

April 29, 2024

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 Regulations 5, 7, and 11

Dear Cannabis Compliance Board Members and Director Humm,

Thank you for considering this written comment as part of the regulatory workshop on April 30, 2024.

Attached please find an expert report prepared by David Vaillencourt and the GMP Collective analyzing Nevada's lot sizes and recommending an increase to 20 lbs. or larger, along with the implementation of standardized, statistically relevant sampling protocols such as those outlined in ASTM D8334/D8334M-20.

As outlined in the report, Nevada's maximum 5 lb. flower lot size is the smallest maximum flower lot size across the United States. Among the 38 states with legalized cannabis, 92% permit lot/batch sizes exceeding 5 lbs., with 13 states imposing no maximum limitations at all. As noted in the report, Nevada's existing regulations requiring quality control and good manufacturing practices are far more important to quality and safety than maintaining a small lot size for testing.

We hope that you will review the attached report and consider our request to increase lot sizes as part of the laboratory standards regulations being workshopped.

Thank you for your consideration of these comments, and we look forward to further discussing the proposed changes at the workshop.

Respectfully,

Mart

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



## **TECHNICAL REPORT:**

Evaluating Batch Size Limits For Cannabis Products And Evidence Of Effectively Protecting Public Health And Safety

Prepared for: Nevada Cannabis Association

Approved By:

David Vaillencourt, CEO

Date: April 24, 2024



## Executive Summary: Batch Sizes for Cannabis Products and Effectiveness of Protecting Public Health and Safety

#### About The GMP Collective and Voluntary Consensus Standards

The GMP Collective is a consulting and strategy firm comprised of senior scientists, engineers, and former public health officials across the pharmaceutical, food, and natural products industries. We are recognized leaders in protecting consumer health and safety by leveraging evidence-based consensus standards to drive policy and stable marketplaces. We are trusted by governments and industry alike – as leaders at ASTM International's Committee D37 on Cannabis.

ASTM International, originally known as American Society for Testing and Materials, is an accredited<sup>1</sup> international standards development organization where government, industry, academia, consumers, and users of a wide range of materials products, systems, and services develop and publish technical for over 90 industries.<sup>2</sup> Its processes ensure that market relevant standards are created in an open and transparent manner. A testament to its credibility and effectiveness, over 6,000 ASTM standards are cited in the United State Code of Federal Regulations. The recommendations herein rely heavily on, and reference, approved consensus standards developed in ASTM's Committee D37 on Cannabis.

From powder free exam gloves, building materials, bulletproof vests for law enforcement, to children's markers that are certified as toxin free, ASTM standards underpin our national infrastructure. Cannabis products are no exception.

#### Executive Summary

The team at The GMP Collective understands the concerns around balancing public health and safety through the potential limiting of batch sizes of cannabis flower in the State of Nevada.

The GMP Collective undertook a comprehensive review of literature, standards, and regulations to assess the impact of lot/batch sizes and sampling protocols on the health and safety of heterogeneous commodities which poses inherent health risks, like cannabis and food. The study aimed to evaluate the rationale behind and the efficacy of imposing lot/batch size limitations for final product testing, particularly in light of recommendations by BOTEC advocating for a maximum lot size of 5 pounds (lbs) for harvested cannabis inflorescence ("flower").

#### Core Findings of Analysis:

(1) Absence of industry precedent: There is no established precedent for lot/batch size limitations within comparable industries. These industries consistently prioritize comprehensive quality management

<sup>&</sup>lt;sup>1</sup> <u>https://www.standardsportal.org/usa\_en/standards\_system.aspx</u>

<sup>&</sup>lt;sup>2</sup> OECD (2021), International Regulatory Co-operation and International Organisations: The Case of ASTM International, OECD. <u>https://web-archive.oecd.org/2021-09-10/597825-irc-astm-case-study.pdf</u>



systems over arbitrary batch size restrictions.

(2) Consumer safety evidence: We uncovered no evidence suggesting that smaller batch sizes contribute to enhanced consumer safety. This dispels the notion that reducing lot sizes correlates with an increased protection for consumers.

(3) Reevaluation of BOTEC Findings: The recommendations posited by BOTEC Analysis are founded on a narrow scope of research that is both limited and outdated. Crucially, this body of work overlooks a substantial amount of contemporary evidence that opposes its conclusions.

(4) **Protection of Public Health:** The most potent strategy for protecting public health involves implementing market-relevant, accredited standards and best practices, such as Quality Management Systems and Good Manufacturing Practices (GMPs), rather than restricting batch sizes. Nevada's current regulations on cannabis products already reflect many of these practices.

#### Implications and Supportive Evidence:

- 1. National Regulatory Trends: Among the 38 states with legalized cannabis marketplaces, an overwhelming 92% permit lot/batch sizes exceeding 5 lbs, with 13 states imposing no maximum limitations at all.
- 2. Manufacturing Practices Impact: An analysis of other industry practices and other state regulations reveals that the quality and safety of consumable products are predominantly influenced by upstream Good Manufacturing Practices (GMPs) rather than reliance on end product testing. This comprehensive approach to quality includes written protocols, personnel training, selection of quality raw materials, in-process controls, process validation, and other product lifecycle management practices.
- 3. Recall Data Analysis: In reviewing available recall data, the 7 states that have implemented GMP or Quality Management System (QMS) requirements for cannabis flower producers, including Nevada, have experienced fewer product recalls compared to states lacking such regulatory measures. Notably, Nevada remains the only state of these 7 states enforcing a 5 lb limit on flower lot sizes for testing purposes.
- 4. Sampling Methodologies: ASTM International's Committee D37 on Cannabis published a Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches (ASTM D8334/D8334M-20<sup>3</sup>), 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 lbs, thereby ensuring representativeness and accuracy in laboratory analyses.
- 5. **Regulatory Comparison:** To our knowledge, there is no other industry or federal regulatory framework that establishes limits for lot/batch size for consumable products. Rather, quality and safety are maintained through GMPs and QMS implemented throughout the product lifecycle. This includes statistically relevant sampling plans that increase composite sample sizes as lot/batch size increases to ensure accurate test results. Therefore, there is no evidence to support that

<sup>&</sup>lt;sup>3</sup> https://www.astm.org/d8334\_d8334m-20.html



limiting lot/batch sizes for testing is "safer."

In conclusion, our findings advocate for a regulatory focus on quality and safety that does not rest on the limitation of batch sizes. We recommend that Nevada, and indeed all states considering similar measures, place their trust in robust, proven quality management practices over arbitrary numerical limits.

#### Recommendations

- 1. Amend regulations to permit maximum lot sizes of 20 lbs or larger, aligning with global best practices and regulatory standards.
- 2. Implement standardized, statistically relevant sampling protocols such as those outlined in ASTM D8334/D8334M-20, to compile composite samples reflective of the lot's heterogeneity, ensuring a minimum 0.5% of the lot weight is included in the sample. This methodology, rooted in GMPs and statistically representative sampling to mitigate risks, has been effectively utilized in numerous industries handling consumable products associated with health risks as well as products that are considered life-critical<sup>4</sup>.

