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

Final Statement of Reasons

Subject Matter of Proposed Regulations: Standard cannabinoids test method and standardized operating procedures for all licensed commercial cannabis testing laboratories.

Sections Affected: California Code of Regulations (CCR), title 4, section 15712.1 and 15712.2.

Background

On October 5, 2021, Governor Gavin Newsom signed California Senate Bill 544, which requires the Department of Cannabis Control (Department) to establish a standard cannabinoids test method, including standardized operating procedures, for use by all licensed testing laboratories. The law permits the development of the test method by the Department or through a reference laboratory. The law became effective January 1, 2022 and requires the establishment of one or more test methods by January 1, 2023.

Update To Informative Digest

On June 17, 2022, the Department issued a Notice of Proposed Rulemaking and began a 45-day comment period on the proposed regulations. The Department held a virtual public hearing on August 1, 2022. The Department received hundreds of comments, both oral and written, on the proposed regulations. Based on review of the comments received, the Department determined that there were several sufficiently related changes to the proposed regulations that were necessary to clarify certain sections and provisions. The changes included the addition of definitions of terms such as “Matrix Post-dilution Spike”, “Reagent Blank”, “Solvent Blank”, clarification of the definition of “Method Blank”, removal of the proposed definition of “Reporting Limit” and removal of all references to “Reporting Limit”, removal of all references to “hemp”, all instances of “um” were changed to ““µm”, and “ml” was changed to “mL”. Additional changes included removing the 1L solvent bottle requirement, addition of sentence clarifying that any size reduction equipment capable of grinding samples to less than 1mm could be used for grinding samples, addition of the words “at least” to clarify that labs should vortex a centrifuge tube for at least one minute, and that any method of cryogrinding or size reduction equipment is acceptable provided it can grind the samples to less than 1 mm the words “cannabis infused edible” and “topicals” were added to clarify the type of oil in the Procedure section of the Standard Operating Procedures. CAS Numbers and Volume:Volume were also added for greater clarity, the word “standards” replaced “CRMs”, “injections” was removed and replaced with “samples”, “check standard” was removed and replaced with “Continuing Calibration Verification”, “mid-range” was added to read as “mid-range calibration standards”, “solvent” was added to the word “blank” to

read as “solvent blank”, “laboratory replicate sample” was added to replace “sample duplicate”, “methyl cellulose” was added to replace “40 mL extraction solvent” and to help clarify the definition of the Method Blank, “correlation coefficient” was removed and replaced with “coefficient of determination or r2 value ≥”, a clarifying sentence stating “the Method Blank must not exceed the LOQ for any analyte” was added, a sentence was added to state the additional calibration standards could be added to the seven point calibration curve, “sequence/sample” was removed and replaced with “analytical” to read “analytical batch”.

Pursuant to Government Code section 11346.8, subdivision (c) and California Code of Regulations, title 1, section 44, the Department made substantive and sufficiently related changes to the proposed regulations and circulated them to the public for a comment period of at least 15 days (first 15-day comment period) beginning on August 31, 2022 and ending on September 16, 2022. During the 15-day comment period beginning on August 31, 2022 and ending on September 16, 2022, the Department received almost two hundred comments on the proposed regulations. Based on review of comments received, the Department determined that there were several sufficiently related changes to the proposed regulations that were necessary to clarify certain sections and provisions. The changes included the narrowing of the proposed testing method to apply to dried flower, including pre-rolls, and removal of language and references in the proposed regulatory text and Standard Operating Procedures to application of the testing method to juice, beverages, edibles, edible oil, topicals, and all cannabis products and the “sample matrices” were removed from the method verification, and a definition for “standard” was added. Cryogenic grinder was removed from the Apparatus and Materials section of the Standard Operating Procedures, and language was added to clarify that stock standard solutions using mixtures or combined standard solutions are acceptable, and further clarifying language was added to provide clarity in how to add acetonitrile/methanol as diluent when using mixtures or combined standard solutions in the cannabinoids mix working standard solutions. Typical dilutions were amended to provide dilutions for dried flowers, including pre-rolls, and other sample matrix dilutions were removed for concentrate/vape oil, edibles, and beverages. The word “replicate” was added to replace “duplicate” to clarify nomenclature, and storage instructions for standards and storage vials were clarified, additional clarifying sentences were added to the Quality Control section to clarify that a solvent blank should be free of the target analytes, and provide instruction on how and when to rerun a solvent blank if target analytes are over the LOQ. Language was also added to the Quality Control section to clarify a set of cannabinoids standards from a source external to the laboratory and different from the source of the calibration standards should be used to ensure consistent nomenclature and clarity. Clarifying language was added to clarify when the calibration curve standards are injected in the Retention Time Acceptance Window section.

Pursuant to Government Code section 11346.8, subdivision (c) and California Code of Regulations, title 1, section 44, the Department made substantive and sufficiently

related changes to the proposed regulations and circulated them to the public for a comment period of at least 15 days (second 15-day comment period) beginning on October 4, 2022 and ending on October 20, 2022. During the 15-day comment period beginning on October 4, 2022 and ending on October 20, 2022, the Department received 61 comments on the proposed regulations.

Pursuant to Government Code section 11346.8, subdivision (c) and California Code of Regulations, title 1, section 44, the Department made substantive and sufficiently related changes to the proposed regulations and circulated them to the public for a comment period of at least 15 days (third 15-day comment period) beginning on May 8, 2023 and ending on May 23, 2023.

Section 15712.1. Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls.

The title of the section has been amended to “Cannabinoid Test Method for Dried Flower, including Non-infused Pre-Rolls” for syntax. Additionally, “non-infused” has been added to “pre-rolls” throughout for greater accuracy as the proposed cannabinoid test method is only applicable to non-infused pre-rolls and does not apply to infused pre-rolls. Further, the phrase “test method” has been revised throughout to “cannabinoid test method” to provide additional clarity regarding the subject of the test method and “High Performance Liquid Chromatography (HPLC)” has been added to ensure both the full term and acronym are identified.

The date in proposed section 15712.1(b) was updated to 4/10/2023. The edit is necessary for clarity as the SOP was updated on April 10, 2023. Lastly, the date for licensed laboratories to implement the cannabinoid test method has been amended to three months after the effective date of the regulation.

The phrase “and obtain Department approval prior to use of the proposed method” has been removed from proposed section 15712(i).

Section 15712.2. Verification of Test Method for Dried Flower, including Non-Infused Pre-Rolls.

Consistent with edits made in proposed section 15712.1, this section has been renamed “Verification of Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls.” A new subsection (c) has been added to incorporate the definition for “reagent blank” which has been moved from the SOP to provide greater clarity as the term is not used in the SOP but is used in this regulatory section. The remaining subsections have been renumbered accordingly. Lastly, non-substantive syntaxial edits were made to the section to provide additional clarity regarding method verification.

Determination of Cannabinoids Concentration by High Performance Liquid Chromatography (HPLC) for Dried Flower, including Non-Infused Pre-Rolls, (New 04/10/2023) (incorporated by reference in CCR, tit. 4, §15712.1(b)).

Consistent with edits made in sections 15712.1 and 15712.2, the title of the SOP has been amended to add the term "non-infused" to "pre-rolls" to provide additional clarity regarding the applicability of the SOP to non-infused pre-rolls.

The date has been updated to 04/10/2023 for accuracy.

SOP Definitions.

The definitions section has been amended by removing the definition for "certified reference material" as the term is no longer used in the SOP. The definition for "liquid chromatography" has been removed as the term is no longer used in the SOP and all areas where it was used have been replaced by HPLC for greater accuracy. The definition of "method blank" has been revised by adding the phrase "or proportions" to align with the definition in section 15700. Lastly, the definition for "reagent blank" has been removed from the SOP as the term is not used in the SOP and it has been added to section 15712.2 because the term is used in section 15712.2. The remaining definitions have been renumbered accordingly.

SOP §I. Safety.

The Safety section of the SOP has been amended to remove the first three sentences related to limiting health hazards and exposure to chemical compounds as well as compliance with the "Laboratory Safety Guidance" established by the Occupational Safety and Health Administration (OSHA).

SOP §II. Apparatus and Materials.

Subsection H has been amended to remove the term "effectively."

Subsection M has been amended to replace "LC" with "HPLC" for consistency of terms used throughout the SOP.

Subsection Q has been amended to remove the descriptor of an analog vortex mixer and refer only to vortex mixer for accuracy as any vortex mixer is permissible under this SOP.

SOP §V. Procedure.

Subsection B.1. has been amended to add "any size reduction equipment" as an option for homogenizing samples.

Subsection C.6. has been amended for clarity by removing the statement "[t]he expected concentration can be calculated based on labels of samples or past experience on similar samples."

Subsection C.7. has been amended to align with the intent of this subsection which requires the specific action to obtain a concentration within the range of calibration curve. To clarify that this step is mandatory, the word “should” has been replaced with “shall.” Subsection D.1. has been amended to replace “LC” with “HPLC” for consistency of terms used throughout the SOP and regulatory sections.

Subsection E.5. has been amended to add the term “mid-range” to Continuing Calibration Verification (CCV) for accuracy and to align requirements for all CCV to be in the mid-range. This subsection has also been amended to update the cross-reference to Section VII.A.3.

SOP §VII. Quality Control.

The section has been amended to replace the word “should” with “shall” in the first sentence and subsections A.2., A.3., and B., to align with the intent of this section which is to require licensees to meet existing requirements regarding the use of quality control samples.

Subsection A.3. has also been amended to update the cross-reference to Section IV.C.

Subsection B has been amended to replace the word processed with prepared.

Subsection B.1. has been amended to remove the last sentence regarding other plant material cannabis matrices.

Subsection B.2. has been amended to add that mid-range is the amount to be spiked into the blank matrix.

Subsection E. has been amended to clarify that if the laboratory is unable to deconvolve the cannabinoid from the interference the sample shall be re-analyzed in accordance with the requirements of section 15730 of the Department’s regulations.

SOP §VIII. Acceptance Criteria for Quality Control Samples.

This section has been amended for syntax to replace “need to” with shall.

SOP §IX. Reporting Results.

This section has been amended to remove subsection B. as it is repetitive and unnecessary as subsection A. contains all requirements for reporting results.

During the 15-day comment period beginning on May 8, 2023 and ending on May 23, 2023, the Department received 12 comments on the proposed regulations. The Department determined that there were no further related changes to the proposed regulations that were necessary to clarify the proposed sections and provisions.

Update To Initial Statement of Reasons

There have been no substantial changes in applicable laws or to the effect of the proposed regulations from the laws and effects described in the Notice of Proposed Regulatory Action.

Updates have been made to the Economic Impact Assessment to reflect costs associated with the narrowed scope of the proposed cannabinoid test method. More specifically, the updated Economic Impact Assessment calculated costs using the basis of 100 samples per week as the Department estimates a range of 40-100 flower and pre-roll samples are analyzed on average each week by a given laboratory. The estimate has been updated to reflect the costs of a laboratory using 100 filter tips, 100 syringes totaling 10,400 syringes and filter tips per year at an average cost of $1.12 per filter and $0.215 per syringe resulting in a cost of $6,942 for filtering samples in a year. The total number of Matrix Post-dilution spikes needed per week is five based on an estimate of 100 samples per week, and the total spike material needed per week assuming the lowest spike amount of 50 µL yields a total of 250 microliters of total spike material per week, and a total of 13 mL per year to run samples using the new method. The estimated cost per combination standard vial is $879. Estimating 13 vials are needed each year, the estimated cost is $11,427 per year of combination standard vial. Solvent blanks are not estimated to cost an additional amount as most laboratories are already running solvent blanks. The solvent required for each sample extraction is 40 mL, not including dilutions which are already performed by laboratories. The increased use of the extraction solvent requires an estimated additional 26 4L bottles of solvent a year, the estimated cost is $3796. A licensed laboratory may also purchase a column with an estimated cost of $937.

Further, the estimated costs for hazardous waste disposal are estimated to be $9.70 per liter of solvent. The cost of a five-gallon drum of either waste stream (acetonitrile or methanol) is an estimated cost of $158.13 plus the estimated cost of the five-gallon drum at $26 totaling $184.13 per five-gallon drum. The proposed method would generate roughly 104 liters of solvent per year based on 100 samples per week, totaling an estimated hazardous waste disposal cost of $1,008 per year.

The previous Economic Impact Assessment did not reflect the cost of filter tips, syringes, Matrix Post-dilution spike, combination standard vials, solvent blanks, and hazardous waste disposal. The Department's estimate of costs for a HPLC system that meets the proposed regulatory requirements remains approximately $60,000, and similarly, the cost of a capable grinder remains $25,000 in the updated Economic Impact Assessment. The cost of a cryogrinder listed as a cost of $20,000-$35,000 in the original Initial Statement of Reasons and liquid cryogens listed as a cost of $10,000 were removed from the updated Economic Impact assessment, as the cryogenic grinder and liquid cryogens are no longer necessary for the test method and have been removed from section (II) of the Standard Operating Procedures.

To calculate the approximate costs a business may incur annually to comply with this regulation, the upper range of costs to run 100 samples is $84,110 if a laboratory must purchase a column, grinder, and HPLC system, while the lower end of annual costs is estimated to be $23,118 if a laboratory does not need to purchase a column, grinder, and HPLC system.

To calculate the approximate total statewide costs a business may incur to comply with this regulation over its lifetime, the upper range of costs is approximately $841,108 and the lowest range estimate of complying with this proposed method for a total 10-year lifetime cost is $231,118.

Section 15712.1. Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls.

The title of the section has been amended to “Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls” to for syntax. Additionally, “non-infused” has been added to “pre-rolls’ throughout for greater accuracy as the proposed cannabinoid test method is only applicable to non-infused pre-rolls and does not apply to infused pre-rolls. Further, the phrase “test method” has been revised throughout to “cannabinoid test method” to provide additional clarity regarding the subject of the test method and “High Performance Liquid Chromatography (HPLC)” has been added to ensure both the full term and acronym are identified. The Department determined that HPLC and Liquid Chromatography (LC) are used interchangeably in the laboratory testing industry and throughout this SOP, thus amending to HPLC for all is necessary for consistency. These edits are also necessary to provide further clarity and accuracy of terms.

The date in proposed section 15712.1(b) was updated to 4/10/2023. The edit is necessary for clarity as the SOP was updated on April 10, 2023. Lastly, the date for licensed laboratories to implement the cannabinoid test method has been amended to three months after the effective date of the regulation. This change is necessary due to the extended rulemaking period and ensures licensees have enough time to implement the cannabinoid test method. As licensees will need time to acquire equipment and train staff on the new test method, a date beyond the effective date for the regulation is necessary.

The phrase “and obtain Department approval prior to use of the proposed method” has been removed from proposed section 15712(i) as it is unnecessary and does not provide additional clarity. The Department has determined that the cross reference to section 15713 which precedes the phrase sufficiently informs licensees of the requirement.

Section 15712.2. Verification of Test Method for Dried Flower, including Non-Infused Pre-Rolls.

Consistent with edits made in proposed section 15712.1, this section has been renamed "Verification of Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls." A new subsection (c) has been added to incorporate the definition for "reagent blank" which has been moved from the SOP and is necessary to provide greater clarity because the term is used in this regulatory section, not the SOP. The remaining subsections have been renumbered accordingly. Lastly, non-substantive syntaxial edits were made to the section to provide additional clarity regarding method verification.

Determination of Cannabinoids Concentration for Dried Flower, including Non-infused Pre-Rolls, by High Performance Liquid Chromatography (HPLC) (New 04/X/2023) (incorporated by reference in CCR, tit. 4, §15712.1(b)).

Consistent with edits made in sections 15712.1 and 15712.2, the title of the Standard Operating Procedure (SOP) has been amended to add the term "non-infused" to "pre-rolls" to provide additional clarity regarding the applicability of the SOP to non-infused pre-rolls. Additionally, this change is necessary as pre-rolls may be both infused and non-infused. Including "non-infused" here ensures that licensees have clear direction regarding the applicability of the test method.

The date has been updated to 04/10/2023 for accuracy and identifies that the SOP was updated in April of 2023.

SOP Definitions.

The definitions section has been amended by removing the definition for "certified reference material" as the term is no longer used in the SOP. The definition for "liquid chromatography" has been removed as the term is no longer used in the SOP and all areas where it was used have been replaced by HPLC for greater accuracy and consistency in use of terms as discussed above. The definition of "method blank" has been revised by adding the phrase "or proportions" to align with the definition in section 15700. This edit is necessary for accuracy and consistency in defined terms. Lastly the definition for "reagent blank" has been removed from the SOP as the term is not used in the SOP and added to section 15712.2 because the term is used in section 15712.2. The remaining definitions have been renumbered accordingly.

SOP §I. Safety.

The Safety section of the SOP has been amended to remove the first three sentences related to limiting health hazards and exposure to chemical compounds as well as compliance with the "Laboratory Safety Guidance" established by the Occupational Safety and Health Administration (OSHA). This revision is necessary to avoid duplication of requirements. Laboratories are already required to comply with Title 29 of the Code of Federal Regulations, section 1910.1450 (OSHA 3404-11R (2011), thus including the requirement here is duplicative and unnecessary.

SOP §II. Apparatus and Materials.

Subsection H has been amended to remove the term “effectively.” This is necessary for consistency of terms and alignment with phrasing in subsection M.

Subsection M has been amended to replace “LC” with “HPLC” for consistency of terms used throughout the SOP as discussed above.

Subsection Q has been amended to remove the descriptor of an analog vortex mixer and now refers only to vortex mixer for accuracy as any vortex mixer is permissible under this SOP. The Department determined that the additional descriptor language was unnecessary as any vortex mixer will meet the requirements of this section.

SOP §V. Procedure.

Subsection B.1. has been amended to add “any size reduction equipment” as an option for homogenizing samples. This is necessary to clarify the equipment that may be used to grind the samples.

Subsection C.6. has been amended for clarity by removing the statement “[t]he expected concentration can be calculated based on labels of samples or past experience on similar samples.” The Department determined this sentence was unnecessary and did not supply additional direction to licensees. As the sentence is unnecessary it has been deleted.

Subsection C.7. has been amended to align with the intent of this subsection which requires the specific action to obtain a concentration within the range of calibration curve. To clarify that this step is mandatory the word “should” has been replaced with “shall.” This edit is necessary as the original ISOR provide that subsection C provides the specific instructions for sample extraction. As the specific steps were verified in the Department’s method validation, the Department has determined that the steps contained in this section must be conducted as specified. The edit benefits licensees by ensuring they have accurate instruction on the steps they must take and ensures accuracy in the test results.

Subsection D.1. has been amended to replace “LC” with “HPLC” for consistency of terms used throughout the SOP and regulatory section as discussed above.

Subsection E.5. has been amended to add the term “mid-range” to Continuing Calibration Verification (CCV) for accuracy and alignment with requirements for all CCV to be in the mid-range. This change is necessary to ensure accuracy in testing by providing specific direction regarding the appropriate range for CCV. This subsection has also been amended to update the cross-reference to Section VII.A.3. This is necessary for accuracy as section VII.A.3. contains the calibration standards.

SOP §VII. Quality Control.

The section has been amended to replace the word “should” with “shall” in the first sentence and subsection A.2., A.3., and B., to align with the intent of this section which is to require licensees to meet existing requirements regarding the use of quality control samples. This edit is necessary to clarify that licensed laboratories are required to meet existing requirements regarding use of quality control samples. Quality control samples are used to measure method accuracy, precision, contamination, and matrix effects. Quality control samples are necessary because quality control sample results are used to ensure that data released by the license laboratory is valid, reliable and reproducible. Thus, providing specific clarity to licensees regarding the requirements is necessary to ensure accuracy and ensures public health and safety is protected through accurate testing.

Subsection A.3. has also been amended to update the cross-reference to Section IV.C. This is necessary as Section IV.C. contains the calibration licensees must use for this step of the method.

Subsection B has been amended to replace the word processed with prepared. This is necessary for consistency with Section 15700(f) and accuracy as a batch is defined as samples that are prepared together.

Subsection B.1. has been amended to remove the last sentence regarding other plant material cannabis matrices. This is necessary for accuracy as the test method only applies to dried flower, including non-infused pre-rolls, thus there are no other matrices that apply.

Subsection B.2. has been amended to add that mid-range is the amount to be spiked into the blank matrix. This is necessary for accuracy and consistency with the definition of laboratory control samples (LCS) in section 15700(ff) which specifies LCS is required to be at mid-range. This is also consistent with edits made to CCV which also require mid-range.

Subsection E. has been amended to clarify that if the laboratory is unable to deconvolve the cannabinoid from the interference the sample shall be re-analyzed in accordance with the requirements of section 15730 of the Department’s regulations. This is necessary as the section previously provided that a licensed laboratory may deconvolve a cannabinoid from interference but did not include what the licensee’s options would be if unable to deconvolve. This edit provides clarity and direction to licensed laboratories and is necessary to ensure accuracy of testing.

SOP §VIII. Acceptance Criteria for Quality Control Samples.

This section has been amended for syntax to replace “need to” with shall. No substantive changes have been made however the Department determined the edit was necessary for consistency of terms used.

SOP §IX. Reporting Results.

This section has been amended to remove subsection B. as it is repetitive and unnecessary as subsection A. has all requirements for reporting testing results. Removal of this subsection is necessary to ensure the SOP is readily understandable by licensees so that they can accurately report the results of testing. This edit also ensures that licensees are using the same reporting parameters for all test methods used by the laboratory.

As authorized by Government Code section 11346.9 subdivision (d), the Department hereby incorporates the Initial Statement of Reasons prepared in this rulemaking. Unless a specific basis is stated for any modification to the regulations as initially proposed, the necessity for the adoption of new regulations as set forth in the Initial Statement of Reasons continues to apply to the regulations as adopted.

All modifications from the initially proposed text of the regulations are summarized below.

Modifications Made Available for the First 15-Day Comment Period from August 31, 2022 to September 16, 2022

Section 15712.1. Test Method for Cannabinoids

The phrase “and shall not utilize any other cannabinoid test method for the purpose of regulatory compliance testing” was added to proposed section 15712.1(a). The Department received multiple comments asking for flexibility in the test method. The Department determined that enough flexibility was built into the language of the Standard Operating Procedures and that allowing any cannabinoid test method not established by the Department would undermine the intent of SB 544 to develop a standard cannabinoid testing method for regulatory compliance testing. The amendment was necessary to further clarify the intent of this subsection is for the cannabinoid test method established by these regulations to be the only cannabinoid test method that may be utilized by licensed testing laboratories for purposes of regulatory compliance testing and reporting.

The acronym “SOP” in proposed section 15712.1(g) was replaced with the word “Standard Operating Procedures” for clarity and consistency. There were no substantive changes to the substance of the section due to these changes.

Proposed section 15712.1(i) was added to allow licensed laboratories to test for additional cannabinoid analytes beyond those listed in section (IV)(A) of the Standard Operating Procedures. This section requires a full method validation for additional cannabinoid analytes to be submitted for Department approval prior to use of the proposed testing method. The Department received multiple comments indicating common industry practice was to test beyond the nine listed cannabinoid analytes listed in section (IV)(A) of the Standard Operating Procedures. This amendment clarifies that the listed cannabinoid analytes are a floor, not a ceiling, for allowable cannabinoid

analyte testing and reiterates the criteria that a proposed testing method must comply with prior to usage. This amendment is necessary for clarity and consistency, and requires licensed laboratories to follow the same procedures that are used for testing analytes other than cannabinoids.

Determination of Cannabinoids Concentration by HPLC, Standard Operating Procedures (New 08/23/2022) (incorporated by reference in CCR, tit. 4, §15712.1(b)).

All instances of 'ml' have been changed to 'mL' to designate milliliters. This does not change to the substance of the section.

Definitions.

A definition of Method Blank has been added to proposed Definitions, subsection (10). Method Blank is proposed to be defined in alignment with the definition of Method Blank in CCR section 15700(oo). This edit is necessary for accuracy and consistency of terms used throughout the regulations. As a result, the remaining definitions have been renumbered.

A definition of Matrix Post-dilution Spike has been added to proposed Definitions, subsection (11). Matrix Post-dilution Spike is proposed to be defined as spiking a known amount of cannabinoids mix standards into a diluted sample after extraction. A Matrix Post-dilution Spike is used to evaluate the effects of sample matrices on the performance of the analytical method. This edit is necessary to clarify what a Matrix Post-dilution Spike is, as the Department is proposing to require laboratories to perform a Matrix Post-dilution Spike in the Quality Control section (VII) of the Standard Operating Procedures. Matrix Post-dilution Spike was not previously defined, and the Department learned through public comment that a definition of Matrix Post-dilution Spike would provide greater clarity for laboratories complying with the Standard Operating Procedures Quality Control section.

A definition of Reagent Blank has been added to proposed Definitions, subsection (14) and replaces the original proposed subsection (14). Reagent Blank is proposed to be defined as reagents which are used in the procedure taken through the entire method and which are added in the same volumes as used in the sample preparation. A Reagent Blank is analyzed in the same manner as the representative sample. This edit is necessary to provide clarity, accuracy, and consistency of terms used throughout the regulations. The Department received multiple comments requesting a definition for "Reagent Blank".

The proposed definition of Reporting Limit has been removed from the proposed Definitions. In review of comments received during the 45-day comment period, the Department determined there was significant confusion regarding the intent of this subsection. Comments expressed concern that the reported Limit of Quantification (LOQ) on the Certificate of Analysis would have different meanings between analytical tests as the Reporting Limit was only required in the Standard Operating Procedures but was not required to be stated on the Certificate of Analysis. Further, some commenters suggested removing the reporting limit from the Standard Operating Procedures or setting a minimum reporting limit. The Department also recognized that

the introduction of a reporting limit had implications on the reporting of results on the Certificate of Analysis and subsequent product packaging. The Department has removed the definition for Reporting Limit and no significant reporting impacts are foreseen.

A definition of Solvent Blank has been added to proposed Definitions, subsection (19). Solvent Blank is proposed to be defined as the same dilution solvent, acetonitrile/methanol (80:20) and is run in pairing with the ICV and/or CCV. A Solvent Blank is used to determine that the instrument system is clean and free of contamination. This edit is necessary to provide clarity, accuracy, and consistency of terms used throughout the regulations. The Department received multiple comments requesting a definition for “Solvent Blank”.

Standard Operating Procedures, Section II. Apparatus and Materials.

1L has been removed from proposed section (II)(P) to allow HPLC solvent bottles of any size to be used in the Standard Operating Procedures. Commenters suggested removing the 1L requirement from the Standard Operating Procedures Apparatus and Materials section to allow for more flexibility. The Department determined that allowing HPLC solvent bottles of any size would provide some flexibility in the method without altering the method itself.

A clarifying phrase has been added to proposed section (II)(T) to allow for a tissue homogenizer “or any size reduction equipment” capable of grinding samples to less than 1 mm. This edit was necessary to provide clarity to the Standard Operating Procedures. The Department received public comments that indicated confusion regarding tissue homogenizers. Commenters interpreted this section to mean that the Department was only permitting commercial tissue homogenizers, which is inaccurate. Licensees are allowed to grind samples using other methods so long as the size reduction equipment is capable of grinding samples to less than 1 mm. This edit aligns with the intent of this subsection, which was to allow licensees some flexibility in size reduction equipment. The intent and substance of this subsection have not changed.

In response to comments received during the 45-day comment period, a clarifying sentence has been added the proposed section (II)(U) stating “Any method of cryogrinding or size reduction equipment using liquid nitrogen, dry ice or other cryogens, that can lower the temperature to less than -70 Celsius is acceptable provided that it grinds the sample to less than 1 mm.” This edit was necessary to provide clarity to the Standard Operating Procedures. The Department received public comments that indicated confusion regarding cryogrinders. Commenters interpreted this section to mean that the Department was only permitting commercial cryogrinders which is inaccurate. However, after receiving comments during the 15-day comment period from August 31, 2022 to September 16, 2022, the Department removed the sentence from proposed section (II)(U) stating, ““Any method of cryogrinding or size reduction equipment using liquid nitrogen, dry ice or other cryogens, that can lower the temperature to less than -70 Celsius is acceptable provided that it grinds the sample to less than 1 mm.” After the second 15-day comment period from October 4, 2022 to October 20, 2022, the Department determined the test method would govern only dried flower, including pre-rolls, and would not apply to other cannabis products. As a result,

the Department removed cryogrinders from the Standard Operating Procedures as they were no longer necessary in a test method that governed dried flower and pre-rolls, but not other cannabis products.

Standard Operating Procedures, Section IV. Calibration Standard.

CAS Numbers have been added to each of the nine listed analytes in proposed section (IV)(A)(1-9) for greater clarity and accuracy. The Department received public comments requesting required target analytes to be listed with the CAS number as is typically done in a Standard Operating Procedure. The Department determined that the suggestion to include the CAS number of each analyte was warranted and provided greater clarity and accuracy. The intent and substance of this subsection have not changed. The word "standard" has been added to each of the nine listed analytes in proposed section (IV)(A)(1-9) to clarify that the 1.0 mg/mL measurement applies to the standard needed for the stock standard solution. This edit is necessary for clarity and allows greater accuracy in preparing the stock standard solution.

The word "standards" has been added to replace "CRMs" in proposed section (IV)(B)(1). This edit is necessary because the definition of "CRM" in proposed Definitions subsection (3) would require all standards to be in matrix when preparing a calibration curve. It is not the intent of the proposed method to make such a requirement and the Department does not want laboratories to do their curves in matrix. As such, the change to "standards" and removal of "CRM" is necessary to provide clarity and allow greater accuracy to reflect the composition of the calibration curve.

The phrase "Volume:Volume" has been added to proposed section (IV)(B)(1-4) and (IV)(C)(1-2) to remove ambiguity. The Department received several comments asking what the 80:20 ratio refers to. This edit clarifies that 80:20 is the volume ratio of the mixture acetonitrile/methanol. This edit is necessary for clarity and accuracy.

An additional clarifying sentence has been added to proposed section (IV)(C)(3) which clarifies that additional calibration standards may be added to the standards above the 0.5, 2, 5, 10, 20, 50 and 100 ppm calibration standards. The Department received public comments stating that the seven-point calibration curve was too narrow and that there should be an allowance for standards up to 500-600 ppm in the calibration curve. This edit is necessary to clarify that the seven calibration standards listed in the calibration standard solutions section are a minimum and that laboratories may have calibration standards beyond the seven required calibration standards.

Standard Operating Procedures, Section V. Procedure.

The word "hemp" was removed from proposed section (V)(B) for accuracy. The Department does not regulate hemp and the inclusion of the word "hemp" was an error. This edit is necessary for clarity and accuracy.

In response to the comments received during the 45-day comment period, the word "juice" was removed from proposed section (V)(B)(1) and replaced with the word "beverage." This edit was necessary for clarity, consistency, and accuracy of nomenclature, as the sample preparation section of the Standard Operating Procedures applies to all beverages, not just "juice" as defined by the regulations. However, after

the first 15-day comment period from August 31, 2022 to September 16, 2022, the Department determined the test method would govern only dried flower, including pre-rolls, and would not apply to other cannabis products. As a result, the proposed language that replaced “juice” with the word “beverage” in section (V)(B)(1) was not adopted and all sentences describing sample preparation for cannabis products in section (V) of the Standard Operating Procedures were removed.

