



August 2, 2022

DCC Legal Affairs Division
Department of Cannabis Control
2920 Kilgore Road
Rancho Cordova CA 95670

Submitted via Electronic Mail: publiccomment@cannabis.ca.gov

RE: Comments regarding notice of proposed rulemaking to adopt regulations for standard cannabinoids test method and standardized operating procedures, and notice of proposed rulemaking to adopt regulations for large cultivation licenses and conversion to large and medium licenses

To Whom it May Concern:

The California Cannabis Industry Association (“CCIA”) is one of the state’s largest cannabis trade organizations, representing over 400 operators and ancillary business members. CCIA respectfully submits these public comments to the Department of Cannabis Control (“DCC” or the “Department”).

- Section 1 summarizes CCIA member feedback on the *Proposal to adopt regulations for standard cannabinoids test method and standardized operating procedures* released on June 17, 2022.
- Section 2 summarizes member feedback on the *Proposal to adopt regulations for large cultivation licenses and conversion to large and medium licenses*, also released on June 17, 2022.

Before we address our specific recommendations, we want to reiterate our desire to be more productively engaged in the rulemaking process. While the public comments are meaningful, we believe that we can have a more fruitful collaboration if the Department solicits industry earlier on.

The draft changes to the testing regulations underscore the value and importance of stakeholder input. CCIA’s Quality Control Committee -- which includes numerous

chemists, product makers, and other scientific experts -- has identified a number of serious issues with the Cannabinoids Test Method, issues that could significantly impact public safety.

Chief among these concerns is the requirement that laboratories use a single method to test all product types. As currently drafted, this regulatory limitation could result in the **underreporting** of THC potency for some products, like gummies, hard candies, fruit chews, and beverages, an outcome we know the Department and industry both wish to avoid.

Specifically, the proposed preparation method fails to account for the ever expanding number of products in the regulated California cannabis market, ranging from traditional flower to transdermal patches to nano emulsified beverages. Historically, licensed cannabis testing labs have developed specialized extraction techniques to accurately measure the cannabinoid content of different types of products. The proposed rules will eliminate this flexibility and may result in inaccurate test results that grossly underestimate the potency of edibles in particular.

We are also concerned that several new requirements will impose an unnecessary financial burden on the industry while failing to provide a tangible benefit to the Department or public. This includes changes related to tissue homogenizers, cryomills, and Laboratory Quality Control samples. The proposed sample preparation requirements, for example, could add hundreds of thousands of dollars in operational overhead. Other rules that require labs to run concentrate samples twice to satisfy the 1mg/g reporting limit and bring high potency vapes within curve range would also add significant expense.

We would like to note that the authorizing language in SB 544 (Laird, 2021) affords the Department the flexibility to establish more than one method for testing. SB 544 amended [BPC 26100 as follows](#):

(f) (1) Standards for residual levels of volatile organic compounds shall be established by the department.

*(2) On or before January 1, 2023, the department shall establish a standard cannabinoids test method, including standardized operating procedures, that shall be utilized by all testing laboratories. **The department may establish more than one method for use by testing laboratories and these standards may be developed through a reference laboratory.***

We strongly encourage the Department to exercise this authority, which will provide additional flexibility to utilize equivalent testing methods. We also recommend that the

Department incorporate mechanisms into the regulations to allow for greater flexibility if and when more reliable cannabinoid test methods are identified.

Additional comments and recommendations are outlined below.

Section 1: Comments on Proposal to Adopt Regulations for Standard Cannabinoids Test Method and Standardized Operating Procedures

Test Method for Cannabinoids

§15712.1(a): *“Notwithstanding section 15712, a licensed laboratory shall utilize the cannabinoids test method required by this section.”*

Comment: Rather than specifying a specific method, we suggest that this section allow licensed laboratories to utilize either the cannabinoid test method required by this section or a cannabinoid test method that has been demonstrated to be equivalent. Alternatively, we recommend limiting this requirement to flower and concentrates.

§15712.1(b): *“The licensed laboratory shall use Determination of Cannabinoids Concentration by HPLC, Standard Operating Procedures (New 05/15/2022), which is incorporated by reference herein, to perform the cannabinoid content analysis required by section 15724.”*

Comment: Again, we suggest that this section be amended to allow licensed laboratories to use the described method or a method that has been demonstrated to be equivalent.

