit size is usually not defined in state regulations, but by individual manufacturers. For instance, a CO_2 cartridge manufacturer's unit is a single cartridge, a baker's unit could be an individual candy bar, or container of gummies. Sampling finished products is easier than cannabis inflorescence because downstream products are for the most part homogenized, or intended to be homogenized, during production. The sampling unit for cannabis-derived products should be a finished, packaged product. The important concept for sampling finished products is the ability to identify and select individual elements at random (good samples). The number of individual units collected as part of the lab sample is determined by the confidence level required and should be outlined in the laboratories

[35] United Nations Office on Drugs, and Crime (2009). Recommended methods for the identification and analysis of Cannabis and Cannabis products: manual for use by national drug testing laboratories. *United Nations Publications*, available at: https://www.unodc.org/unodc/en/scientists/recommended-methods-for-the-identification-and-analysis-of-cannabis-and-cannabis-products.html

[36] Opie, Shaun R., ed. (2021). Cannabis laboratory fundamentals. *Springer International Publishing*, available at: https://link.springer.com/book/10.1007/978-3-030-62716-4

testing protocol. Some states codify the number of units that need to be selected based on the batch size.

Testing products in their final package ensures that contamination has not occurred during the packing process and confirms the packaging itself is not a source of contamination. For extract and concentrate manufacturers, their final product may be sold to producers of other downstream products, rather than an individual consumer.

Special considerations for edibles and drinks

Inconsistent effects from edibles and drinks[37] can be due to uneven distribution of THC throughout the product. Cannabis-infused edibles and drinks continue to face production challenges due to a lack of quality control in manufacturing and a lack of adherence to key food science principles. In addition to standard potency and purity tests, cannabis-infused products containing more than one serving should be tested for homogeneity. This means not homogenizing the individual units but testing various serving portions against each other. For example, a 100 mg candy bar may be scored into ten squares each containing 10 mg of THC. Individual squares should be tested against each other, not the entire bar. In another example, in a 100-mg pack of candies with 20 units, each candy should be 5 mg. Some states allow products to forgo homogeneity testing after each production run if the product has demonstrated homogeneity in previous testing and the recipe is unchanged. Homogeneity is critical for appropriate dosing to avoid over-intoxication, drugged-driving, or over-dose.

Analytical sampling of cannabis-derived products

Analytical samples of downstream products follow the same principles discussed previously. The goal in the collection of the analytical sample is to ensure that it is representative of the whole. This usually begins with comminuting the material to the necessary particle size to perform testing and solubilizing the test portion. It is far simpler to collect a test sample from liquid cannabis material compared to solid samples some heterogeneity may exist depending upon the viscosity of the liquids but can be overcome by mixing or stirring the sample, and by using proper sampling tools, which help mitigate extraction errors. It is important in subsampling that there is no preferential selection or avoidance based on particle size, location or chemical property that causes adherence to sampling tools.[38] Processed cannabis matrices, or product types, can be difficult to analyze due to their lack of solubility and limited availability of non-interferent solvents.[39] For example, gummies are a cannabis-infused edible where comminuting is difficult without cryo-milling. Depending on the test being performed and the analyte of interest, heating a sample can chemically alter the molecular structure in ways that interfere with the detection of specific analytes. When testing for cannabinoids, solvent selection, pH, and temperature are

---

[37] Blake, A., & Nahtigal, I. (2019). The evolving landscape of cannabis edibles. Current Opinion in Food Science, 28, 25-31.

[38] Thiex, N., C. Ramsey, R. Bhikha, J. Cook, A. Crawford, D. Danielson, Q. Graves et al. (2015). "Guidance on obtaining defensible samples." GOODSamples: Sampling and Sample Handling Working Group.

[39] Opie, S. R. (Ed.). (2021). Cannabis laboratory fundamentals. Springer International Publishing.

important considerations when solubilizing oils, tinctures, resins, and concentrates. Cold solvents and cryo-freezing when grinding may mitigate these unwanted conversions.[40]

Tensions in Testing Procedures and the broader context for adult-use cannabis.

Testing is a vital component of market for any regulated consumer good. In the context of regulated cannabis markets, an accurate testing regime informs individual consumption by providing consumers with a quantifiable metric with which to gauge personal consumption. Moreover, by guaranteeing that products are free from potentially harmful adulterants, lab testing bolsters confidence in regulators and consumers, thus safeguarding the broader viability of the regulated cannabis market and earning and protecting the regulated market's demand share in relation to illicit analogues. However, the relationship between lab testing, and public welfare is complex, requiring introspection into the nuanced interactions between the scientific testing of products, consumer confidence (knowledge, beliefs, and attitudes) and price. A comprehensive analysis of these interrelating dynamics is beyond the scope of this report, but the following summary illustrates the importance of an accurate testing regime in regulated cannabis.

The appeal and price of regulated cannabis products are important to consumers and regulators balancing public safety with the imperative to starve out the illicit market. Indeed, BOTEC's interviews with cannabis licensees in Washington state[41] described how consumer decisions were informed almost exclusively by those two factors. In general, producers looking to distinguish their product offerings with other features (e.g., innovations in terpenes, locally grown products, organic production methods) have found that consumers are unwilling to pay a premium for their products. In contrast, larger producers operating at scale could undersell competitors. The success of the regulated cannabis marketplace demonstrates consumer preference for licit products, but within the regulated space, high cannabinoid content is often the only product characteristic for which consumers are willing to pay a premium.