In response to the comments received during the 45-day comment period, the words “cannabis infused edible” were added to clarify the type of oil in proposed section (V)(B)(1). This edit was necessary for clarity, consistency, and accuracy of nomenclature as the sample preparation section of the Standard Operating Procedures applies to cannabis infused edible oil samples specifically. However, after the first 15-day comment period from August 31, 2022 to September 16, 2022, the Department determined the test method would govern only dried flower, including pre-rolls, and would not apply to other cannabis products. As a result, the proposed language that added “cannabis infused edible” in section (V)(B)(1) was not adopted and all sentences describing sample preparation for cannabis products in section (V) of the Standard Operating Procedures were removed.

In response to the comments received during the 45-day comment period, the word “edible” was added to clarify the type of oil in proposed section (V)(B)(2). This edit was necessary for clarity, consistency, and accuracy of nomenclature as the sample preparation section of the Standard Operating Procedures applies to cannabis infused edible oil samples specifically. However, after the first 15-day comment period from August 31, 2022 to September 16, 2022, the Department determined the test method would govern only dried flower, including pre-rolls, and would not apply to other cannabis products. As a result, the proposed language that added “edible” in section (V)(B)(2) was not adopted and all sentences describing sample preparation for cannabis products in section (V) of the Standard Operating Procedures were removed.

In response to the comments received during the 45-day comment period, the word ‘topicals’ was added to clarify the type of oil in proposed section (V)(B)(2). This edit was necessary for clarity and accuracy to ensure topicals are included in the Standard Operating Procedures. However, after the 15-day comment period from August 31, 2022 to September 16, 2022, the Department determined the test method would govern only dried flower, including pre-rolls, and would not apply to other cannabis products. As a result, the proposed language that added “topicals” in section (V)(B)(2) was not adopted and all sentences describing sample preparation for cannabis products in section (V) of the Standard Operating Procedures were removed.

The phrase “Volume:Volume” has been added to proposed section (V)(C)(1) to remove ambiguity. The Department received several comments asking what the 80:20 ratio refers to. This edit clarifies that 80:20 is the volume ratio of the mixture acetonitrile/methanol. This edit is necessary for clarity and accuracy.

The phrase “at least” has been added to proposed section (V)(C)(2) to allow labs to vortex a centrifuge tube for at least one minute to mix the sample and extraction solvent well. The Department learned from comments that some laboratories prefer to vortex for longer periods than one minute. The Department determined that labs may vortex samples for a minimum of one minute.

All instances of “um” in proposed sections (V)(C)(5) and (V)(D) have been amended to “µm” to accurately indicate micrometer as the unit of measurement. This edit is necessary for consistency and clarity of nomenclature. The intent and substance of this subsection have not changed.

The phrase “Volume:Volume” has been added to proposed section (V)(D)(1) to remove ambiguity. The Department received several comments asking what the 80:20 ratio refers to. This edit clarifies that 80:20 is the volume ratio of the mixture acetonitrile/methanol. This edit is necessary for clarity and accuracy.

A clarifying sentence has been added to proposed section (V)(E)(2) to clarify that if a valid calibration curve and valid Initial Calibration Curve (ICV) already exist for this method and specific instrument, a Continuing Calibration Verification (CCV) may be analyzed in place of a new calibration curve and ICV so long as the CCV meets the requirements in California Code of Regulations, title 4, section 15730. The Department received many comments that indicated confusion regarding whether calibration was necessary with every batch. The Department felt that clarification was necessary and determined that once a valid calibration curve was generated and a valid ICV exists for this method and specific instrument, a CCV may be analyzed in place of a new calibration curve and ICV and a calibration curve would not need to be re-run each sequence. This amendment is necessary for clarity and accuracy.

The phrase “method blanks” at proposed section (V)(E)(3) has been changed to “method blank” as a minor grammatical error. There were no changes to the substance of the section.

The word “injections” has been removed and “samples” has been added to proposed section (V)(E)(4) for clarity, accuracy, and consistency as the current regulations refer to ten samples rather than to ten injections. Further, not all injections are samples. This change is necessary for alignment with current regulations and greater clarity.

“Check standard” has been removed from proposed section (V)(E)(4) and replaced with “Continuing Calibration Verification (CCV)” for clarity, accuracy, and consistency. Check standard is an instrument-based term, and instrument language may vary by vendor. By contrast, CCV is a defined term subject to the Laboratory Quality Control requirements. This change is necessary for alignment with current regulations.

The phrase “mid-range” has been added to proposed section (V)(E)(4) to read as “mid-range calibration standards.” This edit is necessary because it clarifies that the CCV must be mid-range and not any other calibration standard. The regulatory definition of CCV specifies that a continuing calibration verification is a standard that must be at mid-range of the calibration curve. In the original text, the Standard Operating Procedures did not specify a type of standard to be used. To clarify the requirements, the addition of “mid-range” was added to further specify which calibration standards may be used for

the CCV. The Department received comments requesting greater specificity and clarity on the calibration standard. This edit addresses a comment requesting specificity of the calibration standard. This amendment is necessary for alignment and consistency within the regulations and clarity.

The word “Solvent” has been added to proposed section (V)(E)(4) to read as “Solvent Blank” rather than “blank” for clarity and accuracy. There was no specification previously as to whether this section refers to a Solvent Blank or Method Blank, and the Department received comments asking for further specification. This change is necessary for alignment with current regulations and nomenclature.

Proposed section (V)(E)(4) has been changed to correct a grammatical error. “Quality control purpose” has been changed to “quality control purposes.” This change is not substantive.

The word “check standard” has been removed from proposed section (V)(E)(5) and replaced with “CCV” for clarity, accuracy, and consistency. Check standard is an instrument-based term, and instrument language may vary by vendor. By contrast, CCV is a defined term subject to the Laboratory Quality Control requirements. This change is necessary for alignment with current regulations.

The word “Solvent” was added to proposed section (V)(E)(5) to read as “Solvent Blank” rather than “blank” for clarity and accuracy. There was no specification previously as to whether this section refers to a Solvent Blank or Method Blank, and the Department received comments asking for further specification. This change is necessary for alignment with current regulations and nomenclature.

Proposed section (V)(E)(5) has been changed to correct a grammatical error. The phrase “quality control purpose” has been changed to “quality control purposes.” This change is not substantive.

After the first 15-day comment period from August 31, 2022 to September 16, 2022, the phrase “or lower” was added to proposed section (V)(E)(6) to allow samples to be stored at 4°C or lower. The Department received comments indicating confusion over whether temperatures lower than 4°C were acceptable. The Department determined that any temperature below 4°C was acceptable. However, after the second 15-day comment period, the sentence “6. Store samples and Standards in the HPLC autosampler or a refrigerator in dark at 4°C or lower” was removed from proposed section (V)(E)(6) and replaced with the following sentence: “After the run finishes, recap the standards and sample vials and store them in –20°C freezer”. This amendment was made in responses to comments requesting consistency with previous standards storage instruction and to provide clarity in storage of standards.

<u>Standard Operating Procedures, Section VI. Method Limit of Quantification (LOQ).</u>

The words “and Reporting Limit (RL)” have been removed from the title of proposed section (VI). The Department received public comments indicating a significant amount of confusion regarding the introduction of a Reporting Limit and concern regarding how the new reporting limit might impact the interpretation of existing methods, how the reporting limit value might be stated on the Certificate of Analysis (COA), and the

potential impact of setting a minimum reporting limit. The Department determined that there was significant confusion regarding the introduction of the reporting limit. This section has been amended to remove all references to a reporting limit and to instead use Limit of Quantitation (LOQ). The use of the LOQ is consistent with the requirements for all other methods within the regulations as required by California Code of Regulations, title 4, section 15713. This amendment was necessary to avoid confusion regarding the reported LOQ on the COA, and confusion on cannabis product packaging and labeling using the reporting limit.

Standard Operating Procedures, Section VII. Quality Control.

The words “analytical sequence” were added to proposed section (VII)(A) to replace every instance of “sample batch” with “analytical sequence” because “sample batch” would erroneously define an analytical sequence and is an instrument vendor based term which creates confusion for the regulatory requirements of the cadence of the ICV and CCV. Further, the ICVs and CCVs are based on the analytical sequence or the sequential injection of samples. This edit is necessary for consistency, accuracy, and clarity.

The number “20” and phrase “or less that is processed together” were removed from proposed section (VII)(A) to ensure a clear definition was provided for an “analytical sequence.” As previously discussed, the definition of “sample batch” erroneously defined an analytical sequence and language including “20” and the phrase “or less that is processed together” was removed as they were part of the definition of sample batch. This edit is necessary for consistency, accuracy, and clarity.

The phrase “Volume: Volume” has been added to proposed section (VII)(A)(1) to remove ambiguity. The Department received several comments asking what the 80:20 ratio refers to. This edit clarifies that 80:20 is the volume ratio of the mixture acetonitrile/methanol. This edit is necessary for clarity and accuracy.

The word “standards” has been added to replace “CRMs” in proposed section (VII)(A)(2). The edit is necessary because the definition of “CRM” in the Definitions proposed subsection (3) would require all standards to be in matrix when preparing a calibration curve. It is not the intent of the proposed method to make such a requirement and the Department does not want laboratories to do their curves in matrix. As such, the change to “standards” and removal of “CRM” is necessary to provide clarity and allow greater accuracy to reflect the composition of the calibration curve.

The phrase “curve is valid” has been added to replace “standards are good” in proposed section (VII)(A)(2). This edit is necessary for greater clarity and accuracy as the reason the ICV is prepared from a set of standards from a second source is to ensure the calibration curve is valid, not whether the calibration standards are good. This edit is necessary for accuracy, and clarity.

The word “sample” has been added to replace “injection” in proposed section (VII)(A)(3) for clarity, accuracy, and consistency as the current regulations refer to samples rather than to injections. Further, not all injections are samples. This change is necessary for alignment with current regulations and greater clarity.

The word ”mid-range” has been added to proposed section (VII)(A)(3) because it clarifies that the requirement that the CCV must be mid-range should be analyzed rather than any calibration standard. The regulatory definition of CCV specifies that a continuing calibration verification is a standard that must be at midrange of the calibration curve. In the original text, the SOP did not specify a type of standard to be used. To clarify the requirements, the addition of “mid-range” was added to further specify which calibration standards may be used for the CCV. The Department received comments requesting greater specificity and clarity on the calibration standard. This edit addresses a comment requesting specificity of the calibration standard. This amendment is necessary for alignment and consistency within the regulations and clarity. A sentence defining “analytical batch” has been added to proposed section (VII)(B) because the existing regulations require that the quality control samples are run on an analytical batch basis. Further, analytical batch is a defined term in California Code of Regulations, title 4, section 15700(f) and using the defined term ensures clarity and consistency within the regulations.

The words “sequence/sample” have been removed from proposed section (VII)(B) and replaced with “analytical” because “sequence/sample batch” would erroneously define an analytical batch and is an instrument vendor-based term which creates confusion for the regulatory requirements of the cadence of the required Method Blank, Laboratory Control Sample (LCS), and Matrix Post-dilution spike. The frequency of the Method Blank, LCS, and Matrix-Post dilution spike are based on the analytical batch, which requires them to be prepared with every 20 samples or less. This edit is necessary for consistency, accuracy, and clarity.

The words “laboratory replicate sample (LRS)” have been added to replace “sample duplicate” at proposed section (VII)(B). This edit is necessary because LRS is an existing defined term in California Code of Regulations, title 4, section 15700(gg) and using the defined term ensures clarity and consistency within the regulations.

The definition of “Method Blank” was added to proposed section (VII)(B)(1) to align with the current regulatory definition provided in California Code of Regulations, title 4, section 15700(oo). Using the existing defined term ensures clarity and consistency within the regulations.

Minor grammatical changes such as “the Method Blank” and “the” were added to proposed section (VII)(B)(1) to ensure the sentences read properly. Substance and intent were not changed by these edits.

In response to the comments received during the 45-day comment period , the word “juice” was removed, and “beverage” was added in its place at proposed section (VII)(B)(1). This edit was necessary for clarity, consistency, and accuracy of nomenclature, as the sample preparation section of the Standard Operating Procedures applies to all beverages, not just “juice” as defined by the regulations. However, after the first 15-day comment period from August 31, 2022 to September 16, 2022, the Department determined the test method would govern only dried flower, including pre-rolls, and would not apply to other cannabis products. As a result, the proposed language that replaced “juice” with “beverage” in section (VII)(B)(1) of the Standard Operating Procedures was removed.

“Methyl cellulose” was added to proposed section (VII)(B)(1) to replace “40 ml extraction solvent’.” The regulatory definition of a method blank requires that it be composed of an “analyte free matrix.” In the original text, the Standard Operating Procedures did not specify the analyte free matrix to be used. However, after the first 15-day comment period from August 31, 2022 to September 16, 2022, the Department determined additional clarification was needed and removed “methyl”. The composition of the method blank was clarified to include cellulose to meet the regulatory definition and matches the analyte free matrix used in the method validation. This edit addresses several comments regarding the definition of the method blank and its required composition. This edit is necessary for consistency, accuracy, and clarity.

The word “standards” was added to replace “CRM” in proposed section (VII)(B)(2). This edit is necessary because the definition of “CRM” in proposed Definitions subsection (3) would require all standards to be in matrix when preparing a calibration curve. It is not the intent of the proposed method to make such a requirement and the Department does not want laboratories to do their curves in matrix. As such, the change to “standards” and removal of “CRM” is necessary to provide clarity and allow greater accuracy to reflect the composition of the calibration curve.

The words “Laboratory Replicate Sample (LRS)” were added to replace “Sample Duplicate” in proposed section (VII)(B)(3). This edit is necessary because LRS is an existing defined term in California Code of Regulations, title 4, section 15700(gg) and using the defined term ensures clarity and consistency within the regulations.

Standard Operating Procedures, Section VIII. Acceptance Criteria for Quality Control Samples.

The words “correlation coefficient” in proposed section (VIII) were removed and replaced with “coefficient of determination or r2 value ≥” because the term “correlation coefficient” is incorrect. Correlation coefficient refers to the r value, not the r2 value. The regulations define the r2 value as the coefficient of determination in California Code of Regulations, title 4, section 15700(q). The r2 value should be greater than or equal to 0.99. This edit is necessary to be scientifically correct for statistical models of the residuals.

The word “CCVs” in proposed section (VIII) has been added to replace “the calibration check standards” for clarity, accuracy, and consistency. Check standard is an instrument-based term and instrument language may vary by vendor. By contrast, CCV is a defined term subject to the Laboratory Quality Control requirements. This change is necessary for alignment with current regulations.

The word “the” was removed in in proposed section (VIII) and a comma was added to correct a minor grammatical error. There were no changes to the substance of the section due to these changes.

A sentence stating “the Method Blank must not exceed the LOQ for any analyte” was added to proposed section (VII) to address a comment on missing method blank criteria. This edit is necessary to provide clarity and ensure greater accuracy in the Standard Operating Procedures and for alignment with current regulations.

The letter “L” and words “laboratory,” and “(LQCs)” were added to proposed section (VII) for greater clarity and consistency of nomenclature. There were no substantive changes to the substance of the section due to these changes.

Standard Operating Procedures, Section IX. Reporting Results.

Proposed section (IX)(C) was removed because it referred to the reporting limit. As previously mentioned, the Department determined that there was significant confusion regarding the intent of the reporting limit. As such, all references to the reporting limit have been removed.

There were no other changes in the laws related to the proposed action or to the effect of the proposed regulation from the laws and effects described in the Notice of the Proposed Regulatory Action.

Section 15712.2. Verification of Test Method for Cannabinoids.

The word “reagent” was added to replace “matrix” in proposed section 15712.2(c) for consistency of nomenclature and clarity. As previously mentioned, a reagent blank is analyzed in the same manner as the representative sample. This edit is necessary to provide clarity, accuracy, and consistency of terms used throughout the regulations. The Department received multiple comments requesting definitions for each of the different types of method blanks.

There were no other changes in the laws related to the proposed action or to the effect of the proposed regulation from the laws and effects described in the Notice of the Proposed Regulatory Action.

Modifications Made Available for a 15-Day Comment Period from October 4, 2022 to October 20, 2022

The primary modifications to the proposed regulations limit applicability of the proposed cannabinoid test method and reporting requirements to the testing of dried flower, including pre-rolls. The Department received multiple comments requesting further study of the method’s use for infused products. 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 served as 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 determined that limiting the applicability of the method to dried flower, including pre-rolls, is appropriate at this time to allow for further research and development related to the appropriate

standardized method for the testing of cannabis products.

Section 15712.1. Test Method for Cannabinoids.

The phrase “for Dried Flower, including Pre-Rolls” was added to proposed section 15712.1. The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the cannabinoid test method established by these regulations to be the only cannabinoid test method that may be utilized by licensed testing laboratories for purposes of regulatory compliance testing and reporting for dried flower, including pre-rolls.

The phrase “results for dried flower, including pre-rolls” was added to proposed section 15712.1(a) so the sentence reads as follows: “Notwithstanding section 15712, a licensed laboratory shall utilize the cannabinoids test method required by this section and shall not utilize any other cannabinoid test method for the purpose of regulatory compliance testing and reporting results for dried flower, including pre-rolls.” The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoids for dried flower, including pre-rolls. This amendment is necessary to further clarify that the cannabinoid test method established by these regulations to be the only cannabinoid test method that may be utilized by licensed testing laboratories for purposes of regulatory compliance testing and reporting for dried flower, including pre-rolls.

The sentence, “a licensed laboratory is not required to use the method required by this section for cannabis products, including infused pre-rolls” was added to proposed section 15712.1(a). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoids for dried flower, including pre-rolls. The addition of this sentence clarifies that the proposed testing method is not required for cannabis products, including infused pre-rolls.

The phrase “for Dried Flower, including Pre-Rolls” was added to proposed section 15712.1(b) to provide clarity in the title of the Standard Operating Procedures. This addition is necessary, so it is clear the Determination of Cannabinoids Concentration by HPLC is for dried flower, including pre-rolls.

The date in proposed section 15712.1(b) was updated to 09/23/2022. The edit is necessary for clarity as the Standard Operating Procedures were updated on September 23, 2022.

The phrase “and in additional matrices beyond those covered in” was added to proposed section 15712.1(i). This edit is necessary to clarify that laboratories may test for additional matrices and ensures labs will still perform method validations for matrices and analytes not covered by the Standard Operating Procedures.

The word “of” was removed from proposed section 15712.1(i). This is a necessary grammatical change.

The phrase “and additional matrices” was added to proposed section 15712.1(i). This edit is necessary to clarify that laboratories may test for additional matrices and ensures laboratories will still perform method validations for matrices and analytes not covered by the Standard Operating Procedures.

Section 15712.2. Verification of Test Method for Cannabinoids for Dried Flower, including Pre-Rolls.

The phrase “for Dried Flower, including Pre-Rolls” was added to proposed section 15712.2. The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the verification of test method for cannabinoids applies to dried flower, including pre-rolls.

The row in the table in proposed subsection 15712.2(c) listing the criteria for sample matrices, number required, and notes has been removed. This amendment is necessary to further clarify that the verification of test method for cannabinoids applies to dried flower, including pre-rolls, rather than to both cannabis and cannabis products. The phrase “of cannabis and cannabis products” was removed from proposed section 15712.2(h). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the verification of test method for cannabinoids applies to dried flower, including pre-rolls, rather than to cannabis and cannabis products.

Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New 09/23/2022) (incorporated by reference in CCR, tit. 4, §15712.1(b)).

The phrase “for Dried Flower, including Pre-Rolls” has been added to the title of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New 09/23/2022). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed Standard Operating Procedures shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures

for determination of cannabinoids concentration by HPLC apply to dried flower, including pre-rolls.

The date has been updated to 09/23/2022 in the title of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New 09/23/2022) because the Standard Operating Procedures were updated on September 23, 2022. The edit is necessary for clarity as the Standard Operating Procedures were updated on September 23, 2022, and the previous date of August 23, 2022 is no longer the proposed version.

Scope.

The phrase “for Dried Flower, including Pre-Rolls” has been added to the proposed Scope section of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New 09/23/2022). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures apply to dried flower, including pre-rolls.

Application.

The phrase “for dried flower, including pre-rolls” has been added to the proposed Application section of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New 09/23/2022). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures apply to dried flower, including pre-rolls.

The sentence “This method does not cover the determination of cannabinoid concentration in cannabis products, including infused pre-rolls” has been added to the proposed Application section of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New 09/23/2022). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures does not apply to cannabis products and infused pre-rolls.

A definition for “standard” has been added to the Definition section of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New 09/23/2022). The definition states, “Standard” means a certified reference standard comprised of one or more of the target analytes prepared at a known concentration by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation.” This edit is necessary because it directly addresses several comments requesting greater clarity of the standards needed for analysis.

Standard Operating Procedures, Section II. Apparatus and Materials.

The apparatus in proposed section (II)(U) of the Standard Operating Procedures stating “cryogenic grinder capable of grinding samples to less than 1 mm. Any method of cryogrinding or size reduction equipment using liquid nitrogen, dry ice or other cryogens, that can lower the temperature to less than -70 Celsius is acceptable provided that it grinds the sample to less than 1mm” has been removed. The cryogenic grinder was only necessary to grind samples of manufactured cannabis products. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls; manufactured cannabis products are not included in the proposed test method. This amendment is necessary to further clarify that the Standard Operating Procedures does not apply to manufactured cannabis products.

Standard Operating Procedures, Section IV. Calibration Standard.

The sentence, “with the following analytes at the listed concentration. Mixtures or combined standard solutions of the listed analytes at their specified concentration or single standard solutions of the analytes at their specified concentrations may be used for the following stock standard solution” has been added to proposed section (IV)(A). The Department received comments related to whether mixtures or combined standards could be used. This edit is necessary to make clear standard mixes are allowable.

The phrase, “mL” was added to proposed section (IV)(A)(6). This amendment is necessary for consistent nomenclature. This edit is non-substantive.

A period was added to proposed section (IV)(B)(1) for grammar. This edit is necessary and non-substantive.

A colon was deleted from proposed section (IV)(B)(1) for grammar. This edit is necessary and non-substantive.

The phrase “using single standard solutions of the target analytes,” and the word “the” have been added to proposed section (IV)(B)(1). This edit is necessary to show that this is the procedure for single standard solutions.

The sentence, “For mixtures or combined standard solutions, add acetonitrile/methanol (80:20 Volume:Volume) as diluent. Vortex to mix well” has been added to proposed section (IV)(B)(1). This edit is necessary to provide clarity and specificity so laboratories

have a clear procedure to make the stock solution in the event a mixture or combined standard is used. The public comments demonstrated a large demand from laboratories and vendors to ensure standard mixes, which are commonly used, are allowed in the proposed method.

The phrase “second source:” and replaced with the following phrase was added to proposed section (VI)(B)(3): “different source of the calibration standards and source external to the laboratory.” This edit is necessary for consistency as “second source” is not a defined term and the phrase replacing “second source” is clearer regarding what source is acceptable.

The phrase “using single standard solutions of the target analytes,” was added to proposed section (IV)(B)(3). This edit is necessary to show that this is the procedure for single standard solutions. The public comments demonstrated a large demand from labs and vendors to ensure standard mixes, which are commonly used, are allowed in the proposed method.

The sentence, “For mixtures or combined standard solutions, add acetonitrile/methanol (80:20 Volume:Volume) as diluent. Vortex to mix well” has been added to proposed section (IV)(B)(3). This edit is necessary to provide clarity and specificity so laboratories have a clear procedure to make the stock solution in the event a mixture or combined standard is used. The public comments demonstrated a large demand from laboratories and vendors to ensure standard mixes, which are commonly used, are allowed in the proposed method.

The word “the” was added to proposed section (IV)(B)(3). This edit is necessary and non-substantive.

The phrase “or per the manufacturer’s specifications.” was added to proposed section (IV)(B)(5). This edit is necessary to address a request for further clarification on standard storage. This amendment provides specificity to allow laboratories to preserve the condition of the standards by storing standards in the manner recommended by the manufacturer.

<u>Standard Operating Procedures, Section V. Procedure.</u>

The sentence, “Notes: Group samples by type (e.g., plant material, juice, oil, chocolate, hard candy, gummy and cookie)” has been removed from proposed section (V)(B). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures does not apply to cannabis products and infused pre-rolls.

Standard Operating Procedures, Section (V)(B). Sample Preparation.

The phrase “as follows” was removed and the phrase “by using” was added to proposed section (V)(B) so the sentence states, “Homogenize the samples by using”. This amendment is necessary for clarity, as the Standard Operating Procedures no longer apply to cannabis products and infused pre-rolls. As such, there is only one method to homogenize samples under the Sample Preparation section, as all samples will be plant material.

The phrase “For plant material, use” was removed from proposed section (V)(B)(1). This amendment is necessary for clarity, as the Standard Operating Procedures no longer apply to cannabis products and infused pre-rolls. As such, all samples will be plant material and it would be redundant to specify what one must use for a plant material sample.

The sentence “For pre-rolls, include the rolling paper in the homogenized samples” was added to proposed section (V)(B)(1). This amendment is necessary for clarity, as the paper in a pre-roll consumed and should be tested as part of the over sample product.

The sentence, “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”, has been removed from proposed section (V)(B)(1). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to clarify that the Standard Operating Procedures does not apply to cannabis products such as chocolates, hard candy, gummy and cookie samples.

The sentence, “For beverage and cannabis infused edible oil samples, invert the container 3 or more times to ensure homogeneity of the liquids,” has been removed from proposed section (V)(B)(1). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to clarify that the Standard Operating Procedures does not apply to cannabis products such as beverages and cannabis infused edible oil.

The phrase “200 mg” was added and the phrase “appropriate amount” was removed first sentence of proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, all samples for plant material should weigh 200 mg, as no other sample types will be used in the proposed test method. This amendment is necessary to clarify the sample weight for plant material, as the Standard

Operating Procedures do not apply to other cannabis products.

The phrase “indicated below, that corresponds to the sample type” was removed from proposed section (V)(B)(2). This edit is necessary because there are no longer multiple sample types and masses determine by the sample type because the Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls.

The phrase “Plant material/concentrate/vape oil: 200 mg” was removed from proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, all samples for plant material should weigh 200 mg, as no other sample types will be used in the proposed test method. This amendment is necessary to clarify that the sample weight does not include concentrate or vape oil samples.

The phrase “Cannabis infused edible oil: 0.5 g” was removed from proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, no other sample types will be used in the proposed test method. This amendment is necessary to clarify that the sample weight does not include cannabis infused edible oil samples.

The phrase “Chocolate/hard candy/gummy/cookie/other edibles/topicals: 2 g” was removed from proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, no other sample types will be used in the proposed test method. This amendment is necessary to clarify that the sample weight does not include chocolate, hard candy, gummy, cookie, other edibles, or topical samples.

The phrase “Juice/water/beverage:5 mL” was removed from proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, no other sample types will be used in the proposed test method. This amendment is necessary to clarify that the sample weight does not include juice, water, or beverage samples.

Standard Operating Procedures, Section (V)(C). Sample Extraction.

The phrase “For plant material” was removed from proposed section (V)(C)(1). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to plant material, and no longer apply to cannabis products and infused pre-rolls. As such, there is only one method for sample extraction in the Sample Extraction section, as all samples will be plant material.

The “u” in “use” was capitalized in proposed section (V)(C)(1). This amendment is necessary for grammar and clarity, as the word “use” is the first word in the sentence.

The sentence “for everything else, use methanol as extraction solvent” was removed from proposed section (V)(C)(1). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to plant material, and no longer apply to cannabis products and infused pre-rolls. As such, there is only one method for sample extraction in the Sample Extraction section, as all samples will be plant material.

The word “the” was added to proposed section (V)(C)(1). This amendment is necessary for grammar and clarity, as there is only one typical dilution for dried flower, including pre-rolls, as all samples will be plant material.

The phrase “at least” was added to proposed section (V)(C)(3). This amendment is necessary to address public comment and clarify that laboratories may sonicate for longer than thirty minutes.

The phrase “with acetonitrile/methanol (80:20 Volume:Volume) was added to proposed section (V)(C)(6) to address public comment and clarify what diluent is used to dilute the sample extract.

The “T” in “typical” in proposed section (V)(C)(6) has been changed to a lower case “t” in proposed section (V)(C)(6). This amendment is necessary for grammar and clarity, as the word ‘the’ is the first word in the sentence and “typical” is now the second word.

The “s” in “dilutions” in proposed section (V)(C)(6) has been removed. This amendment is necessary for grammar and clarity, as there is now only one typical dilution for dried flower.

The phrase “for dried flower, including pre-rolls, is 20” was added to proposed section (V)(C)(6). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls. As such, there is only one typical dilution, as all samples will be plant material.

The phrase “are given in the following table” and the table providing sample matrix for flower/plant material, concentrate/vape oil, edibles, and beverages and respective dilution were removed from proposed section (V)(C)(6). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls. As such, there is only one typical dilution, as all samples will be plant material and the other sample matrices listed are not included in this method.

Standard Operating Procedures, Section (V)(E). Instrument Analysis.

The word “replicate” was added to proposed section (V)(E)(3) to replace the word “duplicate”. This edit is necessary for consistency of nomenclature. The regulations refer to sample replicate rather than sample duplicate.

The sentence “6. Store samples and Standards in the HPLC autosampler or a refrigerator in dark at 4°C or lower” was removed from proposed section (V)(E)(6) and replaced with the following sentence: “After the run finishes, recap the standards and sample vials and store them in –20°C freezer”. This amendment is necessary to be consistent with previous standards storage instruction and provides clarity in storage of standards.

Standard Operating Procedures, Section (VI). Method Limit of Quantification (LOQ).

The word “minimum” was added to the proposed section (VI). This edit is necessary for clarity and consistency. The calibration points listed are a minimum and laboratories may choose to add additional calibration points.

Standard Operating Procedures, Section (VII)(A). Quality Control.

The following sentences were added to proposed section (VII)(A)(1): “The solvent blank should be free of the target analytes such that no target analyte is present over the LOQ to meet acceptance criteria. If target analytes are present over the LOQ, rerun the solvent blank once or until the target analytes are no longer present over the LOQ. If the problem persists, locate the source of contamination and rerun the CCV or ICV.” This edit is necessary to set an acceptance criteria for the solvent blank to ensure accuracy of the testing results. The Department set this acceptance criteria because solvent blanks are used to flush instrumentation and monitor any carryover in analysis. If there is an analyte in the solvent blank above the LOQ concentration, this carryover could be reported as a result incorrectly.

The phrase “second source” was removed and replaced with the following phrase was added to proposed section (VII)(A)(2): “source external to the laboratory and different from the source of the calibration standards”. The phrase “second source” has not previously been used and this edit is necessary for clarity and consistency.

The phrase “percent recovery” was added to proposed section (VII)(A)(2-3). This edit is necessary to clarify what 30% refers to.

Standard Operating Procedures, Section (VII)(B). Quality Control.

The sentence “Use Deionized (DI) water as the Method Blank for beverage sample matrices and follow the same extraction procedures” has been removed from proposed section (VII)(B)(1). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls. As such, there is only one blank matrix for this method, as juice and beverage sample matrices are not included in this method.

