From: Sent: To: Subject: Dan S <danthebiologist21@gmail.com> Friday, September 15, 2023 11:08 PM CCB Meetings LIMS

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NCCR 11.030 Establishment of policies for adequate chain of custody and requirements for samples of products provided to testing laboratory

Laboratory information management software. Its required software in some industries, Generally as samples come in they are entered into the LIMS. and a barcode is printed that can be attached to the vial/container the sample is in. This helps track the sample and helps with analysis, result reporting and more.

Nevada could create a Cannabis LIMS that connects well with Metrc seed to sale. This software could be used nationwide, while boosting the local economy.

From: Sent: To: Subject: Dan S <danthebiologist21@gmail.com> Monday, September 25, 2023 8:04 AM CCB Meetings reg 7,11,12 suggestions

<u>WARNING</u> - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

REG 7

Budtenders should have stools/chairs. A Lot of the staff are medical patients themselves who want to help others. To require them to stand for a full shift Is just unacceptable.

As Nevadans are frequenting dispensaries, and waiting in a line. There could be staff who are there to teach people a variety of things. For example, enhance the experience of the products by providing a manual to do yoga at home. Or some other knowledge that can improve the lives of these people who support the industry with their own dollar.

Scholarships could be provided by cannabis companies.

I'd think most cannabis flower on dispensary shelves right now could be recalled for aspergillus contamination. But honest/accurate lab testing is needed to confirm that (RT-qPCR testing recommended for accuracy).

Addition of a regulation to help stop money laundering that occurs at the dispensary. Dispensaries are likely where money laundering occurs.

REG 11

Laboratories have been providing faulty results for cannabis due to a lack of competence and compassion for the industry they operate in. The industry advises elderly, injured and people who have diseases to use cannabis from a dispensary in a medical capacity. But all the while labs are knowingly passing dirty cannabis/inflating potency numbers, for a higher profit margin.

Assuming ISO proficiency testing records come back with red flags, all labs should be shut down permanently by loss of their credentials (ISO 17025). It's only a matter of time until they shut down naturally anyways. These labs are owned and managed by business people, not scientists. There is too much that goes on in an analytical laboratory to allow business people to operate them.

A single or multiple state laboratory can replace them all, while being much more beneficial to the industry, public health, and economy. Nevada's state laboratory could become the laboratory regulating/standard for the cannabis industry across the country. A Nevada state analytical lab would be much more proficient and new regs could be developed around that.

In an instance where independent testing labs are not permanently shut down.

- 1. 2.
- 3. Methanol is poured down in a chemical fume hood. (OSHA)
- 4.
- 5.
- 6.
- 7. All chemical waste is logged and recorded when it is picked up for removal. Particularly
- 8. these kinds of places think it's okay to pour their LC mobile phase down the drain. Which is methanol with all types of analytes from standards mixed in it.
- 9.
- 10.

11.

- 12. Bi-annual to quarterly, State provided, proficiency testing is done with samples off
- 13. the shelf from a dispensary.

14.

15.

16.

- 17. Staff of labs performing proficiency testing is not the same individual, and needs to
- 18. be repeatable throughout the laboratory.
- 19.
- 20.

21.

- 22. Labs collecting samples need to do so in excellent camera view, after self-mixing the
- 23. bag/tub. These labs pick samples to be tested from the same spot every time. Which opens up lots of variables for the overall batch quality. Grows could be putting a completely different batch for analysis, while the rest of the batch is molded/contaminated.
- 24. They could mold treat just the bud they grab while the rest of the batch is contaminated.

25.

- 26.
- 27.
- 28. There could be an additional option for Director requirements, -replacing years of experience
- 29. with proven understanding of laboratories.

30.

REG 12

Labels should list at the very top, In a larger font:

1. 2.

- 3. The children warning
- 4.

5.

- 6.
- 7. It contains THC.
- 8.
- 9.
- 10.
- 11. Ingredients for allergies.

12.

13. 14.

- 15. List that the THC used in the product, comes from remediated cannabis that previously16. failed a test for X, Y, and/or Z.17.

From:	Glenn C Miller <glennm@unr.edu></glennm@unr.edu>
Sent:	Monday, September 25, 2023 8:44 AM
То:	CCB Regulations
Subject:	Comments on potential changes in cannabis regulation
Attachments:	Cannabis comments.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Cannabis Control Board,

Attached are comments related to regulations on cannabis. These are focused on reducing the analytical costs of cannabis production, while maintaining the requirement of producing a product that is uncontaminated with problematic chemicals. The cost of legal cannabis products is potentially driving users to illegally produced products which very often do not have any of the requirements for determining contaminants. Increasing the costs of legal cannabis products or products just because of cost differentials.