<sup>&</sup>lt;sup>4</sup> Since the mid-1900s, the Department of Defense has relied on statistical sampling methodologies to ensure life-critical safety components to protect our country are effective and reliable. For example, see the Defense Construction Management Agency's Critical Safety Items – QA Standard Operating Procedure available here: <u>https://www.dcma.mil/Portals/31/Documents/Policy/DCMA-INST-303.pdf</u>



# Technical Report: Batch Sizes for Cannabis Products and Effectiveness of Protecting Public Health and Safety Technical Report

#### Introduction

In Nevada, "batches" are defined as usable flower and trim of the same strain harvested on or before a specified harvest date. Batches are made up of one or more "lots," which are defined by a maximum quantity for the purposes of compliance testing (5 lb for flower and 15 lb for trim). These lot size requirements were originally adopted in regulation based on a 2013 report by BOTEC Analysis ("BOTEC") created for the State of Washington to advocate for a 5 lb flower lot size<sup>5</sup>. Since then, BOTEC has released an updated 2023 report reiterating many of the same arguments. BOTEC's overarching theme is that there is no research to suggest a scientific basis for changing the 5 lb lot size. Ironically, there was no statistical or scientific basis from the 2013 report establishing the 5 lb lot size in the first place, nor is there any data to prove that a 5 lb lot size improves public health and safety better than any other lot size. In this report, we address the positions presented in the 2013 and 2023 BOTEC reports and propose considerations for revising these limits based on an extensive literature review and evaluation of relatable industries and public health data.

While respecting BOTEC's expertise and contributions to cannabis regulation, we believe the argument against increasing flower lot sizes overlooks the dynamic nature of cannabis research and industry practices. The exponential growth in cannabis-related scientific publications, from 13,038 articles between 1970 and 2013 (the year the 5 lb flower lot size was first recommended) to 25,652 articles from 2014 to 2024, underscores the rapid evolution of our understanding in this field.<sup>6</sup>

#### Methods

The GMP Collective's research team conducted a thorough literature and regulatory review to understand the health and safety impacts of sampling schemes and lot/batch sizes for commodity products that are known to be heterogenous in nature and have human health impacts. This included official methods of analysis and monographs for botanical medicines and agricultural commodities, statistical sampling techniques in parallel industries, cannabis and cannabinoid research, and an extensive review of rules and regulations across the United States and internationally.

#### Review of Other States' and Canada's Regulations of Cannabis

Nevada's maximum 5 lb flower lot size is the smallest maximum flower lot size across the United States. In fact, only two other states with extremely small cannabis marketplaces, Delaware and Montana, restrict flower lot sizes to 5 lbs.

<sup>&</sup>lt;sup>5</sup> In 2022, the State of Washington revised its regulations and increased the allowable maximum batch size from 5 lbs to 50 lbs.

<sup>&</sup>lt;sup>6</sup> The GMP Collective analysis of the keyword "cannabis" on PubMed.



A survey of 38 states' regulations reveals a **trend towards larger flower lot/batch sizes**, with an overwhelming 92% permitting lot/batch sizes exceeding 5 lbs. Further, since 26 out 38 total cannabis state marketplaces allow for bigger lot sizes of 20 lbs or more or do not limit lot sizes at all, this attests to a regulatory precedent of more sophisticated approaches to quality and safety rather than relying on lot/batch size constraints. (see Figure 1).<sup>7</sup>



#### Figure 1. Flower Lot/Batch Sizes in 38 States

Coincidentally, the states that allow for larger flower lot sizes often incorporate requirements rooted in Good Manufacturing Practices (GMPs) or Quality Management System (QMS) standards for producers and processors that emphasize product quality throughout the production lifecycle rather than relying solely on end-point testing. This shows that public health and safety risks can be mitigated in the cannabis industry through the adoption of GMPs and QMS principles as they are in other industries. Other industries rely on comprehensive GMPs and QMS that prioritize control and quality throughout the product lifecycle. This contrasts with the cannabis industry's current approach, which often emphasizes end-product testing with strict lot size limitations.

Seven states have implemented GMP or QMS requirements for cannabis flower producers, **including Nevada**. In reviewing available recall data, the states that have GMP or QMS requirements for flower producers, have experienced fewer product recalls compared to states lacking such regulatory measures. Notably, Nevada remains the only state of these 7 states enforcing a 5 lb limit on flower lot sizes for testing purposes.<sup>8,9</sup>

<sup>&</sup>lt;sup>7</sup> The GMP Collective analysis of 38 states' regulations as of March 2024.

<sup>&</sup>lt;sup>8</sup> The GMP Collective analysis of 38 states' regulations.

<sup>&</sup>lt;sup>9</sup> Trivino, M. How Many Cannabis Products Have Been Recalled in 2023? You Might Never Know. *Cannabis Wire*. <u>https://cannabiswire.com/2023/11/20/how-many-cannabis-products-have-been-recalled-in-2023-you-might-never-know/</u>



In Canada, Good Production Practices (GPPs) are used in the cannabis industry. Similar to GMPs in the United States for the food, dietary supplement, and pharmaceutical industries, GPPs provide a comprehensive approach to ensure quality and safety throughout the cannabis product lifecycle without controlling lot sizes.

When reviewing sample sizes for cannabis flower samples for testing across the United States, we found that sample weights that equate to 0.5% of the lot/batch weight was the highest specified percentage in any state's regulations (see Figure 2). In Canada, sample sizes are not specified, as operators are required to develop their own statistically relevant sampling plans. Nevada does not allow operators to perform their own sampling to limit bias and currently requires 10 g flower samples for every 5 lb lot, i.e., the sample is 0.44% of the lot weight.<sup>10</sup>

% of Lot/Batch Sampled for Testing	# of States
Not Specified	15
0.03% - 0.29%	8
0.30% - 0.49%	7
0.50%	8

Figure 2. Cannabis Flower Sample Sizes in 38 States

#### GMPs and QMS in Other Industries

In the United States, industries that produce consumable products such as food, dietary supplements, and pharmaceuticals have progressively moved towards a more holistic and data-driven risk-based approach to ensuring product quality and safety, significantly emphasizing Good Manufacturing Practices (GMPs) and Quality Management Systems (QMS). This shift is grounded in the understanding that **quality and safety cannot be "tested into" products**; instead, they must be designed and built into the manufacturing process from the outset. GMPs provide a framework for production processes, equipment, personnel, and record-keeping, ensuring that products are consistently produced and controlled according to quality standards. These practices are crucial for preventing contamination, mix-ups, and errors, which could pose significant health risks to consumers.

The preference for GMPs and QMS over limiting lot/batch sizes and performing final end-product testing is informed by several factors. Firstly, **end-product testing is inherently limited; it can only catch quality defects after they have occurred**, rather than preventing them. Additionally, testing every lot/batch is resource-intensive and does not guarantee the safety or efficacy of products, as it does not address the root

<sup>&</sup>lt;sup>10</sup> The GMP Collective analysis of 38 states' regulations.