The word “other” has been removed from proposed section (VII)(B)(1) because this method only applies to one type of sample matrix. This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls, and no other matrices would be included.

The word “plant material” was added to proposed section (VII)(B)(1). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls, and all matrices would be for plant material.

Both instances of the word “methyl” were removed from proposed section (VII)(B)(1) because cellulose powder was used as a blank matrix and cellulose was used as the Method Blank in the method, not methyl cellulose.

The word “methyl” was removed from proposed section (VII)(B)(2) because cellulose powder was used as a blank matrix in the method, not methyl cellulose.

The word “matrix” has been added to proposed section (VII)(B)(4) for clarity and consistency. This amendment is necessary because it must be clear that the “post-dilution” spike refers to the “matrix post-dilution spike”.

Standard Operating Procedures, Section (VII)(D). Retention Time (RT) Acceptance Window.

The phrase “calibration standards” was removed from proposed section (VII)(D) and replaced with the following phrase “target analytes in the CCVs and calibration curve standards injected during”. This edit is necessary because a calibration curve may not be injected every run or analytical sequence and this helps clarify that a laboratory would have no retention times to average in the event that they only ran CCVs in the analytical sequence. The intent is that the laboratory averages the retention time of known standards during the analytical sequence. These retention times will be the metric that the laboratories use to evaluate the identity of the analytes so therefore it is critical to ensure that the labs are able to collect this information from CCVs (which are known standards) to comply with the regulations.

The word “run” was removed and replaced with “analytical sequence” in proposed section (VII)(D). This edit is necessary to clarify that a calibration curve is not injected every run or analytical sequence and to instruct laboratories to use CCVs for the average retention time when a calibration curve has not been injected in the analytical sequence.

The sentences “of the calibration curve standards injected during the same analytical sequence of the samples. Calibration curve standards injected during the same analytical sequence include CCVs and the calibration curve standards. If no calibration curve was injected during the same analytical sequence as the samples, use the CCVs injected during the same analytical sequence as the samples” were added to proposed section (VII)(D). This edit is necessary to clarify that a calibration curve is not injected every run or analytical sequence. This amendment is necessary because without this

amendment, a laboratory would have no retention times to average in the event that they only ran CCVs in the analytical sequence. The intent is that the laboratory averages the retention time of known standards during the analytical sequence. These retention times will be the metric that the laboratories use to evaluate the identity of the analytes so therefore it is critical to ensure that the labs are able to collect this information from CCVs (which are known standards) to comply with the regulations.

The word “curve” was added to proposed section (VII)(D). This edit is necessary to clarify there are 7 calibration curve standards in a calibration curve.

The words “the run” were removed from proposed section (VII)(D) and replaced with “a calibration curve”. This edit is necessary for clarity and consistency.

The word “can be” were added to replace the word “are” in proposed section (VII)(D). This edit is necessary to clarify that seven retention times can be collected.

The phrase “along with 1 retention time of each cannabinoid from every CCV injected in the analytical sequence was added to replace the phrase “from the standards” in proposed section (VII)(D). This amendment is necessary because without this amendment, a laboratory would have no retention times to average in the event that they only ran CCVs in the analytical sequence. The intent is that the laboratory averages the retention time of known standards during the analytical sequence. These retention times will be the metric that the laboratories use to evaluate the identity of the analytes so therefore it is critical to ensure that the labs are able to collect this information from CCVs, which are known standards to comply with the regulations. One retention time of each cannabinoid from every CCV injected in the analytical sequence because there will be one retention time for each cannabinoid in the CCV. The separation gives one retention time for each cannabinoid.

The word “total” was added to replace the word “7” in proposed section (VII)(D). This amendment is necessary because without this amendment, a laboratory would have no retention times to average in the event that they only ran CCVs in the analytical sequence. The intent is that the laboratory averages the retention time of known standards during the analytical sequence. These retention times will be the metric that the laboratories use to evaluate the identity of the analytes so therefore it is critical to ensure that the laboratories are able to collect this information from CCVs (which are known standards) to comply with the regulations.

Modifications Made Available for a 15-Day Comment Period from May 8, 2023 to May 23, 2023

The primary modifications to the proposed regulations would provide additional clarity regarding mandatory actions, make conforming changes in the regulatory text and the standard operating procedure (SOP) incorporated by reference, and make non-substantive edits for syntax.

Section 15712.1. Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls.

The title of the section has been amended to “Cannabinoid Test Method for Dried Flower, including Non-infused Pre-Rolls” for syntax. Additionally, “non-infused” has been added to “pre-rolls” throughout for greater accuracy as the proposed cannabinoid test method is only applicable to non-infused pre-rolls and does not apply to infused pre-rolls. Further, the phrase “test method” has been revised throughout to “cannabinoid test method” to provide additional clarity regarding the subject of the test method and “High Performance Liquid Chromatography (HPLC)” has been added to ensure both the full term and acronym are identified.

The date in proposed section 15712.1(b) was updated to 4/10/2023. The edit is necessary for clarity as the SOP was updated on April 10, 2023. Lastly, the date for licensed laboratories to implement the cannabinoid test method has been amended to three months after the effective date of the regulation.

The phrase “and obtain Department approval prior to use of the proposed method” has been removed from proposed section 15712(i).

Section 15712.2. Verification of Test Method for Dried Flower, including Non-Infused Pre-Rolls.

Consistent with edits made in proposed section 15712.1, this section has been renamed “Verification of Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls.” A new subsection (c) has been added to incorporate the definition for “reagent blank” which has been moved from the SOP to provide greater clarity as the term is not used in the SOP but is used in this regulatory section. The remaining subsections have been renumbered accordingly. Lastly, non-substantive syntaxial edits were made to the section to provide additional clarity regarding method verification.

Determination of Cannabinoids Concentration by High Performance Liquid Chromatography (HPLC) for Dried Flower, including Non-Infused Pre-Rolls, (New 04/10/2023) (incorporated by reference in CCR, tit. 4, §15712.1(b)).

Consistent with edits made in sections 15712.1 and 15712.2, the title of the SOP has been amended to add the term “non-infused” to “pre-rolls” to provide additional clarity regarding the applicability of the SOP to non-infused pre-rolls.

The date has been updated to 04/10/2023 for accuracy.

SOP Definitions.

The definitions section has been amended by removing the definition for “certified reference material” as the term is no longer used in the SOP. The definition for “liquid chromatography” has been removed as the term is no longer used in the SOP and all areas where it was used have been replaced by HPLC for greater accuracy. The definition of “method blank” has been revised by adding the phrase “or proportions” to

align with the definition in section 15700. Lastly, the definition for “reagent blank” has been removed from the SOP as the term is not used in the SOP and it has been added to section 15712.2 because the term is used in section 15712.2. The remaining definitions have been renumbered accordingly.

SOP §I. Safety.

The Safety section of the SOP has been amended to remove the first three sentences related to limiting health hazards and exposure to chemical compounds as well as compliance with the “Laboratory Safety Guidance” established by the Occupational Safety and Health Administration (OSHA).

SOP §II. Apparatus and Materials.

Subsection H has been amended to remove the term “effectively.”

Subsection M has been amended to replace “LC” with “HPLC” for consistency of terms used throughout the SOP.

Subsection Q has been amended to remove the descriptor of an analog vortex mixer and refer only to vortex mixer for accuracy as any vortex mixer is permissible under this SOP.

SOP §V. Procedure.

Subsection B.1. has been amended to add “any size reduction equipment” as an option for homogenizing samples.

Subsection C.6. has been amended for clarity by removing the statement “[t]he expected concentration can be calculated based on labels of samples or past experience on similar samples.”

Subsection C.7. has been amended to align with the intent of this subsection which requires the specific action to obtain a concentration within the range of calibration curve. To clarify that this step is mandatory, the word “should” has been replaced with “shall.” Subsection D.1. has been amended to replace “LC” with “HPLC” for consistency of terms used throughout the SOP and regulatory sections.

Subsection E.5. has been amended to add the term “mid-range” to Continuing Calibration Verification (CCV) for accuracy and to align requirements for all CCV to be in the mid-range. This subsection has also been amended to update the cross-reference to Section VII.A.3.

SOP §VII. Quality Control.

The section has been amended to replace the word “should” with “shall” in the first sentence and subsections A.2., A.3., and B., to align with the intent of this section which is to require licensees to meet existing requirements regarding the use of quality control samples.

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15712.1(b)	282, 283	Commenter states cannabis specific testing standards have been issued by other organizations and state policy should reflect previously identified best practices. Commenter requests the Department publish the reference method's performance specifications/method validation packet. Proper validation studies as outlined in AOAC's Guidelines for Single-Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals (Appendix K) would include activities such as but not limited to: wavelength optimization (selectivity), analytical accuracy, and analytical precision. Commenter has observed that the required analysis wavelength of 220 nm is a region where matrix interference often occurs due to the absorption of many non-targeted non-cannabinoid analytes at this wavelength. Using this wavelength will reduce the total number of cannabinoids laboratories are able to accurately quantitate.	The Department agrees in part with this comment. 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.
15712.1(h)	208, 209, 214, 215, 526	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 disagrees with this comment. 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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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.
15712.1(b)	49,55, 73,	Commenters indicate the	The Department

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
and Definitions	79,83, 86, 87, 99, 113, 155, 216, 325, 352. 354, 376, 402, 411, 413, 483, 501, 522, 524, 527, 537, 557, 587, 592, 635, 639, 643, 644, 657	introduction of “reporting limit” in the SOP for cannabinoids has implications for the interpretation of the existing methods. If the Department introduces this term and distinctions in the cannabinoids method only, the reported LOQ on the Certificate of Analysis will have different meanings between the analytical tests. Further, the SOP does not require that the “reporting limit” value be stated on the COA. Commenters also ask whether the DCC method specify a specific Cannabinoids additional homogenization step described in Section (V)(B) after collecting Micro aliquots. Some commenters recommend removing reporting limit altogether, or setting a minimum reporting limit.	agrees in part with this comment and removed reporting limit from the regulations.
15712.2	94, 581	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 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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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	107, 585, 673, 648	Commenter states that in its current form, proposed section 15712.2 fails to provide enough information about how the method was validated to ensure proper verification of the method as performed by the Department. As currently written, the ambiguity of this regulation will lead different laboratories to interpret these steps differently. This could lead different laboratories to have significantly different "standardized" methods in each laboratory. This would run counter to the stated goal of having a single standardized cannabinoid test method for every testing laboratory.	The Department disagrees with this comment. The method lists the verification requirements in section 15712.2(c). 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	224	Commenter states section 15712.2 appears to conflict with section 15713. It is unclear if new laboratories will be required to complete both method validation and method verification for cannabinoids. Commenter suggests	The Department agrees in part with this comment. Section 15712.2 states that laboratories must perform a verification before using the

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
		the Department only require a method validation and include any updates as a subsection in section 15713. If method verification remains, suggestion to include clearer details on what is required and when. This is important for both laboratory licensees as well as the Department, which reviews the submitted documents/reports for compliance with the regulations.	method. Additionally, the Department added section 15712.1(i), which states that full validation must be performed for cannabinoid analytes and matrices other than dried flower, including pre-rolls. The method verification requirements are also outlined in the SOP.
15712.2(c)	226, 314, 480, 554	Commenters suggest adding definition of matrix blank to the text of the regulations for clarification.	The Department agrees with this comment and has amended to SOP to include definitions for “reagent blank” and “method blank”.
15712.2(c)	315, 480, 555	Commenters state that there is no recommendation as to what the “Spike concentration levels" should be. The specific spike concentration levels should be required in these regulations.	The Department disagrees with this comment. The SOP does not prescribe specific spike levels but does prescribe the acceptance criteria for the recovery must be between 70-130%. The Department believes this is sufficient to obtain accurate results.
15712.2	578	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	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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
		run two separate runs at two different dilutions.	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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			future.
15712.2	250	Commenter states only a single matrix is required for validation of the method. Commenter recommends validating with multiple matrices because of the difference in composition between flower and edibles and recommends at requiring a successfully complete a PT sample for each additional matrix that the laboratory tests (outside of the matrix used for full method validation).	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 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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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	262	Commenter asserts that laboratories only need to test one matrix to verify method performance for a method that will ultimately be used for many sample types. Commenter states this is completely inappropriate! There are many method validation and verification documents that exist and have been created, updated, and referenced within the analytical chemistry community and should have been reference here.	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 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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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(c)	313, 480, 553	Commenter asserts that the matrices used during the validation of this method are not readily available, so the list of validated matrices remains unknown to laboratories. In order for laboratories to select a validated matrix, please provide the full validation report to all laboratories.	The Department disagrees with this comment. 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. The standardized test method for the determination of cannabinoids concentration was

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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(f)	481	Commenter states this section implies that more than one method can be used. We appreciate this language but it is inconsistent with guidance provided elsewhere.	The Department disagrees with this comment. The regulation requires use of the test method proposed in these regulations. As the SOP only contains one test method at this time, it is the only method that may be used for determining cannabinoids concentration in dried flower, including non-infused pre-rolls.
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 disagrees with this comment. HPLC and LC are separately defined terms in the SOP.
SOP Definition	363, 368, 369, 506, 507, 574	Commenters indicate that the SOP 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.	The Department agrees with this comment. Definitions for “method blank” and “reagent blank” have been included in the SOP. “Method Blank” (MB) means an analyte free matrix to which all reagents are added in the same volumes as used in the sample preparation and which is processed in exactly the same manner as the representative

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			sample. “Reagent Blank” means reagents which are used in the procedure taken through the entire method and which are added in the same volumes as used in the sample preparation. A Reagent Blank is analyzed in the same manner as the representative sample. “Solvent Blank” means the same dilution solvent used to create the calibration working standards, acetonitrile/methanol (80:20), and is run in pairing with the ICV and/or CCV. A Solvent Blank is used to determine that the instrument system is clean and free of contamination.
SOP Definition – Certified Reference Material	21	Commenter requests clarification whether all cannabinoid Certified Reference Materials are required to be purchased in-matrix, based on the definition of Certified Reference Material in the SOP which states that CRMs come from a “cannabis or similar non-cannabis matrix”. Using extracted-from-matrix cannabinoids for all calibrations and quality control samples would be impractical and prohibitively expensive.	The Department agrees in part with this comment. Calibration standards are not required to be purchased in matrix or prepared from a CRM in cannabis or similar non-cannabis matrix. The SOP has been updated to clarify this and removed “CRM” language that was previously included.
SOP Definition - Method Verification	251	Commenter states that definition 11 describes “moisture content” as the percentage of water in a sample. In the Procedure section V, paragraph A it is stated “The moisture content of dried flower, including pre-rolls , shall be tested and	The Department disagrees with this comment. Moisture content is defined in section 15700(pp) as meaning the percentage of water in

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		reported as required by California Code of Regulations, title 4, section 15717". Section 15717 of the Code of Regulations does not specifically state that moisture content is water. Commenter asks, if moisture content is water, should a technique that is specific to water measurement be required for its determination. Commenter states that if loss on drying is used, for example, it is not specific to water as volatile compounds in the sample other than water could contribute to the overall determination.	a sample, by weight.
SOP Definition – Resolution	114	Commenter asks for a clearer definition of Resolution. Commenter states the peak width is specifically at the baseline. For peaks to be considered baseline resolved, the Rs = 1.5 or greater and Rs values between 1 and 1.5 are generally acceptable [3].	The Department disagrees with this comment. A good resolution is essential to achieve high accuracy and precision in a HPLC testing method. Based on the Department's experience, lower resolution than 1.3 may cause overlap of cannabinoid peaks and inaccuracy in results, in particular for delta 8 and delta-9 THC. The SOP is written to allow for differences in HPLC systems. Each system and software have their own individual algorithm for calculation of baseline, peak width, and resolution. Rather than be prescriptive and require each laboratory to use the same exact HPLC system, same software, and exactly the same algorithm; the Department has allowed laboratories to

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			choose their own HPLC system. This is necessary as systems are upgraded and replaced in the laboratory, alternate systems can be used in the performance of the method.
SOP (II)	19, 127, 456	Commenters state PTFE syringe filters tend to yield lower recoveries and nylon syringe filters should be acceptable. Some commenters state syringe filtration is unnecessary.	The Department disagrees with this comment. PTFE filters are very common and affordable. The method was validated using PTFE filters. Introducing alternate nylon filters may or may not achieve acceptable results in method verification and may be a source of variance in results.
SOP (II)	28, 124, 156, 432, 457, 612	Commenters state that requiring a Cryo-Grinder or Tissue Homogenizer is not necessary. The cost to operate and maintain a cryo-grinder is extensive and burdens both labs and clients with slower processing times. There is also a greater safety risk associated with using a Cryo-Grinder. The job loss associated with requiring a cryo-grinder amounts to about 3 to 4 jobs in the laboratory being made obsolete. Commentor states sample homogenization can be just as effectively done by human hand and using dry ice.	The Department agrees in part with this comment and removed the cryogrinder requirement. The Department also added a language allowing the use of any size reduction equipment capable of grinding samples to less than 1 mm.
SOP (II)	433, 434, 601	Commenter states only the Aqueous phase of the HPLC eluent needs to be acidified. Commenter states that prescribing both the aqueous and organic phases is unnecessary, adds cost and labor, and does not influence accuracy. Commenter also states that they recommend changing the	The Department disagrees with this comment. The Department's method validation data is part of the rulemaking file and can be accessed on the Department's website or provided

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		specifications language around the making of working standards as it is improper to store acidic and neutral cannabinoids together in solution. Commenter also asserts there should be an allowance for standards up to 500-600 ppm in the calibration curve. Commenter states that limiting to 100 ppm causes the samples analyzed to be more highly diluted. Commenter recommends a calibration curve from 1-600 for major cannabinoids. Commenter states that the quantitative dynamic range of the proposed method of 0.5 to 100 ppm is half of what is industry norm. Commenter asserts the limited window in which a sample must fit to be measured will create a significant amount of re-runs for laboratories.	upon request to the Department. 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

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			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 (II)	95, 583	Commenter states there has never been a resolution requirement listed in the Department regulations until now and there are several widely accepted ways to calculate resolution. Commenter states the definition in section 15712, is somewhat vague and makes several assumptions that need clarification.	The Department disagrees with this comment. A good resolution is essential to achieve high accuracy and precision in a HPLC testing method. Based on the Department's experience, lower resolution than 1.3 may cause overlap of cannabinoid peaks and inaccuracy in results, in particular for delta 8 and delta9-THC. The SOP is written to allow for differences in HPLC systems. Each system and software have their own individual algorithm for calculation of baseline, peak width, and resolution. Rather than be prescriptive and require each laboratory to use the same exact HPLC system, same software, and exactly the same algorithm; the Department has allowed laboratories to choose their own

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			HPLC system. This is necessary as systems are upgraded and replaced in the laboratory, alternate systems can be used in the performance of the method.
SOP (II)	104, 592	Commenter asks why there is a limit on the cannabinoids that can be tested. Commenter states that essentially any modifications to any method would require a full validation of the proposed method, so this would just be another requirement of the method validation. Commenter asks if this was the intention of the Department or will there be regulatory flexibility for adjustments as needed for different instruments.	The Department agrees in part with this comment. The Department disagrees with this comment. The method was only validated for the cannabinoids stated in the SOP. This includes all of the analytes required for regulatory compliance testing, as well as several additional analytes. This method only has to be verified by the laboratory. If the laboratory makes the business decision to analyze and report cannabinoid analytes not required for regulatory compliance testing and not contained in the SOP, the laboratory must validate the method to ensure accurate and scientifically valid testing, as required by section 15713. Within the SOP, the Department has allowed the use of some different instruments that meet the performance requirements, when doing so will not lead to inaccurate results. The Department looks

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			forward to working with stakeholders on the development of new test methods in the future.
SOP (II)	324, 326, 330,355, 403, 485, 488, 502, 536,558, 602, 603, 606, 676	Commenters state the Department validation reports indicate that this method does not separate peaks with a minimum resolution of 1.3 therefore the resolution requirement should be removed. The resolution reported in the validation report from CMCR does not calculate resolution according to the definition in this document and this erroneously shows a greater resolution than the method achieves. One Commenter suggests removing the resolution requirement. Another commenter asserts that the only key measurement detailed is "Resolution" defined in Definition #13, which states "Resolution means a quantitative measure of how well two elution peaks can be differentiated in a chromatic separation. It is measured by dividing the difference in peak retention times by the average peak width." In our opinion, this definition is incorrect due to its vague wording, and reference to "average peak width". Commenters ask that the DCC consider a more detailed, accurate and accepted definition, as well as consider how software integration/calculation will differ from lab to lab. Other commenters assert the resolution of the method proposed from peak to peak is not adequate. If you start adding large amounts of one anolyte versus the other, you will no longer resolve the anolytes. For example, if you have a high Delta-8 THC in concentration and a	The Department disagrees with this comment. A good resolution is essential to achieve high accuracy and precision in a HPLC testing method. Based on the Department's experience, lower resolution than 1.3 may cause overlap of cannabinoid peaks and inaccuracy in results, in particular for delta 8 and delta 9 THC. The SOP is written to allow for differences in HPLC systems. Each system and software have their own individual algorithm for calculation of baseline, peak width, and resolution. Rather than be prescriptive and require each laboratory to use the same exact HPLC system, same software, and exactly the same algorithm; the Department has allowed laboratories to choose their own HPLC system. This is necessary as systems are upgraded and replaced in the laboratory, alternate systems can be used in the performance of the method.

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		low Delta-9 THC concentration, you will front the Delta-8 and bleed out the Delta-9.	
SOP (II)	410, 526	Commenter asserts 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.	The Department disagrees with this comment. The Department has built flexibility into the language of the proposed SOP (V)(D) to allow the application of other instrument parameters, such as the commenter suggested, mobile phases, and injection volume.
SOP (II)	431, 456, 628	Commenters request that the use of syringe filters be modified to allow for centrifugation as an alternate where this appears. Other commenters recommend that additional products be allowed for use.	The Department disagrees with this comment. The standardization of the testing method was aimed to reduce the interlaboratory variation. In the Department's experience, the use of different filters in some cases caused absorption of cannabinoids and inaccuracy in the results. PTFE filters are very common and affordable and were used as part of the interlaboratory validation.
SOP(II)	103, 591	Commenter states the language of section 15712 implies laboratories can have different LC instrumentation and a different column as long as we achieve the minimum performance (resolution) requirements. This is presumably why there is now a requirement for an acceptable separation by requiring a $R_S \geq 1.3$. In the	The Department agrees in part that a different LC instrumentation and different column are acceptable so long as they achieve the minimum performance requirements and can collect a UV-Vis

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		"Apparatus and Materials" section A, the requirements of the HPLC instrument are defined as, "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." If a single wavelength is to be used across all cannabinoids, can a lab simply use a UV-Vis HPLC capable of achieving the 220nm laid out in section 15712.	spectrum. A UV-Vis HPLC capable of achieving 220 nm is allowed. A tunable detector or photodiode-array detection module is still needed because it will be used to collect the UV-Vis spectrum of a peak when the peak identification is in doubt, as stated in SOP (VII)(E).
SOP (II)(C)	327	Commenter states it is unclear whether or not greater precision is allowed. If so, "weighing to, at least, the nearest 0.1 mg" and "weighing to, at least, the nearest 0.1 g", respectively, would be better. Greater precision should be allowed and the term 'at least' should be applied to both requirements.	The Department disagrees with this comment. The language of the SOP (II)(C), which states "capable of weighing to the nearest," allows for greater precision than 0.1 mg.
SOP (II)(E)	328, 486, 559	Commenters states the following pieces of equipment are not further referenced, so it is unclear why they are included in this document: E. Disposable glass Pasteur pipette; F. Pipettes and pipet tips; J. Ice bucket; R. Griffin glass beakers; S. Graduated cylinder. If they are not strictly required, then they should be removed. Additionally, "pipet" should be changed to "pipette" for consistency's sake. Commenters suggest that items should be removed if they are not required in the SOPs.	The Department disagrees with this comment. These are laboratory supplies used during sample and calibration standards preparation. "E. Disposable glass Pasteur pipette" is used to transfer the stock standards from the ampule to HPLC vials . "F. Pipettes and pipet tips" are used to measure the amount of standards and samples to be used when preparing standards and dilutions of samples after extraction. "J. Ice bucket" is used to transfer the ice used in

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			the sonication procedure from the ice-making machine to the sonicator. “Griffin glass beakers” are used as containers for solvents, reagents and waste. “S graduated cylinder” is used to make mobile phases and to measure the 40mL extraction solvent. While specific equipment is referenced for guidance in the Apparatus and Materials section II, these are not specifically required to be used in the procedure of the SOP because chemical sample preparation includes the use of laboratory equipment including pipettes.
SOP (II)(G)	435	Commenter proposes allowing G.Conical polypropylene centrifuge tubes (50 ml), or equivalent vial appropriate for chemical extraction, including glass.	The Department disagrees 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

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			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. The conical polypropylene centrifuge tubes were used in the method. Other materials were not tested and may cause inaccuracies in the reporting of results.

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			These tubes are economical and readily available to laboratories.
SOP (II)(K)	329, 455, 487, 436, 560	Commenters states it is unclear why amber vials are specified. If clear vials were found to be unsuitable the reason should be stated. If the color of the vial has not been shown to make a difference in the analysis, vial color should not be required.	The Department disagrees with this comment. Amber vials are used to prevent THCA and CBDA degradation from light.
SOP (II)(P)	331, 489, 561	Commenter states it is unclear why a 1L solvent bottle is specified. Commenter uses 4L bottles with our cannabinoid method, but 2L bottles are also an industry standard. Laboratories should be allowed to select the most appropriate bottle-size for their instruments. “1 L” should be removed from this line.	The Department agrees, and clarification was added to allow for any sized bottle in SOP (II)(P).
SOP (II)(T) and (V)(B)(1)	16	Commenter recommends use of Stomacher Lab Blenders for grinding plant material which uses paddles and a disposable sterile sample bags which can be used to collect plant material samples. Stomacher blender is more practical and efficient and less time consuming with high product volume.	The Department disagrees with this comment. The stomacher type homogenizer is not suitable for sample preparation of plant material. The pressure applied by the paddles is not strong enough to break down the hard plant material like cannabis flower or leaves into fine powder. The stomacher cannot provide enough shear force to reduce the particle size to <1 mm, which is required by SOP (II) “Apparatus and Materials. Without proper grinding of samples, there will be an incomplete extraction of cannabinoids and

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			generation of inaccurate results. Therefore, the stomacher should not be recommended.
SOP (III)	45	Commenter states “0.05% formic acid” is lacking units.	The Department agrees with this comment and has added 0.05 " Volume/Volume” for clarification.
SOP (IV)	266	Commenter states existing standard methods that were based upon industry stakeholder needs to include more cannabinoids than these. See AOAC OMA 2018.11 and other methods developed by instrument manufacturers. Also, the provided method does not address the challenges of delta-8 THC products.	The Department disagrees with this comment. The method was only validated for the cannabinoids stated in the SOP. This includes all of the analytes required for regulatory compliance testing, as well as several additional analytes. These include delta-8 THC. If the laboratory makes the business decision to analyze and report cannabinoid analytes not required for regulatory compliance testing and not contained in the SOP, the laboratory must validate the method to ensure accurate and scientifically valid testing, as required by section 15713. The Department looks forward to working with stakeholders on the development of new test methods in the future.
SOP (IV)	332	Commenter states the method is very limited in the cannabinoids included. The following additional cannabinoids should be included in	The Department disagrees with this comment. The method was only validated for

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		this method: CBGA, CBNA, THCVA, CBDV, CBDVA, CBCA, CBL.	the cannabinoids stated in the SOP. This includes all of the analytes required for regulatory compliance testing, as well as several additional analytes. If the laboratory makes the business decision to analyze and report cannabinoid analytes not required for regulatory compliance testing and not contained in the SOP, the laboratory must validate the method to ensure accurate and scientifically valid testing, as required by section 15713. The Department looks forward to working with stakeholders on the development of new test methods in the future.
SOP (IV)	334, 646	Commenter states 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.	The Department disagrees with this comment. SOP (A), (B), and (C) are sufficient to describe to laboratories the method to prepare calibration standards and is consistent with other standard SOP's in literature. The SOP procedure includes the initial standard concentration, the working standards concentration, the diluent, the storage condition, and the concentrations and range of the final calibration standards.

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SOP (IV)(A)	36, 58, 63, 76, 80,102, 108,116, 139, 248, 294, 425, 562, 586, 589, 590, 605, 661, 674, 677	Commenters state coverage of only 9 analytes is not representative of the desires of current marketplace with 12-16 cannabinoids being common. Commenters state laboratories will not be able to provide testing on additional compounds because the additional compounds are likely/can coelute with target compounds.	The Department disagrees with this comment. The method was only validated for the cannabinoids stated in the SOP. This includes all of the analytes required for regulatory compliance testing, as well as several additional analytes. In validating the method, chromatography and retention time for each analyte were reviewed thoroughly for coeluting analytes. If the laboratory makes the business decision to analyze and report cannabinoid analytes not required for regulatory compliance testing and not contained in the SOP, the laboratory must validate the method to ensure accurate and scientifically valid testing, as required by section 15713. The Department looks forward to working with stakeholders on the development of new test methods in the future.
SOP (IV)(B)(3) and (VII)(A)(2)	298	Commenter states that the terminology, second source, is mentioned a handful of times but is not listed in the definitions section. Commenter asks if a second source CRM will describe a separate manufacturing lot (different day, different chemist) of the same vendor catalog number for purchase, or will it mean a separate	The Department agrees in part with this comment and has clarified the SOP (IV)(B)(3) by removing the term “second source”. Section 15700(z) defines Initial Calibration Verification (ICV) clearly as a

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		CRM vendor altogether. Commenter states it is not clear what is meant by second source. Commenter recommends adding a definition for second source to provide clarity on how certified testing laboratories should go about sourcing their CRMs so there is no confusion. “Second Lot” may be a more accurate statement if the Department is not requiring the second set of working standards to be made from CRMs sourced from a separate vendor than the first set.	solution of each of the target method analytes of known concentration that is obtained from a source external to the laboratory and different from the source of calibration standards. A different day or different chemist are not an external source.
SOP (IV)(B)(5)	297	Commenter recommends stating the stability of the combined working standard solution. Guidance on how long certified testing laboratories should expect these mixtures to be stable at the prescribed conditions, “freezer (-20°C)”, will help eliminate the possibility of expired or degraded standard from being used. It is not clear how long the certified testing laboratories can use these mixtures for calibration and other QA purposes. ISO/IEC 17034 Vendor CoA expiration dates are attached to flame sealed, nitrogen blanketed ampules. Claims on stated stability are not applicable once the standard ampule is cracked and or mixed. Commenter strongly suggests that certified testing labs perform in house stability studies of these mixtures to understand their mixed stability in each laboratory’s unique conditions. Commenter does not recommend having mixed solutions of acidic and neutral cannabinoids containing methanol and acetonitrile stored for long amounts of time. The Department should consider referring to each vendor’s unique CRM CoA for appropriate handling and storage	The Department disagrees with the comment. How long the mixtures of working standards is stable at the prescribed conditions is not necessary for the SOP and is contingent on what method of storage is used. The ICV and CCV in the SOP (V)(E)(2) provides acceptance parameters for standards used in analysis and calibration. If these acceptance parameters are not met, the laboratory must create new standards and recalibrate the instrument. Additionally, the Department has modified the requirement to allow laboratories to store working standards per the manufacturer’s specifications as an alternative to storage at -20°C .