Sincerely,

Glenn C. Miller, Ph.D., Professor Emeritus Department of Natural Resources and Environmental Science University of Nevada Reno, NV 89557

775-846-4516 glennm@unr.edu

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

no

Glenn C. Miller, Ph.D. Professor Emeritus, University of Nevada 581 Creighton Way Reno, NV 89503

glennm@unr.edu 775-846-4516

From:	Chaohsiung Tung <doc@g3labsllc.com></doc@g3labsllc.com>
Sent:	Sunday, September 24, 2023 7:15 AM
То:	CCB Regulations; Elizabeth Perez
Cc:	Isaac Maceo; Alicia R. Ashcraft
Subject:	October 26 Hearing to adopt proposed change to NCCR 11.070.5

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I recommend the Board to be consistent in the requirements in the regulations.

Specific example:

Proposed NCCR Regulation 11 11.070 9. 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....

However the current NCCR 11.050.7. A cannabis independent testing laboratory shall provide the final certificate of analysis to the Board and to the cannabis establishment from which the sample was collected within 2 business days after obtaining the results.

The industry welcome the proposed 11.070.9 language. However, the efforts for the adoption of the proposed language will be futile nullified if the "2 business days" requirement in the current 11.050.7 still stands.

In this case, it is strongly recommended to modify the current 11.050.7 text to be the same as the proposed 11.070.9.

On another subject in the NCCR, 11.025 requires the independent testing labs to follow the adopted references. Unfortunately, some of those references are not up to date with the technology development. It actually hinders the testing operations if a testing lab adhere/follow the practices in those references. I recommend the CCB modify the text for the references as references only.

Cheers Chao-Hsiung Tung, Ph.D. G3 Labs, LLC



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

FILE NO.

KIMBERLY MAXSON-RUSHTON EMAIL: krushton@cooperlevenson.com

September 25, 2023

Via E-mail

Nevada Cannabis Compliance Board 700 East Warm Springs Road, Suite 100 Las Vegas, Nevada 89119

Re: Proposed NCCR 11.010(1)

Dear Cannabis Compliance Board:

On behalf of LettuceTest, LLC ("LTL") please allow this correspondence to serve as an objection to Staff's proposed change to NCCR 11.010(1) – the residency requirement for a testing laboratory's scientific director.

LTL's objection is specifically based on Article IV, Sec. 2 of the U.S. Constitution otherwise referred to as the Privileges and Immunities Clause, which provides that the "Citizens of each State shall be entitled to all Privileges (i.e. the right to work) and Immunities of Citizens in the several States." *New Hampshire v. Piper*, 470 U.S. 274 (1985). Said clause having been derived from the Commerce Clause, its intent was to create a national economic union amongst the states.

As evidenced by the long line of Supreme Court cases, which specifically address this point, the Privileges and Immunities Clause guarantees to citizens of one State (i.e. Arizona) the privilege of doing business in another State (i.e. Nevada) on substantially equal terms as the citizens of that State. See, *Toomer v. Witsell*, 224 U.S. 385, 396 (1948). Therefore, sans a showing that there is a "substantial" reason for precluding residents of another State from serving as a scientific lab director for a cannabis testing laboratory the proposed regulation violates the Privileges and Immunities Clause of the U.S. Constitution.

Based on the legal authority set forth herein, LTL submits that the proposed residency requirement is unconstitutional and as such, it should be removed from the draft regulation.

Sincerely. Kimberly Maxson-Rushton, Es



RE: Public Comments – NCCR 11.060

To Whom It May Concern:

On behalf of TapRoot Brands, a licensed production facility, I would like to express my concerns over the proposed changes to NCCR 11.060, specifically the proposal to set a hard cap of the THC limits for edible products which is currently defined in NCCR 9.045 Section 2 as 100mg THC for multiple serving edibles and 10 mg for a single serving.

I do understand the intention to strictly adhere to the maximum allowable value, which is influenced by two equally important factors: 1) the targeted amount of THC produced by the manufacturer, and 2) the accuracy of lab testing to quantify that targeted amount. Quite simply, the proposed changes to NCCR 11.060 attempts to address one side of that equation without taking into consideration the other.

Using the example of a typical single serving edible, the logical operational impact of this proposal would mean that producers would have to lower their targeted THC from 10mg to roughly 8.5mg to ensure that the upper limit of the +/- 15% testing variance would not result in anything greater than 10.0 mg THC. Otherwise, maintaining a potency target of 10mg with the same +/-15% variance could result in nearly half of the produced batches failing for being above 10mg.

If a production facility does not lower their targets, they will be faced with the costs of multiple failed lab tests, delays in order fulfillment and unsellable product.

From a consumer standpoint, in Nevada we have nearly 9 years of customers accustomed to purchasing edibles in the standard 10mg size for a single serving, and now would be implementing a change that would most likely lower the standard to 8.5mg while still needing to charge the customer the full price of the product. This would significantly damage the consumer's trust in the integrity and consistency of our products.

Although I would agree with the intention of ensuring that the potency caps are adhered to, I believe that there will be detrimental repercussions for both producers and consumers if we don't also address testing accuracy, which historically has been the biggest challenge in product consistency.

For these reasons we object to the changes proposed in NCCR 11.060.