Economic theory suggests that higher prices will reduce demand for products. In the context of cannabis, the addictive nature of the product and the persistence of illicit analogues may make consumer decisions especially responsive to price, though the heterogeneity of users presents a challenge to precisely identifying the price elasticity of cannabis products.[42] In a regulated market, compliance costs are passed on to the consumer, increasing the price of licit goods over the black

---

[40] Macherone, A. (2021). Cannabinoid Detection and Quantitation. *Cannabis Laboratory Fundamentals*, 171-189.

[41] Kleiman, M., Hampsher, S. Davenport, S., Manning, C., Heussler, L., Interviews with Cannabis Licensees in Washington State: A Report for the Washington State Liquor & Cannabis Board (August 14, 2019). Available at SSRN: https://ssrn.com/abstract=3437462 or http://dx.doi.org/10.2139/ssrn.3437462

[42] Pacula RL, Lundberg R. Why Changes in Price Matter When Thinking About Marijuana Policy: A Review of the Literature on the Elasticity of Demand. Public Health Rev. 2014;35(2):1-18. doi: 10.1007/BF03391701. PMID: 25642015; PMCID: PMC4310503.

market. However, in the illicit market, the risk of prosecution must also be compensated giving regulated producers a competitive advantage. How these cost drivers balance out in a specific market, and the resulting product prices, plays a central role in the degree to which regulated markets replace pre-existing and co-occurring illicit ones. However, affordability is not the only relevant factor: as the demand for regulated products suggests, consumer behavior indicates a willingness to pay a premium for regulated products if they perceive other advantages over illicit analogues. Such advantages may include a greater diversity of product offerings, or (crucially for the purposes of this paper) greater consumer confidence in the safety or quality of the products. Confidence in the regulated market may help win consumers from the illicit market and/or prevent demand subsequently slipping to illicit analogues in response to tax increases or other regulatory interventions.

The lab testing regime informs both the affordability and appeal of regulated products. However, to some extent, a trade-off exists between the two: A more accurate testing regime (resulting from a smaller lot size testing requirement) provides more precise assessments and, if adequately communicated to the consumer, may increase consumer confidence in the regulated product. On the other hand, more frequent testing will increase producer-borne costs, some of which may be passed on to the consumer, which could make regulated products relatively less appealing. Examining the counterfactual, it may be argued that relaxed testing protocols, including larger lot sizes, could reduce the cost of testing borne by the producer and passed on to consumers. Research to date supports that consumers care about safety, and their confidence is eroded when standards slip. Further, while larger lot sizes may decrease testing costs as a proportion of canopy produced, it is not clear this would reduce product prices. First, larger lot sizes require producers to sacrifice greater quantities of their crop with each failed test. Producers would need to compensate themselves for the incurred costs. Second, reducing the number of tests required would not necessarily lead to a commensurate reduction in the total price paid to the labs. Testing prices respond to both demand and supply. Regulatory changes that reduce the demand for testing could be expected to reduce the number of cannabis testing laboratories, and this drives up prices. Common blood tests are much cheaper than rare ones.

Cannabis sales in the United States are projected to grow from $25 billion in 2021 to $40 billion in 2026,[43] and as demand for testing increases, costs may come down. Reducing the demand for testing by relaxing lot size has the potential to reverse this effect. The reduction in producer costs associated with less stringent testing standards should not therefore be expected to benefit the consumer. Further, larger lot sizes could disproportionately harm smaller producers who risk a larger relative portion of their crop with each test than larger producers. That may provide a competitive advantage to those who are able to produce at scale. However, once again, larger lot size does not necessarily increase public welfare. If larger lot sizes do contribute to market

[43] DeAngelo, D. (2022). The Hockey Stick Turns into Bell Curve: A New Report Sheds Light On Cannabis Industry Growth, *Forbes Magazine*, available at:

https://www.forbes.com/sites/andrewdeangelo/2022/10/04/the-hockey-stick-turns-into-bell-curve-a-new-report-from-bdsa-sheds-light-on-cannabis-industry-growth/?sh=2a56a9b566f2, accessed February 13, 2023.

concentration around scale (a phenomenon evident in adult use markets in other states) that could flood the market with low priced product. Cheap product reduces the tax revenues the state derives from sales (along with any utility derived from those revenues). Lower product prices could plausibly remove any existing price-impediment against youth use and increase consumption (an effect which is likely concentrated among price-sensitive groups including heavy users). Lower product prices may push some producers (especially smaller ones) out of the marketplace entirely. The latter effect could undermine the goal of a diversified and equitable marketplace. A more concentrated marketplace would also undermine diversity of product offerings and leave insolvent producers with a greater incentive to divert crops to the illicit space,[41] with consequent harm to the regulated market.

These responses are not a foregone conclusion. If large-scale producers derive a benefit from a less stringent rule on lot size, it is not clear that they would reduce prices. It is possible that the beneficiaries of a hypothetical rule change could leverage their increased market power to raise product prices. But while it may be argued that this would avoid the unintended consequences resulting from lower product prices, the scenario is also risky: compared with the status quo, higher product prices make regulated products less competitive, possibly stimulating demand for illicit products.