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		recommendations.	
SOP (IV)(C)	317	Commenter states that the cost of standards is dramatically underestimated. Commenter states the total annual recurring cost in standards looks like about $212,404.50 assuming 10 batches run on the HPLC per day based on the standard preparation below.	The Department disagrees with this comment. The Department's average estimated costs represents the average additional costs the proposed method may introduce to a laboratory's existing costs. Different laboratories process different number of samples per week, therefore, an average was calculated. The Department updated its initial estimate after changes were made to the proposed regulations as a result of the comment periods.
SOP (IV)(C)	98, 586	Commenter states, as written, the required calibration curve does not include a standard level at LOQ for the data provided in section 15712 (IV)(C). Commenter asks whether this is a change in the regulatory framework or if it only applies for this new method.	The Department agrees in part with this comment. The Department agrees that the lowest point of the calibration curve should be at or above the LOQ. The Department has clarified the SOP by removing the reporting limit and providing greater clarity for the minimum requirements for the LOQ, including that the LOQ for analytes tested shall be within the range of the calibration curve. The laboratories are given the flexibility to achieve lower concentration limits by adjusting to a

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			lower dilution factor or adding a lower calibration point. If the experimental LOQ calculation is not within the calibration range, it is appropriate for the laboratory to report the lowest calibration point times the dilution factor as their LOQ. For example, the LOQ in the SOP with the dilution factor of 20X can be calculated as follows: (Lowest calibration point 0.5 ug/mL)(40 ml extraction volume)(20X))/200 mg= 2 mg/g. Additionally because of the flexibility mentioned another example when the dilution factor is changed to 10 X can be calculated as follows: (Lowest calibration point 0.5 ug/mL)(40 ml extraction volume)(10X dilution instead))/200 mg= 1 mg/g.
SOP (V)	404	Commenter states the cryogenic grinder only allows one sample to be ground at a time. This will be expensive and time consuming to use and require the purchase of multiple expensive units to maintain laboratory throughput. The SOP should not require a cryogenic grinder, but require that samples are “ground prior to weighing the aliquot for sample prep”.	The Department agrees in part with this comment and removed the cryogrinder requirement. SOP (II) provides that flower must be homogenized to less than 1 mm. The SOP requires that the sample be ground prior to weighing the aliquot for sample prep,

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			this is specifically outlined in section (V)(B). Grinding equipment is available that can grind more than one sample at a time. It is up to the laboratory to determine what equipment is best suited for their needs, such as single or multiple sample grinding, as long as it meets the 1 mm specifications in the SOP.
SOP (V)	78, 82	Commenters state that in SOP (V), using the typical dilution scheme provided, the lowest calibration point allowed, and the updated minimum mass requirements will lead to the lowest quantifiable amount of THC at 8 mg/g for concentrates which contradicts section 15724(b). The same can be seen for the plant matrix.	The Department disagree with this comment. The laboratories are given the flexibility to achieve lower concentration limits by adjusting to a lower dilution factor or adding a lower calibration point. The LOQ in the SOP with the dilution factor of 20X can be calculated as follows: (Lowest calibration point 0.5 ug/mL)(40 ml extraction volume)(20X))/200 mg= 2 mg/g. Additionally because of the flexibility mentioned another example when the dilution factor is changed to 10 X can be calculated as follows: (Lowest calibration point 0.5 ug/mL)(40 ml extraction volume)(10X dilution instead))/200 mg= 1 mg/g.
SOP (V)(A)(2)	234, 235, 333, 382,	Commenters state the current	The Department agrees with this

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	384, 438, 441, 442, 439, 461, 465, 490, 541, 563	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).)	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 concentration than 10 ppm or use another dilution scheme.
SOP (V)(B)	126	Commenter states there is no mention of how to ensure proper homogenization of concentrates in this procedure. Commenter asks if the Department has explored methods for ensuring homogeneity of concentrate samples.	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 subject to further testing and validation

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			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.
SOP (V)(B)	167,168, 194, 195, 626	Commenters states the sample preparation methods are lacking. For example, requiring cryogenic	The Department disagrees in part with this comment. The

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		grinding for all chocolate, hard candy, gummy and cookies samples and then extracting with only a specified extraction solvent is neither effective nor cost-effective. There are other means to ensure homogeneity of samples that do not involve costly and time-consuming cryogenic grinding. Furthermore, products within the broad categories listed can vary widely in their matrix elements.	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

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			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 (V)(B)	172, 176, 180, 184, 200, 675	Commenters state the proposed single preparation and extraction method is impractical and will have dire adverse effects on the reliability of test results due to its failure to account for the innumerable differences amongst different sample types and targets. Commenter states it is impossible to prescribe a single procedure that can accurately analyze them all.	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 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 (V)(B)	249	Commenter states that SOP (V)(B), refers to hemp oil as a sample matrix. Hemp is not currently regulated by the Department and commenter suggests eliminating the word “hemp”.	The Department agrees with this comment and has removed hemp from the regulation.
SOP (V)(B)	299	Commenter states it is not clear which homogenization step is recommended for this category or if there is a separate recommendation for homogenization of topicals (e. g. lotions) altogether.	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

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			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

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			test methods in the future.
SOP (V)(B)	336, 492	Commenter asks for clarity on what this means or why this is necessary and asks the Department to expand on exactly how samples should be grouped by type and why that is necessary.	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 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

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			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 (V)(B)	337	Commenter states the term "juice" is not defined in this document and not a matrix typically encountered by testing laboratories. In fact, regulations currently prohibit perishables. If this is intended to reflect "Liquid Infused Products" or "Liquid Edibles" then that should be stated.	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 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

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			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.
SOP (V)(B)	338,339, 493,494, 565, 566, 626	Commenters state it is not clear why for plant matter, the particle size needs to be less than 1 mm for complete extraction. It is not clear from the Department's validation data that particle sizes of homogenized samples were measured. Where an SOP specifies that something must be done, an ISO 17025 accreditor will expect the laboratories to demonstrate that they have a way of doing such. To measure the particle size of every particle in a homogenized sample and document this is overly	The Department disagrees with this comment. SOP (II) Apparatus and Materials specifies that flower must be homogenized to less than 1 mm. Less than 1 mm is necessary to allow extraction of all cannabinoids in the validated SOP and give acceptable recovery.

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		burdensome as it has not been shown by the Department that they are carrying out this requirement. This should be changed to not specify a particle size.	
SOP (V)(B)(1)	443	Commenter recommends that samples be homogenized as follows: 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. Alternatively, push the flower material through a 1 mm wire mesh. For chocolate, hard candy, gummy and cookie samples, process samples by one of the following means: A. use a cryogenic grinder which can grind the samples to less than 1 mm, following manufacturer's instructions. B. Dissolve samples in water C. Freeze samples and homogenize by method that demonstrates accuracy.	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 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

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			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. Further, the SOP prescribes in Section (II) Apparatus and Materials that flower must be homogenized to less than 1 mm and this is specific guidance and direction which is the size the sample must be ground to.
SOP (V)(B)(1)	91,92, 579, 580	Commenters ask whether the device used to homogenize only needs to be capable of grinding a sample to less than 1 mm. Commenters inquire as to whether particle size needs to be verified during method verification and how it was validated. Commenters also ask whether homogenization in a tube shaker or tube vortexer are an acceptable alternative to tissue homogenizers to achieve particle size.	The Department disagrees with this comment in part. The particle size matters because it is critical for the extraction efficiency. However, based on section 15713 (c), the method validation shall follow the FDA “Guidelines for the Validation of Chemical Methods”, which does not require the verification of particle size at method

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			validation or verification. Other homogenization and sized reduction methods are acceptable as long as they grind samples to <1 mm.
SOP (V)(B)(1)	204, 207, 210, 213, 444, 454, 613	Commenters state mandating the use of a commercially available cryogenic grinding machine for packaged products would limit the laboratory's ability to process large batches as well as place an undue financial burden on labs that do not already use such a machine. Commenter requests the Department allow, as an alternative, the option to manually freeze samples in an ultra-low temperature freezer (-20° C – 180° C) and grind samples using physical benchtop methods, specifically a mortar/pestle, which is common practice across the analytical testing industry. Commenter states allowing a physical benchtop method would allow laboratories to utilize a more cost-effective process, as well as offer an affordable compliant backup solution for laboratories that can afford cryogrinds, while still ensuring that all samples are ground to the required consistency of less than 1mm. In the alternative, commenter requests allowing sample prep via freeze and homogenize by a method that demonstrates accuracy.	The Department agrees with this comment in part. The cryogrinder has been removed from the apparatus listed in the SOP, and cryogrinding has been removed from the sample preparation section of the SOP. SOP (II) Apparatus and Materials requires flower to be homogenized to less than 1 mm. As long as the laboratory grinds the sample to the appropriate size, the method mentioned of freezing and hand grinding is acceptable. Cryogrinding is no longer a requirement for the SOP.
SOP (V)(B)(1)	467, 543	Commenter states that weighing out 200mg of flower will increase variance and inconsistency. It will also make potency easier to inflate	The Department disagrees in part with this comment. The standardized test

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		as people can skew results easier with targeted sampling. Referencing the spex particle size study there would be an uncertainty of about 20% if weighing out 200mg flower at 1mm particle size. Commenter also states that weighing out 5ml of juice or water in 40ml of solvent will lead to low recovery in some samples due to the high water content (11.1%). Juice and water are homogenous products and so 5ml is not necessary for accuracy and only increases waste and adds expense. Commenter recommends increasing the minimum amount for plant material, decrease juice/water, and make required amounts minimums to allow labs to get better averages if necessary. Allow labs to use more or less solvent as necessary as long as extraction goes to completion and recovery on curve is acceptable.	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

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			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 (V)(B)(2)	2, 33, 85, 125, 150, 217, 479, 552	Commenters suggest replacing 200 mg with 0.5 mg for flower sample size.	The Department disagrees 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

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			2021. The method was validated using 200 mg for flower. Changing this measurement can lead to inaccurate results.
SOP (V)(B)(2)	23, 93, 299, 300, 582	Commenters request clarification on the distinction between "vape oil" and "cannabis-infused oil" as used in the table of sample masses for different matrices. Commenters request recommendation for the appropriate amount of sample to start with regarding topicals. Commenter recommends a sample weight of 0.5g. If “Cannabis infused oil” is meant to cover topicals, please specify.	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 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

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			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 (V)(B)(2)	68	Commenter states the sample weight for the testing differs from the regulations currently asking for 0.5 grams. Commenter asks if the difference will be aligned in new regulations.	The Department disagrees with this comment. The Department has limited the applicability of the method to dried flower, including pre-rolls. Section 15712.1(d) states that 200 mg shall be used for dried flower and pre-rolls in the cannabinoid test method, notwithstanding the requirements of section 15724(a). All cannabis products, including infused pre-rolls, not covered in this method should utilize the sample mass requirement in section 15724(a).
SOP (V)(B)(2)	340, 344, 345, 495, 496, 567, 568	Commenters note grammatical error in section. Commenters also state that the instruction to weigh a sample is inconsistent with the	The Department acknowledges this comment. Grammar issues have been

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		requirement to report that sample weight in mL. Commenters 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. Commenters also asserts 40 ml of extraction solvent is an unnecessarily large volume.	amended. 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

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			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 (V)(B)(2)	341, 342, 343, 664	Commenters state the exact masses are listed here, the allowable mass ranges should be listed e.g. “100-300 mg” or (200 +- 100 mg) rather than “200 mg”. Another alternative would be “at least 200 mg”. The same applies to the other specific values. One commenter suggests the amount of sample needed will impact smaller laboratories.	The Department disagrees with this comment. The test method has been amended to require 200 mg of sample and to record the actual weight. 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

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			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.
SOP (V)(B)(2)	445, 446	Commenter suggests that sample size be as follows: 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: 5-15ml.	The Department agrees in part with this comment. Plant material sample size is 200 mg. The standardized test method for the determination of cannabinoids concentration was developed and validated by the Department's cannabis testing laboratory

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			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

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			stakeholders on the development of new test methods in the future.
SOP (V) (C)	468, 544,	Commenter states that 40ml is excessive for 200 mg of flower and limiting for edibles and beverages creating an unneeded expense on solvent and increasing waste. Commenter recommends labs be allowed to extract plant material with just methanol. Commenter recommends the following: Reconsider solvent amounts to allow using less as long as extraction goes to completion. Remove ice from sonicator, or use genogrinder, if low temperature is decreasing solubility and preventing full extraction at higher concentrations. Allow to extract plant material with just methanol as creating mixtures will increase chance for contamination and lab error. Methanol has been proven to be an effective extraction solvent by itself. Lab would also be able to use less of the more toxic solvent, acetonitrile.	The Department disagrees with this comment. The standardization of the testing method was aimed to reduce the inter lab variation and standardizing the extraction volume is one part. 40ml Solvent has been demonstrated through multi-laboratory validation to completely extract the cannabinoids from cannabis using the sample size mentioned in the SOP.
SOP (V) (C)(4)	450	Commenter recommends the following change: Centrifuge an aliquot to a minimum of 3900 rpm for a minimum of 10 ~~15~~ minutes.	The Department disagrees 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

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			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. Based on the Department's experience, shorter times would give incomplete clarification of centrifuged samples, this would lead to inaccuracies in the reporting of results.
SOP (V)(B)(2)	408, 524	Commenter states they would like to review this data as further clarity is desired in how the optimum sample size was determined, especially given that variable sample dilution is allowed. Commenter recommends 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.	The Department agrees in part with this comment. 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.
SOP(V)(C)	41, 96, 97, 132, 150,157, 441, 449, 463, 472, 548, 584, 585, 627, 662	Commenters state ice is unnecessary in the water bath and would prefer a specification using temperature. Some commenters state extraction temperature is not an important factor in cannabinoid recovery from flower and ice would impede partitioning of the cannabinoids. Commenter provides suggestion to keep in sonicating bath for 20 minute minimum, no ice in the water bath.	The Department disagrees with this comment. 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

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			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.
SOP(V)(C)	42	Commenters state centrifuging samples for 15 minutes is unnecessary.	The Department disagrees 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

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			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. The Department has determined through validation of the method that 15 minutes is appropriate. A change in the centrifuge process may or may not achieve acceptable results in method verification and may be a source of variance in results. The steps of centrifuging samples for 15 minutes, and filtering are done to prevent damage to the HPLC system. Use of filtering only for samples would introduce particulates, cause degradation of the HPLC system, and result in a loss of performance.
SOP (V)(C)	128, 346, 609, 624	Commenters state extraction strategy for beverages lacks sensitivity and does not account for micro and nano encapsulated cannabinoids. Commenter states the best method for testing beverages is to extract some volume of the beverage with an equal volume of acetonitrile, followed by treatment with Quechers salts to phase separate the water and acetonitrile. Commenter states the regulation should specify an appropriate extraction solvent for the sample type rather than	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

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		acetonitrile/methanol 80:20.	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.

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SOP (V)(C)	129, 130, 615	Commenter states it has tested over a dozen different extraction systems for flower samples. None made a significant difference in recovery. This is also backed up by testing performed by Restek. Commenter states utilizing this solvent mix adds unnecessary cost (acetonitrile is much more expensive than methanol) to testing because there is no benefit when compared to methanol only extraction. Commenter states if there is benefit, please provide the data that shows this to be the case.	The Department disagrees 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.
SOP (V)(C)	131, 198	Commenter states it was unable to completely dissolve gummies in methanol. It took a mixture of acetonitrile and water with an acid modifier to dissolve them. Their treatment requires Quechers salts. This also had the benefit of leaving the water-soluble compounds behind, which results in a cleaner sample for injection. This method works well for the other edibles as well.	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

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			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

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			development of new test methods in the future.
SOP (V)(C)	151	Commenter states the calibration curve does not include the LOQ point.	The Department disagrees with this comment. The SOP has been updated so that LOQs for target analytes shall be within the range of the calibration curve. Laboratories may add additional low points to the calibration curve or raise the LOQ to the lowest calibration point as needed.
SOP (V)(C)	534, 535	Commenters state there are method problems and recommends a dilution of 80 for concentrate vape oil is likely to try to get the major cannabinoid to the mid-point of the calibration curve. For a sample of a pure cannabinoid at a .2 g prep mass a dilution factor of 50 would bring the concentration in a diluted extract to the 100 µg/mL high point of the calibration curve. This would result in a reporting limit of 5 mg/g for all analytes which conflicts with the existing reporting requirement of at most 1 mg/g.	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 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

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			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.
SOP(V)(C)	252	Commenter states adding methanol extraction solvent directly to a beverage sample will dilute it since water and methanol are miscible. Commenter suggests adding detail regarding either (1) direct analysis of undiluted beverage ("as is" without addition of solvent) or (2) additional of salts to force the formation of an organic and aqueous layer.	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

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			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.

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SOP (V)(C)	350, 499	Commenters state 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 could work better here. 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”.	The Department disagrees with this comment. Based on the Department’s experience, HPLC vials are the most appropriate container to use for placing the extract into the instruments’ autosampler. The laboratory may consider placing a HPLC vial insert into the HPLC vial if they are concerned about removing the extract in the future.
SOP (V)(C)(1)	205, 211	Commenter states the proposed extraction method limits the solvent used for infused products to methanol. From our experience methanol extraction often does not work for testing food items. Commenter requests DCC propose an approval process for alternative solvents, such as dimethyl sulfoxide (DMSO) for edibles or novel products.	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 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

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			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.
SOP (V)(C)(1)	20,39, 40, 65, 66, 67, 69, 105, 119, 121, 130, 131, 198, 265, 302, 303, 417, 430, 444, 447, 462, 469, 470, 528, 545, 546, 583, 589, 594, 622, 647	Commenters state cannabinoids are not effectively extracted from every sample type using ACN/MeOH and non-plant samples must be extracted with pure methanol. Commenter requests that ACN be permitted as an extraction solvent to allow for proper testing of all matrices sold in the state. Commenters also state support for the need for differing sample preparation and extraction techniques. Commenter suggests splitting the extraction volume in	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

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		half and moving through the protocol twice can help achieve better recoveries of cannabinoids using less solvent.	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

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			future.
SOP (V)(C)(2)	188, 206, 212	Commenters suggest changing the proposed rules for sample vortexing limit to 5 minutes.	The Department disagrees with this comment. However, the Department has amended the SOP to clarify as follows: "Vortex each centrifuge tube for at least 1 minute." With this clarification to the text, the sample may be vortexed for 5 minutes, if desired.
SOP (V)(C)(2)	347, 448, 460, 497, 569, 570	Commenters state the SOP requires multi-tube vortex mixer for efficiency thereby creating a burdensome cost to testing laboratories and the Department should allow other equivalent procedures to be used for sample extraction. Commenters assert vortexing these standards is not best practice and should not be specified. Commenter indicates that the best practice is to mix using a Pasteur pipet to prevent the solution from depositing inside the lid and drying from such a technique as Vortexing. More care should be taken with cannabinoid standard handling. Other commenters state that the new requirement that labs use a multi-tube vortex mixer may be unduly expensive for some testing laboratories. Commenters ask that the Department allow equivalent procedures and equipment to be used to extract samples.	The Department disagrees with this comment. SOP (II)(Q) only lists a "Vortex mixer" therefore a multi-tube vortex mixer is not required. Vortex mixers are one of the primary technologies for mixing laboratory samples. They use a fairly simple mechanism to agitate samples and encourage reactions or homogenization with a high degree of precision. The cost of Vortex mixers are minimal typically in the range of $200-$400 for laboratories and not considered burdensome.
SOP (V)(C)(4)	471, 547,	Commenter states sample cleanup is dependent on the kind of instrument configuration the lab is using and shouldn't be controlled within the SOP. Centrifuging all sample types is unnecessary and redundant when	The Department disagrees. The process was part of the multi-lab method validation. A Change in the centrifuge process may or may not achieve

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		using a PTFE filter and PTFE filters are not necessary in all cases. In addition, PTFE filters are expensive, time consuming, and have potential to retain cannabinoids. The extra time of centrifuging and filtering when not necessary will be labor and cost intensive. Commenter recommends letting labs decide how to cleanup their samples depending on their instrument configuration. Commenter suggests amending language to "Centrifuge and filter sample extract as necessary.	acceptable results in method verification and may be a source of variance in results. The steps of centrifuging samples and filtering are done to prevent damage to the HPLC system. Use of filtering only for samples would introduce particulates, cause degradation of the HPLC system, and loss of performance.
SOP (V)(C)(4)	229	Commenter states in Section V(C)(4) the use of rpm is not as appropriate as the use of "g" when defining a centrifuge, to account for varying radii in different centrifuges.	The Department agrees in part with this comment. RPM can be converted to g by using the following formula: $g = rpm^2 \times r \times 1.118x10^{-5}$ so long as the radius of the centrifuge is known. The radius of the rotor used in this SOP is 19 cm, giving a g force of 3231.
SOP (V)(C)(4)	348, 349, 451, 498, 499, 570	Commenters state it is unclear how 3900 rpm was determined. Reasoning should be provided or language updated to reflect "at least 3900 rpm" instead. Centrifugation is not a necessary step to sample extraction and should not be required. Purchasing centrifuges to keep up with high sample flow is a high and burdensome cost. If a centrifuge is necessary the speed should not be set in the SOP unless it has been shown to impact the method.	The Department disagrees with this comment. It is standard HPLC laboratory practice to centrifuge complex materials before analysis to prevent interferences and clogging of the HPLC. The use of 3900 rpm is a typical choice for clarifying complex mixtures and prevent small particles from being introduced into the HPLC, causing interferences, creating clogs, and giving inaccurate results.
SOP	538	Commenter states the SOP	The Department

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(V)(C)(5)		specifies using the labeled concentration and/or previous experience with the samples to calculate the Dilutions. Several parameters required for the calculations of the final values, e.g. package net weight of serving-based products, number of servings per package, labeled concentrations, etc. are not always available for laboratories as there is no requirement for distributors to provide and laboratories to verify that information. (Is it something that will be required for all licensed distributors to provide to testing labs as part of their order information, or is it just advised for labs to retrieve that information from them? Timely communication with clients can be challenging sometimes, which could delay the process if not required up front.)	disagrees with this comment. SOP (V) provides suggested dilutions. The request to require distributors to provide information is not necessary in the performance of the method.
SOP (V)(C)(6)	351, 500	Commenters state that 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.	The Department disagrees with this comment. Dilution of samples will be highly dependent on the cannabinoid concentrations of the samples analyzed. Specific requirements are not given as this is typically standard HPLC practice to choose a dilution based on prior experience. If sample results are beyond the calibration curve being used, additional dilution is needed as per standard HPLC practice. The use of a surrogate compound was not necessary for the validation of the SOP. It would be an extra step, which adds

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			cost and complexity to the method.
SOP (V)(C)(6)	77, 81, 133, 304	Commenters state that in SOP (V)(C)(6), DCC should set the initial dilution pathway because handling concentrations outside of this is given in SOP (V)(C)(7). Commenters also recommend that the sample diluent be clearly stated in SOP (V)(C)(6). If the final diluted sample matches the extraction solvents/standards, for example, acetonitrile/methanol (80:20) as diluent, it will be too strong and may cause peak splitting in early eluting compounds.	The Department disagrees with this comment. "Typical dilutions" are given in the SOP, so it leaves flexibility for the laboratory to apply their own dilution scheme. The SOP (V)(C)(6) has been updated to include the sample diluent.
SOP (V)(C)(7)	353	Commenter states the “range of calibration curve” should be “range of the calibration curve.”	The Department disagrees with this comment and believes the current phrase is clear.
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 or previous experience with similar samples. This clearly implies that dilutions are at the laboratory’s discretion.
SOP (V)(C)(7)	44	Commenter states “re-analyze” the sample is not clear and questions the stability of the originally prepared sample by the time data is generated and reviewed.	The Department disagrees. The SOP refers to section 15730 which gives clarity on when samples can be re-analyzed, or need to

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			be re-prepped and re-analyzed.
SOP(V)(D)	24	Commenter requests clarification on SOP provision that "Instrumental Parameters are column and system specific and will vary according to the specific HPLC column and system used." Specifically, whether instrument parameters (flow rate, injection volume, etc.) are subject to change so long as resolution is at or above 1.3.	The Department agrees with this comment. The SOP and ISOR explain that instrumental requirements are to separate the cannabinoids tested with a minimum resolution of 1.3. Based on the Department's experience, lower resolution than 1.3 may cause overlap of cannabinoid peaks and inaccuracy in results. The SOP is written to allow for differences in HPLC systems. Each system and software have their own individual algorithm for calculation of baseline, peak width, and resolution. Rather than be proscriptive and require each laboratory to use the same exact HPLC system, same software, and exactly the same algorithm; the Department has allowed laboratories to choose their own HPLC system. This is necessary as systems are upgraded and replaced in the laboratory, alternate systems can be used in the performance of the method.
SOP (V)(D)	267	Commenters indicates that laboratories must adopt the method and cannot alter, and yet the SOP states, "Instrumental parameters	The Department agrees in part and has updated language in SOP (V)(D) for greater

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		are column and system specific and will vary according to the specific HOLC column and system used." Scientists know this, but the previous language conflicts with this hint of flexibility.	clarity. This statement clarifies that only column and instrumental parameters may vary based on the specific column and instrument used.
SOP (V)(D)(1)	306	Commenter states that in SOP (V)(D)(1) they would suggest adding the specification for flow cell on the instrumentation that was used to validate the method. Flow cell volume will greatly impact achievable resolution for the method and may be something that labs will want to check on before setting out to verify the method in their own labs.	The Department agrees in part with this comment. The specification of the flow cell and other parts of the instrument can be obtained from the vendor of the instrumentation used. 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.
SOP (V)(D)(1)	46	Commenter states autosampler temperature can be colder to increase stability of samples	The Department disagrees 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

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			Diego's Center for Medicinal Cannabis Research, which was established in 2000; its laboratory has been the reference laboratory for the Department since 2021. 15 °C is a common autosampler temperature for LC testing methods. There is no evidence showing cannabinoids degrades significantly at 15 °C in as short of a time as one analytical batch. In addition, the SOP gives flexibility for the autosampler temperature, and the labs are allowed to make their own decisions as stated in the SOP (V)(D).: "Instrumental Parameters are column and system specific and will vary according to the specific HPLC column and system used."
SOP (V)(D)(1)	47	Commenter states column dimensions are listed with µm particle size (not um)	The Department agrees with this comment and has changed "u" to "µ" in the SOP.
SOP (V)(D)(1)	48	Commenter states 2 µL injection reproducibility is possible but not with all common/older HPLC models. This could force labs to purchase new instrumentation.	The Department disagrees with this comment. SOP (D) indicates "Instrumental Parameters are column and system specific and will vary according to the specific HPLC column and system used." This language provides flexibility for the HPLC system

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			used, as long as the performance requirements are met.
SOP (V)(D)(I)	137	Commenter asks if the Department has any information regarding the lifetime of these columns after performing the validation testing of this method. Commenter states that larger internal diameter columns have the ability to accept larger on-column masses (i.e injection volumes), which should improve sensitivity at the low end of the calibration curve and large ID columns also have longer lifetimes when dealing with relatively dirty matrices.	The Department notes commenter's inquiry. The Department does not have information on the lifetime of the specific column used at this time. The vendor of the column is listed in SOP (V)(D)(1) additional information.
SOP (V)(D)(1)	136, 223, 253, 268, 322	Commenters state the Department testing was performed on an HPLC system that rarely encountered CA cannabis.	The Department disagrees with this comment, as an HPLC system with a photodiode-array detection module is currently utilized by the majority of licensed cannabis testing laboratories in California for the testing of cannabinoids
SOP (V)(D)(1)	138	Commenter states that isocratic separation may not suit the purposes of laboratories with larger cannabinoid panels. Commenter states they use a gradient method because it reduces peak broadening and it allows resolution of more compounds. Commenter states isocratic methods with increasing portions of organic phase allow for washing while performing analysis. Commenter states the run could be shortened slightly by skipping a wash step and reducing the equilibration to two column volumes (2.1 minutes). Commenter states it may not seem like a lot of time, but shaving two minutes off of a method increases throughput.	The Department disagrees with this comment. Although the Restek Raptor ARC-18 2.1 x 150mm, 2.7um column is used in this test method, the SOP allows for "equivalent" columns to be used by laboratories. Length of run time and the gradient used was chosen to be accurate, easily approached, and economical. The investigation of isocratic and different gradients has been left

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			up to the laboratories as long as the resolution requirements are met.
SOP (V)	629	Commenter states the calibration and working standard protocol outlined in the SOP requires the use of isolated cannabinoid standards. Reference standard manufacturers have several cannabinoid mixtures of multiple cannabinoids at 1 mg/mL (also 500 µg/mL, 250 µg/mL, and 100 µg/mL.) Using commercially available multi-cannabinoid mixtures reduces: reference standard costs, labor overhead, potential for error, and inventory management requirements. The laboratory should be able to prepare the 100 µg/mL working standards using any available certified reference standards and in any manner that results in the desired concentration of the required compounds.	The Department agrees with this comment and added clarifying language to the SOP section IV to allow for the use of 1000ppm or 1mg/mL mixed stock standard solutions. 1000ppm or 1mg/mL concentration for the stock standard solutions was chosen because this is the most common one available from vendors. "Stock standard solution with the following analytes at the listed concentration. Mixtures or combined standard solutions of the listed analytes at their specified concentration or single standard solutions of the analytes at their specified concentrations may be used for the following stock standard solution." The intention of the SOP (IV) calibration standard is to show the required concentrations of the specific analytes, as listed by CAS number, that are to be utilized for the method. The

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			Department has not restricted the use of standard mixtures and they will continue to be acceptable, given that the analytes and concentrations meet their respective requirements (i.e. correct CAS number and concentration).
SOP (V)(D)(2)	140, 165, 166, 192, 193, 502, 614, 630	Commenter states that customizing wavelengths for compounds can improve sensitivity at the low end. It also aids in quantification of closely eluting compounds with significantly different UV/vis spectra.	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. However, as stated in the SOP

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			(V)(D) "Note: Instrumental Parameters are column and system specific and will vary according to the specific HPLC column and system used." The instrument parameters including the selection of wavelength can be modified by the testing labs as long as it achieves a minimum resolution of 1.3.
SOP (V)(E)	593, 637, 640, 645	Commenters request that the Department allow the use of stored calibration data. As written in SOP(V)(E), the standards are to be injected as part of every analysis.	The Department agrees with this comment. A calibration is not required for each batch. The Department has made changes to clarify SOP (V)(E)(2), which includes “If a valid calibration curve and a valid ICV already exist for this method and specific instrument, a CCV may be analyzed in place of a new calibration curve and ICV, so long as the CCV meets the requirements in section 15730.”
SOP (V)(E)	356, 503, 571	Commenters state that there is no valid reason given to specify a 30 minute equilibration. If necessary the procedure should read “The HPLC should be equilibrated to the initial method conditions prior to injecting samples” The word “equilibrate” specifies the condition to be met and this is likely to happen in less than 30 minutes. Requiring 30 minutes will create additional hazardous waste and expense and waste time.	The Department disagrees 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