§15712.1(c): *“The cannabinoid test method identified in subsection (b) shall not be altered by the licensed laboratory.”*

Comment: We support the Department’s stated goal to “to prevent changes to the procedure that may render it less accurate and reliable.” However, we recommend amending this language so that laboratories are not prevented from introducing procedures that improve the accuracy and reliability of cannabis testing results.

§15712.1(d): *“Notwithstanding the requirements of section 15724(a), the licensed laboratory shall analyze the sample size of the representative sample as indicated by the cannabinoid test method identified in subsection (b).”*

Comment: We oppose the proposed changes to the sample mass requirements.

The cannabinoid test method has a narrow calibration range and allows for variable sample dilution. The existing regulatory sample minimum preparation mass can be used with the cannabinoid test method especially if the extraction solvent volume is lowered or left up to the labs.

Verification of Test Method for Cannabinoids.

§15712.2.(c): *To complete the method verification of a cannabinoid test method identified in section 15712.1(b), the laboratory shall address the criteria listed in the following table:*

Criteria	Number Required	Notes
Sample matrices	≥1	A single matrix can be selected even if the original method is applicable to multiple matrices
Matrix blanks	≥1	
Method blanks	≥1	
Spike concentration levels	≥2	
Spike replicates	≥3	

Comment: The matrices used during the validation of this method are not readily available. We request that the Department provide the full validation report so that laboratories are able to select a validated matrix. Additionally, the term “Matrix blank” is used here, but not defined. We ask that the Department provide a definition for this term or remove it. And, finally, there is no recommendation as to what the “Spike concentration levels” should be. This information is needed to verify the specified LOQ and upper end of the calibration curve.

§15712.2.(f): *“The licensed laboratory shall generate a verification report for each cannabinoid test method used. Each verification report shall include the following information:”*

Comment: This section implies that more than one method can be used. We appreciate this language but it is inconsistent with guidance provided elsewhere.

Standard Operating Procedures

General: *“ppm”*

Comment: “ppm” is used throughout the document but is undefined. We suggest

standardizing on the use of either “µg/g” or “µg/mL” as appropriate in place of “ppm” to remove ambiguity.

Definitions. 14. Reporting Limit: *“Reporting Limit(RL) means the lowest concentration at which an analyte can be detected in a sample in each analytical batch. RL for each batch of samples are determined by multiplying the lowest concentration of the working calibration standard 0.5 ppm by total dilution factor, depending on the samples.”*

Comment: This definition is incorrect because “the lowest concentration at which an analyte can be detected in a sample in each analytical batch” is the Limit of Detection rather than the Reporting Limit. The meaning of “Depending on the samples” is also unclear and should be clarified in the definition or elsewhere in the document.

Definitions. 4 & 6: HPLC vs. LC

Comment: We question why LC is defined exclusively as LC Column and LC Parameters. We recommend referring to these instead as “HPLC Column” and “HPLC Parameters.”

Apparatus and Materials. (II)(A): *“HPLC equipment, consisting of a column module, solvent delivery module, photodiode-array detection module and sampling module that is capable of separating the cannabinoids of interest to achieve a minimum resolution of 1.3”*

Comment: The DCC validation reports indicate that this method does not separate peaks with a minimum resolution of 1.3. We therefore ask that the resolution requirement be removed.

Apparatus and Materials. (II)(E): *“Disposable glass Pasteur pipette”; “F. Pipettes and pipet tips”; “J. Ice bucket”; “R. Griffin glass beakers”; “S. Graduated cylinder”*

Comment: There are no further references in the document to these pieces of equipment, so it is unclear why they are included. If they are not strictly required, they should be removed. Additionally, “pipet” should be changed to “pipette” for consistency.

Apparatus and Materials. (II)(K): *“HPLC vials, amber”*

Comment: It is unclear why amber vials are specified. If clear vials were found to be unsuitable, we ask that the Department share the reason.

Apparatus and Materials. (II)(M): *“LC Column capable of separating the cannabinoids of interest to achieve a minimum resolution of 1.3”*

Comment: Again, the DCC validation reports indicate that this method does not separate peaks with a minimum resolution of 1.3. Therefore, we ask that the resolution requirement be removed.