Ultimately, the accuracy of lab tests is driven by the skill and precision of the labs, but also by the selection criteria mandated by regulation, and by selections made by the producers. In some states, the ability of producers to self-select product for sampling creates an opportunity for gaming[44] which may lead to lab-testing results which, while accurate in themselves, are not representative of the broader product batch. There is another mechanism by which the lab-testing regime may be gamed: BOTEC's interviews with Washington's cannabis industry stakeholders, [41] including testing lab operators, identified reports that producers would 'lab-shop' – selecting labs which delivered an artificially high THC reading. Especially since cannabis products typically carry a premium for potency, both examples of gaming could result in consumers paying arbitrarily high prices for regulated products. Either of these efforts are sure to disappoint consumers if not regulators. The public health is not directly endangered when a consumer pays for more THC than she is getting, but the converse is worrisome.

Since more potent products command higher prices, gaming could artificially inflate the prices of regulated products *en masse*, reducing the ability of the regulated market to compete against the illicit one. Further, the same dynamics that allow for gaming to result in higher THC readings could also lead to testing failures for contaminants. In some instances, this could directly threaten public health, along with (again) the reputation of the testing labs and other industry stakeholders.

The five-pound lot size is based on sound sampling methodologies aimed at reducing sampling error and ensuring that the potency and purity of the lot can be inferred from test results. Relaxation of the testing requirement, including increasing the lot size would not only undermine

---

[44] Kleiman, Mark and Hampsher, Sam and Davenport, Steven and Manning, Clarissa and Heussler, Lowry, Interviews with Cannabis Licensees in Washington State: A Report for the Washington State Liquor & Cannabis Board (August 14, 2019). Available at:
SSRN: https://ssrn.com/abstract=3437462 or http://dx.doi.org/10.2139/ssrn.3437462

the accuracy of lab testing, plausibly reducing consumer confidence in regulated products and risking the other unintended consequences discussed above. Changes to the current testing regime should not proceed without full consideration of these effects.

Limitations

This paper is limited to a discussion of sampling ratios in retail cannabis testing for purity and potency, i.e., how much useable cannabis will be destroyed by testing in order to ensure that the remainder is identical to the sample? In practical terms, this means figuring out how much cannabis should be contained in each lot from which the laboratory will draw a single sample for testing. We do not address ancillary issues, and therefore caution the reader about three assumptions necessary for this work. First, we assume a high degree of competence from laboratories and the accuracy, robustness, and reproducibility of their methodologies. It is imperative that any laboratory providing testing be able to demonstrate at least 95% accuracy of the testing methodology by passing a blind proficiency test of random samples, and that procedures are followed to prevent contamination from being introduced in the lab. Third, we assume that samples will be drawn from lots by the independent lab as required in the regulations.

Conclusion & recommendations

Since BOTEC first researched the matter of lot sizes for cannabis testing in 2013, a burgeoning market has provided new information allowing for better techniques that may be reflected in testing regulations, but none of this data suggests that a change in the five-pound lot size would be useful for any stakeholders.

Each cannabis plant has natural variation in cannabinoid profile and potency of useable cannabis, but consistency may be improved by farming techniques. Plant genetics may play a major role in potency and homogeneity, but as of now, informing the consumer about the strain of cannabis offered for purchase does not provide much information about the psychoactive content of the product. Continuous testing of harvests is the only way to provide customers with information that is both accurate and useful.

Representative samples are fundamental of accurate results. If sampling protocols are not designed to ensure representation of the entire crop, then the testing will be biased[45]. Standardized statistical sampling methods are needed to ensure customer safety and to support a supply chain capable of producing consumer goods with high standards of purity and quality. Lot size must be small enough to reveal the unique makeup of a particular harvest. The extent of variability in cannabis is not infinite and at a certain point, there are diminishing returns of reducing lot size. Required methods for gathering lots and retrieving samples must attempt to reduce variability and any opportunity for the results to be manipulated while at once keeping down the cost of testing.

The various methodologies and constraints of sampling methodologies have been explained herein. However, additional research to improve sampling and testing would further the mission of ensuring the quality, consistency, and accurate labeling of cannabis products.

The priority in testing cannabis and cannabis-derived products should always be public health and safety. Lot sizes should not exceed five (5) pounds and at least .5% of the lot should be tested. Sampling should be conducted by a licensed, certified lab that is qualified to certify that the test samples are representative of the lot or batch and obtained in accordance with a standardized sampling protocol.

[45] Atkins, P. L. (2019). Sample processing and preparation considerations for solid cannabis products. Journal of AOAC International, 102(2), 427-433.

References

Atkins, P. L. (2019). Sample processing and preparation considerations for solid cannabis products. Journal of AOAC International, 102(2), 427-433.

Bheda, R. (2010). What is acceptable quality level? Rajesh Bheda Consulting. Available from: http://rajeshbheda.com/pdf/rbc-article9.pdf.

Blake, A., & Nahtigal, I. (2019). The evolving landscape of cannabis edibles. Current Opinion in Food Science, 28, 25-31.

Burgdorf, J.R., Kilmer, B., & Pacula, R.L. (2011). Heterogeneity in the composition of marijuana seized in California. *Drug Alcohol Depend, 117*, 59–61.

BBC Research, "Global Market for Botanical and Plant-Derived Drugs Worth $32.9 Billion In 2013", BCC Research LLC

Canada, H. (2008). Industrial Hemp Technical Manual. B. o. D. Surveillance. Canada, Therapeutic Products Directorate.

