Department of Cannabis Control
California Code of Regulations Title 4, Division 19

Standard Cannabinoids Test Method and Standardized Operating Procedures for All Licensed Commercial Cannabis Testing Laboratories

Addendum to Final Statement of Reasons

The Department hereby incorporates this addendum to its Final Statement of Reasons as part of the rulemaking record.

Update to Summary of Comments Received During the 45-Day Comment Period

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
15712.1(h)	208, 209, 214, 215	Commenters state the proposed implementation date of July 1, 2023, with a 6-month lead time does not allow sufficient time to purchase additional equipment and reagents, implement the methodology and make the required personnel and workflow changes to ensure compliance for small minority owned businesses. Commenters request the Department of Cannabis Control change the effective date for new potency testing from July 1, 2023, to October 1, 2023, to allow sufficient time to execute the required changes.	The Department agrees in part with this comment. The regulation will not go into effect on the date that they are approved by the Office of Administrative Law and filed with the Secretary of State. Rather, it will be effective on the quarterly date applicable for the time it was filed with the Secretary of State. If approved and filed between June 1 and August 31, they will be effective on October 1. Licensees must begin complying with the regulation no later than 3 months after the effective date which will be January 1, 2024. Laboratories only need to verify the test method, which has now been restricted to dried flower, including pre-rolls, and utilizes equipment that is used by most licensees already. The standardized test method for the determination of cannabinoids concentration was developed and validated by the Department's cannabis testing laboratory which is ISO/IEC 17025 accredited for the cannabinoids test method. The test method was also subject to further

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			testing and validation for its use in dried flower, including pre-rolls, by the University of California San Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. Although dried flower has been tested and analyzed in research facilities for many years, cannabis products are widely varied and rapidly developing. After considering the robust comments related to the applicability of the method to infused cannabis products, the Department has determined that additional time for further research and development related to the appropriate standardized method for the testing of cannabis products would be beneficial. As a result, the Department has limited the applicability of the method to dried flower, including pre-rolls. The Department looks forward to working with stakeholders on the development of new test methods in the future.
15712.2	94	Commenter states that there are currently 3 acceptable options listed for calculating LOD and 3 accepted options for calculating LOQ in section 15731. Commenter asks which of the methods listed in 15731 were used to determine the reported LOD and LOQ values listed in section 15712.2.	The Department agrees with this comment. As indicated in the method validation data, LOD samples were prepared by spiking 20 µg of cannabinoids to blank matrix (cellulose powder). The samples then went through all sample prep procedures following the SOP. The concentration of these samples was equivalent to 0.1 mg/g in flower sample and 0.5 ppm

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			in vial. 0.5 ppm is also the lowest calibration point. 7 LOD sample replicates were prepared separately and were run in one sequence. The LOD was calculated from the standard deviation with the formula: LOD = t x S, where t=3.14 for 7 replicates at 99% confidence level. LOQ = 3 x LOD. The LOQ should be within the calibration curve and it should be 1.0 mg/g or lower for all cannabinoids analyzed and reported. The Department's method validation data is part of the rulemaking file and can be accessed on the Department's website or provided upon request to the Department.
15712.2	578, 581	Commenter states that the test method results in low precision (high RSD%) for some of the matrices, insufficient homogenization for concentrate oils, and is unable to detect minor cannabinoids with such high dilution factors, and concerns that the smaller sampling size for flower and concentrates may lead to a representative same causing large variations in recorded values. Commenter states to detect major and minor cannabinoids at such high dilution factors they will need to run two separate runs at two different dilutions.	The Department agrees in part with this comment. The standardized test method for the determination of cannabinoids concentration was developed and validated by the Department's cannabis testing laboratory which is ISO/IEC 17025 accredited for the cannabinoids test method. The test method was also subject to further testing and validation for its use in dried flower, including pre-rolls, by the University of California San Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. Although dried flower has been tested and analyzed in research facilities for many years, cannabis