Regards,

Shane Terry

TapRoot Brands Founder/CEO

P: 702.858.2465 E: <u>info@taprootbrands.com</u> 1930 Village Center Cir #3 – 1747 Las Vegas, NV 89134



September 25, 2023

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

Good afternoon,

We understand there will be a workshop on Sept. 26th to solicit comments on the proposed changes to NCCR 11. We extend our gratitude to the CCB for providing licensees with the opportunity to provide feedback. As we are unable to attend the workshop, we would like to provide comment via email.

We are requesting your consideration of our questions and comments regarding the following proposed changes:

- 1. NCCR 11.050(9) Certificate of Analysis is valid for one year unless the product has a shorter shelf-life as specified by the Board.
 - Questions:
 - <u>Will unexpired products tied to an expired COA need to be retested?</u> If yes, we believe this will create confusion among establishments who will need to track both the use by dates of cannabis and cannabis products and the expiration dates of COAs. A new COA will also require retail establishments to re-label each product item with the new test date and test results. Many in the industry are facing financial hardship and the cost of retesting and of relabeling would be unwelcome and likely passed down to patients who may be inclined to turn to the black market to avoid price hikes in legal dispensaries.
 - Who takes on the responsibility for retesting if the product has been transferred to a retail license? This needs to be clarified as there is no path for laboratory testing of cannabis and cannabis products in a retail environment.
- 2. NCCR 11.060(3)(b) No concentration of THC in a sample may exceed the THC limits for sale in NCCR 9.045(2).

Question:

• <u>Would this conflict with the 15% variance statement requirement in NCCR 11.060(3)(a)?</u>

For example, a 10mg serving has an allowed variance of 1.5mg which would put the mg serving out of compliance with this proposed change.



- 3. NCCR 11.085(3)(a-b) adds new sections regarding responsibility for costs associated with testing arising out of an investigation. The cultivation or production facility under investigation would be required to pay for the testing even if the investigation does not lead to a substantiated violation of the law. Questions:
 - If an investigation concluded the testing lab was in error, would a cultivation or production facility still be required to pay for retesting? Or would the cultivation or production facility carry the burden regardless of who was at fault?

Again, thank you for your time and please reach out if you have any questions.

Best,

Lindsay Klimitz Director of Operations and Procurement Natural Medicine L.L.C. Elle Naitoh Director of Complince Natural Medicine L.L.C.



September 25, 2023

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

Subject: Workshop on Proposed Changes to NCCR Regulation 5, 7 and 11

Dear Cannabis Compliance Board Members and Director Klimas,

On behalf of the Nevada Cannabis Association, we are submitting this public comment on the proposed changes to NCCR 11. Additionally, pursuant to Agenda Item III, we are providing input on additional possible amendments to Regulation 11.

NCCR 11.060

We are concerned about the proposed removal of "and weight" from NCCR 11.060(3)(a), and the resulting impact on consumers. Licensees who consistently target the 10mg/100mg limit still find themselves regularly testing above or below that target. Disallowing any variance above 10mg/100mg would result in licensees having to aim for below 10mg/100mg to not fail testing. As a result, "100mg" products on the shelves in Nevada would consistently contain less than 100mg THC.

Both statute and regulation have acknowledged and allowed a variance since at least 2017. Senate Bill 344 in 2017 required that 10mg edibles be labeled in a manner that indicates the milligrams of THC in the product and a statement that "its potency was tested with an allowable variance of the amount determined by the Division by regulation." The Department of Taxation soon after adopted regulations in July 2017 that set the allowable variance at plus or minus 15% (LCB File No. E001-17). Over the various iterations of the NRS, NAC, and now NCCR, the statute and regulation advising consumers of a 15% plus or minus variance were read together with the statutory caps of 10mg and 100mg in edible products.

The existing variance is smart policy because it acknowledges that small fluctuations will occur even where producers are targeting 10mg/100mg. Further, it adequately warns consumers that in a 10mg or 100mg product, the actual potency could be plus or minus 15 percent. The current policy balances realistic fluctuations in potency (within strict limits) with public safety and consumer education. In the absence of clear legislative direction or significant public safety concerns, this regulation – which has been relied upon by licensees and consumers for at least six years – should not be amended.

Recommendation for Further Changes

We recommend the Board consider amending NCCR 11.050(2) to remove *Aspergillus* from the list of required tests. *Aspergillus* is one of the most ubiquitous organisms in the environment, but the majority of *Aspergillus* species are not pathogenic. Multiple studies state humans breathe in hundreds of spores a day. Healthy people have extremely high innate immunity to *Aspergillus*, and a positive test result would not mean the product is unsafe for most uses for most people.



We respectfully request the Board schedule a workshop or roundtable for further discussion regarding removing the *Aspergillus* testing requirement completely, modifying the testing from pass/fall, and/or providing a warning to immunocompromised consumers in lieu of testing.

Thank you for your consideration of these comments.

Respectfully,

ZMant

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



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

KIMBERLY MAXSON-RUSHTON EMAIL: krushton@cooperlevenson.com

September 25, 2023

Via E-mail

Nevada Cannabis Compliance Board 700 East Warm Springs Road, Suite 100 Las Vegas, Nevada 89119

Re: Proposed Amendments to NCCR 11

Dear Cannabis Compliance Board:

On behalf of the Citizens for Public Safety Alliance ("CPSA") please find herein proposed amendments to NCCR 11 for the Cannabis Compliance Board's ("CCB") review and consideration.