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			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. The method was validated with the equilibration time in the SOP. Improper equilibration of the HPLC would give inaccurate results that would not be consistent between laboratories. In the Department's experience additional waste was minimal.
SOP (V)(E)	357, 362, 453, 473, 504, 549, 572, 593	Commenters state it is unnecessary to run a calibration curve and ICV with every set of samples. Commenters state once the calibration curve has been generated, it does not need to be re-run each sequence.	The Department agrees and has clarified SOP V(E)(2) of the SOP now states the following: If a valid calibration curve and a valid ICV already exist for this method and specific instrument, a CCV may be analyzed in place of a new calibration curve and ICV, so long as the CCV meets the requirements in California Code of Regulations, title 4,

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			section 15730.
SOP (V)(E)	364, 370	Commenters state that "for quality control purpose" is grammatically incorrect. It should either be "for a quality control purpose" or "for quality control purposes." Additionally, these quality control purposes should be defined.	The Department agrees with in part this comment and has made the grammatical change to SOP V(E)(5) so it now states the following: for quality control purposes. Continuing Calibration Verification is defined in section 15700(r), while solvent blank is defined in the definitions section of the SOP, specifically number 19. CCVs and solvent blanks are part of typical laboratory quality control procedures.
SOP (V)(E)	437, 458, 459, 531	Commenter proposes adding the following italicized language to subsection (A) "Stock standard solution: *To contain cannabinoid or cannabinoids 500-1000 ppm either individually, or in multi-compound mixes obtained as certified reference materials. Cannabinoids for stock standard solution:* Commenters indicate that this section is over specified as it does not allow for 1000 ppm mixes of multiple cannabinoids that are commercially available to be taken advantage of. For example, Restek THC-CBD-CBN mix with all three compounds at 1000 ppm. Additionally, some suppliers (for example, Ceriliant) have specific modifications to their DEA licenses that only allow for 500 ppm mixes to be produced in some cases. Noting again that cannabinoids are one of the most frequently used and expensive supplied in the lab. Not providing for the use of mixes that are generally more economically is	The Department agrees with this comment and added clarifying language to the SOP (IV) to allow for the use of 1000ppm or 1mg/mL mixed stock standard solutions. 1000ppm or 1mg/mL concentration for the stock standard solutions was chosen because this is the most common one available from vendors. "Stock standard solution with the following analytes at the listed concentration. Mixtures or combined standard solutions of the listed analytes at their specified concentration or single standard solutions of the analytes at their

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		an unnecessary preclusion. The Department should allow the use of mixes.	specified concentrations may be used for the following stock standard solution." The intention of the SOP (IV) calibration standard is to show the required concentrations of the specific analytes, as listed by CAS number, that are to be utilized for the method. The Department has not restricted the use of standard mixtures and they will continue to be acceptable, given that the analytes and concentrations meet their respective requirements (i.e. correct CAS number and concentration).
SOP (V)(E)	632	Commenter agrees with and appreciates the acknowledgement in the DCC cannabinoids method that the matrix spike protocol must be adjusted to accommodate for the limit of concentrated cannabinoids stock standards. Commenter states the adjustments to what controls are needed for cannabinoid analytical batches will be beneficial in a number of ways and they support the changes.	The Department agrees with this comment and notes commenter's support.
SOP (V)(E)(2)	383, 512	Commenter states that 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.	The Department agrees with this comment. SOP (VII)(A)(3) and (4) address this.
SOP (V)(E)(3)	230	Commenter suggest referring to "Sample Duplicate" as "LRS" for	The Department agrees with this

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		consistency with current regulations i.e. 15730, 15700(gg).	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 (V)(E)(3)	237, 239	Commenter suggests adding "CCV" to Section (V)(E)(3) to better clarify injection requirements in analysis and adding an example injection order to give requirements of injecting an ICV and CCV to verify calibration prior to analysis.	The Department agrees with this comment and has clarified the language provided in the method by modifying the proposed SOP. The SOP has been updated to clarify analytical batch, analytical sequence, and the required laboratory quality control samples for each. A CCV is required to be run at the beginning of the analytical sequence in

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			pairing with a solvent blank and after 10 samples. Further, the Department removed all previous references to "check standard" and this was replaced with the defined term "continuing calibration verification (CCV)."
SOP (V)(E)(3)	240	Commenter states that Section (V)(E)(3), typo in section. Plural form used to describe a unit of one. Suggestion replace "1 method blanks" with "1 method blank."	The Department agrees and the text has been updated to "1 method blank".
SOP (V)(E)(4)	106, 109, 142, 154, 236, 238, 361, 365, 371, 584, 587	Commenter states that as written (V)(E)(4) a calibration standard needs to be analyzed every 10th injection. This has been changed from the wording from every 10th sample. Commenter asks if this is a re-write in the policy that will be enforced for this method or does this represent a wide-reaching change in the regulations for all methods. Commenters state if this is to be applied to all methods in the future, this would represent a significant increase in the cost per batch for no clear scientific gain. Commenters ask if there is any data to suggest this is a necessary change. Commenter asks what the impetus for this change is.	The Department agrees with this comment and has clarified the CCV frequency requirements by modifying the proposed SOP. The SOP (V)(E)(4) has been updated to specify a CCV is required every 10 samples, instead of every 10 injections.
SOP (V)(E)(4-5)	232, 366, 367	Commenter states this should specify injecting a continuing calibration verification (CCV) instead of "Check Standard".	The Department agrees with this comment and has removed "check standard" to replace this with "CCV".
SOP (V)(E)(6)	372, 373, 508, 539	Commenters state it is unclear why it is required to be in the dark or how much light exposure would be allowed. The Department should clarify why these storage conditions are required. Other commenters	The Department agrees with this comment. The SOP has been amended and no longer states samples and standards

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		state, 'in the dark' and refrigeration at 4C not necessary. Other commenters state that Section V (E)(6) specifies the storage conditions for the samples and Standards at 4°C in the dark however, Section IV (B) 3 says to store Working standards in the freezer at -20°C. Commenters assert Department did not provide solution stability information which could impact current storage conditions and possibly lead to additional expense for alternate storage equipment.	must be stored at 4°C in the dark.
SOP (V)(E)(6)	305	Commenter states that in reference to section V.E.6 they do not recommend storing samples or standards inside the HPLC autosampler. Samples that need to be repeated should be freshly prepped. Furthermore, in SectionIV.B.5, it is mentioned that standards made up in the diluent should be stored in the Freezer (-20°C). In Section V.E.6, the certified testing lab is instructed to store them at 4°C. Commenter recommends that the desired storage temperature be consistent throughout for the prepared standards. We also would re-cap any standards that were injected and have a pierced septa. Acetonitrile is very volatile and capping standards that you plan to inject again is the best way to preserve the standard in lieu of a fresh preparation.	The Department agrees with this comment. The SOP has been updated with storage conditions for sample and standards in SOP (V)(E)(6).
SOP(VI)	50, 591	Commenter states that there is not text to explain the LOD and LOQ data shown.	The Department disagrees with this comment. 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

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			Department. 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 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.
SOP (VI)	100, 101, 588, 589, 591	Commenters state that the proposed dilution factors and range of the calibration curve would not make it possible to meet the state requirements for a 1 mg/g LOQ while also remaining on the calibration curve for higher concentrates. For example, in order for an oil sample that is at 90% (900,000 ppm) to be on the calibration curve proposed, a dilution factor of 9,000 would be a minimum and even then, unsatisfactory for quantitation purposes. The lowest calibration	The Department disagrees with the comment. The commentator is calculating the LOQ post dilution for a specific sample, however, the Department calculates LOQs pre- dilution to establish that the instrument is able to quantify ≤ 1.0 mg/g. The given “Typical dilutions" aims at

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		point proposed by the Department would be 0.5 ppm, if one multiplies 0.5 ppm by 9,000 then the LOQ would be 4,500ppm or 4.5mg/g, With the proposed standards and calibration point range, it would therefore be impossible for a laboratory to quantitate properly and meet state requirement for LOQ and LOD. High potency flower would even become difficult. There are standards available at 500 ug/g that come premixed and ready to run on the instrument from ISO 17025 laboratories that would allow a range from 500 ppm to as low as a laboratory can effectively quantitate. Commenter states they can provide these mixtures to the Department for their review.	achieving a mid-range cannabinoids concentration of an average sample, not aiming at achieving the lowest quantifiable amount or LOQ as suggested by the commenter. The laboratories are given the flexibility to achieving lower concentration limits by adjusting to a lower dilution factor or adding a lower calibration point. If the experimental LOQ calculation is not within the calibration range, it is appropriate for the laboratory to report the lowest calibration point as their LOQ. For example, the LOQ in the SOP with the dilution factor of 20X can be calculated as follows: (Lowest calibration point 0.5 ug/mL)(40 ml extraction volume)(20X))/200 mg= 2 mg/g. Additionally because of the flexibility mentioned another example when the dilution factor is changed to 10 X can be calculated as follows: (Lowest calibration point 0.5 ug/mL)(40 ml extraction volume)(10X dilution instead))/200 mg= 1 mg/g.
SOP (VI)	111	Commenter asks what the confidence interval in Limit of	The Department acknowledges this comment. The LOD

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		detection (LOD) is.	was calculated at confidence level of 99%. However, the regulation does not specify the allowable confidence interval. 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.
SOP (VI)	112	Commenter asks what the predefined goals for bias and imprecision in Limit of Quantitation (LOQ).	The Department acknowledges this comment. The predefined goals for Precision and is RSD% within 20% for samples analyzed on 3 different days. The regulation does not specify requirement for predefined goals for bias and imprecision. Laboratories do not need to do this part as it is part of the validation process, while they are only required to perform method verification. 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.
SOP (VI)	135	Commenter states it is stated that >ULOQ samples can be further diluted, this is true, but does not account for changes in LOQ with further dilution.	The Department disagrees with the comment. DCC calculates LOQs pre-dilution to establish that the instrument is able

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			to quantify ≤ 1.0 mg/g. The testing laboratories are given the flexibility to achieving lower concentration limits by adjusting to a lower dilution factor or adding a lower calibration point. The flexibilities are given in SOP(V)(C). and (IV)(C). If the experimental LOQ calculation is not within the calibration range, it is appropriate for the laboratory to report the lowest calibration point as their LOQ. For example, the LOQ in the SOP with the dilution factor of 20X can be calculated as follows: (Lowest calibration point 0.5 ug/mL)(40 ml extraction volume)(20X))/200 mg= 2 mg/g. Additionally because of the flexibility mentioned another example when the dilution factor is changed to 10 X can be calculated as follows: (Lowest calibration point 0.5 ug/mL)(40 ml extraction volume)(10X dilution instead))/200 mg= 1 mg/g. For the "ULOQ", while not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.

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SOP (VI)	143; 144	Commenter asks what the in-vial concentration of the cannabinoids listed in the LOD/LOQ table is. Commenter asks how this LOQ was calculated. Commenter states that calculating the LOQ using [11] is far too generous for LOQ calculations. Commenter states seeing a peak with S/N > 10 at these levels is not realistic using the formula in line 15731(2) of the regs when using PDA or any other single pass Beer-Lambert based optical spectroscopy device. The more realistic value is using line 15731(1) of the regs. If a peak can be seen with S/N > 10, it is a real peak and can be quantified [9]. Commenter asks if the numbers in the LOD/LOQ table are really reported in mg/g. Commenter states the reporting limit is called out a 0.5 ppm x total dilution factor. Commenter states seeing the level of the provided peaks for concentrate (0.00003125 ppm) and flower (0.000125 ppm) seems unlikely.	The Department disagrees with this comment. The in-vial concentration is reported in mg/L and the LOD/LOQ in sample are reported in mg/g. The calculations used are standard statistical methods for determination of LOD and LOQ. Section 15731 addresses LOD and LOQ for Quantitative Analyses. The determination was done explicitly as: LOD samples were prepared by spiking 20 ug of cannabinoids to blank matrix (cellulose powder), then going through all sample prep procedures, preparing 7 sample replicates separately and analyzing them in one sequence, and calculating the LOD from the standard deviation (LOD = t x S, where t=3.14 for 7 replicates at 99% confidence level). LOQ = 3 x LOD, should be in calibration curve and 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.
SOP (VI)	152	Commenter states the calculated LOD and LOQ values appear to be	The Department disagrees with this

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		much lower than reasonably expected for an optical absorption instrument based on the Beer-Lambert law. The chosen calculation method is not reflective of what a chromatographer would see when looking at a chromatogram.	comment. The in-vial concentration is reported in mg/L and the LOD/LOQ in sample are reported in mg/g. The calculations used are standard statistical methods for determination of LOD and LOQ. Section 15731 addresses LOD and LOQ for Quantitative Analyses. The determination was done explicitly as: LOD samples were prepared by spiking 20 ug of cannabinoids to blank matrix (cellulose powder), then going through all sample prep procedures, preparing 7 sample replicates separately and analyzing them in one sequence, and calculating the LOD from the standard deviation (LOD = t x S, where t=3.14 for 7 replicates at 99% confidence level). LOQ = 3 x LOD, should be in calibration curve and 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.
SOP (VI)	374, 509	Commenter states that the laboratory should be allowed to determine its own low limit to the calibration range and resulting	The Department agrees with this comment. The SOP(IV)(C)(3) has

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		reporting limit.	been updated to allow lower calibrants to be used.
SOP (VI)	375	Commenter states it is unclear how these LOQs and LODs are determined. This procedure should clarify how these are determined.	The Department disagrees with this comment. The in-vial concentration is reported in mg/L and the LOD/LOQ in sample are reported in mg/g. The calculations used are standard statistical methods for determination of LOD and LOQ. Section 15731 addresses LOD and LOQ for Quantitative Analyses. The determination was done explicitly as: LOD samples were prepared by spiking 20 ug of cannabinoids to blank matrix (cellulose powder), then going through all sample prep procedures, preparing 7 sample replicates separately and analyzing them in one sequence, and calculating the LOD from the standard deviation (LOD = t x S, where t=3.14 for 7 replicates at 99% confidence level). LOQ = 3 x LOD, should be in calibration curve and 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

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			Department.
SOP (VII)	218	Commenter states SOP clarification may be needed for “sample batch” as this appears to be slightly different from the current regulations and the definition of an “analytical batch sequence” & requirement in 15730.	The Department agrees with this comment. The SOP has been updated to clarify analytical batch, analytical sequence, and the required laboratory quality control samples for each.
SOP (VII)	254, 255	Commenter states requirements for ICV and CCV of +/- 30% seems rather broad. Commenter suggests 10% would be appropriate for this application.	The Department disagrees with this comment. The quality control acceptance criteria for an ICV and CCV are prescribed in sections 15713 and 15730.
SOP (VII)	256	Commenter asks why the Department is using cellulose powder for the LCS.	The Department disagrees with this comment. Cellulose powder is used as a blank matrix that is free of analytes (cannabinoids) and it is readily available for purchase from certified vendors to ensure it is free of contaminants and the analytes of interest.
SOP (VII)	257	Commenter states % RPD range of 30% is too high. Repeatability in AOAC SMPRs for cannabinoids in chocolate is 5%.	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

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			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

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			test methods in the future.
SOP (VII)	258	Commenter states Post Dilution MS sample, acceptable range of 30% is too high.	The Department disagrees with this comment. The acceptable range for Matrix Post-Dilution spikes are 70-130% recovery of the spiked amount as in the SOP (VIII).
SOP (VII)(A)	22, 43, 72, 115, 122, 312, 610, 611, 630, 656, 686, 228, 335, 440, 466, 491, 532, 542, 564, 607	Commenters state the calibration range was too narrow and found it limiting. Some commenters request a more expansive concentration range of the calibration curve to allow lower level of detection in a single analysis. Some commenters state it is cost prohibitive to spike cannabinoids standards at the mid-range to the calibration curve for LCS samples.	The Department agrees with this comment. The Department has added clarifying language to state that the calibration curve points listed are a minimum and additional calibration points may be added as long as the minimum recommended in the SOP are included.
SOP (VII)(A)	281	Commenter states that even if we assume the observed cannabinoid discrepancies are purely technical in nature, the proposed technical solution does not reduce result variance to a negligible impact. Commenter suggests the Department require Cannabinoid Method Recovery Requirements to align with current published analytical method performance recoveries that are specific to cannabinoids at various concentration ranges as outlined in AOAC SMPRs: 2017.001Standard Method Performance Requirements (SMPR®) for Quantitation of Cannabinoids in Cannabis Concentrates, 2017.002 Standard Method Performance Requirements (SMPR®) for Quantitation of Cannabinoids in Dried Plant Materials, and 2017.019 Standard	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 subject to further testing and validation for its use in dried flower, including pre-rolls, by the University of California San

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		Method Performance Requirements (SMPR®) for Quantitation of Cannabinoids in Edible Chocolate	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.
SOP (VII)(A)	145	Commenter questions running a solvent blank in a pair with each instance of a CCV. Commenter states there are rarely carry over problems with systems that utilize needle rinsing and flushing as part of the injection cycle.	The Department disagrees with this comment. The method runs a solvent blank in a pair with each instance of a CCV is to ensure no carry over

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			from high concentration samples. Further the SOP has been updated with a definition for Solvent Blank and the acceptance criteria is listed in SOP (VII) Quality Control.
SOP (VII)(A)(2)	381, 511	Commenter asks if this is a new requirement in addition to the regulations which require an ICV be run with each calibration. Commenter states there is no reason to run an ICV with every batch of samples, but only along with the calibration standards. This requirement should be removed.	The Department agrees with this comment. The ICV should be run with every calibration curve to ensure the curve is valid for use. The SOP has been updated to require an ICV with every calibration curve only and not every batch. The SOP has also been updated to clarify the analytical sequence and analytical batch definitions and required LQC samples for each.
SOP (VII)(3)	512	Commenter states the reference to "Section IV.D.2" should be to "Section IV.C" or possibly "Section IV.C.1" to be more restrictive.	The Department agrees and has made the correction.
SOP (VII)(4)	385, 513	Commenter states that section, 15730(f) does not specify acceptance criteria or corrective actions for 'blank' , 'solvent blank', 'ICV', or 'post-dilution spiked sample'. These samples should thus not be required as there is no guidance or requirement on how they are used.	The Department disagrees in part with this comment. The SOP has been updated with a definition of Matrix Post-dilution Spike to the SOP. An ICV is already required to be run with every calibration curve pursuant to section 15713 and ICV is necessary. The SOP continues to require this. The SOP defines the acceptance criteria for the required LQC

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			samples in SOP (V) Quality Control. When LQC samples do not meet the acceptance criteria, please refer to section 15730 for remedial actions.
SOP (VII)(B)	388, 514	Commenter states section, 15730(d)(3) requires a laboratory replicate sample or a matrix spike sample. It is inappropriate and conflicting to require both in this SOP.	The Department disagrees with this comment. The SOP requires a laboratory replicate sample and a Matrix Post-dilution Spike. The Matrix Post-dilution Spike is not the same as a Matrix Spike Sample referenced. The SOP has been revised to include a definition for the Matrix Post-dilution spike.
SOP (VII)(B)(1)	389, 391,409,525, 515, 576	Commenter states Method Blank definition conflicts with California Code of Regulations Section, title 4, 15700(oo). This conflict should be resolved in the SOP. Commenter also requests clarification on how the optimum extraction solvent and dilutions were determined.	The Department agrees in part and has clarified several definitions provided in the method by modifying the proposed SOP. “Method Blank” (MB) means an analyte free matrix to which all reagents are added in the same volumes as used in the sample preparation and which is processed in exactly the same manner as the representative sample. “Reagent Blank” means reagents which are used in the procedure taken through the entire method and which are added in the same volumes as used in the sample preparation. A Reagent Blank is analyzed in the same

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			manner as the representative sample. "Solvent Blank" means the same dilution solvent used to create the calibration working standards, acetonitrile/methanol (80:20), and is run in pairing with the ICV and/or CCV. A Solvent Blank is used to determine that the instrument system is clean and free of contamination. The Department determined through method validation that the extraction solvent outlined in the SOP provided optimal results.
SOP (VII)(B)(2)	1, 32, 84, 225, 390	Commenters state the method blank requirement does not use a blank matrix and is not in alignment with current interpretation of the regulations because water is not considered a matrix. Suggests substituting cellulose powder for deionized water.	The Department agrees with this comment and has clarified some of the definitions provided in the method by modifying the proposed SOP. The blank matrix for the method blank has been updated to include cellulose powder. "Method Blank" (MB) means an analyte free matrix to which all reagents are added in the same volumes as used in the sample preparation and which is processed in exactly the same manner as the representative sample. "Reagent Blank" means reagents which

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			are used in the procedure taken through the entire method and which are added in the same volumes as used in the sample preparation. A Reagent Blank is analyzed in the same manner as the representative sample. "Solvent Blank" means the same dilution solvent used to create the calibration working pairing with the ICV and/or CCV. A Solvent Blank is used to determine that the instrument system is clean and free of contamination. The Department confirms that cellulose powder is used as a blank matrix that is free of analytes (cannabinoids) and it is readily available for purchase from certified vendors to ensure it is free of contaminants and the analytes of interest.
SOP (VII)(B)(2)	392	Commenter states it is unclear what mass of cellulose powder should be used. This should be specified.	The Department disagrees with this comment. The amount of cellulose powder does not need to be specified. The LCS, should be extracted in the same manner as the representative sample, which would include the amount needed for analysis. A minimum of 200 mg is required for sample

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			analysis, the expectation is that the amount of cellulose powder used will be a minimum of 200 mg as well.
SOP (VII)(B)(2)	388, 393, 394, 514, 616	Commenters state the specific procedure for creating a LCS should be included in the definition of LCS. Commenters state the Preparation for an LCS should be defined as a post-dilution spike, given the high cost and low concentration of the available cannabinoid certified reference materials. Commenters recommend adding a clause in the SOP to allow spiking of the LCS at lower concentrations than the mid-range	The Department disagrees with this comment as the SOP provides the procedure. The LCS is spiked with the target analytes into the blank matrix and then analyzed in the same manner as the representative samples, as noted in SOP (VII) Quality Control. When spiking onto blank matrix as instructed, this should occur prior to extraction or dilution. The Matrix Post-dilution Spike is prepared by spiking target analytes into the diluted samples as instructed, this should occur after extraction or dilution. The mid-range of the calibration curve is any concentration not at the lowest or highest amount of the calibration curve.
SOP (VII)(B)(2)	396	Commenter states it is not stated what the desired spike level is for these samples. This should be included.	The Department disagrees with this comment. Laboratories can decide which spike concentration is most appropriate, so long as it meets the definition of LCS, in section 15700 (ff).

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SOP (VII)(B)(3)	241, 386	Commenter states that in Section (VII)(B)(3), “sample duplicate” used instead of regulatory nomenclature of “LRS” or “laboratory replicate sample.” For consistency with current regulations, suggestion to remove “sample duplicate” and replace with “laboratory replicate sample.” (15730, 15700(gg).)	The Department agrees with this comment. All instances of “lab duplicate” were replaced with “laboratory replicate sample” as appropriate in the updated SOP. 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)(B)(4)	25, 220	Commenter requests clarification on the SOP provisions that "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."	The Department agrees with this comment and updated the SOP to add the definition of Matrix Post -dilution Spike for clarification purposes. “Matrix Post-dilution Spike” means spiking a known amount of cannabinoids mix standards into a diluted sample after extraction. A Matrix Post-dilution Spike is used to evaluate the effects of sample matrices on the performance of the analytical method.
SOP	141, 146	Commenter asks for the purpose of	The Department

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(VII)(B)(4)		a post dilution spiked sample. Commenter asks why they would spike a sample that already has cannabinoids in it. Commenter asks if the Department means a post-dilution spike of a clean matrix. Commenter requests if so, it be expressed explicitly. Commenter states if a post dilution spike is performed on a customer sample that has some amount of various cannabinoids, there is no way that the results will fall within 70-130% of the expected value of the spike.	disagrees. The post-dilution spike is a spike in diluted flower sample, not clean matrix. A 70-130% recovery of the expected value of the spike is in agreement with the recoveries of an ICV or a CCV from the regulations.
SOP (VII)(B)(4)	358, 359, 360, 387, 395,397, 505, 514, 517, 573, 617	Commenters ask if it is 100% true that "given the limit of concentrated cannabinoids stock standards, matrix spike is not applicable" but that is exactly what is required above for an LCS. Commenters state it should be specified that only an LCS is required, power regulations, but that should appropriately be prepared as a post-dilution spike for the reasons listed. Commenters request that this requirement be stricken.	The Department agrees in part. The Department has added a definition of Matrix Post-dilution Spike to the SOP. "Matrix Post-dilution Spike" means spiking a known amount of cannabinoids mix standards into a diluted sample after extraction. A Matrix Post-dilution Spike is used to evaluate the effects of sample matrices on the performance of the analytical method.
SOP (VII)(C)	134; 148	Commenter asserts the SOP should have provided chromatograms of each standard and samples so that the laboratories can see the results. Commenter states it is not possible to properly understand a chromatographic method without seeing chromatograms.	The Department disagrees with this comment. The chromatograms of each standard and samples are available in the validation package which is part of the rulemaking file and can be found on the Department's website.
SOP (VII)(C)	398, 518, 577, 598, 599, 600, 604, 631	Commenters state that the chromatographic method listed in this SOP has an analyte co-elution issue with many naturally-occurring	The Department disagrees. This method was not validated to include additional

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		cannabinoids. This will require, on the basis of poor chromatography herein, much manual intervention in integration. This will lead to a high burden of time and effort from the laboratories to document manual integrations and is likely to have laboratories stick with poor and inconsistent automatic integration rather than properly manually integrating peaks in order to save time and effort. The validation undertaken by UCSD CMCR shows many examples of poor automatic integrations that would be markedly improved by manual integration at the high cost of time and effort in documentation. This requirement should be struck from the SOP. Some commenters state the described chromatographic method fails to address many of the common technical issues the industry currently faces, Commenter states there are known co-elutions of other cannabinoids which are not part of the nine (9) target analytes. As an example, commenter provides a chromatogram of the exact method, ran in a Phenomenex laboratory. In this experiment we included additional, VERY common cannabinoids reported in the market today. Exo-THC co-elutes with D9-THC, while CBNA co-elutes with D8-THC. The former presents a very significant opportunity to over quantitate D9-THC. Other commenters state their analyses show that CBNA co-elutes withdelta-9-THC in this method, as shown by the distorted peak shape of delta-9-THC in the chromatogram below. This co-elution also affects the resolution of delta-8-THC anddelta-9-THC.	cannabinoids . At this time, the method is suitable for only the cannabinoids stated in the method SOP and includes the following analytes: CBDA, CBG, CBD, THCV, CBN, Delta9-THC, Delta8-THC, CBC, and THCA and chromatography and retention time for each analyte were reviewed thoroughly for coeluting analytes. Manual integration is part of GLP and analysts cannot solely rely on automated integration. DCC encourages the laboratory to adopt manual integration techniques that are consistent, scientifically defensible, and follow GLP. “Good laboratory practice” (GLP) means a system of management controls for laboratories to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of analyses performed by the testing laboratory, as defined in section 15700(w).

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SOP (VII)(C)	529	Commenter requests an example of this deconvolution.	The Department acknowledges this comment. Deconvolution is entirely dependent on the software being used, and its mathematical algorithm. To review what software the Department used, please refer to the Empower 3 Data Acquisition and Processing Theory Guide, Revision A, by the Waters Corporation 2010, pages 27-75 which provide detail for this process of peak identification, integration, and if needed deconvolution. 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.
SOP (VII)(D)	51	Commenter states retention time drift greater than 2.5% can occur due to column condition and conditioning as well as specific sample types with high coextractives. CCVs and be used to monitor this and allow for retention time identification better than an average of calibration standards because CCVs bracket samples.	The Department disagrees. 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. The SOP allows for both using CCVs and/or calibration curve standards injected during the same analytical sequence for retention time identification which provides flexibly.
SOP (VII)(D)	399, 519	Commenters state 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. Additionally, all calibration standards run at the beginning of a sequence. It would be better to base the retention time acceptance window on the average of the CCV retention times which run throughout the sequence.	The Department agrees. SOP (VII)(D) has been updated to allow CCV's to be used for retention time acceptance window.
SOP (VII)(E)	52, 53	Commenter states spectral matching is a useful tool when compound identification is in doubt, but this only works well in certain concentration ranges.	The Department agrees with this comment. However, that is the best a LC-UV method can do. This is the limitation of the UV-PDA detector, it requires a good signal, or larger concentration to generate a good spectra. The SOP provides clear

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			separation of cannabinoids. 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.
SOP (VII)(E)	244	Commenter states that in Section VII(E), DCC appears to be giving guidance on peak identification. Given the possibility of matrix interference or presence of non-target analytes, suggestion to add the use of the LCS along with the CCV to determine presence of a peak. This adds additional resource for the lab to utilize by comparing target analytes that have undergone the extraction process with matrix, with those of a known standard without potential interferents. Typically, a LCS would give a "real life" conditions comparison which may include shifts in RT relative to just using the	The Department disagrees with this comment. Laboratories may add additional QCs if they want but they cannot perform less than the required QCs.

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		CCV alone. Commenter suggests adding "LCS" and update section to read: "Whenever identification of a sample analyte peak is in doubt, the UV-Visible spectrum of that peak shall be visually compared to the UV-Visible spectrum of a standard CCV and LCS cannabinoid peak or compared using the method from the instrument's software."	
SOP (VII)(E)	269	Commenter states "Whenever identification of a sample analyte peak is in doubt…" is so vague and part of the problem with low resolution HPLC methods! This is entirely subjective.	The Department disagrees with this comment. The use of the UV-Visible spectrum for analytes versus standards is commonly used in HPLC and referenced in FDA and AOAC. SOP (VII)(D) prescribes that the sample peak must have a retention time within the acceptance window of +/- 2.5% . This is part of Good Laboratory Practices as defined in section 15700(w), in operation of HPLC instrumentation.
SOP (VIII)	54	Commenter states correlation coefficient does not indicate accuracy of the curve and only indicates how well a mathematical model represents data. High bias can exist in regions of the curve. This bias (high or low) can result in in accurate results. Commenter recommends using and setting criteria for residuals of a calibration curve can reduce/minimize bias.	The Department agrees with this comment and has clarified the method by modifying the proposed SOP language. The use of the term "correlation coefficient" has been replaced with the "coefficient of determination" in the SOP to measure the mathematical model. Calibration curves must have a coefficient of determination or r2

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			value ≥ 0.99. A "Coefficient of Determination" (commonly denoted as "r2") means a statistical measure that determines how well the regression approximates the actual data points in the calibration curve, with a regression of 1 being a perfect fit, as defined in section 15700(q).
SOP (VIII)	245	Commenter states that in Section VIII, the SOP incorrectly refers to "r2" as "correlation coefficient" and incorrectly states the regulatory requirements for the numerical value. This is a major typo as r and r2 are statistically different values. r= correlation coefficient, whereas r2= coefficient of determination. Section 15700(q) defines: the coefficient of determination (commonly denoted as r2), and is required to be equal to or greater than 0.99 by section 15713(c)(1)(C)(i). Commenter recommends updating Section VIII with the correct terminology and value of "coefficient of determination" or "r2."	The Department agrees with this comment and has removed "correlation coefficient" from SOP (VIII) and added "a coefficient of determination or r^2 value" in its place.
SOP (VIII)	246	Commenter states in Section VIII, only some LQC sample acceptance criteria listed. Current proposed SOP only lists acceptance criteria of CCV (referred to as "check standard" in SOP), LCS, and Matrix post dilution spike. Commenter recommends adding acceptance criteria of method blank. Suggested language to read: "All target analytes not to exceed the LOQ (or <LOQ) for the method blank".	The Department agrees with this comment and has clarified the SOP (VII) to state that "the Method Blank must not exceed the LOQ for any analyte".