Chandra S., Lata, H., Khan, I.A., & Elsohly, M.A. (2008). Photosynthetic response of *Cannabis sativa* L. to variations in photosynthetic photon flux densities, temperature and CO2 conditions. *Physiol Mol Biol Plants 14*, 299–306

DeAngelo, D. (2022). The Hockey Stick Turns into Bell Curve: A New Report Sheds Light On Cannabis Industry Growth, *Forbes Magazine*, available at:

https://www.forbes.com/sites/andrewdeangelo/2022/10/04/the-hockey-stick-turns-into-bell-curve-a-new-report-from-bdsa-sheds-light-on-cannabis-industry-growth/?sh=2a56a9b566f2, accessed February 13, 2023.

de Meijer, E.P., Bagatta, M., Carboni, A., Crucitti, P., Moliterni, V.M., Ranalli, P., & Mandolino, G. (2003). The inheritance of chemical phenotype in *Cannabis sativa* L. *Genetics, 163*,335–46.

De Prato, L., Ansari, O., Hardy, G. E. S. J., Howieson, J., O'Hara, G., & Ruthrof, K. X. (2022). The cannabinoid profile and growth of hemp (Cannabis sativa L.) is influenced by tropical daylengths and temperatures, genotype and nitrogen nutrition. Industrial Crops and Products, 178, 114605.

Decorte, T., Potter, G., & Bouchard, M. (2011). *World Wide Weed: Global Trends in Cannabis Cultivation and its' contro*l. Ashgate Publishers, Farnham, Surrey UK. 314 pp.

Doorenbos, N.J., Fettermsn, P.S., Quimby, M.W. & Turner, C.E. (1971). Cultivation, extraction and analysis of *Cannabis sativa* L. *Annals of the New York Academy of Sciences, 191*, 3–14.

Fataar, F., Goodman, S., Wadsworth, E., & Hammond, D. (2021). Consumer perceptions of 'legal'and 'illegal'cannabis in US states with legal cannabis sales. Addictive behaviors, 112, 106563.

Knight, G., Hansen, S., Connor, M., Poulsen, H., McGovern, C. & Stacey, J. (2010). The results of an experimental indoor hydroponic Cannabis growing study, using the 'Screen of Green' (ScrOG) method – Yield, tetrahydrocannabinol (THC) and DNA analysis. *Forensic Science International, 202*,36–44.

Lydon, J., Teramura, A.H. & Coffman, C.B. (1987). UV-B radiation effects on photosynthesis, growth and cannabinoid production of two *Cannabis sativa* chemotypes. *Photochemistry and Photobiology, 46*(2),201–206.

Macherone, A. (2021). Cannabinoid Detection and Quantitation. Cannabis Laboratory Fundamentals, 171-189.

Mechtler, K.B., Bailer, J. & de Hueber, K. (2004). Variations of Δ^9-THC content in single plants of hemp varieties. *Industrial Crops and Products*, *19*(1), 19–24.

Mehmedic, Z., Chandra, S., Slade, D., Denham, H., Foster, S., Patel, A.S., Ross, S.A., Khan, I.A., ElSohly, M.A. (2010). Potency trends of Δ^9-THC and other cannabinoids in confiscated cannabis preparations from 1993 to 2008. *Journal of Forensic Sciences 55*, 1209–1217.

Opie, S. R. (Ed.). (2021). Cannabis laboratory fundamentals. Springer International Publishing.

Pijlman, F.T., Rigter, S.M., Hoek, J., Goldschmidt, H.M. & Niesink, R.J. (2005). Strong increase in total Δ-THC in cannabis preparations sold in Dutch coffee shops. *Addiction Biology 10*171–180.

Potter, D. J. (2014). A review of the cultivation and processing of cannabis (Cannabis sativa L.) for production of prescription medicines in the UK. Drug testing and analysis, 6(1-2), 31-38.

Potter, D.J. & Duncombe, P. (2012). The effect of electrical lighting power and irradiance on indoor-grown cannabis potency and yield. *Journal of Forensic Sciences 57*, 618–622.

Sandhu, S. S., Chiluwal, A., Brym, Z. T., Irey, M., McCray, J. M., Odero, D. C., & Sandhu, H. S. (2022). Evaluating Growth, Biomass and Cannabinoid Profiles of Floral Hemp Varieties under Different Planting Dates in Organic Soils of Florida. Agronomy, 12(11), 2845.

Schwabe, A. L., & McGlaughlin, M. E. (2019). Genetic tools weed out misconceptions of strain reliability in Cannabis sativa: implications for a budding industry. Journal of Cannabis Research, 1(1), 1-16.

Small, E. & Beckstead, H.D. (1973). Common cannabinoid phenotypes in 350 stocks of Cannabis. *Lloydia 36*, 144-65.

Thiex, N., C. Ramsey, R. Bhikha, J. Cook, A. Crawford, D. Danielson, Q. Graves et al. "Guidance on obtaining defensible samples." GOODSamples: Sampling and Sample Handling Working Group (2015).

USDA (2013). *Plant Health*. Available from: http://www.aphis.usda.gov/plant_health /cphst/index.shtml.

Wang, P., Lei, J.P., Li, M.H. & Yu, F.H. (2012). Spatial heterogeneity in light supply affects intraspecific competition of a stoloniferous clonal plant. *PLoS One* 7:e39105.