By way of background, the CPSA is a non-profit association committed to ensuring the safety of cannabis in Nevada. To this end, the CSPA's primary focus is on the independent testing laboratories and the development of objective, scientifically based cannabis testing standards.

I. Independent Laboratory Advisory Committee

The CPSA respectfully requests that NCCR 11 be amended to reinstate the Independent Laboratory Advisory Committee as established pursuant to Nevada Administrative Code ("NAC") 453A.666. Specifically, the CPSA requests the following regulation language be adopted:

Independent Laboratory Advisory Committee: Establishment; duties.

1. The Cannabis Compliance Board will establish an Independent Laboratory Advisory Committee comprised of members which ensure that the membership of the Advisory Committee is representative of the independent testing laboratories and other cannabis establishments in this State.

2. The Advisory Committee shall:

(a) Provide recommendations to the Board regarding the testing of cannabis;

(b) Make recommendations to the Board for any changes to this chapter relating to the testing of cannabis; and

COOPER LEVENSON, P.A.

Nevada Cannabis Compliance Board September 25, 2023 Page 2

(c) Assist the Board in creating and updating a policy manual to be used by the Board to guide the testing of edible cannabis products and cannabis-infused products by independent testing laboratories.

As evidenced by the former regulation and the attached meeting notices, between 2014 - 2017, ILAC was utilized by the Division of Public and Behavioral Health to develop testing levels / standards for medical marijuana; thereby serving as the foundation for the development of testing standards now used by the CCB. By reinstating ILAC, the CCB will have more objective, scientifically based standards to ensure the safety of all cannabis products sold in Nevada.

II. Amendment to NCCR 11.050(7)

The CPSA further requests that NCCR 11.050(7) be amended as follows:

7. A cannabis independent testing laboratory shall provide the final certificate of analysis to the Board [and to the cannabis establishment from which the sample was collected] within 2 business days after obtaining the results.

As the CCB is well aware the cannabis testing labs have continuously had problems collecting testing fees from cultivators / producers. As a result, testing labs have been forced to subsidize the industry by continuing to perform testing services without compensation for their work. In response, many of Nevada's labs have suffered financial hardship through no fault of their own. In an effort to address this issue the CPSA recommends that testing labs be relieved of the obligation to provide a licensee with a final Certificate of Analysis until the lab has been paid in full. Further support for this proposed regulation modification can be found in NCCR 11.085(3), which requires cultivators / producers to pay for all fees associated with retesting cannabis.

As always, thank you in advance for your review and consideration of the proposed regulation changes requested herein. On behalf of the CPSA we look forward to working with the CCB on this matter and hope that going forward we can serve as a resource to the Board.

Sincerely,

Kimberly Maxson-Rushton, Èsq.

NEVADA DIVISION OF PUBLIC AND BEHAVIORAL HEALTH (DPBH) Medical Marijuana Laboratory Advisory Committee (ILAC)

AGENDA

March 4, 2015 3:30 p.m.

MEETING LOCATIONS

Board Attending

Department of Health Care Finance and Policy 1100 E. William St. 2nd floor conference room Carson City, Nevada 89701 Nevada Early Intervention Services 3811 W. Charleston Ste 112 Las Vegas, NV 89102

AGENDA ITEMS MAY BE TAKEN OUT OF ORDER, COMBINED FOR CONSIDERATION, AND/OR REMOVED FROM THE AGENDA

THE CHAIRPERSON MAY CALL FOR A BREAK AT HIS/HER DISCRETION

- 1. Call to order
- 2. Approval of Jan 29, 2015 ILAC Meeting Minutes

PUBLIC COMMENT FOR POSSIBLE ACTION

- 3. Presentation: Open Meeting Law (OML) requirements for the ILAC. The Division will present information about the OML to ensure committee members understand the requirements of the law as it relates to public committee meetings and other methods by which the committee may choose to conduct its business.
- 4. Discussion and possible action: Selection of Chair and Vice Chair. Committee members who wish to be considered for Committee Chair or Vice Chair will indicate their desire to the group and describe their qualifications to serve in these positions. After public comments are complete, committee members will vote and select members to these positions.

PUBLIC COMMENT FOR POSSIBLE ACTION

5. Discussion and possible action: By-laws for committee meetings. Possible action will be for the committee to recommend adoption of By-laws to the Division for approval.

PUBLIC COMMENT FOR POSSIBLE ACTION

6. Discussion and possible action: NAC 453A.658(9) states,

"The Independent Laboratory Advisory Committee established pursuant to <u>NAC</u> <u>453A.666</u> shall establish the list of pesticides approved for use in the cultivation and production of marijuana, edible marijuana products and marijuana-infused products to be sold or used in this State. For the purposes of the pesticide chemical residue test, a sample provided to an independent testing laboratory pursuant to this section shall be deemed to have passed if it satisfies the most stringent acceptable standard for an approved pesticide chemical residue in any food item as set forth in Subpart C of 40 C.F.R. Part 180."