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			products are widely varied and rapidly developing. After considering the robust comments related to the applicability of the method to infused cannabis products, the Department has determined that additional time for further research and development related to the appropriate standardized method for the testing of cannabis products would be beneficial. As a result, the Department has limited the applicability of the method to dried flower, including pre-rolls. The Department looks forward to working with stakeholders on the development of new test methods in the future.
SOP Definition	323, 484	Commenters indicate it is unclear why LC is defined and only used as LC Column and LC Parameters instead of calling them “HPLC Column” and “HPLC Parameters”. Commenter requests that either “LC” or “HPLC” be used but not both.	The Department agrees with this comment. The definition for “LC” has been deleted and all references to “LC” have been replaced with “HPLC”.
SOP (V)(A)(2)	234, 235, 333, 382, 384, 438, 441, 442, 439, 461, 465, 490, 541, 563	Commenters state the current language to describe the ICV appears to be subjective, referring to check whether calibration standards are ”good.” Commenters suggest updating language to read “ICV prepared from a set of cannabinoids CRMs from a second source, to ensure the calibration curve is valid for quantifying unknown samples.” Commenters suggest that the updated language will be useful in citation of why compliance is needed, for enforcement purposes, as well as more accurately describing the ICV to labs. (ICV required per 15730 & defined 15700(z).) Commenters state the ICV concentration should not be set at 10 ppm but should be allowed to be chosen by the laboratory. Commenters suggest amending dilution amount to 100-600 ppm and allowing methanol only as diluent. Commenters further recommends deleting references to .5, 2.5, and 10 ppm to less than 10 ppm	The Department agrees with this comment and has clarified the definition of an ICV. Initial Calibration Verification (ICV) is defined as prepared from a set of cannabinoids standards from a source external to the laboratory and different from the source of the calibration standards, to check whether the calibration curve is valid. ICV should fall within +/- 30% percent recovery of the expected value of 10 ppm. The SOP has been updated to replace “good” with “valid.” The purpose of the ICV is to ensure the calibration curve is valid prior to use. Laboratories may use ICV of other

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		and adding methanol only as diluent.	concentration than 10 ppm or use another dilution scheme. The sections regarding calibration standards as written provide licensees with clarity and direction, thus additional edits are unnecessary.
SOP (V)(C)(7)	452	Commenter suggests the Department add the word "suggested' to dilution in the table so it reads "suggested dilution".	The Department disagrees with this comment. The word "typical" in the SOP and the word "suggested" given by the commenter are synonyms. The table has been removed from the SOP and replaced with a statement in SOP (V)(C)(6), which explains that the laboratory should dilute based on label claims. This clearly implies that dilutions are at the laboratory's discretion.
SOP (V)(E)(3)	230, 514	Commenter suggest referring to "Sample Duplicate" as "LRS" for consistency with current regulations i.e. 15730, 15700(gg).	The Department agrees with this comment and has clarified the definition in the method by modifying the proposed SOP. All references to "sample duplicate" were replaced with the defined term, "laboratory replicate sample." A Laboratory Replicate Sample (LRS) measures the precision of the analytical process. Duplicate analysis involves a replicate sample, sub-sampled in the laboratory. Method precision is documented and controlled based on the relative percent difference (RPD). The RPD must meet the acceptance criteria of RPD ≤30% as required by section 15730.
SOP (VII)(C)	529	Commenter states the method appears to be validated for a very small sample throughput. Licensed labs are facing much higher throughput of samples. Commenter states the method will work insufficiently in real-life conditions	The Department disagrees in part with this comment. The standardized test method for the determination of cannabinoids concentration

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		compared to ideal validation conditions, slowing down testing time and impacting customer satisfaction. Commenter also states the method would have serious negative, unintended consequences for the production, testing, sale, and consumption of infused products.	was developed and validated by the Department's cannabis testing laboratory which is ISO/IEC 17025 accredited for the cannabinoids test method. The test method was also subject to further testing and validation for its use in dried flower, including pre-rolls, by the University of California San Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. Although dried flower has been tested and analyzed in research facilities for many years, cannabis products are widely varied and rapidly developing. After considering the robust comments related to the applicability of the method to infused cannabis products, the Department has determined that additional time for further research and development related to the appropriate standardized method for the testing of cannabis products would be beneficial. As a result, the Department has limited the applicability of the method to dried flower, including pre-rolls. The Department looks forward to working with stakeholders on the development of new test methods in the future.
General Comment	15, 418, 419	Commenter states public health and safety demands that the Department authorize more than one sample preparation and extraction method for all of the various product matrices present on the cannabis market today. Therefore,	The Department disagrees in part with this comment. The standardized test method for the determination of cannabinoids concentration was developed and