WHO (1998). Quality Control Methods for Medicinal Plant Materials. World Health Organization, England, 214 pp. Available from: http://whqlibdoc.who.int /publications/1998/9241545100.pdf.

WHO (2004). *Concerning the Data Requirements for Active Substances of Plant Protection Products Made from Plants or Plant Extracts*. Directorate-General HACP: European Commission,

Health & Consumer Protection Directorate-General. Available from: http://ec.europa.eu/food/plant/protection/evaluation/plant_extracts.pdf.

WHO (2007). The manufacture of herbal medicines. In: *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials*. World Health Organization, India, pp 254-275. Available from:

http://www.who.int/medicines
/areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf.

WHO (2011). Prequalification of quality control laboratories. Procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies. WHO Technical Report Series, No. 961, Annex 12, pp 393–402. World Health Organization. Available from: http://apps.who.int/medicinedocs /documents/s18680en/s18680en.pdf.

Zamengo, L., G. Frison, et al. (2013). "Variability of cannabis potency in the Venice area (Italy): A survey over the period 2010-2012." Drug Test Anal.

Increasing Lot Size Limits and Production Runs for testing put patients' and consumers' safety at risk.

Here's why:

1- Larger lot sizes make it less likely that the lab result shown on the package accurately represents the contents.
2- The lot needs to be sufficiently small to collect a representative sample. The larger the lot size from which the sample is collected, the larger the result will vary and the lower is the accuracy regardless of the sampling protocol.
3- Accurate testing resulting from a smaller lot size provides more precise assessments and accurate product label which increases consumer confidence in the regulated product.
4- increase in size has implications for quality, safety and product recalls. Only testing the final product could easily result in large losses to the producer of the product if samples failed and significant risks to the consumers if there were "false negative" allowing contaminated product to make its way to the consumer. These issues could result in harm to cannabis consumers, especially medical cannabis patients, and tarnish the reputation of Nevada's well establish and robust cannabis adult-use program.
5- The accuracy of lab tests is driven by the skill and precision of the labs, but also by the lot size and selection criteria mandated by regulations.
6- The five-pound lot size is based on sound sampling methodologies aimed at reducing sampling error and ensuring that the accuracy of the reported results reflect the true potency and purity of the lot.
7- Representative samples are fundamental of accurate results. Lot size must be small enough to reveal the unique makeup of that portion of any particular harvest.
8- When compliance samples for testing—whether for cannabinoid content, mold, mycotoxins, or pesticides, etc.—are drawn from 5-lb batches, issues are easy to spot. Samples drawn from a larger batch size are more likely to

Miss hotspots of contamination. Why does this happen? It's all about representative sampling and testing.

9- Smaller lot size increase results accuracy, consistency, and accurate labeling of cannabis products. therefore, therefore providing an increased level of safety for cannabis consumers.

10-Tolerance levels for products that are inhaled (cannabis) are generally lower than for products that are eaten (food). Five of Nevada cannabis pesticides the maximum residual level is zero, meaning that no trace of those residues may legally be detected in a sample of cannabis.

11-The loss of cannabis that must be destroyed if a batch fails testing accounts for a larger share of the total costs (associated with testing) than does the cost of the lab tests themselves.

12-Testing, which provides valuable safeguards and information to the consumer, involves cost, but losses inflicted by destroying cannabis that fails testing is a larger component of overall costs. Low or zero tolerance levels for pesticide residues, presence of mold or trace level of solvent are the most demanding requirements, and result in the greatest share of safety compliance testing failures.

Conclusion

Lot sizes should not exceed five (5) pounds, and the amounts acquired for sampling should be at least (0.5-1.0%) of the lot.

CPSA

Citizens Public Safety Alliance

In Nevada, there has been much discussion and debate surrounding testing requirements and increasing lot sizes. Given the ongoing debate, BOTEC Analysis (BOTEC) undertook a further evaluation of its original 2013 study, *Sampling Cannabis for Analytical Purpose*, to determine whether the evolving and growing landscape in the cannabis marketplace changed or altered its original findings. In its 2023 study, *Sampling Cannabis for Analytical Purposes: Evidence review and best practices*, BOTEC affirms that, despite the evolution of the cannabis industry, Nevada's current lot-size sampling policy is a "best practices" policy.

In addressing the debate between certainty for consumers and the cost for cultivators and producers, BOTEC noted:

> *Choosing a maximum lot size requires a trade-off between the certainty of homogeneity and cost. Larger lot sizes reduce the number of tests that a producer will have to pay for but decrease assurance that the tested sample is the same as the rest of the lot. Furthermore, a testing failure due to the presence of contaminants in a large lot that is not sufficiently homogenous will require the destruction of more cannabis, not all of which might be contaminated. And of course, if the lot contains contaminants that are not present in the sample drawn by the lab, contaminated cannabis ends up on the store shelves.*[1]