Possible action is for the ILAC to recommend a list of pesticides/analytes that would be acceptable for use in the cultivation of medical marijuana to the Division for approval.

PUBLIC COMMENT FOR POSSIBLE ACTION

 Discussion and possible action: Pesticide chemical residual analytical testing, equipment and methods. Possible action is for the LAC to recommend to the Division the adoption of standardized methods and equipment requirements pertaining to the testing of medical marijuana.

PUBLIC COMMENT FOR POSSIBLE ACTION

8. Discussion: Heavy metal limits and the Division's new policy on heavy metal testing limits. The Division will present information regarding the NAC 453A regulations, the referenced scientific standard, and the newly adopted policy. Possible action is for the LAC to make recommendations to the MME Laboratories regarding compliance, and/or recommend to the Division revisions to the policy or regulations for further clarification.

PUBLIC COMMENT FOR POSSIBLE ACTION

9. Adjournment

AGENDA POSTING LOCATIONS

Division of Public and Behavioral Health, 4150 Technology Way, Carson City Nevada State Library and Archives, 100 Stewart Street, Carson City Washoe County District Health Department, Ninth and Wells, Reno Emergency Medical Systems, 1020 Ruby Vista Dr., Ste 102, Elko Division of Public and Behavioral Health, 1650 Community College Drive, Rawson Neal Training Room B-193, Las Vegas

On the Internet at the Division of Public and Behavioral Health website: http://www.health.nv.gov

In the event of videoconference technical difficulties, the meeting may be conducted by teleconference from the same locations.

We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements are necessary or if you need supporting documents for this meeting, please notify Alicia Mazy, (775) 684-5925 with the Division of Public and Behavioral Health. Supporting materials are also available for the public at the Division of Public and Behavioral Health 4150 Technology Way, Suite 101, Carson City, NV 89706 or by calling (775) 684-3487 before the meeting date.

Anyone who wants to be on the Medical Marijuana Laboratory Advisory Committee mailing list must submit a written request every six months to the Division of Public and Behavioral Health at the address listed in the previous paragraph.

NEVADA DIVISION OF PUBLIC AND BEHAVIORAL HEALTH (DPBH) Medical Marijuana Independent Laboratory Advisory Committee (ILAC)

AGENDA April 6, 2016 2:00 p.m.

MEETING LOCATIONS

Division of Public and Behavioral Health 4150 Technology Way, Room 303 Carson City, Nevada Rawson-Neal Psychiatric Hospital 1650 Community College Dr., Room B-193 Las Vegas, NV

AGENDA ITEMS MAY BE TAKEN OUT OF ORDER, COMBINED FOR CONSIDERATION, AND/OR REMOVED FROM THE AGENDA. PUBLIC COMMENTS MAY BE LIMITED TO 3 OR FEWER MINUTES PER PERSON. THE CHAIRPERSON MAY CALL FOR A BREAK AT HIS/HER DISCRETION

- 1. Call to order; determine quorum.
- 2. Public comment No action may be taken on a matter raised under this item of the agenda until the matter itself has been specifically included on an agenda as an item upon which action will be taken.
- 3. Approval of February 3, 2016, ILAC meeting minutes. For Possible Action
- 4. Election of Chair and Vice Chair. For Possible Action
- Discussion and recommendation concerning cannabinoid and terpenoid potency testing and labelling.
 <u>Public Comment</u> <u>For Possible Action</u>
- Discussion and recommendation concerning standardization on reporting THC results based on "dry weight" vs. "as received."
 <u>Public Comment</u> For Possible Action
- 7. Public comment No action may be taken on a matter raised under this item of the agenda until the matter itself has been specifically included on an agenda as an item upon which action will be taken.
- 8. Adjournment.

AGENDA POSTING LOCATIONS

Nevada State Library and Archives, 100 Stewart Street, Carson City Emergency Medical Systems, 1020 Ruby Vista Drive, Ste. 102, Elko Washoe County District Health Department, Ninth and Wells Streets, Reno Division of Public and Behavioral Health, 4150 Technology Way, Carson City Rawson-Neal Psychiatric Hospital, 1650 Community College Drive, Las Vegas On the Internet at the Division of Public and Behavioral Health website: <u>http://dpbh.nv.gov/Reg/MME/Boards/ILAC/Meetings/2016/Independent_Laboratory_Advisory_Committee_(ILAC)_-</u>

2016 Meeting Information/

In the event of videoconference technical difficulties, the meeting may be conducted by teleconference from the same locations.

We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements are necessary or if you need supporting documents for this meeting, please notify Jamie Chittenden, (702) 486-5403 with the Division of Public and Behavioral Health. Supporting materials are available for the public at the Division of Public and Behavioral Health, 4150 Technology Way, Suite 106, Carson City, NV 89706 or by calling (702) 486-5403 before the meeting date.

Anyone who wants to be on the Medical Marijuana Laboratory Advisory Committee mailing list must submit a written request every six months to the Division of Public and Behavioral Health at the address listed in the previous paragraph.