Apparatus and Materials. (II)(P): *“HPLC solvent bottles, 1 L”*

Comment: It is unclear why a 1L solvent bottle is specified. Some testing laboratories use 4L bottles; 2L bottles are also common. Laboratories should be allowed to select the appropriate bottle-size for their instruments.

Apparatus and Materials. (IV)(B)(4): *“Working Standard (D): Prepare 10 ppm cannabinoids mix working standards for Initial Calibration Verification (ICV) (D) by appropriate dilution of the 100 ppm solution from Section IV.B.3 using acetonitrile/methanol (80:20) as diluent.”*

Comment: It is unclear why this section specifies that a 10 ppm ICV is prepared from a 100 ppm working standard. Labs should be able to prepare an appropriate concentration ICV directly in order to reduce waste and cost. Additionally, aprotic solvents like acetonitrile are preferable to protic solvents like methanol for diluting cannabinoid standards as the decarboxylation of acidic cannabinoids is an acid catalyzed process and proceeds more slowly in aprotic solvents. And, finally, the appropriate preparation of calibration standards is integral to ensuring accuracy. A complete procedure should be given here specifying appropriate methods to prepare the standards.

Apparatus and Materials. (IV)(C): *“Calibration standard solutions: Prepare 0.5, 2, 5, 10, 20, 50 and 100 ppm calibration standard solutions as follows:”*

Comment: The calibration range from 0.5 to 100 ppm is unnecessarily narrow. A wider calibration range (or leaving calibration range up to the laboratories) will allow for more efficient and lower cost analysis and minimize the need to re-dilute samples.

Procedure. (V)(B): *“Sample Preparation: Group samples by type (e.g., plant material, juice, hemp oil, chocolate, hard candy, gummy and cookie).”*

Comment: It is unclear what this means or why this is necessary. We recommend that the Department expand on exactly how samples should be

grouped by type and why that is necessary.

Procedure. (V)(B)(1): *“For plant material, use a tissue homogenizer or grinding device which can grind the samples to less than 1 mm, following the manufacturer’s instructions.”*

Comment: It is not clear why the particle size needs to be less than 1mm for complete extraction. (Nor is it clear how the particle sizes of homogenized samples were measured in the DCC’s validation data.) Measuring the size of every particle in a homogenized sample is unrealistic and unnecessary to achieve accurate results. We ask that this requirement be removed.

Procedure. (V)(B)(1): *“For chocolate, hard candy, gummy and cookie samples, use a cryogenic grinder which can grind the samples to less than 1 mm, following manufacturer’s instructions.”*

Comment: : A cryogenic grinder and the associated consumable cryogenic liquid or solid is expensive to purchase and operate. Labs can homogenize flower, chocolate, and hard candy more efficiently by other means and should be allowed to do so.

Procedure. (V)(B)(2): *“From the homogenized composite sample, weigh the appropriate amount of sample, indicated below, that corresponds to the sample type into a labeled 50 ml centrifuge tube and record the weight.”*

- *Plant material/concentrate/vape oil: 200 mg.*
- *Cannabis infused oil: 0.5 g.*
- *Chocolate/hard candy/gummy/cookie/other edibles: 2 g.*
- *Juice/water/beverage: 5 ml.*

Comment: The instruction to **weigh** a sample is inconsistent with the requirement to report that sample weight in mL. We recommend that beverages be assigned a mass target rather than a volume target. Additionally, a 50 mL centrifuge tube is overly restrictive. The SOP should note an appropriate extraction vessel and merely give the example of a 50 mL centrifuge tube.

Procedure. (V)(C)(1): *“Sample Extraction: Add 40 ml extraction solvent to the 50 mL centrifuge tube with the sample”*

Comment: 40 mL is a needlessly large volume of extraction solvent for the sample masses specified previously. As further dilution of the sample is necessary it would be better to reduce this amount to a maximum of 20 mL or

allow the labs to choose an appropriate volume in order to reduce both hazard waste and unnecessary expense.

Procedure. (V)(C)(2): *“Vortex each centrifuge tube for 1 minute to mix the sample and extraction solvent well.”*

Comment: The new requirement that labs use a multi-tube vortex mixer may be unduly expensive for some testing laboratories. We ask that the department allow equivalent procedures and equipment to be used to extract samples.