Simply put, the debate evolves around cultivators and producers desiring to cut their testing costs by increasing lot sizes when doing so, according to BOTEC, increases the likelihood of contaminated products ending up on store shelves. Moreover, BOTEC affirms the position of cultivators and producers is truly short sighted as an increase in lot size testing has the very real potential of the destruction of more (not less) product. By way of example, if the lot test size test is 20 pounds and there is a single failed test then all 20 pounds would have to be destroyed whereas if the test size is 5 pounds and that same 20 pounds is subjected to four tests of 5 pounds each and it endures a single failed test then only 5 pounds is destroyed but the other 15 pounds of uncontaminated product can be sold into the marketplace to the benefit of the cultivator or producer. Furthermore, the smaller lot testing size is beneficial to many of the smaller local cultivators and producers who cannot afford to destroy significant portions of their harvest or product based upon a single failed test of a large lot size. To this end, BOTEC confirmed "research does not show a scientific basis for changing the 5-pound lot size"[2] and noting that:

> *.. none of this data suggest that a change in the five-pound lot size would be useful for any stakeholders...and, the priority in testing cannabis and cannabis-derived products should always be public health and safety. Lot size should not exceed five (5) pounds and at least .5% of the lot should be tested. Sampling should be conducted by a licensed, certified lab that is qualified to certify that the test samples are representative of the lot or batch and obtained in accordance with a standardized sampling protocol.*[3]
>
> *The five-pound lot size is based on sound sampling methodologies aimed at reducing sampling error and ensuring that the potency and purity of the lot can be inferred from test results. Relaxation of the testing requirement, including increasing the lot size would not only undermine the accuracy of lab testing, plausibly reducing consumer confidence in regulated products and risking the other unintended consequences discussed above. Changes to the current testing regime should not proceed without full consideration of these effects.*[4]

---

[1] *See Sampling Cannabis for Analytical Purposes: Evidence review and best practices* at pg. 8.
[2] *Id.* at pg. 5.
[3] *Id.* at pg. 29.
[4] *Id.* at pgs. 26-27.

While there have been several ill-conceived proposals to dramatically increase the lot size required for sampling, apparently in an effort to benefit large MSO cannabis operations at the expense of smaller Nevada-based cannabis establishments,[5] such unscientific measures would damage Nevada's carefully constructed, independent cannabis laboratory testing program and should be permanently stopped. The legislature should require that any changes made to the existing testing programs be done, only after careful review, extensive discussion and with full consideration of the potential negative effects. BOTEC has reviewed Nevada's sampling procedures and lot size. Consistent with their recommendations, we strongly urge that Nevada maintain the 5-pound lot size for sampling and testing in order to protect the consumer and by extension the integrity and survival of Nevada's regulated cannabis program.

As always, we appreciate your consideration and review of BOTEC's scientific analysis of this important issue. If you have any questions, comments or wish to discuss this important issue further, please feel free to contact the undersigned directly.

Sincerely,

Jay Matos CPSA,
Government Affairs
https://www.mmjnv.com/

ABOUT BOTEC

For nearly 40 years BOTEC has been at the forefront of assisting governments throughout the United States, Canada, and many countries around the world. They helped develop sound, evidence-based policies for numerous states and countries. BOTEC was founded in 1984 by then-Harvard professor Mark Kleiman and his colleagues at Harvard, the RAND Corporation, and other universities and think tanks across America. As a former director of policy and management analysis for the Department of Justice's Criminal division, Mark understood that academia often moved too slowly to do more than observe and report policy problems, but he sensed an eagerness among his fellow professors to break free from an inefficient model and transform the policy space. BOTEC was born to streamline policy problems, offer cost-effective and innovative solutions, and test them rigorously. A review of the BOTEC website provides a full understanding of who and what BOTEC is and allows one to fully appreciate the extensive scope of their worldwide work. According to their website "There is nothing simple about how government policies affect public health and safety. BOTEC Analysis is a group of researchers, practitioners, and former policymakers who help governments and NGO's deliver public goods to their citizens through the intersection of scholarship and practice. BOTEC forges connections between experienced policymakers and groundbreaking researchers to solve problems of public health and safety… BOTEC unlocks the power of academia. We leverage the capacities of scholars at universities, policy institutes, and non-profits to assist government agencies and NGO's with policy problems." At BOTEC they affirm that "Research + Practice = Better Policy".

[5] As noted in the referenced study "[l]ower product prices may push some producers (especially smaller ones) out of the marketplace entirely. [This] effect could undermine the goal of a diversified and equitable marketplace. A more concentrated marketplace would also undermine diversity of product offerings and leave insolvent producers with a greater incentive to divert crops to the illicit space, with consequent harm to the regulated market… [Moreover] If large-scale producers derive a benefit from a less stringent rule on lot size, it is not clear that they would reduce prices. It is possible that the beneficiaries of a hypothetical rule change could leverage their increased market power to raise product prices. But while it may be argued that this would avoid the unintended consequences resulting from lower product prices, the scenario is also risky: compared with the status quo, higher product prices make regulated products less competitive, possibly stimulating demand for illicit products." *Id.* at pgs. 26-27.

Nov 10, 2022

Honorable Michael L. Douglas, Chairman, Cannabis Compliance Board

Tyler Klimas, Executive Director, Cannabis Compliance Board

555 E. Washington Street

Las Vegas, Nevada 89101

Dear Sirs:

Scientists for Consumer Safety (SCS) is a group of Nevada cannabis laboratories dedicated to the safety of cannabis consumers through the establishment of appropriate, science-based regulations for cannabis laboratories. SCS has been advocating for increased oversight and transparency in the regulation of cannabis laboratories to protect the consumer from unsafe cannabis and fraudulently represented products. The comments below are provided in response to Sierra Cannabis Coalition's Petition submitted on Oct. 28, 2022 and included in the CCB's Nov. 15, 2022 Board Meeting as agenda item VII.