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SOP (VIII)	400, 520	Commenter states that not all quality control samples in this SOP are covered by section 15730. Only LQC samples defined by section 15730.	The Department agrees with this comment. The SOP was revised to include definitions of Solvent Blank, Matrix Post-dilution Spike, Method Blank, and Reagent Blank. The acceptance criteria of the required LQC samples are listed in SOP (VII) Quality Control. All CCVs, LCS, ICVs, and Matrix Post-dilution Spikes must be within 70-130% recovery of the spiked amount. The Method Blank must not exceed the LOQ for any analyte. If any of the laboratory quality control samples (LQCs) did not meet the acceptance criteria, the samples associated with failed LQCs need to be re-analyzed in accordance with section 15730.
SOP (IX)	401, 521	Commenter states the appropriate number of significant figures used for reporting results is a function of the method itself. 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” or allow the labs to to report with	The Department disagrees with this comment. The requirement of 3 significant figures is a general convention for reporting the sample results and not dependent on the uncertainty of the measurements or method.

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		great precision e.g.: “cannabinoid concentrations should be reported to at least the nearest 0.1mg/g”. Please note that the following values are all reported to three significant figures: 1.00 * 10^2 %, 10.0 %, 1.00%, 0.100%, 0.0100%, 0.00100%.	
SOP (IX)	56	Commenter does not understand the stipulation to report results to 3 significant digits. This should be determined by the validation data and measurement uncertainty. It would be nice if the public could assess the method validation.	The Department disagrees in part with this comment. The standardization of the testing method was aimed to reduce the inter lab variation. Standardizing the reporting method is one part or reducing variation. 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.
SOP (IX)	222	Commenter states samples with higher concentrations may likely be rounded as “Results for all samples shall be reported with 3 significant figures.” Clarification may be needed regarding appropriate mathematical rounding (we have witnessed clever rounding in the past).	The Department disagrees with this comment. Laboratories should be following good laboratory practices in accordance with section 15730. This practice includes rounding based on industry standards.
General Comment	14	Commenter applauds the Department’s step toward potency standardization and the method is very adequate for most if not all laboratories due to its simplicity and budget friendliness.	The Department agrees with this comment.
General Comment	26,153, 288, 289, 290, 317, 516, 531,	Commenters note the approximated yearly costs of $800 for standards and $500 for solvents, is a significant underestimation for the	The Department disagrees in part with this comment. However, the

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	608, 621, 649, 655, 669	costs of chemicals for laboratories running daily quality controls and multiple calibrations per year. Commentors note the method will affect data quality and incur significant additional costs for laboratories. One comment provides an estimate that 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.	Department has revised its estimate of costs, which includes costs of standards, filters, and solvents, as well as accounts for this method only applying to dried flower, including pre-rolls.
General Comment	27, 287, 291, 307, 427, 665	Commenter expresses concern with the requirement for use of 50 ml of solvent per sample. Commenter notes the new requirement effectively increases the total amount of hazardous waste generated by testing labs by 5 times. Commenter also notes there will be a huge financial burden placed on the testing labs for solvent and hazardous waste disposal including shipment out of state for destruction. Commenter notes the Department was very careful with the environmental impacts when drafting the original regulations. One commenter indicates that the solvent requirements are larger than necessary and will contribute to hazardous waste.	The Department disagrees 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. The validation included the use of 40 ml solvent and changing amount may result in inaccuracies.
General	29, 88, 89,	Commenters state the new	The Department

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Comment	90,110,164, 191, 293, 588, 619, 636, 650, 651, 653, 659, 660, 663, 666, 670, 672, 681, 685, 687	regulations are a step in the right direction but do not cover everything to ensure testing labs do not inflate cannabinoid results. Commenters suggest deterrence from inflating cannabinoid testing results should include other enforcement actions and audits of pipetting logs or any type of log or bench sheet.	agrees in part. The standard method will assist in reducing interlaboratory result variability. While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
General Comment	30	Commenter requests clarification on the basic definitions and techniques provided in the method.	The Department agrees in part with this comment and has clarified several definitions and techniques provided in the method by modifying the proposed SOP.
General Comment	31	Commenter states the SOP does not seem to define all of the required QCs that are in the regulations.	The Department agrees with this comment and has provided definitions of new laboratory quality control samples including method blank, Reagent Blank and Matrix Post-dilution Spike.
General Comment	37	Commenter suggests using performance based criteria to dictate chromatographic performance	The Department disagrees. Performance based criteria is included as resolution, or differentiation of chromatographic peaks.
General Comment	38, 91, 123, 444, 579	Commenters disagree with using a tissue homogenizer to grind samples to less than 1 mm as the method does not protect loss of trichomes during milling. Commenters also recommend dissolving samples in water to prepare samples like hard candies and gummies and then extracting	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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		cannabinoids.	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,

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			including pre-rolls. The Department looks forward to working with stakeholders on the development of new test methods in the future.
General Comment	57	Commenter recommends using a consensus method that has published validation data and has been vetted by methods organizations like AOAC. Verification is only allowed for standardized methods (ISO/IEC 17025).	The Department disagrees with this comment in part. ISO 17025, part 7.2.1.4 specifies methods that are regional standard methods, methods from reputable organizations, or laboratory developed methods can be used. 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. The method creates accurate and reliable results utilizing

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			equipment most laboratories already have. Further, Laboratories only need to verify this method as per ISO part 7.2.1.5 . 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. The Department looks forward to future potential work with stakeholders on the development of new test methods in the future.
General Comment	59	Commenter recommends fixing ambiguous technical language and units.	The Department agrees and has updated units for consistency and clarity.
General Comment	60	Commenter recommends publishing validation data.	The Department agrees with this comment. 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.
General Comment	61	Commenter recommends that an explicit statement be proposed that equivalency is not accepted.	The Department agrees with the comment and has added clarifying language to the text. The laboratories must follow the proposed method as written in the proposed SOP.
General Comment	62	Commenter recommends some form of verbiage to state all	The Department agrees with this

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		laboratories must demonstrate verification of this SOP.	comment. This is clearly stated in the SOP and in section 15712.2. Verification of Test Method for Cannabinoids.
General Comment	64, 623	Commenters suggest allowing verbiage to include or allow the use of surrogate or internal standards since both account for in-matrix effects. Commenters asks for clarification when performing verification as surrogates and internal standards are an easy way for labs to get things to pass especially under the stress of verification. Commenters state the proposed SOP also does not mention or allow for use of an internal standard. Internal standard areas can be used to track the dilutions post-acquisition and help determine if dilutions were done correctly and identify potential errors. Commenter recommends allowing the use of technology to dilute samples in a way that is equivalent to the method described as well as provide an internal standard for the method.	The Department disagrees with this comment. The proposed method does not apply surrogate or internal standards. 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. Surrogate and internal standards would add cost and complexity to the method and it was not

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			necessary in the validation. This is why they are not included.
General Comment	70	Commenter asks how the Department plans to approach measurement uncertainty. Commenter states that hemp regulations for example require measurement uncertainty of the test to be included on test reports. As long as the result including uncertainty is within the pass range, the sample passes. Commenter asks if this will be incorporated at a future date to reconcile hemp regulations with cannabis regulations in California. Current regulations include ISO 17025 accreditation requirement which has strict standards on measurement uncertainty. Commenter asks if these be adopted into current regulations. Incorporating measurement uncertainty, along with this standardized SOP should reveal the general variance amongst labs.	The Department disagrees with this comment. Requirements on measurement of uncertainty are not needed in the regulations. Uncertainty is part of ISO 17025 for each laboratory and as part of this laboratories determine this individually. 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.
General Comment	71	Commenter asks will there be validation data that proves this method works. Commenter asks where are the chromatograms, and hard data used to establish this SOP and if it will be available. Commenter asks how you know you are not getting coelution and how will you effectively monitor issues of coelution of other minor cannabinoids around the ones required by the state. If compounds coelute with THC for example, what are labs to do in those cases when broadening or shouldering occurs. Some methods currently provided by places like Restek, Thermo, Perkin-Elmer and Agilent have methods that can distinguish 17 or more cannabinoids. Some of those cannabinoids appear as one larger	The Department disagrees with this comment. The method was proved to work well, free of co-elution of the 9 cannabinoids in the method validation. 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.

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		peak in lesser established methods leading to over-reporting. Commenter asks how to resolve issues when co-elution occurs and data demonstrates it is a co-eluting cannabinoid. The current SOP dictates that the lab is responsible for integration training, however, cases, where coelution occurs by this method, are not mentioned. Commenter asks if this will be case by case. Sometimes the integration software will drop down or T-up by itself and this can even occur in calibration. This leads to incorrect linearity which can sometimes be fixed by manual integration.	
General Comment	74	Commenter asks at what point will DCC assess other analytes like pesticides like establishing an Action limit for category I's as opposed to setting LODs as AL's as well as change the monitoring of captan to THPI as captan is HIGHLY unstable and degrades rather quickly, 30 minutes in soil, and degrades rather quickly in current methods used to analyze it, like GC-MS.Commenter recommends either removing or increasing the AL for captan and add THPI to the list.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
General Comment	75	Commenter recommends adding in clarification on the usage of qualifiers and quantifiers as different matrices have differing levels of success on different MRM transitions and fragments. There are plenty of interlaboratory organizations that have combined forces to work on problems of this magnitude and would be excellent resources.	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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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.

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General Comment	117	Commenter states it is well known that exo-THC can closely elute with d8-THC and asks if this method accounts for that.	The Department disagrees with this comment. Exo-THC is not a natural cannabinoid that can be produced by the cannabis plant. 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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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	118	Commenter requests the Department list the primary vendor for calibrators and secondary vendor for ICVs. The labs are required to submit this information for validation purposes and data packet requests.	The Department agrees with this comment and the validation package describes this information including the primary vendor for calibrators and secondary vendor for ICVs.
General Comment	120, 159	Commenters state it is not clearly stated that the full sample received from the customer should be homogenized in its entirety and does not say how much of the sample should be homogenized. Commenter states leaving any room for interpretation on this can lead to inter lab variability.	The Department disagrees with this comment. SOP Apparatus and Materials provides that flower must be homogenized to less than 1 mm. The SOP requires that the sample be ground prior to weighing the aliquot for sample prep, this is specifically outlined in SOP (V)(B).
General Comment	147	Commenter states this method is not state of the art relative to the	The Department notes commenter's

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		number of compounds included in the panel.	suggestion and looks forward to working with stakeholders on future policy development. The regulation language has been updated to allow testing of additional cannabinoids.
General Comment	158	Commenter states method does not address problems with representative sample collection at the customer site, which does lead to intra and inter lab variability.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
General Comment	88, 160, 163, 170, 175, 179, 183, 187,190, 197, 203, 259, 260, 261, 270, 285, 286, 530, 618, 620, 625, 631, 654, 668, 678, 679	Commenters state this method is geared toward novice laboratory operators. The more experienced laboratories in the space already have better, purpose-built methods in use.	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 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

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			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	161	Commenter states if laboratories can use methods that exceed these requirements, it should be stated as such.	The Department disagrees with this comment. The regulation states that all licensed laboratories are required to use this standardized method for cannabinoid testing for dried flower, including pre-rolls.

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General Comment	162, 189, 525, 527, 688	Commenter states the Legislature intended that more than one method should be developed, if necessary. Commenters request the Department allow modifications to method where necessary such as allowing more than one sample preparation and extraction method. Commenter states it is hard to understand how the Department could undertake this effort so directly impacting the testing industry without providing those the laboratories with the accuracy and precision data for its method. Commenter states the Department has not demonstrated data quality objectives (DQO's) for their regulated labs, including acceptable limits for potency testing accuracy and precision. If the Department has measured the accuracy and precision produced by laboratories in the state for potency testing activities, they have not demonstrated how this data compares with Department's DQO's.	The Department disagrees with this comment. At this time, the Department has developed and validated one standardized cannabinoids method. 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. 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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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	169, 196	Commenter states when a compendial method identifies more than one analyte, it is common to define a critical pair (two compounds that elute close to each other) and to establish a minimal resolution for those compounds. If the method, as implemented using a specific instrument or peripherals (e.g. C18 HPLC column) does not achieve the pre-defined minimal resolution, one is allowed to slightly modify the mobile phase. We would encourage the Department to proactively consider this if proceeding with a single HPLC analysis method.	The Department disagrees with this comment. The minimum resolution requirement of the method is 1.3 and is stated in the SOP (II)(A), (II)(M) and (V)(D). It also stated in the SOP (V)(D): "Note: Instrumental Parameters are column and system specific and will vary according to the specific HPLC column and system used." The instrumental parameters including

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			the selection of mobile phase can be modified by the testing labs.
General Comment	171	Commenter recommends adding a statement to the SOP indicating that separate test portions be prepared from the test sample for microbial contaminant and cannabinoid (or other analytical) testing. Test portions for microbial contaminant analysis should be initially prepared from a laboratory sample to ensure that the integrity of the sample is not impacted. This may occur after grinding (for flower and similar products) but for edible products should be done prior to any processing (e.g. cryogenic grinding) that can impact the ability for methods to properly assess for the presence of pathogens.	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 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

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
			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	173, 174, 177, 178, 181, 182, 185, 186, 201, 202, 278,316, 464, 474, 475, 476, 530, 540, 550, 551	Commenter states it was ill-advised of the legislature to enact this provision in the first place, given the egregious lack of hard scientific data on which to base a standardized test procedure. Commenter also states SB 544 does allow for more than one testing method and urge the Department to allow maximal flexibility in this regard. Commenters state that other provisions of the proposed regulations are overly prescriptive, detailed, and inflexible and recommend DCC implement a process by which testing laboratories may validate their proven and reliable methods for continued utilization in their laboratories. Commenters recommend allowing alterations that improves accuracy and reliability when approved by the department.	The Department disagrees with this comment. At this time, the Department has developed and validated one standard method for cannabinoid testing as required by Business and Professions Code section 26120. 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

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			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	199	Commenter states inflated THC potency really only applies to inhalable cannabis goods because THC potency is the main driver of sales of these products. Edibles and infused products have THC limits	The Department disagrees in part with this comment. The standardized test method for the determination of

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		whereas inhalable products do not.	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

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			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	221	Commenter asks for consideration of future data package reviews, the standardized SOP states that 'laboratories shall have an integration policy that outlines the proper way to integrate chromatographic peaks', what are the requirements of the 'policy'? Is a verbal policy between lab employees sufficient? Or is this required to be captured in the licensed lab's SOP(s)? Or is this information required to be written into the Labs LQA manual? Additional clarification may be needed.	The Department disagrees with this comment. The SOP has clear instructions in SOP(VII)(C) on integration policy and the requirements for the policy.
Solvent Blank	219	Commenter states a solvent blank is required to be ran with a 'sample batch', but there does not appear to be mention of the required method blank. Is the expectation that in addition to the items described in the SOP under VII. Quality Control, all must also include the LQCs required in 15730?	The Department agrees in part with this comment. The SOP has been updated to correctly refer to "analytical sequence" where appropriate and removed "sample batch" in reference to the sequential injection of samples. A solvent blank is required to be analyzed in pairing with a CCV and/or ICV when running an analytical sequence.
General Comment	242	Commenter suggests using consistent nomenclature from regulations in SOP. Commenter suggests replacing "QCs" with "LQCs" in every instance to better	The Department agrees in part with this comment. All instances of "QCs" were replaced

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		reflect the same identity of the samples between the proposed SOP and current regulations. Commenter also suggests including "CCV" to replace "check standard", "LRS" to replace "sample duplicate," etc.	with "LQCs" or "Laboratory Quality Control samples" as appropriate in the updated SOP.
General Comment	233, 243, 247, 377, 378,379, 380, 385, 412, 510, 575, 510, 528, 575	Commenters state some terms not defined in the definitions section including terms newly introduced in the SOP. Commenter states there are no current definitions to solvent blank and Matrix Post-dilution Spike. Commenters suggest adding method blank, solvent blank, and Matrix Post-dilution Spike to the definitions section. Some commenters suggest removing solvent blank requirement.	The Department agrees in part with this comment and included in the SOP definitions for Solvent Blank, Matrix Post-dilution Spike, Method Blank, along with Reagent Blank.
General Comment	533	Commenter asserts that the proposed regulations do not seem to give the SOP the ability to establish new LQC samples. This adds cost for no benefit as acceptance criteria aren't specified for the additional LQC samples.	The Department disagrees with this comment. Definitions for Solvent Blank, Matrix Post-dilution Spike, Method Blank, and Reagent Blank. Acceptance criteria are listed in Section VII, Quality Control and most LQC samples required are already required pursuant to section 15730.
General Comment	263, 272	Commenter states HPLC technology, while routine in many cases, is not fit for purpose when used to separate out and quantify analytes within a short chromatographic range. Cannabis has many cannabinoids, many of which coelute due to similar chemical characteristics. Coelution can be a cause of inaccurate and variable reported concentrations of cannabinoids. Commenter states requiring the use of HPLC will cause labs to LOWER the	The Department disagrees in part with this comment. The method is made to be simple and uses most cost-effective equipment and reagents so that it can be accessible and performed by all testing laboratories regardless of laboratory's economic standing or scientific expertise.

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		resolution of their methods, which has been happening in CA labs as a mechanism to INFLATE THC VALUES.	The SOP has clear separation requirements to eliminate coelution mentioned by the commenter in SOP (II)(A). 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.
General Comment	264	Commenter states they are skeptical that this method is capable of accurately quantifying cannabinoids for this many different sample types.	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 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

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			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	271, 284, 309, 310, 311, 596, 597, 631	Commenters state enforcing a subpar and biased standardized method is NOT an effective solution to the lab shopping and fraud problems in the California cannabis industry. While industry standard methods have great value (see AOAC and USP methods), they have built in flexibility that allow for IMPROVED method performance by using modern and enhanced technology, and innovation… and don't explicitly endorse specific instrument and consumable manufacturers. Enforcing this method punishes labs that are pushing the envelope on science and does not address the true	The Department disagrees with this comment. The Department has built flexibility into the language of the proposed SOP to allow the usage of other instruments that have equivalent capabilities.

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		problems in this industry. Commenters suggest verbiage should be included in the SOP that allows a laboratory to modify the method if equivalency - or quality improvement (e.g. resolution of interferences) - can be demonstrated.	
General Comment	273, 227, 641, 682	Commenters state that limiting laboratories to only using methanol as an extraction solvent will result in incomplete recoveries of cannabinoids in a variety of matrices including but not limited to gummies, hard candies, topicals, fruit chews, and beverages. Commenters suggest adding clarification for non-typical matrices (i.e. suppositories, inhalers, personal lubricants, etc.). Once commenter indicates the method does not cover all the variabilities for different matrices.	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 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

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			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	274, 277, 642	Commenter states since infused products are not currently subject to potency inflation for a variety of regulatory and economic reasons, commenter believes extending the required standard cannabinoids test method to cover these matrices is a solution in search of a problem. Commenter recommends these products be exempt from the rulemaking if at all possible. Commenters strongly recommends that the proposed new methodology be amended to apply only to flower, vape cartridges, and concentrates.	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 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

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			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	275	Commenter requests the text be altered to permit laboratories to use different sample prep and extraction techniques as necessary to accurately quantify the cannabinoids in these matrices.	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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			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,

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			including pre-rolls. The Department looks forward to working with stakeholders on the development of new test methods in the future.
General Comment	276	Commenter states while there were differences between the total cannabinoid content throughout, the results were reasonably similar for five of the six product types. Unfortunately, for gummies, the Department's proposed method achieved an extremely poor cannabinoid recovery rate. Specifically, the sample prep method extracted only about one tenth (1/10th) of the cannabinoids present in gummies, which are the most popular type of edible. We share the Department's strong commitment to public safety and consumer protection. Commenter states the only way to guard against such unintended consequences is to afford licensed labs the ability to customize the testing method to the unique properties of the sample being tested.	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 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

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			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	279, 475, 476	Commenters recommend the Department incorporate mechanisms in the regulations to allow for greater flexibility if and when a more reliable cannabinoid test method is identified.	The Department agrees in part with this comment and some flexibility is allowed in the proposed method where clearly stated. 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

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			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	295, 296	Commenter recommends listing the Cas #s for any cannabinoids included in the scope of the method to avoid confusion with the identity of the cannabinoids since there are often multiple abbreviated names for each target. We would also like	The Department agrees with this comment and CAS#s have been added to SOP.

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		to strongly suggest adding additional targets and validating the method with an expanded list to include acid forms of already included neutral cannabinoid targets and others that are routinely tested for in the current marketplace.	
General Comment	318	Commenter requests use “µ” instead of “u” to indicate “micro’ in the appropriate scientific units. The former is the accepted format.	The Department agrees and has changed to “µ”.
General Comment	319, 482, 556, 633, 634	Commenter states “ppm” is used throughout the document and is undefined. We suggest standardizing on the use of either “µg/g” or “µg/mL” as appropriate, which are unambiguous in place of “ppm”.	The Department disagrees. ppm and µ g/g or µg/mL are interchangeable.
General Comment	320	Commenter requests that DCC capitalize the “L” in scientific units where it is supposed to represent “Liter”. For example milliliters should be abbreviated “mL” rather than “ml”.	The Department agrees and added clarifying language of “L” after each unit “m”. For example, “L” was added to every “m” to correctly abbreviate milliliters.
General Comment	321	Commenter states “acetonitrile/methanol (80:20)” is referred to many times for use in diluting standards and extracting samples. The procedure should clarify on what basis to make this 80% acetonitrile 20% methanol mixture: volumetric, gravimetric, molar, etc.	The Department agrees and added clarifying language of “Volume:Volume” after each 80:20, as this refers to volume ratio.
General Comment	405	Commenter states the Department should clarify how these regulations ensure that laboratories are properly testing cannabis and cannabis products and reporting accurate results. It does not appear from the regulations or SOP itself why this represents any improvement.	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

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			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

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			development of new test methods in the future.
Initial Statement of Reasons	406	Commenter states that the initial statement of reasons implies that the reference method can be altered to some degree to include different detection methods. It is unclear if the language allows for this as the sole means of analysis or to be used in conjunction with the outlined test method.	The Department disagrees with this comment. The Department determined that the LCMS or LCMSMS method was not a feasible alternative at this time due to costs. The SOP (II)(A) language states that the instrument to be used is an HPLC and PDA detector.
Initial Statement of Reasons	407, 523	Commenter states they would like this data made publicly available for review by all relevant stakeholders. It is likely that, through validation, the Department has concluded that the listed methods obtain accurate and reliable test results based on limited tested sample types. It is highly unlikely that the Department has validated that these methods for homogenization are ”the most effective”. For this reason the Department should allow laboratories to demonstrate and use equivalent or improved methods.	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 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

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			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	308	Additionally, the strong limitations on sample preparation are likely to result in inaccurate cannabinoid reporting for some difficult matrix types which will negatively impact consumers.	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

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			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.

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General Comment	414	Commenter states they believe that the most recent PT results for all applicable matrices should be shared to all relevant stakeholders.	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 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

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			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. 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.
General Comment	415	Potency inflation of cannabis flower and concentrated products is a serious issue affecting the California cannabis industry. Without doubt some of the variation in laboratory results is related to the unfortunate fact that cannabis flower and manufactured products are often priced by retailers according to THC content. Potency variation, however, is not a factor for edible, tincture, and topical products which are subject to potency caps based on milligrams not percentage of THC.	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 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

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			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	416, 476, 477, 478, 595	Commenters state the Department should establish more than one method for use by testing laboratories. Commenter suggests licensed laboratories be allowed to utilize either the cannabinoid test method required by this section or a cannabinoid test method that has been demonstrated to be	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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		equivalent. Commenter recommends limiting this requirement to flower and concentrates. Commenter recommends amending this language (15712.1(c)) so that laboratories are not prevented from introducing procedures that improve the accuracy and reliability of cannabis testing results. Commenter comments the method validation performed by the Department did not include any matrix spikes or validation data in matrices other than cannabis flower. Commenter believes it is incorrect to mandate the use of the method in matrices for which it has yet to be evaluated.	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,

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			including pre-rolls. The Department looks forward to working with stakeholders on the development of new test methods in the future. 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.
General Comment	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, commenter requests the Department consider the following alternatives: 1. 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.	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 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

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			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	420	Commenter states DCC should work to improve the chromatographic separation of the method prior to putting this method into required usage.	The Department disagrees with this comment. A good resolution is essential to achieve high accuracy and precision in a HPLC testing method. Based on the Department's experience, lower resolution than 1.3 may cause overlap of cannabinoid peaks and inaccuracy in results.
General Comment	421, 425	Commenter recommends the inclusion of 4 additional cannabinoid acids: Cannabigerolic acid (CBGA),1.0	The Department disagrees with this comment. The method was only validated for

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		mg/ml, (CRM).Cannabinolic Acid (CBNA),1.0 mg/ml, (CRM).Tetrahydrocannabivarinic Acid (THCVA),1.0 mg/ml, (CRM).Cannabichromenic Acid (CBCA),1.0 mg/ml, (CRM).	the cannabinoids stated in the SOP. This includes all of the analytes required for regulatory compliance testing, as well as several additional analytes. In validating the method, chromatography and retention time for each analyte were reviewed thoroughly for coeluting analytes. If the laboratory makes the business decision to analyze and report cannabinoid analytes not required for regulatory compliance testing and not contained in the SOP, the laboratory must validate the method to ensure accurate and scientifically valid testing, as required by section 15713. The Department looks forward to working with stakeholders on the development of new test methods in the future.
General Comment	423	Commenter states the single preparation method proposed would put consumers at risk. A one-size-fits-all approach to standardized testing using methanol as an extraction solvent does not work across all form factors and would result in the incomplete recovery of numerous cannabinoids. Poor recovery directly results in inaccurate THC testing, likely underestimating the THC content. While commenter is supportive of efforts to reduce THC concentration inflation where it is potentially	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

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		occurring, this will not only have the opposite intended effect, but will also put consumers directly at risk of harm. The proposed approach would likely result in the underreporting of cannabinoid content — potentially at the rate of only 10% of actual cannabinoids present. Commenter can't underscore enough how deeply concerning this would be for consumers and public safety across the state.	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

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			test methods in the future.
General Comment	424, 638	Commenter states the proposed method doesn't future proof the industry and is inadequate for current products on the market. The proposed single preparation method is problematic and limits the flexibility needed to allow for the analysis of cannabinoid content in all of the product types available in the regulated California cannabis market. Laboratories often have to develop specialized extraction techniques specific to the sample matrix for each type of cannabis product to accurately assess their cannabinoid content. As a result the testing protocol varies by form factor , and the proposed regulations fail to take the variety of approaches into account. It is particularly problematic as a scientist to find that, in 2022, the Department has reverted to sample preparation technologies with known issues around solubility, analyte recovery and imprecise quantitation, especially when tools have been developed and are routinely leveraged to address these issues.	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 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

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			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	428, 475	Commenters urge the Department to convene a stakeholder workgroup to revisit these proposed regulations and further expand testing methods. The language in SB 544 is clear that the Department may establish more than one method for use by testing laboratories and these standards may be developed through a reference laboratory. The failure to prepare separate methods for various manufactured form factors presents a significant threat to public health and safety, which is the mandate of the agency. The Department has time to revisit the matter before January 1, 2023, and we strongly believe that the Department should be required to allow for unique sample preparation method(s) for other product types of various matrices.	The Department disagrees in part with this comment. The Department has a Cannabis Advisory Committee to provide recommendations to the Department. 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

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			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	429	Commenter requests that the Department provide validation data for proposed methodologies to support industry-wide adoption. Lastly, in the spirit of effectively addressing potency inflation, commenter encourage the Department to consider ad actors, rather than onerous and burdensome requirements for	The Department agrees in part. 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.

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		compliant labs who are already working hard to protect consumer safety across the state	
General Comment	652, 671	Commenter expresses support for the Department developing the standard operating procedure and notes that the Department did not have a long time to develop the procedure and validate the method. Another commenter is encouraged by the Department's attempts to standardize potency testing in California's cannabis space and to bring consistency in testing while trying to reduce the number of bad faith actors in the market.	The Department agrees with this comment.
General Comment	667	Commenter is disappointed that the Department issued the proposed rulemaking without first engaging in dialogue with the laboratories being impacted. Commenter believes the method is flawed in many verifiable areas.	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 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 to conduct cannabis research. 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.
Initial Statement of Reasons, Economic Impact Statement	426, 475, 687	Commenter states this method, as proposed, would increase costs of regulated products. The overly prescriptive sample preparation method, together with the narrow calibration range allowed for the target cannabinoids, will increase laboratory costs by increasing the use of additional consumable equipment, such as vials, filters, and solvent, the use of semi-consumable instrument equipment, such as columns and guard columns, as well as additional personnel hours to perform the analysis. As a corollary, instrument sample time will become more limited, and the cost for analysis to licensees will increase. The further requirements of tissue	The Department agrees in part with this comment and removed the cryogrinder requirement. SOP (II) prescribes “Apparatus and Materials” that flower must be homogenized to less than 1 mm and this is sufficient guidance and direction. The impact statement for businesses is an estimate that is part of the notice of rulemaking. The costs, impacts are outlined there as best estimates at the time.

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		homogenizers or cryomills as well as additional Laboratory Quality Control samples not defined in associated regulation will impose an additional process and unnecessary financial burden on laboratories while failing to provide a tangible benefit to the Department or the public. For some labs, the proposed sample preparation requirements could impose additional operating costs amounting to tens, or even hundreds of thousands of dollars.	
Initial Statement of Reasons, Economic Impact Statement	307, 658	Commenter states they believe implementing this method will incur a high cost to our business not recognized in the DCC's cost estimates. There will be a dramatic increase in the cost, well over $100,000 dollars per year, of certified reference material used as calibration standards. Additionally, there will be high equipment costs associated with the required sample preparation and our throughput needs, multiple cryo-mills, centrifuges and shaker tables costing in the tens of thousands of dollars. Finally, there will be a cost associated with the reduced efficiency of this method as compared to our existing validated methodology. We do not believe these additional costs will represent any improvement in the accuracy of our cannabinoid results.	The Department disagrees with this comments. The impact statement for businesses is an estimate that is part of the notice of rulemaking. The costs, impacts are outlined there as best estimates at the time. The true economic impact cannot be known until the actual implementation at the laboratories, but the Department has made efforts to be as accurate as possible and provided an Updated Economic Assessment in the second 15-Day notice.
Initial Statement of Reasons, Economic Impact Statement	301, 317, 531, 680	Commenters state cost of standards are underestimated and state that the DCC method for flower is about 165% more solvent costly than the current most expensive methods in the industry. Commentor recommends that the Department consider re-evaluating the proposed 80:20 acetonitrile: methanol to consider both reducing the total extraction volume and eliminating acetonitrile as an extraction solvent.	The Department agrees with this comment in part and the estimate of costs has been updated significantly to reflect the cost of standards and solvents as well as filters.