Expert Report: Evaluating Batch Size Limits For Cannabis Products And Evidence Of Effectively Protecting Public Health And Safety | Approved: April 17, 2024 7 of 16



causes of quality issues. Conversely, **GMPs and QMS address quality at its source**, implementing preventive controls and continuous monitoring throughout the production process. This proactive stance is not only more effective in ensuring product safety and quality but also aligns with regulatory expectations and global best practices. **Regulatory bodies, such as the Food and Drug Administration (FDA), enforce strict GMP regulations** for these industries, underscoring the importance of these systems in protecting public health.<sup>11,12,13</sup>

The transition towards GMPs and QMS reflects a paradigm shift in quality assurance — **from a reactive to a proactive and preventive approach**. By integrating quality into every step of the production and organizational processes, these industries can better safeguard consumer health, comply with regulatory standards, and maintain public trust in their products.

After realizing the success of implementing GMPs and QMS in other industries, a growing number of states with legal cannabis programs, including Nevada, are using these frameworks to ensure safety and quality in the manufacture of cannabis products. **Requiring quality assurance measures**, such as GMP and quality control units, throughout the cultivation and processing stages **as Nevada does in Regulation 10 is the best proactive approach to ensuring product safety and consistency**.

#### Leveraging International Voluntary Consensus Standards

Back in 2013 when BOTEC first suggested 5 lb lot/batch sizes, there were no voluntary consensus standards developed by international accredited standard development organizations (SDOs)<sup>14</sup> for the cannabis industry. Now, the three leading SDOs, ASTM International, AOAC International, and the International Organization for Standardization (ISO), all have published standards for the cannabis industry.

ASTM International's Committee D37 on Cannabis was formed in 2017 and now includes over 800 volunteer members from 39 countries. The members have expertise across the vast and complex subject areas needed to bring a nascent industry forward with appropriate safeguards – from pharmacists, physicians, business owners, mechanical and chemical engineers, legacy cultivators, government agencies, policy experts, lawyers, risk assessment experts, insurance carriers, and more. Several D37 members currently or previously work for the United Nations, the U.S. Pharmacopeia (USP), the National Institute of Standards and Technology (NIST), Health Canada, other state and federal agencies, the

<sup>12</sup> FDA. Facts About the Current Good Manufacturing Practice (CGMP). <u>https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp</u>

<sup>&</sup>lt;sup>11</sup> FDA. Current Good Manufacturing Practices (CGMPs) for Food and Dietary Supplements. https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturingpractices-cgmps-food-and-dietary-supplements

<sup>&</sup>lt;sup>13</sup> Gyles, C. Food Safety. Can Vet J. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2629415/</u>

<sup>&</sup>lt;sup>14</sup> What is a Standards Development Organization? More details on the US Standardized System can be found here <u>https://www.standardsportal.org/usa\_en/standards\_system.aspx</u> and here <u>https://www.nist.gov/standardsgov/standards-information-center</u>



American Herbal Products Association (AHPA), world class research institutions, and more.<sup>15,16</sup>

The technical details covered in D37's 53 and counting cannabis-specific standards cover all sectors of the industry, including testing, conducting recalls, handling complaints and adverse events, and more. These standards represent a deep level of knowledge that is critical to ensure specifications and requirements are legally defensible and work towards producing safe and accurately labeled products. ASTM standards are living documents, so as the cannabis industry and science evolve, so too will the standards. They are required to be reviewed at least every five years and are updated based on advancements in the industry. Thus, adopting ASTM standards in regulations can save agencies a significant amount of time and resources when trying to regulate this rapidly evolving industry.

ASTM D8334/D8334M-20 Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses provides standard best practices for representatively sampling cannabis flower for ensuring accurate test results for batches up to 500 kg (1102.7 lbs). **As the total product weight increases, so does the number of containers from the batch that must be sampled and the number of sample increments** (i.e., sample aliquots, sample portions) **that must be taken to produce a composited sample that represents the batch**.<sup>17</sup>

The argument for maintaining small lot sizes based on the heterogeneity of the cannabis plant overlooks the potential for standardized, stratified sampling methods that could more accurately reflect the variability within larger batches. Also, requiring quality assurance measures, such as GMP and quality control units, throughout the cultivation and processing stages as Nevada does in Regulation 10 is the best proactive approach to ensuring product safety and consistency.

#### Direct Responses to the BOTEC Report

In BOTEC's report, they argue that 1) the maximum useable cannabis lot size in Nevada should remain at 5 lb for flower and 15 lb for trim, 2) the minimum representative sample size for testing per lot should be at least 0.5% of the lot size (for 5 lb, 0.5% is 11.34 grams, currently it is 10 grams), and 3) third-party sampling should remain required. Their main arguments are as follows.

- 1. Since BOTEC's 2013 report the market has flourished with most states having cannabis marketplaces with more information and data, however they say no data suggests that a change in the 5 lb lot size would be useful for any stakeholders.
- 2. They argue that natural variation (heterogeneity) of useable cannabis warrants segregating batches into smaller lots and testing each lot separately to keep people safe.
- 3. They argue that representative sampling methods are imperative to ensure testing is not biased and results represent the lot from which they came from. Sampling must be done in a way that reduces

<sup>&</sup>lt;sup>15</sup> ASTM International Committee D37 on Cannabis. <u>https://www.astm.org/get-involved/technical-committees/committee-d37</u>

<sup>&</sup>lt;sup>16</sup> ASTM International and Cannabis Standards. <u>https://www.astmcannabis.org/wp-content/uploads/2022/08/Cannabis-Regulators-June-2022-1.pdf</u>

<sup>&</sup>lt;sup>17</sup> ASTM D8334/D8334M-20 Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses. <u>https://www.astm.org/d8334\_d8334m-20.html</u>



variability and opportunity for manipulation, thus third-party sampling should stay.

### We agree with the minimum representative sample size for testing be 0.5% of the lot size and that third-party sampling should remain required at this time.

#### However, there is no data to suggest that limiting lots to 5 lbs is better for public health.

The reliance on testing small lots/batches is inherently reactive, not proactive. It assumes that quality can be assured by testing the final product, which is less efficient and can be less effective than integrating quality throughout the production process.

A more effective approach is to embed quality assurance processes throughout the cultivation, processing, and packaging phases. This includes Good Manufacturing Practices (GMP) and Quality Management Systems (QMS), which aim to ensure that the product meets quality standards consistently, rather than catching faults in small samples at the end.

There is a need for a shift in perspective from a narrow focus on lot/batch testing as a solution for public safety to a broader, more integrated approach. Such an approach inherently emphasizes quality assurance throughout the production process and adapts to the rapidly expanding base of scientific knowledge about cannabis. Nevada has adopted GMPs in Regulation 10 of their cannabis regulations.

Also, all evidence points to statistically relevant sampling methods being more important for ensuring safety and quality through testing than limiting lot/batch sizes.

The development and **adoption of standardized and statistically relevant sampling techniques will ensure representativeness without necessarily limiting lot sizes or increasing costs**. No other industry limits lot/batch sizes. Rather, they rely on GMPs, which include larger samples for larger lots/batches to ensure representativeness.