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		commenter requests the Department consider the following alternatives: Exempt edible, tincture, and topical products from the current proposed rulemaking, and allow laboratories to continue using their existing testing methodologies for these products. The statute authorizes more than one method and does not require the same method apply to all product types but rather to all licensed laboratories. By establishing one method for laboratories to use for cannabis flower and concentrated products and a separate method for laboratories to use for edibles, tinctures, and topicals, the Department could meet their statutory mandate. Commenters also recommend the Department develop standardized microbial testing. Commenter states it is a pressing issue as it is closely related to patient and client overall health. Commenter states protection of health through the standardization of microbial testing is a more pressing issue than inflated potency results.	validated by the Department's cannabis testing laboratory which is ISO/IEC 17025 accredited for the cannabinoids test method. The test method was also subject to further testing and validation for its use in dried flower, including pre-rolls, by the University of California San Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. Although dried flower has been tested and analyzed in research facilities for many years, cannabis products are widely varied and rapidly developing. After considering the robust comments related to the applicability of the method to infused cannabis products, the Department has determined that additional time for further research and development related to the appropriate standardized method for the testing of cannabis products would be beneficial. As a result, the Department has limited the applicability of the method to dried flower, including pre-rolls. Further, while microbial standardization is not part of this rulemaking, the Department looks forward to working with stakeholders on the development of new test methods in the future.

Update to Summary of Comments Received During the First 15-Day Comment Period

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
15712(a), (b)	13, 19, 25, 26, 32, 33, 34, 35, 36, 37, 38, 39, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 65, 72, 73, 83, 84, 85, 86, 87, 88, 89, 90, 92, 93, 108, 109, 110, 142, 143, 162, 163, 165, 166, 167, 168, 169, 187, 188, 189, 190, 191	Commenters indicate that the Department should establish more than one testing methodology as it is authorized to by SB 544. Some commenters request the Department consider establishing multiple methodologies depending on the types of products being tested. Other Commenters state that there are other ways to combat laboratory shopping without sacrificing scientific rigor and creating unnecessary consumer safety consequences. The Department has the statutory authority to adopt more than one testing method. Some commenters assert that there are serious limitations of using methanol to accurately measure the THC in manufactured cannabis products. Variances between cannabis products tested using methanol and those tested with DMSO have been as high as 18%; a variance of that magnitude cannot be tolerated in a scientific endeavor such as potency testing. Being forced to use methanol may result in products that are higher in potency than the COA reports and lead to potentially harmful consequences for consumers. Other commenters assert that requiring laboratories to use methanol as an extraction solvent will result in incomplete recovery of cannabinoids for many edibles. If adopted, this rule would result in an alarming tenfold increase in the amount of THC a standard edible. Edible overdoses are the single greatest cause of emergency room visits due to cannabis and cause public health concerns. Other commenters assert the method works fine on natural flowers and leaf but there is not a scientifically agreed on method for dealing with other kinds of products. Commenters recommend development of other methods across all product categories. Some commenters request the Department prepare an updated impact statement to businesses in response to	The Department disagrees in part with this comment in part. BPC section 26100(f)(2) requires the Department to develop at least one method. The standardized test method for the determination of cannabinoids concentration was developed and validated by the Department's cannabis testing laboratory which is ISO/IEC 17025 accredited for the cannabinoids test method. The test method was also subject to further testing and validation for its use in dried flower, including pre-rolls, by the University of California San Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. Although dried flower has been tested and analyzed in research facilities for many years, cannabis products are widely varied and rapidly developing. After considering the robust comments related to the applicability of the method to infused cannabis products, the Department has determined that additional time for further research and development related to the appropriate standardized method for the testing of cannabis products would be beneficial. As a result, the Department has limited the applicability of the method to dried flower, including pre-rolls. The Department has revised the economic and fiscal impact statement to reflect the applicability of the method to just dried flower, including pre-rolls. The Department looks forward to working with stakeholders on the development of new test