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		Using less solvent is environmentally friendly and more economical for certified testing labs. Even if the Department decided to only switch to MeOH and keep the same extraction volume this would reduce costs and could also help to eliminate prep errors in the lab since there would only be one prescribed extraction solvent available to use, methanol. Commentor states the Department analysis also does not capture the cost of organics waste disposal resulting from the large volumes of solvent waste produced in the proposed method. This cost should be estimated to provide a more accurate picture of total business impact consideration.	
15724(b)	231	Commenter states this method does not appear to meet the LOQ requirement in section 15724(b) for flower/plant and for concentrate/vape oil. Commenter suggest either lowering LOQ for the new cannabinoid method or to update language in 4 CCR 15724(b) as this causes confusion and inconsistency in regulations.	The Department disagrees in part with this comment. As indicated in the method validation data, LOD samples were prepared by spiking 20 ug of cannabinoids to blank matrix (cellulose powder). These LOD samples went through all sample prep procedures, preparing 7 sample replicates separately. These samples were analyzed in one sequence. The LOD was calculated from the standard deviation (LOD = t x S, where t=3.14 for 7 replicates at 99% confidence level). LOQ = 3 x LOD, in calibration curve and 1.0 mg/g or lower for all cannabinoids analyzed

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			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.
Benefit of Proposed Regulation	280, 292	Commenter states mandating the use of a specific analytical method does not address the element of intentional cannabinoid value manipulation by licensed laboratories motivated to leverage test results for profit. Commenter suggests that a simpler method of catching bad actors would be if the state were to spot check packaged cannabis and remove products with fraudulent results from the shelves so they can be retested and relabeled with their true cannabinoid results, and the residents of California can receive honest and true reports of the levels of cannabinoids in their products.	The Department disagrees in part with this comment. The intent of this standardized method is to reduce interlaboratory result variability and accuracy of testing results.
New License Type	192	Commenter recommends creating a new license type that has a low environmental effect including light greenhouse structures, no mixed-light, no light-deprivation, no heater, and same scale of surfaces as the outdoor licenses.	While not on the proposed action, the Department notes commenter's recommendation.
Foreign Funds	193	Commenter recommends permitting associations with 49% of foreign funds.	While not on the proposed action, the Department notes commenter's recommendation.
Large and Medium Cultivation Licenses	27	Commenter requests greater transparency and clarity on the implementation of large and medium cultivation licenses.	While not on the proposed action, the Department notes commenter's recommendation.
Type 5 Licenses	28	Commenter is disappointed to see DCC make the prohibition on owners of Type 5 licenses from holding a Type 11 distribution	While not on the proposed action, the Department notes commenter's

Section of Regulation	Comment Numbers	Summary of Comments Received During 45-Day Comment Period	Department Response
		license even more restrictive by expanding it to capture both owners and financial interest holders. Commenter provides a recommendation to strike prohibition on holding a Type 5 and Type 8, 11 or 12 license.	recommendation.
METRC	29	Commenter suggests that Metrc should integrate both old and new licenses into the system so both tags work until the current batch is harvested and allow licensees to start using tags with the new Type 5 license number when plants are transitioned out of the nursery and into the greenhouses to flower.	While not on the proposed action, the Department notes commenter's recommendation.
Public Hearing	683	Commenter requests clarity regarding whether the public comment hearing was being recorded and whether the recording will be available to the public.	Comments provided at the public hearing can be found in the transcript of the public hearing that was made part of the rulemaking file. The rulemaking file is available for review and will be provided upon request to the Department.
Public Hearing	684	Commenter requests clarity regarding whether the Department would be making comments or addressing any public comments during the public comment hearing.	The Department responds to comments in the Final Statement of Reasons as required by the Administrative Procedure Act.
Taxes	3	Commenter states that taxes are too high and should be around 10%.	While not on the proposed action, the Department notes commenter's recommendation.
Spam Emails	4, 6, 7, 8, 10, 11, 12, 13,	Miscellaneous spam emails.	While not on the proposed action, the Department notes that the email was sent to the Department's public comment inbox during the comment period.
General Question	9	Commenter requests elaboration on Department policies that have been	While not on the proposed action, the

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		developed to protect people and the environment.	Department notes commenter's request.
COAs	17	Commenter states they would like to see COAs public and easily accessible online.	While not on the proposed action, the Department notes commenter's recommendation.
Oregon Testing	18	Commenter shared a handout regarding loopholes found in Oregon's testing requirements.	While not on the proposed action, the Department notes receipt of the comment.
General Grievance	34, 35	Commenter asks if the DCC is unable to follow its own regulations and if they can acknowledge they are not fit to test samples.	While not on the proposed action, the Department notes commenter's request.
DCC Regulations	149	Commenter states that the SOP does not follow several of the DCC's regulations.	While not on the proposed action, the Department notes the comment.
OSHA Requirement	422	Commenter objects to requirement in DCC regulations for licensees to have employees that are OSHA 30 certified. Commenter recommends adopting a California-based safety certification.	While not on the proposed action, the Department notes commenter's suggestion.

Subsection A.3. has also been amended to update the cross-reference to Section IV.C.

Subsection B has been amended to replace the word processed with prepared.

Subsection B.1. has been amended to remove the last sentence regarding other plant material cannabis matrices.

Subsection B.2. has been amended to add that mid-range is the amount to be spiked into the blank matrix.

Subsection E. has been amended to clarify that if the laboratory is unable to deconvolve the cannabinoid from the interference the sample shall be re-analyzed in accordance with the requirements of section 15730 of the Department's regulations.

SOP §VIII. Acceptance Criteria for Quality Control Samples.

This section has been amended for syntax to replace "need to" with shall.

SOP §IX. Reporting Results.

This section has been amended to remove subsection B. as it is repetitive and unnecessary as subsection A. contains all requirements for reporting results.

Non-substantive Modifications

In addition to the modifications described above, the Department has made non-substantive edits to correct typographical errors.

Local Mandate Determination

The proposed regulations do not impose a mandate on local agencies or school districts.

Incorporation by Reference

The following documents are incorporated into the regulations by reference:

Determination of Cannabinoids Concentration by HPLC, Standard Operating Procedures (New 09/23/2022)

Summary and Response to Comments Received During 45-Day Comment Period

Summary and Response to Comments Received During First 15-Day Comment Period from August 31, 2022 to September 16, 2022

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
15712.1	3	Commenter asserts that the only way to deter laboratories from inflating cannabinoid testing results is to make it criminal for any employee to alter or falsify analytical balance, pipetting logs, any type of log or bench sheet and apply fitting consequences, paired with appropriate enforcement. Commenter believes the majority of laboratories producing d9-THC levels above 26% are inflating testing results by altering pipetting and analytical balance measurements via logbooks and bench sheets. In addition, there is a real possibility that cannabis laboratories are augmenting standards for calibration that are skewed higher for potency and manipulating results/numbers to work in favor of higher THC levels in order to maintain clients.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
15712.1	81, 82	Commenter recommends modifications to the filtration	The Department disagrees with this

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
		requirement to include other products commonly used in cannabis testing laboratories, such as filter vials, filtration plates, and our "Tip-on-Tip" filtration pipette tip. These filtration devices all provide data that are accurate, reproducible, and robust. In addition, filtration pipette tips offer several unique advantages over syringe filters. Commenter suggests the Department require less sample handling and therefore, less chance of contamination. Commenter also recommends allowing the use of other products (e.g., pipette filtration tips, 96-well filtration plates) that can substitute for the 0.2 µm PTFE syringe filters in the proposed standardized method. Importantly, this modification would protect data integrity while providing laboratories with an appropriate amount of workflow diversity. By increasing the flexibility within the standardized method, cannabis testing laboratories can substitute filtration products that minimize human error, reduce environmental waste, mitigate health issues resulting from repetitious manual pipetting, improve throughput, are amenable with automated liquid handling systems, and reduce the overall cost of the method.	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. The Department has validated the method using the filters and supplies contained in the SOP and using other filters and supplies could lead to inaccurate results. These supplies are commonly used in existing laboratories and readily available for purchase.
15712.1	8, 14	Commenters indicate that some flexibility is critical to ensure accuracy and reliability of cannabis product testing and product labels.	The Department disagrees in part with this comment. BPC section 26100(f)(2) requires the Department to establish at least one standard cannabinoid test method for all laboratories. After considering the robust comments related to the applicability of the method

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
			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 has removed references to cannabis products. The Department looks forward to working with stakeholders on the development of new test methods in the future.
15712.1	9, 15	Commenters assert that the proposed SOP has poor cannabinoid recovery rates for edibles like gummies and other edibles resulting in underreporting of THC concentration; mandatory use of SOP is concerning.	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 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

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
			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.
15712.1	10, 16	Commenter asserts that mandating use of a test method with inaccurate cannabinoid levels for edibles is disastrous and noncompliant products give rise to increased liability for companies and laboratories using this testing method. There will likely be unwanted significant litigation as a result of mandated use of a test method that gives inaccurate cannabinoid levels.	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 subject to further testing and validation for its use in dried flower, including pre-rolls, by the

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
			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.
15712.1	11, 17	Commenters assert that THC levels are arguably the most critical data point from a product liability perspective for public health and safety to ensure THC potency not be underreported in cannabis products.	The Department agrees with this comment.
15712.1	12, 18, 24	Commenters indicate that inaccurate product testing and labeling results in likely invalidation	While not on the proposed action, the Department notes commenter's

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
		of insurance coverage under product liability and product recall insurance policies. Effective insurance cover is a critical risk management necessity for companies operating in cannabis sector. One commenter asserts that insurance carriers underwriting the cannabis businesses in the state expressed serious concern about their ability to properly provide coverage if companies are forced by the Department to label products that under/misrepresent THC potency.	suggestion and looks forward to working with stakeholders on future policy development.
15712.1(i)	111	Commenter states it is unclear if the laboratory can report additional analytes on regulatory compliance COAs. If the laboratory is allowed to do so, it would be using the prescribed method, but the laboratory is unable to properly validate new analytes on the prescribed method due to poor chromatography. Since this method did not include minor cannabinoids during the method validation, it was not obvious how poorly it separates the included cannabinoids from other non-included cannabinoids. Therefore, this prescribed method will result in many laboratories over-quantifying analytes due to the peak area including other minor cannabinoids.	The Department disagrees with this comment. As stated in the proposed subsection, the laboratory may test for additional cannabinoid analytes beyond those specified in SOP (IV)(A). However, the laboratory must provide a full method validation for additional cannabinoid analytes in accordance with section 15713 and obtain Department approval prior to use of the proposed method. This does not restrict them from using another method to improve their chromatography.
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,	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.	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

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
	86, 87, 88, 89, 90, 92, 93, 108, 109, 110, 142, 143, 162, 163, 165, 166, 167, 168, 169, 187, 188, 189, 190	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.	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

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
		Some commenters request the Department prepare an updated impact statement to businesses in response to 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.	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 methods in the future.
15712.1	144	Commenter states that the statement: “Shall not utilize any other cannabinoid test method for the purpose of regulatory compliance testing and reporting,” was added to the text but sections 15712.1 (i), and SOP sections II. Apparatus and Materials (T) and (U), and IV. Calibration Standard, (C. 3), and V. Procedure (C. 7), and (D) all permit necessary modifications to replicate the performance of method. This is confusing as it is stated in the SOP some modification to the method will be necessary depending on homogenization equipment and chemical instrumentation used, as well as the calibration range and cannabinoids tested by each laboratory performing the method.	The Department disagrees with this comment. Some degree of modification and flexibility are allowed for the testing laboratories, such as homogenization equipment and calibration range. When such modifications are applied, it is still considered to be the same cannabinoids testing method and should produce accurate results.

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15712.1	41	Commenter asserts that they validated 11 methods for cannabinoids concentration by HPLC, which were previously approved by the Department. This will require laboratories to revalidate potency methods for the extra 2 components, which are not in the proposed SOP.	The Department disagrees with this comment. The method was only validated for the cannabinoids stated in the SOP. This includes all of the analytes required for regulatory compliance testing, as well as several additional analytes. If the laboratory makes the business decision to analyze and report cannabinoid analytes not required for regulatory compliance testing and not contained in the SOP, the laboratory must validate the method to ensure accurate and scientifically valid testing, as required by section 15713. The Department looks forward to working with stakeholders on the development of new test methods in the future.
SOP	104	Commenter thanks the Department for its efforts on improving the regulatory language and the associated SOP. Specifically, commenter thinks adding flexibility in the homogenization techniques, allowing for other methods to be utilized outside of compliance purposes, allowing for laboratories to report additional cannabinoids, and allowing for a greater calibration range were greatly beneficial changes.	The Department agrees with this comment.
SOP Definition – Method Blank	112	Commenter states it is impossible to have a blank matrix for this assay that is truly reflective of cannabis samples. The matrices suggested by the Department are entirely devoid of any interferences that would be present in cannabis matrices.	The Department disagrees with this statement. The blank matrices given are stated in SOP (VII). Quality Control. Cellulose powder is an appropriate blank matrix, has been validated

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			as a suitable blank matrix for the method, and is currently widely used in the testing industry as a blank matrix.
SOP Definition – Matrix Post-dilution Spike	113	Commenter states it is unclear what the purpose of this sample is if laboratories are still required to run an LCS that gets spiked pre-extraction. Commenter suggests removing the requirement of an LCS since that would require an abundant amount of cannabinoid standard to prepare and would greatly increase the cost of testing. Commenter also indicates that it is unclear where in the procedure laboratories are supposed to spike the "Matrix Post-dilution Spike". The laboratory assumes it is supposed to be spiked post-extraction and during the dilution process instead of being spiked after the dilution process, since the spike itself would further dilute the sample. If so, then "Post-Dilution" is a misnomer and this sample should be renamed "Post-Extraction". Commenter also indicates that it is also unclear if laboratories are required to prepare a sample once, dilute it twice and then spike only one dilution, or if the laboratory should prepare a sample in duplicate for the purposes of spiking one.	The Department disagrees with this comment. An LCS is required to be prepared with each analytical batch pursuant to section 15730 and re-iterated in this SOP. The LCS should be spiked prior to extraction as a quality control measure for the extraction process. Low recovery of the analytes in the LCS, outside the acceptance criteria of 70-130%, indicates problems with the extraction process and requires remedial action to ensure the accurate reporting of results. A post extraction spike does not provide information on the extraction recovery of the analytical batch. "Matrix Post-dilution Spike" means spiking a known amount of the target analytes into a diluted sample after extraction, hence the descriptive nature of the LQC sample's name of "post-dilution." The Matrix Post-dilution Spike provides information on the accuracy of the results post sample extraction in a quantifiable comparison to the known spike value.
SOP Definition – Matrix Post-dilution Spike	145	Commenter states the purpose of the Matrix Post-dilution Spike is understood and well-received. In VII. Quality Control (B. 4) The	The Department disagrees with this comment. An LCS is required to be prepared

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		statement “A post-dilution spike is used because, given the limit of concentrated cannabinoids stock standards, matrix spike is not applicable”. This same logic can be applied to the LCS, as a LCS requires the same spiking level as a matrix spike sample. It is cost prohibitive to spike cannabinoid standards at the mid-range of the calibration curve for LCS samples. Commenter inquires if the Matrix Post-dilution Spike will replace the LCS or if both will be required.	with each analytical batch pursuant to section 15730 and re-iterated in this SOP. The LCS should be spiked prior to extraction as a quality control measure for the extraction process. Low recovery of the analytes in the LCS, outside the acceptance criteria of 70-130%, indicates problems with the extraction process and requires remedial action to ensure the accurate reporting of results. A post extraction spike does not provide information on the extraction recovery of the analytical batch. "Matrix Post-dilution Spike" means spiking a known amount of the target analytes into a diluted sample after extraction, hence the descriptive nature of the LQC sample's name of "post-dilution." The Matrix Post-dilution spike is required in addition to the LCS for each analytical batch as noted in Section VII. Quality Control. Both LQC samples are required and it is not appropriate to run a Matrix Post-dilution spike in lieu of an LCS.
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	The Department disagrees with the comment. Reagent Blank is required for method verification pursuant to section 15712.2 and therefore is defined in the SOP for further reference. A reagent blank is not required during routine

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		Blank) and that the Reagent Blank and Method Blank serve the same purpose, commenter requests the Reagent Blank be removed from the SOP.	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	115	Commenter states there is no acceptance criteria defined for this sample.	The Department disagrees with this comment. Defined acceptance criteria is not necessary here as this is not a routine regulatory compliance required LQC sample. This sample is run during the method verification process and would be covered in the FDA guidelines. It is not necessary to set an acceptance criteria as its not needed on a routine basis. Generally, any type of "blank" conveys that contamination is present as it should be free of analytes.
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 the SOP for further reference. A reagent blank is not required during routine regulatory compliance testing as part of the LQC samples.
SOP Definition 19 -Solvent Blank	147	Commenter states the purpose of the Solvent Blank is understood and well received but the naming convention is unusual. In EPA methods the Continuing Calibration Blank (CCB) is paired with a CCV	The Department disagrees with this comment. A solvent blank is considered a common injection in the analytical chemistry testing industry

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		as a CCB/CCV. This is a more universal and meaningful naming convention. Commenter requests the solvent blank renamed to CCB for alignment with other industries and for consistency and clarity.	to ensure the instrument is free of contamination prior to testing samples. Many cannabis testing laboratories already use a solvent blank. A solvent blank is required to be run after every ICV and CCV to demonstrate the instrument is free of contamination before sample analysis pursuant to section 15712.1(b) and as referenced in SOP (VII) Quality Control.
SOP Definition 19-Solvent Blank	116	Commenter states there is no acceptance criteria defined for this sample.	The Department agrees with this comment. The acceptance criteria for Solvent Blank has been added in SOP (VII)(A)(1).
SOP-Definition 19- Solvent Blank	117	Commenter states this is an unnecessary blank that will add cost and time to the analysis of samples without showing benefit to the laboratories or consumers. The method blank being free from analytes should serve the purpose of demonstrating that the instrument system is clean and free of contamination. This adds nothing but time and expense.	The Department disagrees with this comment. A solvent blank is considered a common injection in the analytical chemistry testing industry to ensure the instrument is free of contamination prior to testing samples. Many cannabis testing laboratories already use a solvent blank. A solvent blank is required to be run after every ICV and CCV to demonstrate the instrument is free of contamination before sample analysis pursuant to section 15712.1(b) and in SOP (VII). Quality Control of the SOP.
SOP (II)(T)	119	Commenter states they do not believe the Department verified that all samples in its validation work were ground to less than 1 mm. If the Department did not include this step in their own validation, then	The Department disagrees with this comment. The Department allows flexibility in the method to determine the grinding

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		this should be omitted from the SOP as a requirement. If this is to be included as a requirement it should be demonstrated that particles less than 1 mm are a requirement and particles greater than 1 mm are not suitable for use.	method of the laboratory, and how laboratories determine meeting the ≤ 1 mm particle size. This will ensure proper sample diminution and extraction. Having additional requirements would be prescriptive, as well as increase workload and costs. Not all validated standard methods, such as from the AOAC, have this requirement for cannabis.
SOP (II)(T)	118	Commenter states that the particle size of flower samples post-homogenization greatly impacts extraction and there is no check to ensure the particle size of ≤ 1 mm included in the procedure. Unless the Department prescribes a way to ensure a particle size, there would still be great disparity in homogenization thoroughness between laboratories.	The Department disagrees with this comment. Rather than providing a prescriptive way of meeting the particle size, the SOP allows laboratories to determine the grinding method they will use to meet the ≤ 1mm particle size. This will ensure proper sample diminution and extraction. A prescriptive requirement would also likely increase workload and costs for laboratories. Not all validated standard methods, such as from the AOAC, have this requirement for cannabis.
SOP(II)(U)	120	Commenter states that although cryogenic grinders are capable of grinding samples to less than 1 mm, they can be used in a variety of ways that would not result in particles that small.	The Department agrees with this comment in part and the use of a cryogenic grinder was removed. Rather than providing a prescriptive equipment requirement, the Department now indicates in SOP (II), Apparatus and Materials, that laboratories must use size reduction equipment

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			capable of grinding samples to less than 1 mm and allows laboratories to determine how they will meet this requirement.
SOP(II)(U)	121	Commenter states it is unclear why - 70° C is required. Since the entire representative sample will be homogenized together, this temperature requirement would also be applied to all other assays. This is most concerning for the microbial impurities assay as temperatures that low may kill certain microbes, and these cryomills are marketed as being capable of lysing cells (which would also kill microbes). Unless the Department has validated a microbial method using this technique which shows that -70° C and pulverization to ≤1 mm does not adversely impact microbial viability, then this step should be removed entirely. Additionally, the Department should require that any laboratory that puts microbial samples through a cryomill include that step in the method validation as proof that they are not removing contaminants during the homogenization step.	The Department disagrees with this comment. This provision has been removed from the SOP. Moreover, sample preparation for microbial contaminants is not part of this SOP and separate from sample preparation for testing cannabinoids. The Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
SOP(II)(U)	122	Commenter states that they do not believe the department validated the temperature requirement for homogenizing chocolate, hard candy, gummy and cookie samples. Commenter believes the -70 celsius requirement is arbitrary and as such should be removed.	The Department disagrees with this comment in part. This provision has been removed from the SOP. 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

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
			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.
SOP (II)(U)	2, 97	Commenters assert that sample homogenization can be just as effectively done by human hand and using dry ice. The cost to	The Department agrees with this comment in part. This provision has been removed from the SOP.

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		operate and maintain a cryogrinder is extensive and burdens both labs and clients with slower processing times. One commenter asserts Commercially available blast freezers have a temp between -30°C to -40°C, which tends to keep items at -18°C. This freezing process is much safer than handling cryogenic liquids and moving tanks; more environmentally friendly; and more economical vs using cryogens. Furthermore, there is currently a shortage of CO2 (including dry ice.) Commenter indicates their experience is that blast freezing samples is quick, economical, and allows for sufficient sample homogenization using commercially available grinders/mills/homogenizers. Blast freezers are a one-time expense versus the continual expense of purchasing, changing, and storing cryogenic dewars, and thus are less likely to face supply-chain disruptions.	
SOP (III)	78	Commenter asks if the use of an internal standard can be permitted, and states Ibuprofen can be used as an internal standard.	The Department disagrees with this comment. The SOP contains a prescriptive standard preparation to for consistency between laboratories. The preparation of standards is a critical step that influences the outcome of the results, and the intent of BPC section 26100(f)(2) is to reduce interlaboratory variation. These steps are required to ensure laboratories have a common method of standardization and preparation of standards.
SOP (IV)(A)(1-9)	7	Commenter appreciates the usage of CAS numbers for greater clarity;	The Department agrees with this comment.

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		it is a good and warranted clarification.	
SOP (IV)(A)(1-9)	94, 95, 96,	Commenters state Section IV.A(1-9) of the current proposed text of regulations is worded in such a way that only individual CRMs may be used to prepare working standard solutions. Pre-Mixed Multi-Cannabinoid CRMs must be allowed for the preparation of calibration standards. Commenter states that preparing the 100 ppm and 10 ppm cannabinoids mix working standard solution by combining 9 individual standards in the testing laboratory will contribute greater measurement uncertainty to the method than using a multi-standard prepared by an ISO 17034 accredited CRM provider. Such standards are available from multiple reputable providers. Multi-standards reduce the cost of purchasing CRMs and allow for greater starting concentration for routine Laboratory Control Samples and Matrix Spike preparations for validation work. Commenter recommends allowing more flexibility in the CRMs and preparations of standard solutions.	The Department agrees with this comment. SOP (IV) Calibration Standard contains the required concentrations of the specific analytes, as listed by CAS number, that are to be utilized for the method. The Department has not restricted the use of standard mixtures, which will continue to be acceptable, given that the analytes and concentrations meet their respective requirements for the correct CAS number and concentration. The Department added language that clearly states mixtures or combined standard solutions of the analytes at their specified concentration may be used.
SOP (IV)(A)	55	Commenter appreciates the clarity over the floor for number of cannabinoids tested in section IV(A). It is clearer that labs can analyze more than the 9 cannabinoids listed. However, it is not feasible for laboratories to run multiple different methods for the same analysis. If a laboratory develops a method to run 15 total cannabinoids, it would effectively be doubling the sample throughput to create a single set of results for a customer. Again, though the flexibility is good for number of	The Department disagrees with this comment. This includes all of the analytes required for regulatory compliance testing, as well as several additional analytes. If the laboratory makes the business decision to analyze and report additional cannabinoid analytes, the laboratory must validate the method to ensure accurate and scientifically valid testing,

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		reportable cannabinoids, having multiple methods for a longer list is not practical. Commenter asks whether the Department would be able to verify a single method for all 9 + additional desired cannabinoids.	as required by section 15713. The Department looks forward to working with stakeholders on the development of new test methods in the future.
SOP(IV)(A)	59	Commenter asserts that a CRM from Restek, for example, is an exclusive subset of reference standards that meets the following set of strict criteria defined under ISO 17034 and ISO/IEC 17025: made of raw materials characterized via qualified methods on qualified instruments; produced in an ISO-accredited laboratory under documented procedures; and falls under the manufacturer's scopes of accreditation. A certified reference standard does not typically refer to a reference material made up in the presence of a cannabis or non-cannabis matrix. Commenter recommends distinguishing these as certified reference materials to avoid confusion. What is described as the current definition is more akin to a matrix matched reference material, which is provided by some proficiency testing manufactures and is very uncommon in potency analysis due to the lack of representative matrices and cannabinoid free cannabis matrices. Clarification is needed here for the definition so that it is clearer that the materials for calibration should be reference standards that meet the strict criteria for these materials as defined under ISO 17034 and ISO/IEC 17025. "Standards" is a very broad term, which could lead to confusion about materials for calibration. Commenter recommends the Department clarify these terms so that they are consistent with the widely accepted	The Department disagrees with this comment. The definition of CRM is a reference material in cannabis or similar non-cannabis matrix prepared at a known concentration by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation. The definition of standard is a certified reference standard comprised of one or more of the target analytes prepared at a known concentration by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation. The definition of standards does not include the need for matrix.

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		terminology in the analytical testing industry.	
SOP (IV)(B)(5)	60	Commenter recommends stating the stability of the combined working standard solution. Guidance on how long certified testing laboratories should expect these mixtures to be stable at the prescribed conditions, “freezer (-20°C)”, will help eliminate the possibility of expired or degraded standard from being used. It is not clear how long the certified testing laboratory can use these mixtures for calibration and other QA purposes. The Department should consider referring to each vendor’s unique CRM COA for appropriate handling and storage recommendations. Issues with degradation here can lead to inaccurate calculated values as unexpected degradation can occur in mixed solutions without proper evaluation and stability studies to reference. Some vendors add stabilizers to acidic cannabinoid mixtures and others do not, it would be good to clarify again that laboratories need to evaluate stability in house to determine if the standards are still accurate. This can be done by preparing a fresh calibration curve and reinjecting held calibration vials. The Department could add clarity on whether calibration standards should be prepared fresh each time calibration is performed.	The Department disagrees with the comment. How long the mixtures of working standards is stable at the prescribed conditions is not necessary for the SOP and is contingent on what method of storage is used. The ICV and CCV in the SOP (V)(E)(2) provides acceptance parameters for standards used in analysis and calibration. If these acceptance parameters are not met, the laboratory must create new standards and recalibrate the instrument. Additionally, the Department has modified the requirement to allow laboratories to store working standards per the manufacturer’s specifications as an alternative to storage at -20°C .
SOP (IV)(B)	54	In section, IV.B, Working Standard (A) is described as a solution made up of 9 individual 1.0 mg/mL CRMs for the targeted cannabinoids. Will certified testing laboratories be able to use CRM mixtures from ISO/IEC 17034 accredited vendors containing all or some of the outlined 9 cannabinoid targets that	The Department agrees with this comment. SOP (IV) contains the required concentrations of the specific analytes, as listed by CAS number, that are to be utilized for the method. The Department has not restricted the use

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		are offered by vendors at 1.0 mg/mL to prepare their working standards A, B, C, and D. Commenter recommends adding guidance on cannabinoid CRM mixtures since many of the available and routinely purchased offerings on the market are various combinations of the listed target compounds in a single solution. It is not clear whether this will be acceptable or if laboratories will need to have single solutions at 1.0 mg/mL for each target. More clarity over what types of standards (singles vs mixtures) can be used would be good so that laboratories understand what is required.	of standard mixtures, which will continue to be acceptable, given that the analytes and concentrations meet their respective requirements for the correct CAS number and concentration. The Department added language that clearly states mixtures or combined standard solutions of the analytes at their specified concentration may be used.
SOP (IV)(B)	123	Commenter states it is unclear why a laboratory would be unable to determine the ratio of acetonitrile/methanol gravimetrically. It is generally understood that w/w measurements are more accurate than v/v since they are not affected by temperature. The laboratory should be allowed to prepare any solution gravimetrically as opposed to volumetrically.	The Department disagrees with this comment. The SOP is prescriptive for the solvent preparation to have consistency between laboratories. Using a common method to determine the ratio of solvents by volume serves the intent of BPC section 26100(f)(2), which is to reduce interlaboratory variation. In addition, the methanol density at 10°C is 800.8 g/L and at 30°C is 782.0 g/L. If 40 mL of methanol is used, the weight is 32.032 at 10°C and 31.28 at 30°C. The difference between the two weights is less than 1%. Compare this 1% error to the requirement for the matrix spike which allows 30% variance for recovery, the error is very small. In addition, scientific laboratories usually have a room

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			temperature between 15°C to 25°C, which will lead to an even smaller error.
SOP (IV)(B)	124	Commenter asserts that not all certified reference materials for a single cannabinoid are free of other cannabinoid contaminants. For example, it is common to see low levels of THC in a THCa standard. Commenter's laboratory commonly reviews new lots of standards to ensure mixing them will not impact the quantitation of other cannabinoids. For this reason, commenters suggest that the alternative calibration schemes be allowed where not all cannabinoids are required to be mixed together.	The Department agrees in part with this comment. The Department specifies the quality of the standards to be in the SOP. CRM means a reference material in cannabis or similar non-cannabis matrix prepared at a known concentration by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation. The laboratories may additionally use the mentioned procedure in the comments, or others to internally verify the quality of standards used. SOP (IV) Calibration Standard is to show the required concentrations of the specific analytes, as listed by CAS number, that are to be utilized for the method. The Department has not restricted the use of standard mixtures, which will continue to be acceptable, given that the analytes and concentrations meet their respective requirements for the correct CAS number and concentration. The Department added language that clearly states mixtures or combined standard solutions of the analytes at their specified

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			concentration may be used.
SOP (IV)(C)	125	Commenter states that allowing for additional calibration points would change the range of the method. This would mean that laboratories would be verifying parts of the calibration that were never properly validated.	The Department agrees with this comment in part. The Department allows additional calibrations beyond those listed in the standard procedure, which is within the validated method. The laboratories should utilize Good Laboratory Practice as defined in section 15700(w) and required by section 15729 to ensure the extra calibration points used are within the linear range of the instrument.
SOP (IV)(C)(3)	148	Commenter states approving additional calibration levels in the modified text of regulations is agreeable and well received, but laboratories would like flexibility in how the standards are prepared and at what specific concentrations they are prepared at. In the required calibration scheme, two working standards are utilized. This will cause more variance in the residuals of the curves since the three high level calibrators (20, 50, and 100 ppm) are prepared from one working standard, and the four lower calibrators (0.5, 2, 5, and 10 ppm) are prepared from a second working standard. This approach will inherently cause more variance. Commenter prefers making one working standard and performing a 2-fold serial dilution down to the lowest level calibrator. Since there is already flexibility built into the number of calibrators that may be used in the standardized SOP, commenter would like the ability to utilize calibrator levels other than the 7 specified concentrations in the SOP.	The Department disagrees with this comment. The SOP is prescriptive for standard preparation to have consistency between laboratories. Using a common method to determine the ratio of solvents by volume serves the intent of BPC section 26100(f)(2), which is to reduce interlaboratory variation. These steps are required to ensure licensed testing laboratories have a common method of standardization and preparation of standards.