Procedure. (V)(C)(4): *“Centrifuge to 3900 rpm for 15 minutes.”*

Comment: Centrifugation is not necessary for sample extraction and should not be required. The purchase and maintenance of this equipment will create an undue burden and expense. The 3900 rpm number is also needlessly precise.

Procedure. (V)(C)(5): *“Take approximately 1.5 ml of the supernatant and filter through a 0.2um PTFE filter into an HPLC vial.”*

Comment: Filtration should be used in place of, rather than in addition to, centrifugation. We ask that this language be amended to allow one or the other. Additionally, an HPLC vial is not necessarily the best vessel for this purpose as its narrow neck makes it difficult to extract samples from. A microcentrifuge tube is an example of a container that may work better. The SOP should be re-written to replace “into an HPLC vial” with “into an appropriate container, for example an HPLC vial or microcentrifuge tube.”

Procedure. (V)(C)(6): *“Dilute the sample extract to obtain expected concentration within the range of the calibration curve used for the analysis. The expected concentration can be calculated based on labels of samples or past experience on similar samples.”*

Comment: Sample dilution is a critical step to ensure accuracy, therefore specific requirements for dilution should be included. In addition, the use of a surrogate compound to correct for any errors on dilution should be explicitly allowed as it improves method accuracy.

Procedure. (V)(C)(7): *“If the concentration is found to be out of the calibration range, make adjustments of the dilutions to obtain expected concentration within the range of calibration curve and re-analyze the sample. This step should be repeated until the concentration is within the range of calibration curve.”*

Comment: We ask that this section be amended to clarify that the intent is to dilute samples to bring the highest concentration cannabinoid into the range of the calibration curve.

Procedure. (V)(D)(1): *“Instrumental Parameters: 1. LC Column: Restek Raptor ARC-18 2.1 x 150mm, 2.7um or an equivalent column that can separate the cannabinoids of interest to achieve a minimum resolution of 1.3.”*

Comment: The DCC validation reports indicate that this method does not separate peaks with a minimum resolution of 1.3 therefore the resolution requirement should be removed. Additionally, 220 nm is a poor wavelength choice for all analytes. Laboratories should be allowed to choose the best wavelength for each analyte.

Procedure. (V)(E)(1): *“Equilibrate the HPLC system with the mobile phases for at least 30 minutes.”*

Comment: There is no valid reason to specify a 30-minute equilibration and we ask that this time frame be removed. For clarity, the word “equilibrate” specifies the condition to be met, which typically happens in less than 30 minutes. Requiring a full 30-minutes will create additional hazardous waste and added expense.

Procedure. (V)(E)(2): *“Inject the standards used to generate the seven-point calibration curve and the Initial Calibration Verification (ICV).”*

Comment: This language implies that a calibration curve and ICV must be run with every set up sample. This is not necessary for a functioning HPLC. Requiring calibration of the instrument with every batch of samples will be overly costly and burdensome, generate excess hazardous waste, waste time, and increase cost to the industry with no demonstrable benefit to accuracy.

Procedure. (V)(E)(3): *“1 post-dilution spiked sample.”*

Comment: This sample is not required by the regulations and has no acceptance criteria. This sample should be removed or made optional in the SOP.

Procedure. (V)(E)(4): *“After every 10 injections, re-inject a check standard using one of the calibration standards and a blank for quality control purpose.”*

Comment: This requires a “blank” injection but does not define what that is, how

it is prepared, how it is analyzed, and what its acceptance criteria are. “Blank” is not a defined or required LQC sample in the regulations. This should be made optional or omitted.

Procedure. (V)(E)(5): *“At the end of the run, re-inject a check standard (section VI.3) using one of the calibration standards and a blank for quality control purpose.”*

Comment: Again, this requires a “blank” injection but does not define what a blank is, how it is prepared, how it is analyzed and what its acceptance criteria are. “Blank” is not a defined or required LQC sample in the regulations. This should be made optional or omitted.

Procedure. (V)(E)(6): *“Store samples and Standards in the HPLC autosampler or a refrigerator in dark at 4°C.”*

Comment: Requiring refrigeration to be “in the dark” and at 4C is unnecessary.