As the cannabis industry has matured since the initial legalizations in Washington and Colorado, we've seen an impressive evolution in both the regulatory landscape and the technological capabilities for testing. This maturity supports a reevaluation of the 5 lb lot size limit, advocating for larger lots/batches that reflect the industry's growth and capabilities. With larger lot/batch sizes, more samples can be submitted for testing to ensure representativeness. Larger lot/batch sizes and standardized sampling techniques can be leveraged to ensure safety and potency standards are met without disproportionately increasing burdens on producers.

#### Recommendations

In light of these considerations, we recommend the following evidence-based modifications to Nevada's cannabis regulation framework:

- 1. Reevaluate and consider increasing the maximum cannabis flower lot size to at least 20 lbs, drawing on quality assurance, sampling, and testing methodologies that reflect the latest industry best practices.
- **2.** Adopt standardized, detailed sampling methods to create composite samples that are at least 0.5% of the lot/batch weight to account for the heterogeneity of cannabis and ensure that testing

Expert Report: Evaluating Batch Size Limits For Cannabis Products And Evidence Of Effectively Protecting Public Health And Safety | Approved: April 17, 2024 10 of 16



results are representative of the entire lot. To operationalize this approach, Nevada's regulatory framework would benefit from detailed sampling plans that specify: 1) The number of sample increments to be taken from each lot, 2) the locations within each lot (top, middle, bottom) from which samples should be drawn and 3) the method by which these increments are composited into a final sample for testing. **Below are examples of standardized sampling approaches used in cannabis and other industries.** 

- a. **ASTM's Sampling Standard for Cannabis Flower:** ASTM D8334/D8334M-20 Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses.
- b. **USP's Sampling Recommendation for Cannabis Flower:** In their article <sup>18</sup> titled "Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes," the USP recommends using USP general chapter <561> *Articles of Botanical Origin* which describes the sampling procedures applicable to vegetable drugs as a foundation for sampling practices for cannabis flower. Some states, such as Massachusetts, have adapted this approach.
- c. **Proportional Sampling:** A commonly suggested model involves proportional sampling, where the sample size is a fixed percentage of the total batch weight. However, the specific percentage can vary based on the risk assessment of the product, the historical data on contamination levels, and the heterogeneity of the cannabis batch. A starting point might be around 0.5% of the total batch weight, adjusted based on empirical data and risk levels.
- d. **Square Root Plus One Sampling:** Another approach used in some agricultural and pharmaceutical settings is the Square Root Plus One Sampling method, where the number of samples is determined by taking the square root of the total number of units (or a similar measure) in the batch, and then adding one. This method might need adaptation for bulk products like cannabis, where the product isn't naturally divided into discrete units.
- e. **Stratified Random Sampling:** Given the heterogeneity within a cannabis batch, stratified random sampling can be an effective approach. The batch is divided into strata based on known factors (like plant part, position in the growing area, etc.), and samples are taken proportionally from each stratum. This method helps ensure that the sample reflects the variability within the batch.
- 3. Nevada's Regulation 11.045 provides an avenue for continuous improvement through data collection on product quality. With an increased batch size allowance, we encourage the state to monitor and evaluate for any link to batch sizes and product failures and recalls.
- 4. research & development testing. To get Nevada-specific data on how increasing flower lot sizes affects testing and product quality, Nevada could allow for a pilot research study where a minimum of three producers produce 20 lb or larger flower lots and compares potency and contaminant test results from testing 5 lb lots versus 20lb or larger lots.

#### By addressing these recommendations, Nevada can enhance its regulatory framework to better align

<sup>&</sup>lt;sup>18</sup> Sarma, N. D., Waye, A., ElSohly, M. A., Brown, P. N., Elzinga, S., Johnson, H. E., Marles, R. J., Melanson, J. E., Russo, E., Deyton, L., Hudalla, C., Vrdoljak, G. A., Wurzer, J. H., Khan, I. A., Kim, N.-C., & Giancaspro, G. I. (2020). Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes. *Journal of Natural Products*, *83*(4), 1334–1351. <u>https://doi.org/10.1021/acs.jnatprod.9b01200</u>



with current scientific understanding and industry practices, thereby ensuring public health and safety while supporting the viability of the cannabis industry.



#### Appendix A: Other Resources

While not directly cited in our report, the following is a non-exhaustive list of references that were reviewed to inform our recommendations and findings.

AL Ubeed, H. M. S., Wills, R. B. H., & Chandrapala, J. (2022). Post-Harvest Operations to Generate High-Quality Medicinal Cannabis Products: A Systemic Review. *Molecules*, *27*(5), 1719. https://doi.org/10.3390/molecules27051719

AOAC International. (1927). Sampling of Drugs (AOAC Official Method 927.09; Final Action).

AOAC International. (1935). Sampling of Malt (AOAC Official Method 935.25).

AOAC International. (1960). Sampling of Hops (AOAC Official Method 945.19; Final Action).

AOAC International. (1977). *Sampling for Aflatoxins—Preparation for Sample Procedure* (AOAC Official Method 977.16; First Action 1977).

ASTM International. (1968). *Standard Practice for Probability Sampling of Materials* (Standard Practice E105-58).

Atkins, P. L. (n.d.). Sample Processing and Preparation for Cannabis Products.

Berthold, E. C., Yang, R., Sharma, A., Kamble, S. H., Kanumuri, S. R., King, T. I., Popa, R., Freeman, J. H., Brym, Z. T., Avery, B. A., & McCurdy, C. R. (2020). Regulatory sampling of industrial hemp plant samples (Cannabis sativa L.) using UPLC-MS/MS method for detection and quantification of twelve cannabinoids. *Journal of Cannabis Research*, *2*(1), 42. https://doi.org/10.1186/s42238-020-00050-0

Blake, A., & Nahtigal, I. (2019). The evolving landscape of cannabis edibles. *Current Opinion in Food Science*, *28*, 25–31. <u>https://doi.org/10.1016/j.cofs.2019.03.009</u>

Blanchette, J. G., Pacula, R. L., Smart, R., Lira, M. C., Boustead, A. E., Caulkins, J. P., Kilmer, B., Kerr, W. C., Treffers, R., & Naimi, T. S. (2022). Rating the comparative efficacy of state-level cannabis policies on recreational cannabis markets in the United States. *International Journal of Drug Policy*, *106*, 103744. https://doi.org/10.1016/j.drugpo.2022.103744

Bovens, M., Csesztregi, T., Franc, A., Nagy, J., & Dujourdy, L. (2014). Sampling of illicit drugs for quantitative analysis—Part II. Study of particle size and its influence on mass reduction. *Forensic Science International*, 234, 174–180. <u>https://doi.org/10.1016/j.forsciint.2013.09.001</u>

Cbe, D. O. (n.d.). Attributes Acceptance Sampling – Understanding How it Works.

Cole, M. (n.d.). Principles of microbiological testing: Statistical basis of sampling.

Csesztregi, T., Bovens, M., Dujourdy, L., Franc, A., & Nagy, J. (2014). Sampling of illicit drugs for quantitative analysis – Part III: Sampling plans and sample preparations. *Forensic Science International*, *241*, 212–219. https://doi.org/10.1016/j.forsciint.2014.04.023

Expert Report: Evaluating Batch Size Limits For Cannabis Products And Evidence Of Effectively Protecting Public Health And Safety | Approved: April 17, 2024 13 of 16



D37 Committee. (n.d.-a). *Standard Guide for Sample Preparation of Cannabis and Hemp Inflorescence for Laboratory Analysis*. ASTM International. <u>https://doi.org/10.1520/D8493-23</u>

D37 Committee. (n.d.-b). *Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses*. ASTM International. <u>https://doi.org/10.1520/D8334\_D8334M-20</u>

Dahms, S. (2004). Microbiological sampling plans – Statistical aspects.