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		their requests for additional testing matrices. Other commenters request the Department partner with other laboratories in the state. Commenters request that a multi-laboratory validation study be conducted or a workgroup be formed to develop additional methods. Other commenters assert that gummies do not dissolve well in methanol and chocolates do not dissolve and homogenize at the same level with the proposed solvent extraction conditions. Other commenters request that additional extractions solvents and procedures be permitted, including water, acetonitrile, dimethyl sulfoxide, isopropyl alcohol, 1-octanol, quenchers.	methods in the future.
SOP Definition 14 - Reagent Blank	146	Commenter states that the definition of Reagent Blank was added to the SOP, but there is no reference to when it is required to be analyzed or the frequency at which it should be analyzed in the Instrumental Analysis or Quality Control sections. Given there are multiple blanks in the SOP (Method Blank, Reagent Blank, Solvent Blank) and that the Reagent Blank and Method Blank serve the same purpose, commenter requests the Reagent Blank be removed from the SOP.	The Department disagrees with the comment. Reagent Blank is required for method verification pursuant to section 15712.2 and is thus defined in section 15712.2. A reagent blank is not required during routine regulatory compliance testing as part of the LQC samples. SOP (VII) Quality Control addresses the required LQC samples for regulatory compliance testing.
SOP Definition 14 – Reagent Blank	114	Commenter states the term “Reagent Blank” is not used anywhere in the document outside of this definition and the table in section 5712.2. Commenter believes this should not be required if a Method Blank is already required. The Method Blank includes all the reagents used in the method and is carried throughout the entire procedure, so the Reagent Blank does not provide any new data and should be removed.	The Department disagrees with this comment. Reagent Blank is required for method verification pursuant to section 15712.2 and therefore is defined in section 15712.2. A reagent blank is not required during routine regulatory compliance testing as part of the LQC samples.
SOP (V)(B)(1)	64, 127, 133, 150	Commenter states that regarding V.B.1, “For juice and oil samples, invert the container 3 or more times to ensure homogeneity of the liquid” commenter recommends adding a step to ensure homogenization of the samples such as, vortexing, shaking (on a shaker table), or sonicating. Commenter indicates that oils are not easily mixed by inversion. Another commenter recommends grouping samples by type: juice, oil, chocolate, etc.	The Department disagrees in part with this comment. The standardized test method for the determination of cannabinoids concentration was developed and validated by the Department’s cannabis testing laboratory which is ISO/IEC 17025 accredited for the cannabinoids test method. The test method was also

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		Commenter states that "juice" was replaced with beverage, but still appears in the section notes.	subject to further testing and validation for its use in dried flower, including pre-rolls, by the University of California San Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. Although dried flower has been tested and analyzed in research facilities for many years, cannabis products are widely varied and rapidly developing. After considering the robust comments related to the applicability of the method to infused cannabis products, the Department has determined that additional time for further research and development related to the appropriate standardized method for the testing of cannabis products would be beneficial. As a result, the Department has limited the applicability of the method to dried flower, including pre-rolls and removed all references to "juice". The Department looks forward to working with stakeholders on the development of new test methods in the future.
CRM	58	Commenters strongly suggest a change to the definition of CRM ("Certified Reference Materials") in the proposed rulemaking document throughout. Across the analytical testing industry, a "CRM" refers to a very specific designation of reference standards for many vendors that provide these materials.	The Department disagrees. CRM is defined in section 15700(o).
General Comment	183, 184, 185, 186	Commenters assert that the method they have developed should be used, and that the implementation and requirement to use the standardized method would not only render all that time, effort, and money spent on their validation squandered and unfairly reduce the requirements for potency for other laboratories in their efforts to obtain annual licenses. Other laboratories would	The Department disagrees with this comment. BPC section 26100(f)(2) requires the Department to develop a standard method for use by all laboratories. The standardized test method for the determination of cannabinoids concentration was developed and validated

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		be held to a vastly lower standard by only having to perform a simple verification on the standardized potency method rather than a full validation.	by the Department's cannabis testing laboratory which is ISO/IEC 17025 accredited for the cannabinoids test method. The test method was also subject to further testing and validation for its use in dried flower, including pre-rolls, by the University of California San Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. Although dried flower has been tested and analyzed in research facilities for many years, cannabis products are widely varied and rapidly developing. After considering the robust comments related to the applicability of the method to infused cannabis products, the Department has determined that additional time for further research and development related to the appropriate standardized method for the testing of cannabis products would be beneficial. As a result, the Department has limited the applicability of the method to dried flower, including pre-rolls. The Department looks forward to working with stakeholders on the development of new test methods in the future.