Method Limit of Quantification (LOQ) and Reporting Limit (RL). (VI): *“The calibration standard range is from 0.5 to 100 ppm.”*

Comment: The laboratory should be allowed to determine its own low limit to the calibration range and resulting reporting limit. Absent that, we’d like to understand how these LOQs and LODs are determined and what these values correspond to in-sample.

Quality Control. (VII)(A)(1): *“Solvent Blank to determine that the instrument system is clean and free of contamination. The solvent blank is the same as the dilution solvent (acetonitrile/methanol (80:20)).”*

Comment: A solvent blank is not required by California Code of Regulations, title 4, section 15730. A solvent blank does not give additional information that a passing method blank lacks making this an unnecessary requirement that will increase cost, time, and the production of hazardous waste. There is no reason that a solvent blank should always be paired with an ICV or CCV.

Quality Control. (VII)(A)(2): *“Initial Calibration Verification (ICV) prepared from a set of cannabinoids CRMs from a second source, to check whether the calibration standards are good. ICV should fall within +/- 30% of the expected value of 10 ppm.”*

Comment: This is a new requirement. There is no reason to run an ICV with every batch of samples given that the regulations already require an ICV with

each calibration. Additionally, the ICV concentration should not be arbitrarily set at 10 ppm but should be set by the laboratory (just as the CCV concentration is suggested but not required to be 50 ppm).

Quality Control. (VII)(A)(3): *“Continuing Calibration Verification (CCV) using established calibration from Section IV.D.2. Check the calibration of the instrument at every 10th injection by analyzing one of the calibration standards (e.g. 50 ppm). CCV should fall within +/- 30% of the chosen calibration standards concentration.”*

Comment: The reference to “Section IV.D.2” should be to “Section IV.C” or possibly “Section IV.C.1” to be more restrictive. Also, we question why 10 ppm is required for the ICV and 50 ppm recommended for the CCV.

Quality Control. (VII)(A)(4): *“Actions to take when quality control failures occur are specified in California Code of Regulations Section, title 4, 15730(f), which include the frequency of calibration when CCVs fail.”*

Comment: California Code of Regulations Section, title 4, 15730(f) does not specify acceptance criteria or corrective actions for “blank,” “solvent blank,” “ICV,” or “post-dilution spiked sample.” These samples should not be required when there is no guidance or requirement on how they are used.

Quality Control. (VII)(B): *“Every sequence/sample batch processed should include at least 1 method blank, 1 laboratory control sample (LCS), 1 sample duplicate and 1 matrix post-dilution spike.”*

Comment: “Sample duplicate” should be referred to as “Laboratory Replicate sample” in reference to California Code of Regulations Section, title 4, 15730. “Matrix post-dilution spike” is not included in California Code of Regulations Section, title 4, 15730 and thus cannot be required here. Additionally, California Code of Regulations Section, title 4, 15730(d)(3) requires a laboratory replicate sample or a matrix spike sample. It is inappropriate and conflicting to require both in this SOP.

Quality Control. (VII)(B)(1): *“A Method Blank is used to determine that no contamination resulted from sample extraction procedures. Use Deionized (DI) water as the method blank for juice sample matrices and follow the same extraction procedures. For all other cannabis matrices, use 40ml extraction solvent as the method blank.”*

Comment: This definition conflicts with California Code of Regulations Section, title 4, 15700 (oo). Additionally, it is inappropriate to specify the

volume of extraction solvent to use here. Specifying 40mL to fill, at max, a 2 mL vial represents an unnecessary waste of materials and the needless creation of hazardous waste.

Quality Control. (VII)(B)(2): *“A Laboratory Control Sample (LCS) is a blank matrix to which known concentrations of each of the target method analytes is added. The LCS is analyzed in the same manner as the representative sample. Cellulose powder is used as a blank matrix for this method and a mixture of 9 cannabinoids (CRM) at known amount is spiked into the blank matrix. Recovery of the LCS must be 70-130% of the spiked amount.”*

Comment: The specific procedure for creating a LCS should be included here. To purchase a set of the 9 standards outlined in the DCC SOP from cerilliant is \$1,103.40 and can be used to make 10 mL of 100 µg/mL mixed standard. The additional calibration levels are made from this. From one set of standards 5 mL of each of the 7 levels can be prepared. If we use 250 µL in vial inserts that is 20 sets of calibration standards. If a lab is running 10 sample batches per day that is: \$1,103.40 per 20 sets. This is an overly burdensome cost with little impact on the quality of data.