Dryburgh, L. M., Bolan, N. S., Grof, C. P. L., Galettis, P., Schneider, J., Lucas, C. J., & Martin, J. H. (2018). Cannabis contaminants: Sources, distribution, human toxicity and pharmacologic effects. *British Journal of Clinical Pharmacology*, *84*(11), 2468–2476. <u>https://doi.org/10.1111/bcp.13695</u>

Dujourdy, L., Csesztregi, T., Bovens, M., Franc, A., & Nagy, J. (2013). Sampling of illicit drugs for quantitative analysis. Part I: Heterogeneity study of illicit drugs in Europe. *Forensic Science International*, *231*(1–3), 249–256. <u>https://doi.org/10.1016/j.forsciint.2013.05.022</u>

Flowers, R. S., & Freier, T. A. (n.d.). Sampling Plans for Microbiological Testing – How to Construct and Role in Testing.

Food and Agriculture Organization of the United Nations. (n.d.). *General Guidelines on Sampling* (CAC/GL 50-2004).

Gómez Velásquez, S., Amaya Heredia, Á. M., Bedoya Moncada, S., Patiño González, J. E., & Martínez Ramírez, J. A. (2023). Cannabis recreativo: Perfil de los cannabinoides presentes en muestras de marihuana suministradas por población consumidora. *Salud Colectiva*, *19*, e4385. https://doi.org/10.18294/sc.2023.4385

Goundar, P., Macaulay, T., & Szafron, M. (2021). A comparative analysis of laws on recreational cannabis edibles between Canada and the United States of America. *International Journal of Drug Policy*, 94, 103191. https://doi.org/10.1016/j.drugpo.2021.103191

Hunt, K. (n.d.). Representative Sampling of Cannabis. *ASTM Standardization News*.

Jameson, L. E., Conrow, K. D., Pinkhasova, D. V., Boulanger, H. L., Ha, H., Jourabchian, N., Johnson, S. A., Simeone, M. P., Afia, I. A., Cahill, T. M., Orser, C. S., & Leung, M. C. K. (2022). Comparison of State-Level Regulations for Cannabis Contaminants and Implications for Public Health. *Environmental Health Perspectives*, *130*(9), 097001. <u>https://doi.org/10.1289/EHP11206</u>

Jongenburger, I., Den Besten, H. M. W., & Zwietering, M. H. (2015). Statistical Aspects of Food Safety Sampling. *Annual Review of Food Science and Technology*, 6(1), 479–503. <u>https://doi.org/10.1146/annurev-food-022814-015546</u>

Kazusaki, M. (2018). Sampling Plan Based on Operating Characteristic Curve. *Science Journal of Analytical Chemistry*, 6(3), 21. <u>https://doi.org/10.11648/j.sjac.20180603.11</u>

Kritikos, A. F., & Pacula, R. L. (2022). Characterization of Cannabis Products Purchased for Medical Use in New York State. *JAMA Network Open*, 5(8), e2227735. <u>https://doi.org/10.1001/jamanetworkopen.2022.27735</u>

Expert Report: Evaluating Batch Size Limits For Cannabis Products And Evidence Of Effectively Protecting Public Health And Safety | Approved: April 17, 2024 14 of 16



Lehotay, S. J., & Cook, J. M. (2015). Sampling and Sample Processing in Pesticide Residue Analysis. *Journal of Agricultural and Food Chemistry*, 63(18), 4395–4404. <u>https://doi.org/10.1021/jf5056985</u>

MacCallum, C. A., Lo, L. A., Pistawka, C. A., & Boivin, M. (2023). A Clinical Framework for Evaluating Cannabis Product Quality and Safety. *Cannabis and Cannabinoid Research*, *8*(3), 567–574. https://doi.org/10.1089/can.2021.0137

Mead, A. (2019). Legal and Regulatory Issues Governing Cannabis and Cannabis-Derived Products in the United States. *Frontiers in Plant Science*, *10*, 697. <u>https://doi.org/10.3389/fpls.2019.00697</u>

Orenstein, D. G., & Glantz, S. A. (2018). Regulating Cannabis Manufacturing: Applying Public Health Best Practices from Tobacco Control. *Journal of Psychoactive Drugs*, 50(1), 19–32. https://doi.org/10.1080/02791072.2017.1422816

Peng, H., & Shahidi, F. (2021). Cannabis and Cannabis Edibles: A Review. *Journal of Agricultural and Food Chemistry*, 69(6), 1751–1774. <u>https://doi.org/10.1021/acs.jafc.0c07472</u>

Pinkhasova, D. V., Jameson, L. E., Conrow, K. D., Simeone, M. P., Davis, A. P., Wiegers, T. C., Mattingly, C. J., & Leung, M. C. K. (2021). Regulatory status of pesticide residues in cannabis: Implications to medical use in neurological diseases. *Current Research in Toxicology, 2,* 140–148. https://doi.org/10.1016/j.crtox.2021.02.007

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. https://doi.org/10.1002/dta.1531

Powell, M. R. (2014). Optimal Food Safety Sampling Under a Budget Constraint. *Risk Analysis*, *34*(1), 93–100. <u>https://doi.org/10.1111/risa.12054</u>

Pruyn, S. A., Wang, Q., Wu, C. G., & Taylor, C. L. (2022). Quality Standards in State Programs Permitting Cannabis for Medical Uses. *Cannabis and Cannabinoid Research*, 7(6), 728–735. https://doi.org/10.1089/can.2021.0164

Pusiak, R. J., Cox, C., & Harris, C. S. (2021). Growing pains: An overview of cannabis quality control and quality assurance in Canada. *International Journal of Drug Policy*, 93, 103111. https://doi.org/10.1016/j.drugpo.2021.103111

Richard, E. L., Althouse, A. D., Arnsten, J. H., Bulls, H. W., Kansagara, D., Kerbag, M. N., Lichius, C., Lipsey, D., Morasco, B. J., Nugent, S. M., Merlin, J. S., & Starrels, J. L. (2021). How medical are states' medical cannabis policies?: Proposing a standardized scale. *International Journal of Drug Policy*, *94*, 103202. https://doi.org/10.1016/j.drugpo.2021.103202

Santos-Fernández, E., Govindaraju, K., & Jones, G. (2014). A new variables acceptance sampling plan for food safety. *Food Control*, *44*, 249–257. <u>https://doi.org/10.1016/j.foodcont.2014.03.051</u>

Seltenrich, N. (2019). Cannabis Contaminants: Regulating Solvents, Microbes, and Metals in Legal Weed. *Environmental Health Perspectives*, *127*(8), 082001. <u>https://doi.org/10.1289/EHP5785</u>

Expert Report: Evaluating Batch Size Limits For Cannabis Products And Evidence Of Effectively Protecting Public Health And Safety | Approved: April 17, 2024 15 of 16



Smith, C. J., Vergara, D., Keegan, B., & Jikomes, N. (2022). The phytochemical diversity of commercial Cannabis in the United States. *PLOS ONE*, *17*(5), e0267498. <u>https://doi.org/10.1371/journal.pone.0267498</u>

Smith, Brian. (2020, August). A Proposed Representative Sampling Plan for Hemp Grows. *Cannabis Science and Technology*, *3*(6), 10–13.