NEVADA DIVISION OF PUBLIC AND BEHAVIORAL HEALTH (DPBH) Medical Marijuana Independent Laboratory Advisory Committee (ILAC)

AGENDA April 05, 2017 2:00 p.m.

MEETING LOCATIONS

Division of Public and Behavioral Health 4150 Technology Way, Room 303 Carson City, Nevada Rawson-Neal Psychiatric Hospital 1650 Community College Dr., Room B-193 Las Vegas, NV

AGENDA ITEMS MAY BE TAKEN OUT OF ORDER, COMBINED FOR CONSIDERATION, AND/OR REMOVED FROM THE AGENDA. PUBLIC COMMENTS MAY BE LIMITED TO 3 OR FEWER MINUTES PER PERSON.

THE CHAIRPERSON MAY CALL FOR A BREAK AT HIS/HER DISCRETION

- 1. Call to order; determine quorum.
- 2. Public comment No action may be taken on a matter raised under this item of the agenda until the matter itself has been specifically included on an agenda as an item upon which action will be taken.
- 3. Approval of the February 1, 2017, meeting minutes. **For Possible Action**.
- 4. Election of officers (Chair & Vice Chair) For Possible Action.
- Discussion and make recommendation regarding the development of a standardized process to update the DPBH pesticide monitoring list in coordination with both the ILAC and Department of Agriculture, and to develop a timeline for lab implementation of new testing requirements.
 For Possible Action.
- Discussion and make recommendation regarding the addition of Imazalil and Thiophanatemethyl to the pesticide monitoring list, and if added, at what detection level. For Possible Action.
- Discussion and make recommendation regarding the addition of Malathion and/or Diazinon to the pesticide monitoring list, and if added, at what detection level. For Possible Action.
- 8. Information Only No Action. Report from Department of Agriculture regarding Myclobutanil.
- 9. Public comment No action may be taken on a matter raised under this item of the agenda until the matter itself has been specifically included on an agenda as an item upon which action will be taken.
- 10. Adjournment.

AGENDA POSTING LOCATIONS

Nevada State Library and Archives, 100 Stewart Street, Carson City Emergency Medical Systems, 1020 Ruby Vista Drive, Suite. 102, Elko Washoe County District Health Department, Ninth and Wells Streets, Reno Division of Public and Behavioral Health, 4150 Technology Way, Carson City Rawson-Neal Psychiatric Hospital, 1650 Community College Drive, Las Vegas Nevada Early Intervention, 1161 South Valley View Boulevard, Las Vegas <u>https://notice.nv.gov/</u>

Agendas are on available at the Division of Public and Behavioral Health website: <u>http://dpbh.nv.gov/Reg/MME/Boards/ILAC/Meetings/2017/Independent_Laboratory_Committee_(ILAC)_</u> <u>_2017_Meeting_Information/</u>

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September 25, 2023

Via Email

Cannabis Compliance Board 700 Warm Springs Rd, Suite 100 Las Vegas, Nevada 89119 <u>regulations@ccb.nv.gov</u>

Re: September 26, 2023 Workshop – Proposed Changes to NCCR 11.060

Dear Board and Executive Director Klimas,

I am writing on behalf of Planet 13 Holdings Inc. and its Nevada subsidiary, MM Development Company Inc., dba Planet 13 and Medizin, which is licensed by the CCB for the cultivation, production, distribution, and retail sale of cannabis and cannabis products, regarding the CCB's proposed changes to NCCR 11.060(3).

NCCR 12.010(2) provides that edible cannabis products may contain a maximum of 10 milligrams of THC per serving, plus or minus 15%:

12.010 Requirements for single packages.

•••

2. An edible cannabis product must be packaged in a manner which indicates the number of servings of THC in the product, measured in servings of a maximum of 10 milligrams of THC per serving, and include a statement that the edible cannabis product contains cannabis and its potency was tested with an allowable variance of plus or minus 15 percent of the allowable limit.

•••

For ease of reference, CCB's proposed changes to NCCR 11.060(3) are provided below:

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) The concentration of THC of each sample must not exceed the THC limits for sale in NCCR 9.045 section 2.

(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.

Cannabis Compliance Board September 25, 2023 Page 2 of 2

and NCCR 9.045(2) referenced therein states as follows:

9.045 Edible cannabis products: Testing to ensure homogeneity of potency; requirements for sale; approval of Board required for certain changes.

•••

2. A cannabis production facility shall not sell an edible cannabis product other than a multiple-serving edible cannabis product or a single-serving edible cannabis product. An edible cannabis product sold as a multiple-serving edible cannabis product must not contain more than 100 milligrams of THC. An edible cannabis product sold as a single-serving edible cannabis product must not contain more than 10 milligrams of THC.

•••

NCCR 9.045(2) does not include the allowable 15% THC potency variance. Because of this, the proposed change to NCCR 11.060(3)(b) also does not account for the allowable variance and would prohibit testing facilities from performing homogeneity testing on edible cannabis products which contain an amount of THC which exceeds 10 milligrams of THC even if the THC content is within 15% of the limit.