Laboratories are a key part of the cannabis industry

Laboratory representatives were not included in the Sept 22, 2022 "industry" roundtable discussions which were the genesis for this petition. Laboratories are one of the most important components of the regulated industry and are suffering under the same economic pressures and regulatory burdens as the rest of the industry. Testing is the #1 factor that distinguishes the regulated industry from the black market.

As explained by the Director of the Sierra Cannabis Coalition, Mr. Will Adler, in his June 2018 interview with Northern Nevada Business Weekly, Nevada is the "gold standard" in cannabis "because we set standards where our marijuana is tested to a pharmaceutical grade."

Taking any action on the petition issued by Sierra Cannabis Coalition without additional roundtable discussions with laboratories at the table would pose a great disservice to the regulated industry and would open the door to the decimation of Nevada's already struggling testing program.

50 lb. flower lots are simply too big to fail

Failing a $90,000 lot would not be possible in this industry. Doing so would all but guarantee that there will be tremendous pressure on laboratories to generate passing test results and will further escalate potency shopping issues. Taking notes from markets like California where the regulated industry is failing- resulting in consumers turning to that state's $8B illicit market- a move to increase lot size is irresponsible, ill-advised, and not something we are looking to emulate for Nevada.

Representative Samples

Nevada currently considers a single, 10g flower sample to be adequately representative of a 5-pound harvest lot. This equates to 0.4% of the material in the lot. In the World Health Organization document "Quality control methods for medicinal plant materials", the recommended sample size of bulk plant material is 10% of the harvest lot. Considering the current inability to achieve representative sampling of a harvest lot with Nevada's 10g flower sample size, proportionally scaled samples from a 50lb lot would be even less representative as a result of the 'bundling' of a larger number of plants in a single harvest lot. 50lb lots would need multiple samples and higher pricing for sampling, processing, storage, and logistics. Also, if any of the samples failed, the whole 50lbs would fail. This is a lose-lose proposition.

Recalls

Thousands of consumers can be impacted by the recall of a single 5lb lot, but 20,000+ may be impacted by a 50lb lot.

5%-10% of retail cost for testing is a grossly overstated number

Last year the industry made about $1B in retail sales, which means that 10% would represent $100M in revenue split among the state's 10 licensed labs. Considering that one of the larger publicly traded labs, Digipath, did $2.5M in 2021 (including CBD and non-cannabis testing), it becomes obvious that that number is completely incorrect - if every lab did on average the $2.5M that Digipath did, then the cost is closer to 2.5% of the total cost - a cost that's in line with other necessary COG considerations like packaging. This is a small price to pay for peace of mind that a product is safe and that its active ingredients are accurately labeled.

Cannabis laboratories are already charging far lower prices for the same tests in other industries

You can't have low prices, fast turnaround, and high quality - one must give way. Quality is always the first pillar to fall. Moving the industry in this direction will put labs in a position to fail at their most important task – quality.

We understand that the cannabis industry is struggling, as we are part of it, and our outstanding AR balances continue to grow. There are sensible regulatory changes that can be proposed by the industry to increase the size of market, to ease operating within that market and improve the regulations under which the industry operates; however, this hasty and ill-conceived petition does not represent such a change and will only serve to degrade the safety of the regulated market, creating further problems. We urge the board to withhold any action on this agenda item until further discussions can be held.

Respectfully,

Scientists for Consumer Safety

From: Glenn C Miller
To: Alex Tanchek; CCB Meetings
Cc: Will Adler
Subject: Re: Public comment from Dr. Glenn Miller
Date: Wednesday, September 18, 2024 5:18:48 PM

Dear Mr. Tanchek,
Thanks for the email. I have discussed my previous letter with Will Adler and feel strongly that the letter continues to identify issues which may reduce the cost of the analyses but does not increase the risk significantly to the users of the product. I do believe that the users of the legal cannabis products will continue to have a much lower risk (and lower cost) with these regulatory changes than purchasing unregulated illegal cannabis products on the black market.

I would be pleased to assist discussions in any manner that I can.

Thanks,

Glenn Miller
775-845-4516

Get Outlook for iOS

From: Alex Tanchek <alex@ssgr.us>
Sent: Wednesday, September 18, 2024 4:30:00 PM
To: CCBmeetings@ccb.nv.gov <CCBmeetings@ccb.nv.gov>
Cc: Will Adler <will@ssgr.us>; Glenn C Miller <glennm@unr.edu>
Subject: Public comment from Dr. Glenn Miller

Good afternoon.

Attached, please find public comment from Dr. Glenn Miller related to agenda item VII on Thursday's CCB agenda. Dr. Miller had submitted this letter regarding a previously proposed regulation, but many of the topics of he discussed are relevant to tomorrow's discussion.

Thank you very much,

--
Alex Tanchek
Senior Associate
Silver State Government Relations
Cell: (775) 636-3350

ssgr.us

September 18, 2023

Memorandum

To: Nevada Cannabis Compliance Board

From: Glenn C. Miller, Ph.D.
Emeritus Professor of Natural Resources and Environmental Science

Re: Proposed Changes to NCCR Regulation 5, 7, and 10.