United Nations Office on Drugs and Crime. (2023). *World Drug Report 2023*. United Nations. https://doi.org/10.18356/9789210028233

Valdes-Donoso, P., Sumner, D. A., & Goldstein, R. (2020). Costs of cannabis testing compliance: Assessing mandatory testing in the California cannabis market. *PLOS ONE*, *15*(4), e0232041. https://doi.org/10.1371/journal.pone.0232041

Von Collani, E. (2004). A Problem Called ISO 2859-1 Sampling Procedures for Inspection by Attributes— Part 1. *Economic Quality Control*, *19*(2). <u>https://doi.org/10.1515/EQC.2004.265</u>

Welling, M. T., Liu, L., Hazekamp, A., Dowell, A., & King, G. J. (2019). Developing Robust Standardised Analytical Procedures for Cannabinoid Quantification: Laying the Foundations for an Emerging Cannabis-Based Pharmaceutical Industry. *Medical Cannabis and Cannabinoids*, *2*(1), 1–13. https://doi.org/10.1159/000496868

Wu, C., Lee, S.-L., Taylor, C., Li, J., Chan, Y.-M., Agarwal, R., Temple, R., Throckmorton, D., & Tyner, K. (2020). Scientific and Regulatory Approach to Botanical Drug Development: A U.S. FDA Perspective. *Journal of Natural Products*, *83*(2), 552–562. <u>https://doi.org/10.1021/acs.jnatprod.9b00949</u>

Yadav, S., Ghimire, N., & Lahutiya, V. (2023). A comprehensive review of the production technology of Cannabis sativa L. with its current legal status and botanical features. *Fundamental and Applied Agriculture*, *8*(1), 458. <u>https://doi.org/10.5455/faa.144546</u>

#### 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>



April 29, 2024

Dear Staff of the Cannabis Compliance Board,

On behalf of GTI Nevada, I write to you today not just with disappointment but with a profound sense of frustration at the continued disregard for a matter of significant concern within our regulatory discussions—the definition of "lot size" found in NCCR 1.125 and its impact on Nevada's cannabis testing program. On January 30, a formal request was submitted to address this issue in the year's workshops, yet here we are, without so much as an acknowledgment on the agendas for either the April 30 or the upcoming May 14 workshops.

The lack of transparency and the seemingly intentional avoidance of this subject is extremely disappointing if not unexpected. The state of Nevada set the current lot sizes—five pounds for flower and 15 pounds for trim—over a decade ago, a decision that has since lagged behind more progressive, economically mindful approaches adopted in other legal cannabis markets. This outdated standard not only stifles our businesses with undue economic strain but also begs the question: What justifies our state's persistence in maintaining these arbitrary limitations?

The inaction and silence on this issue are unacceptable. Nearly two years have passed since the Sierra Cannabis Coalition brought forward a petition to specifically address this matter, yet the CCB appears to have made no significant effort to engage with industry stakeholders on this critical point of economic and operational viability.

It is imperative that the Board rectifies this oversight and demonstrates a commitment to industry progression by amending the May 14 workshop agenda to include a discussion of lot size definitions. The integrity of the Nevada cannabis market relies on regulations that evolve alongside industry standards and practices. To continue to disregard this necessary evolution is to fail the very businesses and consumers we are tasked with serving.

Therefore, I insist on an explanation for this omission and demand the immediate inclusion of the "lot size" definition in the upcoming workshop. It is time for the Board to act responsibly and address the concerns that have been repeatedly raised by the industry. I, and Nevada's Cannabis industry, await your prompt and corrective action on this urgent matter.

All the best,

Will Adler Silver State Government Relations

Silver State Government Relations Creating results for clients throughout the Silver State



April 29, 2024

Cannabis Compliance Board 700 E. Warm Springs Road, Suite 150 Las Vegas, NV 89119

Via email to regulations@ccb.nv.gov

Subject: Chamber of Cannabis Input on Testing Lab Regulations

Dear Cannabis Control Board Members,

As a 501(c)6 business trade organization, the Chamber of Cannabis exists to advocate for the interests of our members across all sectors of the cannabis supply chain.

We appreciate the CCB's renewed commitment to soliciting industry feedback, as this is vital in creating a regulatory environment that protects public safety without negatively impacting the economic potential of legal cannabis in Nevada.

While our membership base includes representation from independent testing labs and we have received feedback from these stakeholders, the leaders of our organization – much like the majority of the CCB Staff and Board– are not accredited scientists. We acknowledge the experience and expertise of the independent testing lab ("Labs") licensees and agent card holders.

Our intention is to share the feedback that we have received from our members in the broader industry context and to highlight shared areas of concern and improvement with the CCB as it seeks to establish requirements relating to the "inspections, certifications, and laboratory testing policies, procedures, and guidelines, and to provide other matters properly relating thereto".

KEY: Regulation X NCCR X.XXX CCB Removal CCB Addition Chamber Addition Chamber Removal Comments & Suggestions

#### Regulation 5: LICENSING, BACKGROUND CHECKS, AND REGISTRATION CARDS

# 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.

#### A: Notice for testing labs as an additional exception

...

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, with or without notice, except that cannabis independent testing laboratories may be inspected with no less than 72 hours notice at least biennially, with interim follow-up activities, with or without notice, 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 operation.

#### OR

## *B:* Specify that no penalties or repercussions will be imposed if key staff is not present or if follow-up visits are necessary

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. In the event that an independent testing laboratory does not have the resources or personnel available for the initial inspection visit, the lab inspection team shall work with the staff to coordinate a return visit within XX days. Nothing in this subsection shall be construed to prohibit an appropriate local administrative authority from conducting an inspection of the facilities or operation.

As suggested by the CCB's proposed exception for Labs being subject to more frequent inspections, Labs are under an increased level of regulatory scrutiny.Labs must not only comply with the CCB's cannabis-specific regulations but also with the International Organization of Standardization, American Society for Testing and Materials (ASTM), Good Laboratory Practice (GLP), AOAC International, FDA, and more.

Given this level of regulatory oversight, it is unreasonable to expect a lab employee or auditor to be able to prepare all of the necessary materials for an inspection without any notice. Even financial institutions receive notice before being audited by the FDIC or the NCUA. Considering the highly technical nature of scientific testing, roles can be highly specialized. Therefore, there is an additional level of coordination and preparation required to prepare for an inspection. Understanding that the purpose of performing these inspections without notice is largely to catch any illicit or unethical activity, this can be accomplished with unscheduled interim follow-up activities.

#### **Regulation 7: CANNABIS SALES FACILITY**

# 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 does not apply to industrial hemp, as defined in NRS 557.040, which is certified and registered with the State Department of Agriculture.