In producing its gummies, chocolates, and beverages, Planet 13 always targets the limit of 10 milligrams of THC per serving, but, as to be expected, there may be a variance above or below that limit. If it is CCB's intent to address licensees targeting a THC concentration above the prescribed limit, Planet 13 suggests that CCB add "intended" to NCCR 11.060(3)(b) as highlighted below:

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) The intended concentration of THC of each sample must not exceed the THC limits for sale in NCCR 9.045 section 2.

(b) No combination of samples which comprise 10 percent or less of the cannabis product contain 20 percent or more of the total TH in the cannabis product.

Thank you for your time and consideration.

Regards, ara Madams

Sara M. Adams

Silver State Government Relations

Principals Will Adler – <u>will@ssgr.us</u> Sarah Adler – <u>sarah@ssgr.us</u> *Associates* Morgan Biaselli – <u>morgan@ssgr.us</u> Alex Tanchek – <u>alex@ssgr.us</u>



September 25, 2023

Members of the Cannabis Compliance Board:

The Sierra Cannabis Coalition is pleased to see the Board's willingness to consider updates to Nevada's cannabis testing regulations. Accountability measures are important in assuring the products that Nevada's cannabis consumers enjoy are safe for consumption. The SCC is concerned, however, that the addition of more than 10 new regulations on Nevada's cannabis laboratories will simply increase the cost of testing that will be borne by the labs, passed on to their customers and, ultimately, onto the consumer.

The SCC doesn't believe these regulations go far enough in contemplating changes to Nevada cannabis testing that ease the economic burden for cannabis business to operate in this state. For example, increasing the lot size from five-pounds for flower and 15-pounds for trim will help alleviate the various labor costs required in breaking down single batches into multiple lots, separately bagging each lot, and testing each lot. Since the five-pound lot size for flower and 15-pound lot size for trim was set in 2014, Nevada's lot sizes continue to be arbitrarily lower compared to other states with legal cannabis. Increased lot sizes, as already exist in other jurisdictions, will not lower any safety standards of cannabis products based on what has been seen in those states. Nevada should join the country's other regulated cannabis markets in reviewing whether the state's current weight limits on how much cannabis can be tested at one time continues to make sense.

The SCC's message and goals have remained consistent: alleviate the core economic issues with Nevada's current cannabis regulatory structure. To further these efforts, the CCB stated they would hold a workshop to discuss those laboratory testing issues previously identified for the cannabis industry to discuss. As that workshop has yet to take place, the SCC would like to reiterate our comments and remind the CCB of their previous commitments to hold this workshop and add lab testing lot sizes to the current list of topics discussed in this round of regulatory changes. The SCC has previously submitted to the CCB through public comment details about Washington State's recent update to their laboratory process, including updates to lot sizes. Similar to the recent changes in the State of Oregon, cannabis testing requirements are being adjusted state-by-state as each of those cannabis regulatory systems matures with their industry.



It is the SCC's greatest hope the CCB will take those same step and address the whole of Nevada's cannabis testing regulations, including what is being tested for and how much can be tested for in a single lot. Ultimately, providing greater efficiency to any and all aspects of Nevada's cannabis regulatory operations will benefit Nevada cannabis businesses, consumers, and the State as a whole.

Sincerely,

Will Adler Director Sierra Cannabis Coalition



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",
- 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) <u>"One standard for each analyte shall be at or near the State action</u> <u>level,"</u>, 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 <u>suggested</u> 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).

<u>NOTE</u>: 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</u> include rinses in the 20 count.

(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)

From:	Jillian Nelson <jnelson@evergreenorganix.com></jnelson@evergreenorganix.com>
Sent:	Tuesday, September 26, 2023 12:52 PM
То:	CCB Regulations
Subject:	Proposed Changes to NCCR 11.060
Attachments:	Rice Cereal Treat 100mg 31022.pdf; Espresso Dark Chocolate Bar 30944.pdf; Cookies &
	Cream Chocolate Bar 30942.pdf; Sugar Free Dark Chocolate Bar 30868.pdf; Dark
	Chocolate Bar 30919.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello!

I would like to provide commentary regarding the proposed changes to NCCR 11.060. The Nevada Cannabis Association says that this proposed regulation change is stemming from some production facilities purposely dosing their products higher than 100mg.

I have concerns of this proposed amendment. Edible dosing is never precise and we have never had a COA come back that matches our dosing with 100% accuracy in our 8+ years of producing edibles. If we reasonably could, every product we make would test back at 100.000mg but that's unfortunately not virtually impossible. Results are typically close, but we always expect some variance (+/-) in what our intended dose is versus what the COA reports back to us. If the CCB was to implement a hard cap of 100mg per edible with no allowable variance above that, it would make dosing 100mg edibles nearly impossible. We would have to dose our products much lower and likely have to further cut our prices in an already tight market. We already experienced these sort of constraints once before in dealing with the City of Las Vegas THC limits that were in effect prior to 2017 and it was frankly a nightmare. Consumers expect 100mg products and if we fall below that, we get complaints and sales drop. I have attached some of our recent 100mg product COAs to this email for reference. All of these products were dosed for 100mg but the COAs report back anywhere in between 94mg-106mg. 3 out of the 5 productions runs here would not be sellable under this proposed amendment.