Quality Control. (VII)(B)(4): *“A Matrix Post-dilution spike is used to evaluate the effects of sample matrices on the performance of the analytical method. A post-dilution spike is used because, given the limit of concentrated cannabinoids stock standards, matrix spike is not applicable. Prepare the post-dilution spike by spiking known amount of cannabinoids mix standards into the diluted samples. The recovery must be 70-130% of the spiked amount.”*

Comment: The DCC correctly states that “given the limit of concentrated cannabinoids stock standards, matrix spike is not applicable.” However, it appears that that is exactly what is required above for LCS. We request that this requirement be stricken.

Quality Control. (VII)(C):

Comment: The chromatographic method listed in this SOP has analyte co-elution issue with many naturally-occurring cannabinoids. This will require, on the basis of poor chromatography herein, much manual intervention in integration. This will make documenting manual integrations more expensive and will likely result in laboratories opting for less reliable automatic integration in order to save time and money. The validation undertaken by UCSD CMCR shows many examples of poor automatic integrations. This requirement should be struck from the SOP.

Quality Control. (VII)(D): Retention Time (RT) Acceptance Window

Comment: The retention time acceptance window should not be based on calibration standard retention times in the same run because calibration standards should not be required to be run with each batch of 20 samples. It would be better to base the retention time acceptance window on the average of the CCV retention times which run throughout the sequence.

Acceptance Criteria for Quality Control Samples. (VIII)

Comment: Not all quality control samples in this SOP are covered by California Code of Regulations, title 4, section 15730. Only LQC samples are defined by California Code of Regulations, title 4, section 15730.

Reporting Results. (IX)(B): *“Results for all samples shall be reported with 3 significant figures.”*

Comment: The appropriate number of significant figures used for reporting results is a function of the method itself. We believe that it is inappropriate to state a requirement that “all samples shall be reported with 3 significant figures.” when there are cases, especially for very small values where this is inappropriate. For example if the THC concentration of a sample is 1.01 mg/g and the reporting limit is 1 mg/g it would be appropriate to report 1 mg/g. It might be better to specify a decimal place to which values should be report e.g. “cannabinoid concentrations should be reported to the nearest 0.1mg/g.”

Reporting Results. (IX)(C): *“Results that are below the reporting limit determined in Section VI are reported as “<RL”.*

Comment: This conflicts with California Code of Regulations, title 4, section 15724 (f). We ask that the discrepancy be resolved.

Statement of Reasons.

“Through validation, the Department has determined the listed methods for homogenization to be the most effective in obtaining accurate and reliable test results based on sample type.”

Comment: We recommend that this data be made publicly available for review by all relevant stakeholders.

“The Department has determined however, through validation of the method, that the 0.5 gram sample size is not optimal for all cannabinoid matrices and has determined that the sample sizes specified in the SOP will yield the most accurate test results for the various matrices.”

Comment: We recommend this data be available to the public for review, as further clarity is desired in how the optimum sample size was determined, especially given that variable sample dilution is allowed.

“Proposed subsection C, Sample Extraction, of the Procedure section provides the specific instructions for sample extraction, including specifying the extraction solvent and dilution based on the sample matrix. The Department has determined through method validation that the specified extraction solvent and dilution provide optimal results. This is necessary in order to achieve the most accurate test results for the various matrices.”

Comment: We request additional clarification on how the optimum extraction solvent and dilutions were determined.

“The provision clarifies that the instrumental parameters will be specific to the column and LC system used by a licensed laboratory, thus the system used by a licensed laboratory may have different parameters to include in its specific SOP. The provision clarifies that an equivalent HPLC system is one that separates the cannabinoids tested with a minimum resolution of 1.3. This gives laboratories flexibility in utilizing a variety of HPLC systems with a clear requirement to guide them. The Department has determined that the instrumental parameters are optimal for the accuracy, precision and overall quality of results for the cannabinoid testing method.”

Comment: This less prescriptive language allowing for different HPLC hardware and columns should be extended to allow for additional mobile phases as well as injection volume used for the method.