**7.035(2)** - The ability for consumers to receive a copy of the soil amendment report along with the CoA upon request is beneficial to consumer confidence and education.

**7.035(4-6)** - We are in favor of requiring cannabis products derived from hemp to require CCB approval prior to being made available to purchase at a cannabis sales facility, even if they are already certified and registered with the State Department of Agriculture. Two observations/points of clarification:

- 1. <u>Hemp is defined in NRS 557.160</u>. There does not appear to be an NRS 557.040 or any specific distinction between hemp and industrial hemp in the NRS.
- 2. May wish to clarify if the State Department of Agriculture in subsection 6 is specific to Nevada's Department of Agriculture (vs. United States vs. another state) to address hemp-derived products certified/registered in other states.

#### <u>Regulation 11: CANNABIS INDEPENDENT TESTING LABORATORY</u> 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 60 days unless an extension is granted by the appropriate Board Agent.

4. A cannabis independent testing laboratory shall-immediately inform the Board within <del>72 hours</del> 7 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 60 days, unless an extension is granted by the appropriate Board Agent.

Understanding the vital role that the Scientific Director plays in ensuring ongoing compliance at a Lab, certain aspects of these requirements are overly prescriptive in relation to other state agencies and appear to be in direct response to the business dynamics of past and current Labs.

That said, the reduction from 90 days to 60 days for an interim executive director in subsection 3 and 5 is in alignment with other states as is the need for the Scientific Director to take ownership in the documentation and review of SOPs.

- Michigan (Laboratory Manager)
- <u>Colorado</u> (Laboratory Director)

While we are in favor of the level of specificity in requiring notification within 3 days (72 hours) of appointing a new scientific director or interim director instead of "immediately", this time frame is shorter than the 7 day notification period outlined by Michigan's CRA and Colorado's MED. Uniformity across states is preferred.

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

. . .

4. A cannabis independent testing laboratory shall implement a safety program which meets all applicable requirements of Laboratory Safety Guidance published by the Occupational Safety and Health Administration of the United States Department of Labor

We are pleased to see that the CCB is now requiring the adoption of OSHA requirements to protect workers beyond the OSHA training that is already required.

<u>Earlier this month</u>, Federal OSHA Officials gave a <u>presentation</u> on the agency's latest guidance and priorities for "protecting workers within the cannabis industry" in the growing number of state-legal markets.

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

From the feedback we have received and from our understanding of the current dynamics and practices in enforcing the standards set out by publications external to these regulations, the reliance upon external sources that are constantly changing causes uncertainty and a lack of clarity.

As much as possible, the preference is to have requirements directly referenced in regulation and to increase the level of specificity. While there is now a stipulation for methodology validation "if these are not available", the intention and process for the following provisions remains unclear:

- "Upon publication of the cannabis appendix, the Board **may** require an accreditation pursuant to this standard" (1b)
- *"Any subsequent standard* as approved by the appropriate Board Agent" (7e)
- "Upon its publication, the Board may adopt the Cannabis Regulators Association (CANNRA) Laboratory Testing and Standardization Guidance as a reference" (8i).

We would like clarification on the process by which the board would decide to and communicate any additional accreditations, approve standards, and/or adopting new references without regulation changes.

We support the inclusion of an ethics policy within the QC/QA program that all staff must be familiar with and adhere to.

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

. . .

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

...

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.

We are pleased to see the introduction of a new category of testing for usable cannabis that is destined for extraction and that all cannabis that is destined for extraction is subject to fewer testing requirements in 11.050(2).

Some of our members have expressed concerns regarding the removal of total coliform testing from usable cannabis, infused pre-and crude collected resins, received, excluding wet cannabis and crude collected resins. Positive tests for coliform are reflective of poor hygiene practices and could be indicative of larger issues.

For NCCR 11.050(3), we would like to understand the intention behind this increase in sample size from 10 grams to 20 grams. In addition to logistical concerns, the increase in product on hand could also lead to increased security risks.

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

It would be beneficial for the CCB to encourage the NV Dept. of Agriculture to maintain an up to date list of approved pesticides. The CCB published <u>this document in 2021</u> which refers to <u>this page</u> from the DOA but <u>the list</u> has not been updated since October 2022 and is difficult to locate. We would like to see this included somewhere on the CCB website to help the industry access this information.

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 of certificate of analysis for tests performed by testing laboratory; grounds for disciplinary action for failure to comply.

We echo the sentiment in the Small Business Impact Summary regarding a need for clarification on the language and intent of the revisions regarding representative sampling and ensuring a homogeneous sample from production facilities in NCCR 11.070(1b).

We understand the reasoning for requiring Labs to keep all samples – regardless of whether the sample passed or failed – in NCCR 11.070 (4) but have concerns that this will further exacerbate the logistical and security concerns that the increase in sample size in NCCR 11.050 will cause.

In regards to the disposal of cannabis that is rendered unusable, we ask that the CCB adopt a more streamlined way for failed flowers that cannot be remediated or sent to extraction to be destroyed without requiring CCB approval for lots that are over 150 grams. One potential solution for this is to allow them to be exited out of METRC with the relevant opened ticket/note and physical waste log.

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.

We are in support of requiring all post-harvest treatment and remediated lots to be documented.

## 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.

In light of the collections crisis the industry is facing, we appreciate the CCB providing this level of specificity regarding the responsibility for costs involved with testing and are in full support of these additions.

Our committee is actively working to identify potential solutions to address contract enforcement and believe that these proposed changes in NCCR 11.085 are in alignment with the CCB's mandate of protecting the public health and safety of our citizens and visitors while holding cannabis licensees to the highest ethical standards.

By embracing the pillars of justice, commerce, and community, the Chamber strives to promote a thriving, responsible, and inclusive cannabis industry. We are dedicated to championing the interests of our members, working towards equitable regulations, fostering economic growth, and building strong partnerships within the cannabis community.

As such, we welcome any follow up discussion or questions from the Board and from the general public.

Thank you for your consideration of ours and the industry's feedback during this workshop.

Highest regards,

Abby Kaufmann on behalf of the Commerce Committee Chamber of Cannabis secretary@cofclv.org



Abby Kaufmann Secretary, Board of Directors Chamber of Cannabis abigailkaufmann94@gmail.com

April 30, 2024

Cannabis Compliance Board 700 E. Warm Springs Road, Suite 150 Las Vegas, NV 89119

Via email to regulations@ccb.nv.gov

Subject: Public Comment for 4.30.2024 Workshop

Dear CCB Staff and Executive Director Humm,

In addition to representing our member's feedback on the regulations included in today's workshop, I would like to submit additional comment on the sentiments expressed in the Small Business Impact Statements, particularly as they relate to the proposed changes to NCCR 11.085, as it is clear that the topic of non-payment and contract enforcement warrants further discussion.

Due to the federal illegality of cannabis, legal businesses do not have access to traditional lending services or business lines of credit to ensure consistent cash flow. In order to maintain operators and make payroll, operators depend upon the vendors and merchants they do business with to pay for the goods and services they provide in a timely manner.