If the CCB is concerned about producers purposely trying to sell 115mg edibles, a way the CCB could reasonably combat this would be to change the labeling regulation. Keep the 15% variance in place on the back end with testing, but require that producers label their products at their intended dose and stop requiring the exact COA cannabinoid information be printed on edibles. This would then deter intentional "over-dosing" by producers because they couldn't label their products at 115mg and have to label their products at 100mg max. Producers would have no benefit in high dosing in that case as they couldn't reasonably advertise it on their products, but it still allows for potency variance that is typical for edibles production. It would also simplify labeling and potentially help streamline some aspects of edibles packaging. This way could be a win-win for the CCB and producers in my opinion.

I sincerely hope the CCB reconsiders the proposed amendment as I fear the outcome of this will cause further harm to an already diminishing edibles market. The 100mg dosing limit is already a huge barrier that drives many consumers to the black market where THC limits do not exist. Consumers can easily order 1000mg edibles that are delivered to their doorstep through the convenience of social media – no taxes, no age verification, no purchase limits. We are unable to compete with this and this ease of black market access makes it very difficult to run a successful, legal cannabis operation in Nevada. This proposed amendment as written is not protecting consumers and merely imposes additional barriers to already struggling businesses.

Thank you for your consideration in this matter.

Jillian Nelson Vice President O: 702-550-4855



------ Forwarded message ------From: **Nevada Cannabis Association** <<u>info@nvdispense.com</u>> Date: Thu, Sep 21, 2023 at 1:35 PM Subject: NCA Member Update: September 21, 2023 To: <<u>layke@nvdispense.com</u>>



Nevada Cannabis

September 21, 2023

The Nevada Cannabis Association is committed to providing regular, timely updates with useful information as we navigate industry developments, changes, and other important events. For more information or to access additional resources, including free employee trainings and more, visit <u>nvcann.org</u>.

Proposed Changes to NCCR 11.060 Affecting Edibles

The CCB's proposed changes to NCCR include the following proposed edit to NCCR 11.060(3) removing the words "and weight":

3. The cannabis independent testing laboratory will verify the homogeneity of the potency of the edible cannabis product only if:

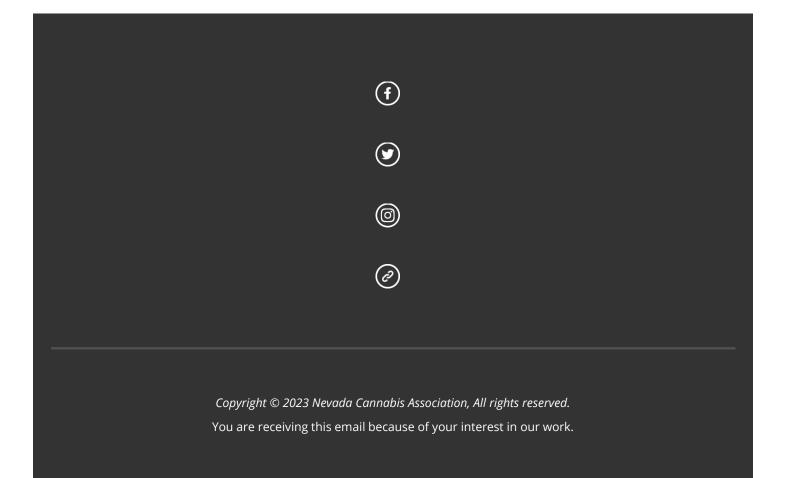
(a) The concentration of THC and weight of each sample is within 15 percent above or below the intended concentration of THC and weight; and
(b) The concentration of THC of each sample must not exceed the THC limits for sale in NCCR 9.045 section 2.
(b) No combination of samples which comprise 10 percent or less of the cannabis product contain 20 percent or more of the total THC in the cannabis product.

We are concerned that when reading NCCR 9.045(2) and the proposed changes to NCCR 11.060(3) together, removing the 15 percent variability by weight would require production facilities to lower potency of edibles in order to ensure that the end product is no more than 100 mgs. In other words, companies would need to make products with 85 mgs or 90 mgs in order to stay below the limits and avoid failing testing. Meanwhile, customers would be paying for (and hoping to receive) products containing 100 mgs.

We spoke with CCB staff about this change, and they said that some production facilities are making their target potency over 100mg THC, which is the reason for the proposed change.

We'll object to this proposed change at <u>next week's workshop</u> on September 26th at 10 a.m. Please share any information on how this change would be detrimental for businesses **and consumers**, by emailing <u>Layke</u> as soon as possible.

While the Nevada Cannabis Association ("NCA") has taken reasonable steps to ensure the information in this communication is correct, it provides no warranty or guarantee the information is accurate, complete, or up-to-date. This update is provided for informational purposes only and is not to be relied upon as legal advice. The NCA does not accept any responsibility or liability for any actions taken as a result of, or in reliance on, information distributed herein. Readers should confirm the accuracy of the information before taking any action in reliance on it, including, but not limited to, consulting a legal professional.



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