Update to Summary of Comments Received During the Second 15-Day Comment Period

Section of Regulation	Comment Numbers	Summary of Comments Received During Second 15-Day Comment Period	Department Response
SOP	59	Commenter requests the Department identify (100%) acetonitrile and (100%) methanol as solvent options to add flexibility to the method for different cannabinoids. Methanol is preferred for diluting neutral cannabinoids and acetonitrile is better for dilution of acidic cannabinoids. Commenter also states that amendments be made to require extraction in a warm water (40C) sonicating bath for at least 30 minutes rather than with ice in the water bath.	The Department agrees with this comment in part, and this is why a mixture of acetonitrile and methanol is used to best accommodate both the neutral and acidic cannabinoids. Ice water during sonication is used to avoid any THCA and CBDA degradation due to heat generated by sonication. The standardized test method for the determination of cannabinoids concentration was developed and validated by the Department's cannabis testing laboratory which is ISO/IEC 17025 accredited for the cannabinoids test method. The test method was also subject to further testing and validation for its use in dried flower, including pre-rolls, by the University of California San Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. Shorter times would give incomplete extraction. This would lead to inaccuracies in the reporting of results.
General Comment	54, 58	Commenter states that while the modifications do not remedy all of our previous concerns, commenter recognizes and applauds the Department's efforts to address them. Commenter continues to stress the importance of the testing laboratories' ability to modify or provide a fully validated equivalent method in order to provide the most accurate results.	The Department agrees with this comment.
General Comment	56, 57	Commenter asserts the proposed standard potency method is known in the industry to present numerous performance issues. Without a proper understanding of method performance metrics, the Department cannot know what constitutes acceptable results. Without the multi-laboratory validation	The Department disagrees in part with this comment. The standardized test method for the determination of cannabinoids concentration was developed and validated by the Department's cannabis testing laboratory which is

Section of Regulation	Comment Numbers	Summary of Comments Received During Second 15-Day Comment Period	Department Response
		required to ensure appropriately published data reduction and performance evaluation, the Department will have no basis for accurately determining underperforming laboratories, and thus no basis to discipline these laboratories. Commenter encourages the Department to perform a thorough multi-laboratory validation of its method. The California Cannabis Working Group members are willing to participate directly in this process, assisting the Department in addressing the most glaring performance issues in the process.	ISO/IEC 17025 accredited for the cannabinoids test method. The test method was also subject to further testing and validation for its use in dried flower, including pre-rolls, by the University of California San Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. Although dried flower has been tested and analyzed in research facilities for many years, cannabis products are widely varied and rapidly developing. After considering the robust comments related to the applicability of the method to infused cannabis products, the Department has determined that additional time for further research and development related to the appropriate standardized method for the testing of cannabis products would be beneficial. As a result, the Department has limited the applicability of the method to dried flower, including pre-rolls. The Department looks forward to working with stakeholders on the development of new test methods in the future.

Update to Summary of Comments Received During the Third 15-Day Comment Period

Section of Regulation	Comment Numbers	Summary of Comments Received During Third 15-Day Comment Period	Department Response
15712.2	4	Commenter states that requiring compliance with the method 3 months after the effective date is not sufficient. Commenter requests extending the date to 6 months. Commenter also states that to comply with the method they will need to purchase new equipment and consumables, implement workflows, and ensure quality control measures are being met.	The Department disagrees with this comment. The regulation will not go into effect on the date that they are approved by the Office of Administrative Law and filed with the Secretary of State. Rather, it will be effective on the quarterly date applicable for the time it was filed with the

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			Secretary of State. If approved and filed between June 1 and August 31, they will be effective on October 1. Licensees must begin complying with the regulation no later than 3 months after the effective date, which will be January 1, 2024.