According to the "*Cannabis Delinquencies: An Existential Threat to the U.S. Cannabis Industry*" report published by Whitney Economics in March 2024, Testing Laboratories take in the least amount of revenue on average which further exacerbates the issue of delinquent payments. While today's discussion will elucidate the non-payment issue for Labs and the CCB's attempts to address this in 11.085, it is important to understand that non-payment has a trickle down effect.

In recent months, the Commerce Committee has identified several potential ways to address this issue by regulation alone.

At this time we are <u>not</u> requesting that the CCB act upon the changes outlined below – we are simply providing suggestions for the CCB to (1) gain visibility into the scale of the problem, (2) establish opportunities for oversight, and/or (3) resolve/enforce non-payment issues.

#### 4.061 Category VII Violations

As written in proposed regulations for May 2024 Workshop

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.

(10) [Consistent] Failure to pay Cannabis Establishment for ...

Similar to how the CCB is proposing that failure to pay a Testing Laboratory for screening and testing with the adoption of changes to NCCR 11.085, non-payment issues could be considered a type of category VI violation across the board. If the CCB is able to adopt the language in NCCR 4.061(1a.4) for Testing Laboratories, it would be logical to address other license types in a similar manner.

The qualifiers (and even the category) for the violation could be based on the number of unpaid invoices, the time that has passed, the percentage of amounts owed, etc;. To address exceptions where businesses may have a mutual understanding or payment agreement, the regulation could include provisions accounting for these types of business relationships.

#### 5.095 Renewal of license.

A person or entity that wishes to renew a license for a cannabis establishment must annually submit to the Board:

1. Payment of the annual licensing fee for the renewal of the license. Payment must include the identification numbers of the establishment and the name of the entity applying to renew the license.

2. Any such other information required by the Board upon request,

3. If a person or entity fails to renew its license by the expiration date, then the licensee shall cease operations until its license is renewed. If the person or entity fails to renew its license within ninety (90) days of the expiration date, then the license shall be deemed voluntarily surrendered.

Should the Board choose to do so, the Board could request that a person or entity provide information regarding their accounts receivables as part of a license renewal. By requesting this information, the Board would have access to the information needed to gauge the true extent of non-payment of contracts to help inform the need for additional regulatory oversight.

### 5.100 Grounds for denial of issuance or renewal of license; notice of denial; opportunity to correct situation.

1. The Board may deny an application for the issuance or renewal of a license for a cannabis establishment on any of the following grounds:

(a) Violation by the applicant or the cannabis establishment of any of the provisions of the NCCR or Title 56 of NRS.

(b) The failure or refusal of an applicant or cannabis establishment to comply with any of the provisions of the NCCR or Title 56 of NRS.

(c) The failure or refusal of a cannabis establishment to carry out the policies and procedures or comply with the statements provided to the Board in the application of the cannabis establishment.

(d) Operating a cannabis establishment without a license, including, but not limited to, the failure to timely submit a renewal application, the failure to timely pay renewal fees, or failure to pay all time and effort billing.

(e) The failure or refusal to return an adequate plan of correction to the Board within 10 business days after receipt of a statement of deficiencies.

(f) The failure or refusal to correct any deficiency specified by the Board within the period specified in a plan of correction approved by the Board.

(g) The failure or refusal to cooperate fully with an investigation or inspection by the Board or Board Agents.

(h) The failure to comply with the provisions of chapters 372A and Title 56 of NRS and chapter 372A of NAC governing the imposition of an excise tax on cannabis establishments.

(i) An owner, officer or board member of the cannabis establishment intentionally provides information that the Board determines is false or misleading.

(j) Failure to adhere to all local requirements, including but not limited to licensing requirements.

(k) Failure to comply with payment terms for the goods and services provided by another cannabis establishment.

2. If the Board denies an application for issuance or renewal of a license for a cannabis establishment, the Board may provide notice to the applicant or cannabis establishment that includes, without limitation, the specific reasons for the denial and provide instructions for opportunities to correct the situation.

The list of items in subsection 1a-1j are grounds for which the Board <u>may</u> deny an application for the issuance or renewal of a license. By adding language to include an

establishment's failure to comply with payment terms, the Board would have the option to leverage non-payment as a reason but would not be required to do so.

The title of this regulation suggests that it should outline opportunities to correct this situation. This is not currently reflected in the body of the regulation but, should any payment noncompliance be added as grounds for denial of issuance or renewal of a license, then it is pertinent to address opportunities for correction by regulation.

## 6.082 Use of seed-to-sale tracking system; payment of fees. A cannabis establishment shall:

1. Use the seed-to-sale tracking system managed by the independent contractor selected by the Board;

2. Connect to the seed-to-sale tracking system using the independent contractor's application programming interface;

3. Pay any fees assessed by the independent contractor for using the seed-to-sale tracking system, including, without limitation, user fees or application programming interface fees; and
4. Ensure cannabis and cannabis products are tagged as required using the seed-to-sale tracking system

Given that the CCB can require cannabis establishments to pay vendor fees with seed-to-sale tracking, there is no reason they cannot have some level of regulatory oversight to ensure that cannabis establishments also pay each other.

If the industry or the CCB itself has concerns regarding the oversight or management of contract enforcement, an alternate approach would be to introduce a regulation requiring all cannabis establishments to work with and pay any fees to an approved vendor that specializes in collecting and sharing A/R data with participating cannabis establishments.

## 6.135 Quarterly reporting concerning production, purchases and sales of cannabis and cannabis products.

Each cannabis cultivation facility, cannabis production facility and cannabis sales facility shall submit the report required pursuant to NRS 372A.285 to the Board on or before the 30th day of each January, April, July and October containing information concerning the 3 months immediately preceding the date of the report. Each cannabis cultivation facility, cannabis production facility and cannabis sales facility shall submit such a report regardless of whether any purchases or sales have occurred.

Whether by regulation or by legislation, the quarterly reporting requirements **could be** expanded to include information pertaining to accounts receivables and/or accounts payables along with the existing financial information that must be submitted in these reports.

The CCB's <u>mission</u> is to govern "Nevada's cannabis industry through strict **regulation of all** <u>areas</u> of its licensing and operations, protecting the public health and safety of our citizens and visitors while holding cannabis licensees to the highest ethical standards."

Yet, by failing to address delinquent payments by regulation, we are <u>creating an environment</u> that "increases illicit activity, hurts small and minority owned businesses and increases public safety risks."

As we prepare for next month's workshop on Disciplinary Actions and further define what constitutes a violation, it is worth noting that the CCB's current descriptions and categories of violations outline activities that: disqualify a person from licensure, that create a present or potential threat to public health or safety, that create a climate conducive to abuses, and that are inconsistent with the orderly regulation of the sale or production of cannabis.

Understanding that many cannabis establishments are opposed to additional regulatory oversight to address the collections crisis our industry is facing, a significant portion of our membership is interested in finding ways to create a regulatory environment that promotes a greater level of accountability and transparency.

Therefore, I kindly request that the CCB consider soliciting industry feedback on this critical topic and to provide the industry with guidance on if/how it plans to address this feedback.

Thank you,

Abby Kaufmann Chamber of Cannabis - Secretary, Board of Directors CRB Monitor - Sales Executive abigailkaufmann94@gmail.com