I have been asked to review the proposed changes to NCCR regulations and comment on existing regulations regarding the analytical aspects of determining cannabis quality. I am a retired member of the UNR faculty with a background in analytical chemistry related to environmental contaminants. While a professor at UNR I taught courses on modern methods for determining organic and inorganic contaminants, toxicology and risk assessment, and also conducted studies on measurements of cannabinoids in a variety of cannabis products. During that work we developed an aqueous extraction method for cannabinoid carboxylic acids (CBDA and THCA). I also served on the original ILAC Committee for considering methods for determining contaminants in cannabis products.

First of all, I note the extensive regulatory development for cannabis products that has occurred since those initial ILAC discussions several years ago. As in other states with legalized cannabis sales, the regulations have evolved in sophistication as a response to issues that have arisen. During the discussions that occurred during the ILAC process, the primary focus was on establishing a framework where human health would be protected under the notion of risk reduction by limiting the exposure to toxic contaminants (e.g., pesticides, metals and microbial toxins), but also wary of how over regulation could increase costs to produce the cannabis products if the risk/benefit ratio was not considered. There is no reason to require excessive costs (in this analytical sense) when there is very little or no risk reduction to human health of a regulation.

Excessive and unwarranted costs may push the public to seek out illegal production of cannabis products, and those costs can ultimately increase the risk to the public by making the illegal (and potentially unsafe) products much cheaper. This balance is always a concern, and in California, the illegal market continues to thrive simply because the cost of the legal products is substantially higher than the illegal products.

I do not have any serious comment on the proposed changes. To a large extent, they are refinements and a response to issues that have arisen. Tightening the regulations will have cost implications but should be acceptable to the labs. I do feel that Section 11.053 has particular merit in that it requires tight analytical control of sample analysis and meets good standards for quality assurance. One additional comment- the requirements that "internal standards have retention times similar to the analytes" and the term ". . . Have similar chemical properties as the analytes being tested. . " are not easily definable. I know what is being asked, but the term "similar" is not really enforceable. The rest of that section is quite good.

Concerns and Suggestions

1. Even during the ILAC discussions the requirement to test 5 pound lots of dried flower did not make much sense. There is no scientific reason to choose 5 pounds compared to other weights. Other options that exist is to use 20-50 lb lots (similar to what Washington State requires). The question must be asked- is there any substantial risk reduction to the general public for using 5 pounds. There is certainly an increased cost, and if the lot size is 20 or 50 lbs, the analytical cost is going to decrease by a factor of 4 to 10. A well-homogenized much larger sample with a larger analytical subsample should provide a clear indication of cannabis quality. I recommend a study be conducted to determine if the larger sample size is sufficient to protect the public, but also reduce the product cost. Homogenization of the flower (or the trim) production, I believe can be accomplished

   Or, particularly in regard to microbial contamination, the regulations could specify the lot size based on the room that the cannabis is planted. Different strains of cannabis should probably also be sampled separately. This would probably affect grower practices but achieve and analytical cost savings. The goal again is to protect the public, but at the same time reduce the cost of the product so that illegal products are less competitive.

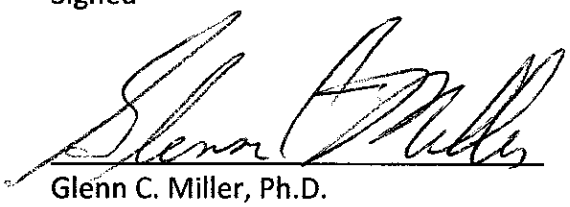
   Similarly, for concentrates, there is really no reason to require 1 kg weights. Liquid samples that are homogeneous should be sampled based on production lot characteristics.

2. During the ILAC discussions, pesticide testing was a major issue, and it appeared to me that the great fear of pesticide residues compelled an overly aggressive requirement for pesticide testing. While this issue is perhaps lessened, I do feel that the cost of this set of analyses can be reduced. If we compare the risks of pesticides in marijuana to the risks in food, there is some basis for suggesting that randomized testing for pesticides can be equally effective in risk reduction. Only a very low percentage of the food we consume is actually examined for pesticides. Although we should expect that analyses of marijuana should be done with increased frequency compared to food, a more randomized testing protocol could effectively both prevent misuse of pesticides for controlling pests on cannabis and reduce the cost of analyses. An increase in lot-weight

would help, but it is also possible to have a reduced list of pesticides determined. This could also involve an assessment of relative risks for use of these chemicals. Not all pesticides have equal toxicity/risk and a further assessment of those risks may be considered. I have both taught courses in pesticide use and risk and do feel that those analytical costs for cannabis can be reduced, without a significant increase in risk.

3. The microbial contamination section also deserves some additional discussion. This is actually similar to the section above. We all consume large amounts of vegetables that have various amounts of microorganisms (mold, fungi and bacteria), which are generally not subject to detailed determinations. While everyone should be concerned about organisms that can cause ill health, I question whether this particular set of tests means much for risk reduction. Failure of cannabis products for microbial contamination are fairly common, and I am not aware that many studies have been conducted on the risk of these sources of microorganisms. I do suggest that this issue be also subject to additional studies and discussions. Again, the cannabis products should be as free from health risk as reasonably possible, but tests that really do not show anything are not helpful.

Signed



Glenn C. Miller, Ph.D.
Professor Emeritus, University of Nevada
581 Creighton Way
Reno, NV 89503

[redacted]