“This provision also provides the method for determining the Reporting Limit for each batch of samples. This is necessary to accommodate the change in the smallest amount of an analyte that can be reported in analysis by the licensed laboratory in a particular batch of samples. Dilution of samples is routinely done to correctly quantify cannabinoids within the calibrated range of the instrument. After dilution, the amount that can be effectively reported is no longer directly determined by the method LOD or LOQ. Dilution must be accounted for in the final result and the mechanism to accurately reflect this change in the reported final result is with a Reporting Limit.”

Comment: The wording around dilutions is confusing. Furthermore, we are

unclear on how to proceed with establishing LOD/LOQ.

“Proposed subsections A and B of the Quality Control section provides a detailed explanation and instructions on the use of quality control samples with sample batches, including solvent blanks, ICV, CCV, method blanks, sample duplicates, post-dilution matrix spikes and laboratory control samples. This is necessary in order for the licensed laboratories to have step by step instructions regarding the use of quality control samples, understand their purpose, and meet requirements of section 15730 for the use of laboratory quality control samples. The levels chosen are consistent with section 15730 and based on standards from the FDA. This is necessary to ensure all licensed laboratories are following the same quality control procedures in order to consistently produce valid and reliable results.”

Comment: Solvent blanks and post-dilution matrix spikes QC samples should not be utilized until more adequately defined.

“This provision provides if the impurity and the cannabinoid spectrums are mixed, the spectra may be deconvolved and reported following the requirements for manual integration set forth in section VII.C. This is necessary to ensure that cannabinoid test results are accurately reported. Peak purity used in conjunction with other Quality Controls is used to give an indication of validity of the method.”

Comment: CCIA and our laboratory partners across the industry would like an example of this deconvolution.

“Reporting limit is the lowest concentration at which an analyte can be detected in a sample in each analytical batch and is necessary for the accuracy of the results report so that the customer can better understand the results.”

Comment: “... the lowest concentration at which an analyte can be detected in a sample in each analytical batch” more accurately describes a Limit of Quantitation (LOQ).

Section 2: Comments on Proposal to Adopt Regulations for Large Cultivation Licenses and Conversion to Large and Medium Licenses

General.

Concern: It would be helpful if the DCC could provide additional clarity about whether applications and conversion notification will open prior to January 1, and, if so, on what timeline? Likewise, does the DCC expect that Metrc functionality and implementation to accommodate Type 5s will occur on or before January 1?

§ 16300.1. Cultivation Requirements for Large Licenses.

Concern: We were disappointed to see the proposed regulations outline additional restrictions on the type of licenses that Large Cultivation licensees can hold. More specifically, the prohibition from holding a Type 11 distributor license. While we recognize that this prohibition was included in Proposition 64 and is, therefore, not something the DCC can address in regulations, we wish to note that we are exploring a legislative solution to amend MAUCRSA to remove this restriction as soon as reasonably possible.

§15027.1. Metrc.

Concern: This section is lacking clarification about how licensees who are transferring license types should handle Metrc plant tag requirements. Specifically, it is not clear whether licensees will be able to transfer existing Metrc plant tags from the old licenses to the new converted license, or whether the DCC will require the licensee to retag all plants on the new large cultivation license. Furthermore, thirty days is not enough time to order new tags, receive new tags, and retag every single plant within a large cultivation license.

Recommendation: Provide clarification on Metrc plant tag requirements and allow 60 days to implement the Metrc requirement as a result of this license conversion process.

§15027.1(d). License Fee Payments.

Concern: The text says the associated license fee must be paid within 30 days. This time frame is not consistent with other fee payment timeframes, which is 60 days. There is a significant amount of planning and preparation that a licensee must do in order to make the operational changes necessary to effectuate these license changes.

Recommendation: Change number of calendar days to pay to 60 calendar days to be consistent with other fee payment deadlines.

In closing, we value our relationship with the Department and appreciate the effort you have dedicated to developing a functional and adaptive, regulated cannabis market. We look forward to building more robust engagement so that we can continue to provide on-the-ground experience in furtherance of a safe and thriving industry.

Respectfully,

A handwritten signature in cursive script that reads "Lindsay Robinson". The signature is written in black ink and is positioned above the printed name.

LINDSAY ROBINSON
Executive Director