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SOP (IV)(C)(3)	149	Commenter states that based on the calibration levels listed; the calibration curves are not calibrated low enough to achieve a compliant LOQ of 1 mg/g per section 15724. It would not be possible to achieve the mandated LOQ of 1 mg/g for a concentrate sample with the calibration range, sample prep, and dilution required in the standardized SOP.	The Department disagrees with this comment. The SOP and method validation address how LOD/LOQ were calculated. Using 40mL and 0.2 grams, or 200X, the lowest calibration point of 0.5 ppm is equal to 0.1 mg/g. Pursuant section 15724(b), the laboratory must establish a LOQ of 1.0 mg/g or lower for all cannabinoids analyzed and reported, therefore the laboratory must ensure that a dilution that produces a LOQ of 1.0 mg/g or lower is met for the analytes in their analysis. The LOQ that meets the criteria of 15724(b) is established as pre-dilution by the lab. This requires that a laboratory to analyze the lowest dilution that meets the LOQ requirement for a given sample, in addition to further dilutions to generate a result within the calibration curve as needed.
SOP (V)(B)	62	Commenter asserts that in section V.B. Sample Preparation, matrices are listed, and the recommendation is to group by sample type. Since the application indicates earlier that topicals are a specific “form” of cannabis sample, it is not clear which homogenization step is recommended for this category or if there is a separate recommendation for homogenization of topicals (e. g. lotions) altogether. Commenter	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

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		recommends clarifying what sample preparation topicals falls into between the prescribed methods in section V.B. so that laboratories know how to properly prepare the sample.	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.
SOP(V)(B)	63	The sample size for topicals is very high at 2g. We would recommend a sample size of 0.5 since matrix in topicals is so challenging to clean	The Department disagrees in part with this comment. The standardized test method

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		up.	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 looks forward

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			to working with stakeholders on the development of new test methods in the future.
SOP (V)(B)	80	Commenter requests clarity on if the use of Quechers for the extraction of cannabinoids in candy has been explored. Commenter states the Agilent method development suggests dissolving gummy and hard candy samples and then using Quechers.	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 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

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			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 (V)(B)	128	Commenter states homogenizing these sample types using a cryomill at a temperature ≤ -70 °C will kill Salmonella and Shiga toxin-Producing Escherichia coli (STEC) if present in the sample. This will cause false-negative test results which poses a large risk to public safety since these human pathogens can be extremely harmful; even fatal. Other cannabis regulators, like the Colorado Department of Public Health & Environment, prohibit homogenizing microbial samples using cryomills for this reason. Since the Department regulations require that the entire representative sample be homogenized together, it would be violative to separate out a portion of sample for microbial analysis prior to homogenization. It is not possible for the laboratory to validate a microbial method in accordance with US Food and Drug Administration's Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition, April 2015 if the cryomilling step is included and it'd be scientifically unethical to omit this step during the validation process. Therefore, the use of cryomills for the homogenization of regulatory compliance samples	The Department disagrees with this comment. Sample preparation for microbial contaminants is not part of this SOP and separate from sample preparation for testing cannabinoids. The Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.

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		should be immediately prohibited in the state of California and removed from this SOP. Additionally, the department should conduct a review of regulatory compliance samples that were tested by labs that use cryomills to homogenize the entire sample before microbial analysis to ensure that product recalls are not warranted at this time.	
SOP(V)(B)	126	Commenter states it is unclear if laboratories will be required to batch sample types separately or not. If laboratories are required to split batches upon according to the sample types listed, it would add additional costs to the cannabis test.	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 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

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			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(V)(B)	129, 131	Commenters states tinctures are not addressed in this section but should similarly be homogenized. Tinctures are defined as concentrates per section 15000(h) of the regulations and are also excluded from “beverages’ per AOAC definition.	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 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

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			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.
SOP(V)(B)	130	Commenter states it is unclear if the weights listed are minimums or exact. The Department should either add ± values to each mass or prescribe an allowable range.	The Department agrees in part with this comment. The test method has been amended to require 200 mg of sample.
SOP(V)(B)	132	Commenter states it is unnecessary to list “Chocolate, “Hard Candy”, “Gummy” and “Cookie” since that same section also includes “Other Edibles”. It would be much more clear if this section instead just listed “Other Edibles” since all of these sample types can be included in that category and the preceding section is for “Cannabis infused edible oil” (the first listed edible).	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 subject to further testing and validation for

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			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.
SOP (V)(B)(1)	64, 127, 133	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	The Department disagrees in part with this comment. The standardized test method for the determination of cannabinoids concentration was developed and validated

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		sonicating. Commenter indicates that oils are not easily mixed by inversion. Another commenter recommends grouping samples by type: juice, oil, chocolate, etc.	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.

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SOP (V)(B)(2)	4, 40	Commenters indicate that Section V.B.2 states that the weight for plant material/concentrate/vape oil should be 200 mg. However, section 15724 states that 0.5 grams must be analyzed at minimum.	The Department disagrees with this comment. The regulation clearly indicates the sample size that shall be used, irrespective of section 15724(a). The test method has been limited to dried flower, including pre-rolls, and has removed references to cannabis products. For cannabis products, laboratories are to utilize the sample mass requirement in section 15724(a).
SOP (V)(B)(2)	98, 151, 152	Commenter states the sample size for flowers and concentrates is not compliant with section 15724 requiring a minimum sample mass of 0.5 g. Commenter recommends that all sample mass units be stated in grams. Commenter asks about the required sample masses for edible, topicals, and other matrices and asks if laboratories can increase the amount of sample that is prepared. Commenter states this is helpful for optimizing extraction efficiency in the complex set of matrices labs encounter.	The Department disagrees with this comment. The regulation clearly indicates the sample size that shall be used, irrespective of section 15724(a). The test method has been limited to dried flower, including pre-rolls, and has removed references to cannabis products. For cannabis products, laboratories are to utilize the sample mass requirement in section 15724(a).
SOP (V)(C)(2)	134	Commenter recommends allowing for agitation techniques other than vortexing. Many laboratories utilize SPEX Geno-Grinders for this step. Not only is this technique equally effective, it is also more standardizable.	The Department agrees with this comment. SOP (II) Apparatus and Materials that flower must be homogenized to less than 1 mm. The proposed validated method applied the SPEX Geno-Grinder and it is included in the requirement for a tissue homogenizer or any size reduction equipment in SOP (II)(T). The word "Geno-Grinder" was

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			removed from the proposed SOP in response to comments indicating that using the word "Geno-grinder" excluded other kinds of size reduction methods.
SOP (V)(C)	1, 66, 67, 68, 69, 70, 71	Commenters assert that the new regulations require 50 ml of solvent which is 5 times the amount of solvent that most laboratories use for the first sample dilution. Most laboratories use 10 ml of solvent for the first dilution. Commenters assert this increases hazardous waste generated by laboratories by 5 times. Some commenters assert the analysis does not capture the cost of organic waste disposal resulting from large volumes of solvent waste produced in the proposed method. Some commenters recommend a two-aliquot extraction protocol, which would reduce the total extraction volume in half and help to achieve better recoveries. Commenter recommends the Department reduce the total extraction volume for plant material to 10-15 mL of extraction solvent from 40 mL. At extraction solvent totals less than 15 mL, costs can also be reduced by eliminating the need for 50 mL tubes and time can be saved. Using a smaller tube also reduces the amount of plastic waste the certified testing lab produces. Commenters assert one of the greatest contributors to costs per sample for a laboratory is the volume of solvent used for the extraction. After reviewing the cost per sample for the 40 mL 80:20 acetonitrile: methanol solvent recommendation in the proposed method, section V.C.1 , we have calculated a cost of $3.76 per plant	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 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

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		material sample for solvent alone. The Department method for flower is about 165% more solvent costly than the current most expensive methods in the industry. Other commenters recommend the Department consider re-evaluating the proposed 80:20 acetonitrile: methanol to consider both reducing the total extraction volume and eliminating acetonitrile as an extraction solvent. Using less solvent is environmentally friendly and more economical for certified testing labs. Even if the Department switched to MeOH and kept the same extraction volume, costs cold be reduced and preparation errors could be reduced.	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. Additionally, the number of preparation errors in preparing a mixed solvent versus only methanol are negligible compared to other sources of errors. The test method has been limited to dried flower, including pre-rolls, and has removed references to cannabis products; thus, reducing the circumstances in which the test method must be used and, in turn, reducing the amount of solvent laboratories are required to use. The Department looks forward to working with stakeholders on the development of new test methods in the future.
SOP(V)(C)	99	Commenter asserts this section does not allow for addition of internal standards. Internal standards improve the ruggedness and accuracy of test methods and are considered an important part of method best practices.	The Department disagrees with this comment. The proposed method does not apply internal standards. 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

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			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. Internal standards would add cost and complexity to the method and it was not necessary in the validation. This is why they are not included. The preparation of standards is a critical step that influences the outcome of the results, and the intent of BPC section 26100(f)(2) is to reduce interlaboratory variation. These steps are required to ensure laboratories have a common method of standardization and preparation of standards.
SOP (V)(C)(3)	135	Commenter states the term "at least" should also be added here, or the duration should be turned into an allowable range if the Department would like to prevent things from being sonicated for much greater than 30 min.	The Department agrees with the comment and the term "at least" was added to the sonication instructions in SOP (V)(C)(3).
SOP (V)(C)(3)	136	Commenter suggests that instead of stating "with ice in the water bath" the Department should prescribe an allowable temperature range since the bath water may remain sufficiently chilled even though all ice has visibly melted.	The Department disagrees with this comment. The Department has written the procedure to prevent heating of the samples by the sonicator which may lead to degradation of cannabinoids. While an

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			allowable temperature range is more specific, the Department's intent was to chill the samples. The Department does not believe it is necessary to be more prescriptive as suggested.
SOP (V)(C)(6)	74	Commenter recommends that the sample diluent be clearly stated in step V.C.6. If the final diluted sample matches the extraction solvents/standards, for example, acetonitrile/methanol (80:20) as diluent, it will be too strong and may cause peak splitting in early eluting compounds.	The Department agrees in part with this comment. The sample diluent has been changed in SOP (V)(C)(6). The method was validated with dilution solvent acetonitrile/methanol (80:20). Use of a different solvent may lead to inaccurate results.
SOP (V)(C)(6)	140	Commenter states the Department recommends diluting these extractions down in section 6 of section C: Sample Extraction, and so by allowing increased solvents laboratories would essentially be incorporating all or part of that step before the extraction process. This also has the added benefit of possibly eliminating pipetting, and therefore, inaccuracies from deliberate or accidental technique.	The Department disagrees with this comment. The activity proposed by commenter would make achieving required LOQs and calibration range and preparation of LCS very difficult and is thus not appropriate for inclusion in this test method.
SOP (V)(D)(1)	76	In section V.D.1 commenter suggests adding the specification for flow cell on the instrumentation that was used to validate the method. Flow cell volume will greatly impact achievable resolution for the method and may be something that laboratories will want to check on before setting out to verify the method.	The Department disagrees with this comment. The Department has determined that the performance of the method based on resolution is sufficient because it produces accurate results. The standardized test method for the determination of cannabinoids concentration was developed and validated

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			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. The specification of the flow cell and other parts of the instrument can be obtained from the vendor of the instrumentation used.
SOP (V)(D)	77	Commenter recommends an isocratic program for better reproducibility and robustness in a standardized method. Gradient methods, while effective, are more strenuous for instrumentation, require longer run times, and are not nearly as robust as isocratic methods, especially when comparing from instrument to instrument. Without challenging isomers in the required testing list, commenter feels that an isocratic method would be sufficient and practical.	The Department agrees with this comment. SOP (V)(D) provides that "Instrumental Parameters are column and system specific and will vary according to the specific HPLC column and system used." Instrumental parameters, such as different gradient methods are allowed.
SOP (V)(D)	79	(V)(D) Instrumental Parameters: can these parameters be changed accordingly to the instrument and column being used? Columns have different diameters so flow rates can affect back pressure. Maybe you can suggest a back pressure as Phenomenex does, then it is up to the user to determine flow rate to	The Department agrees with this comment. SOP (V)(D) provides that "Instrumental Parameters are column and system specific and will vary according to the specific HPLC column and system used." Instrumental

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		match backpressure given by the Department.	parameters, such as different flow rates are allowed.
SOP(V)(D)	153, 154, 155	Commenter states that mobile phases A&B. Acetonitrile is an expensive solvent that can suffer from cost fluctuations and supply chain issues. Laboratories may prefer to use methanol as the mobile phase or extraction solvent since it is affordable, widely available, and provides adequate chromatographic separation and extraction efficiency. Laboratories would like the SOP to allow for using acetonitrile or methanol as the mobile phase or extraction solvent. Commenter states that there are newer Isocratic HLPC methods for cannabinoids that are industry standards. Further, isocratic methods eliminate the problem of baseline drift seen in all gradient cannabinoid methods and produce a flat baseline. This makes auto-integration easier to achieve and helps minimize the need for manual integrations.	The Department disagrees with this comment. SOP (V)(D) provides that "Instrumental Parameters are column and system specific and will vary according to the specific HPLC column and system used." The instrumental parameters including the gradient of the mobile phases can be modified by the testing laboratories.
SOP (V)(E)(2)	137	Commenter states they applaud the Department for making this change rather than overstepping the existing regulations. Along with this needs to come a change in VII. Quality Control D. Retention time (RT) Acceptance Window which references retention times from calibration standards run in the same batch. Instead, this reference should be omitted or changed to use the retention times from CCVs run in the sample batch as those are required in every analytical batch while calibration standards are not.	The Department agrees with this comment. The CCV can be used in the runs without calibration standards to calculate RT window.
SOP (V)(E)(6)	75	Commenter states they do not recommend storing samples or standards inside the HPLC	The Department agrees and has made the recommended changes in

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
		autosampler. Samples that need to be repeated should be freshly prepped. Furthermore, in Section IV.B.5, it is mentioned that standards made up in the diluent should be stored in the Freezer (-20°C). In Section V.E.6, the certified testing lab is instructed to store them at 4°C. Commenter recommends that the desired storage temperature be consistent throughout for the prepared standards. Commenter also suggests re-caping any standards that were injected and have a pierced septa. Acetonitrile is very volatile and capping standards that the laboratory plans to inject again is the best way to preserve the standard in lieu of a fresh preparation.	the SOP.
SOP (VI)	5	Commenter indicates that it is unclear how an instrument level LOD and LOQ determined by section 15731 is translated into a single sample level LOD and LOQ (as shown in Section VI) when there are multiple different possible dilutions depending on matrix type. Only using one dilution to calculate the LOD/LOQs would create confusing results when other dilutions are used. Commenter suggests the regulation be changed to either allow for multiple matrix dependent LOD/LOQs, or the SOP should state that the lowest dilution shall always be performed on all matrices, then the LOD/LOQs corresponding to that dilution factor would be accurate.	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 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

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
			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.
SOP (VI)	157	Commenter asserts that the table of LOD and LOQ values is not titled or explained in the SOP. Commenter asks if these values empirical values generated during the states validation or are they required limits for laboratories to achieve. The LOQ value for THC provided in the table is 0.041 mg/g and is well under the on-curve LOQ. Commenter asks the Department to where this data was derived from and the purpose of having it in the SOP.	The Department disagrees in part 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), then going through all sample prep procedures, preparing 7 sample replicates separately and analyzing them in one sequence, and calculating the LOD from the standard deviation (LOD = t x S, where t=3.14 for 7 replicates at 99% confidence level). LOQ =

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			3 x LOD, should be in calibration curve and 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.
SOP (VI)	156	Commenter states the calibration range is from 0.5 to 100 ppm and based on the low calibrator concentration in the SOP the on curve LOQ does not meet the 1 mg/g required by the section 15731 when the required sample mass and dilution are taken into account.	The Department disagrees with this comment. Section 15731 addresses LOD and LOQ for Quantitative Analyses.
SOP (VII)(A)(2)	160	Commenter states this section states that the "ICV should fall within +/- 30% of the expected value of 10 ppm." Commenter inquires as to what is the unit for the 30% requirement and if it is Accuracy.	The Department agrees with this comment and has added "% percent recovery" to the SOP (VII).
SOP (VII)(A)(2)	159	Commenter states the units of ppm for the ICV are arbitrary and should be further defined. Commenter asks if the ppm is referring to µg/mL or µg/g.	The Department disagrees with this comment. The ICV is comprised of liquid standards in 80:20 ACN:MeOH as described in SOP (IV) Calibration Standard. Therefore, the concentration is µg/mL as the target analytes, represented in µ g per the manufacturer, are in liquid, represented as mL for volumes. The units ug/mL are also referred to as "ppm."
SOP (VII)(A)(2)	158	Commenter states the definition of an ICV does not state that it must be mid-range or define a required concentration, but the preparation	The Department disagrees with this comment. The SOP is prescriptive for standard

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		method produces a 10 ppm ICV. Commenter asks if laboratories can prepare an ICV at different concentrations in the linear range of the curve. Commenter states the practice is employed in EPA methods and is useful to challenge the linearity of the curve. Commenter asks if the calibration curve be considered valid if an ICV was prepared at a different concentration than 10 ppm.	preparation to have consistency between laboratories. Using a common method to determine the ratio of solvents by volume serves the intent of BPC section 26100(f)(2), which is to reduce interlaboratory variation. These steps are required to ensure licensed testing laboratories have a common method of standardization and preparation of standards.
SOP (VII)(B)(1)	161	Commenter states the term "Cellulose Powder" was inserted into the text as the blank matrix but is stated as methyl cellulose below in the same paragraph. The term cellulose powder is ambiguous as there are multiple forms of cellulose available. Also, methyl cellulose is not listed in the Reagents section.	The Department agrees with this comment and has removed the reference to "methyl".
SOP (VII)(B)	100	Commenter asserts every analytical batch processed should include at least 1 Method Blank, 1 laboratory control sample (LCS), 1 laboratory replicate sample (LRS), and 1 Matrix Post Dilution Spike. Commenter requests the Department clarify if both post-matrix spike and a laboratory replicate LQC sample are required for each analytical batch or if CCR Section 15730 prevails (LRS or matrix spike)	The Department disagrees, the updated SOP requires that one method blank, one LCS, one LRS, and one Matrix Post-dilution spike are analyzed per analytical batch. This is clear within the SOP and as noted by the commentor. The SOP also lists the acceptance criteria for all newly introduced quality control samples required for cannabinoid flower/pre-roll regulatory compliance testing. As noted in the SOP, both a LRS and matrix post-dilution spike are required. The laboratory must analyze the new quality control

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			samples as stated in the SOP. Section 15730 still applies to the other existing test methods such as residual pesticides and heavy metals.
SOP (VII)(B)(2)	6	Commenter asserts that it is unclear how an LCS is to be created. It has been previously explained by the Department that “The LCS is analyzed in the same manner as the representative sample”. means that the same extraction volume shall be used. This would mean an LCS sample would have to be extracted in 40 mL of solvent. As explained in Section VII.B.4 there is a limit of concentrated cannabinoids stock standards which would make an LCS as described very difficult and cost prohibitive. Commenter suggests that a post-dilution spiked LCS should be allowed for the same reasons a post-dilution spike is allowed in Section VII.B.4. Alternatively, commenter requests a clarification as to what extraction volumes, dilutions (if any) and standards should be used or would be acceptable.	The Department disagrees with this comment. A LCS is required to be prepared with each analytical batch pursuant to section 15730 and re-iterated in this SOP. The LCS is analyzed in the same manner as the representative sample using 40 mL of solvent. The LCS should be spiked prior to extraction as a quality control measure for the extraction process. A post extraction spike does not provide information on the extraction recovery of the analytical batch. "Matrix Post-dilution Spike" means spiking a known amount of the target analytes into a diluted sample after extraction, hence the descriptive nature of the LQC sample's name of "post-dilution." Thus, it is not appropriate to spike an LCS after dilution or use a Matrix Post-dilution Spike in lieu of an LCS as suggested.
SOP (VII)(B)(2)	138, 139	Commenter states they would like to see extraction solvent amounts, specifically for edibles, tinctures, and topicals, changed from a set amount of 40 ml to a minimum amount of 40 ml along with the	The Department disagrees with this comment. The standardized test method for the determination of cannabinoids

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		extraction vessel to be unconstricting to 50 ml centrifuge tubes. Commenter asserts that 5 ml of beverage in 40 ml (12.5% volume:volume) is too high of a concentration for certain products and that full recovery may not result. Commenter believes that allowing labs to increase solvent volume for infused products is an easy fix to this potentially large issue and it comes at no cost to method integrity or goals of the regulation.	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 looks forward to working with stakeholders on the

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
			development of new test methods in the future.
CAS Numbers	57	Commenter appreciates the Department listing the CAS #s for any cannabinoids included in the scope of the method to avoid confusion with the identity of the cannabinoids since there are often multiple abbreviated names for each target. Commenter strongly suggests adding additional targets and validating the method with an expanded list to particularly include acid forms of already included neutral cannabinoid targets and others that are routinely tested for in the current marketplace.	The Department partly agrees with this comment. CAS #s have been added for clarity. This SOP includes all of the analytes required for regulatory compliance testing, as well as several additional analytes. If the laboratory makes the business decision to analyze and report additional cannabinoid analytes, the laboratory must validate the method to ensure accurate and scientifically valid testing, as required by section 15713. The Department looks forward to working with stakeholders on the development of new test methods in the future.
Co-elution	101, 102, 103	Commenters understand that feedback during this comment period is limited to the recent modifications to the SOP, but wants to address a very significant co-elution that occurs with this proposed method. This co-elution results in potentially significant d9-THC inflation. Because the goal of this method is to address d9-THC inflation, resolving this co-elution is critical to the success of the proposed regulations for creating a standard cannabinoids test method and operating procedures.	While not on the proposed action the Department notes commenters' comment. The method validation established that the method worked well free of co-elution of the 9 cannabinoids in the method validation. 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.
CRM and Calibration Standards	91	Commenter recommends allowing for flexibility in the sample preparation and extraction solvents utilized for testing infused products or the certified reference materials (CRMs) used to prepare working	The Department disagrees with this comment. The SOP (IV) Calibration Standard is to show the required concentrations of the

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		solutions for calibration standards and quality control samples.	specific analytes, as listed by CAS number, that are to be utilized for the method. The Department has not restricted the use of standard mixtures, which will continue to be acceptable, given that the analytes and concentrations meet their respective requirements for the correct CAS number and concentration. The Department also added language that clearly states mixtures or combined standard solutions of the analytes at their specified concentration may be used. Moreover, the Department has limited the method to dried flower, including pre-rolls, and has removed references to cannabis products.
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 as a reference material in cannabis or similar non-cannabis matrix prepared at a known concentration by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation. This definition in the SOP is consistent with section 15700(o).
CRM	56	As a CRM vendor, commenter has seen growing interest in THC isomers, such as delta-10-THC (2 epimers) and delta-11-THC, found in processed cannabis such as oils and concentrates. Commenter asserts that many customers are	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.

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		testing for lists commonly more than 15+ unique cannabinoids with more being continually added over time. Colorado decided to add the stated THC isomers into their total THC calculation. Commenter asks if this be a requirement in California anytime soon to account for bulk biomass processing contaminants/byproducts in oil/concentrate sample types.	
CRM	61	Commenter reaffirms, the terminology, second source, is mentioned a handful of times but is not listed in the definitions section. Commenter asks if a second source CRM describes a separate manufacturing lot (different day, different chemist) of the same vendor catalog number for purchase, or whether it means a separate CRM vendor. Commenter recommends adding a definition for second source to provide clarity on how certified testing labs should go about sourcing their CRMs. "Second Lot" may be a more accurate statement if the Department s not requiring the second set of working standards to be made from CRMs sourced from a separate vendor than the first set.	The Department agrees in part with the comment and clarifying language was added to the SOP. A different or second source does not include a different day or different chemist. The ICV as already defined in section 15700(z), means a solution of each of the target method analytes of known concentration that is obtained from a source external to the laboratory and different from the source of the calibration standards. A different chemist or day of preparation does not meet the requirement of "source external to the laboratory", nor does preparing the same calibration standards with a different chemist or on a different day meet the requirements of "different from the source of the calibration standards." A source external to the laboratory and different from the source of the calibration standards is met through use of a standard from a different vendor or lot from those

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			used in the calibration curve.
LOD/LOQ	42	Commenter inquires about examples of the LOD/ LOQ calculations for laboratories to reference/ For example: 0.2g sample in 40 ml extraction solvent for LCS. Commenter asks how the Department calculated the LOD/LOQ mg/g to get those low numbers in the table section of 15731.	The Department disagrees with this comment. The calculations are referred to in section 15724 Cannabinoid Testing.
General Comment	20	Commenter asserts that the adoption of a singular method to test all product types will result in underreporting of THC potency for some products like gummies, hard candies, fruit chews, and beverages.	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 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

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			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	21, 22, 23	Commenters assert that the proposed rules will eliminate flexibility that laboratories currently have to extract from sugary materials since laboratories have specialized extraction techniques to accurately measure cannabinoid content of different product types. This will result in inaccurate test results that underestimate the THC potency of edibles in particular. This proposed method will produce inaccurate test results on many manufactured goods. Other commenters oppose the method for manufactured goods as it will exacerbate the problem of potency inflation.	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 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

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
			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	105, 141, 164	Commenter states they do not believe that the implementation of this method will reduce fraud or increase the accuracy of cannabinoid test results. Commenter states it is their opinion that proper enforcement of existing regulations would be a better means to resolving these issues. Commenter states that if we assume that the proposed regulations will be subject to the same level of enforcement as existing regulations, it can be assumed that the same bad-actors will remain in the testing industry. Other commenter states a better solution to eliminate laboratory inflation would be to provide	While not on the proposed action, the Department notes commenters' suggestion and looks forward to working with stakeholders on future policy development.

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		adequate policing of labs that are inflating potency. Other commenters state they appreciate the Department addressing potency inflation but event with the best method bad actors will still inflate results to gain market share.	
General Comment	106	Commenter recommends that the Department implement a system of routinely auditing licensed facilities, retesting samples at the retail level and distributing well-characterized to each laboratory for comparative analysis in order to truly standardize testing between laboratories.	While not on the proposed action, the Department notes commenters' suggestion and looks forward to working with stakeholders on future policy development.
General Comment	107, 636	Commenter states implementing this method will greatly increase the cost of cannabinoid analysis at a laboratory; many of these costs were not considered during the Department's cost estimates. Commenter estimates an increase of over $100,000 to implement and verify this method for increased costs associated with the required sample preparation and our throughput needs (vortexers, sonicators, cryomills, filters, more analytical standard, more solvent…etc). Commenter states the implementation of this method would also reduce their throughput and efficiency compared to their existing validated methodology.	The Department agrees in part with this comment. The method has been limited to dried flower and pre-rolls; thereby reducing the costs for laboratories to implement and utilize the method.
General Comment	178	Commenter states ISO standard 7.2.2.3 specifies the requirements for laboratories in performing method validation. The method validation performed by the Department performed spike recovery experiments on only plant or plant-like matrices (cellulose powder and hemp). The title of the validation summary itself is Validation for a UPLC Method for	The Department disagrees 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

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		Cannabinoids Concentration Quantitation in Cannabis Flower. No other matrices were validated, yet the method was written to include preparation and analysis of several different matrices. Without any data or performance characterization on other matrices (edibles, topicals, concentrates, tinctures, etc.), the validation falls short in proving the robustness of the method across multiple matrices.	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	183, 184, 185, 658	Commenters assert that the method they have developed should be used, and that the implementation	The Department disagrees with this comment. BPC section

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		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 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.	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 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

Section of Regulation	Comment Numbers	Summary of Comments Received During First 15-Day Comment Period	Department Response
			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.
Data Package	179	Commenter asserts that the validation data package was not organized in the way the Department requires laboratories to submit their validation reports (separate LQC reports).	The Department agrees with this comment. The Department is not a licensee, thus, not subject to the same requirements. The Department submitted the validation in accordance with ISO 17025 requirements.
Method Verification	180, 181	Commenters states that the method requires that laboratories verify the method to use it. A simple verification is not acceptable for ISO and all laboratories will have to perform a full validation of the method to maintain ISO certification. Commenter also states any changes to the method in the future will trigger a revalidation to harmonize ISO and Department requirements; thus, again the need for a full validation.	The Department disagrees with the comment. Under ISO 17025 7.2.2.1, laboratories need to validate non-standard methods. This proposed method from the Department is a standard method as in ISO 17025 7.2.1.4 and 7.2.1.5 only requiring a method verification. Any changes in the future will be validated as a standard method so that testing laboratories only need to do verifications.
Moisture Correction	172, 174, 175, 176, 177	Commenters assert that moisture correction is not a useful tool for normalizing potency in cured flower. Results from three interlaboratory studies initiated by three different cultivators were performed in 2021 and 2022, and a full analysis of the results of those studies is included as aseparate attachment.	The Department disagrees with this comment. Reporting cannabinoids based on dry weight is required in section 15724. Cannabinoid Testing. Additionally, this is required for related material, hemp testing by

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			the U.S. Department of Agriculture.
ISO 17025	182	Commenter states ISO 17025-accredited laboratories will lose their ability to use their accreditation as required by section 15701 until they have finished validating the method for cannabinoid analysis.	The Department disagrees with this comment. ISO 17025 accredited laboratories will not need to do a full validation, only verification. Laboratories will need add the new standard method to their scope of accreditation.
Sample Size	171, 170, 173	Commenters states with any preparation, consistency and reliability is key. The Department regulations initially stated that 0.5 grams of sample was required for every potency preparation. In the standardized method, the amount suggested to be used for concentrates and flower is 200 mg. Notwithstanding the decreased likelihood of obtaining a representative sample, the lower sample mass increases the potential variability of measurement. Considering a case in which a technician inadvertently deposits 20 mg of concentrate on the outside of the preparation tube, in which case it would contribute to the sample mass but not the cannabinoid content. The impact of the error: 20 mg/200 mg = 10% error in prep. In the same situation with 0.5 grams of sample, 20 mg/500 mg = 4% error in prep. A lower sample size will lead to a higher variability in sample preparation. Commenter states that it may have been that this decrease in sample size in the method from the original requirement in the regulations was due to a small dynamic range in the calibration curve, resulting in the necessity for small sample sizes and large dilutions. This can easily be remedied by including higher single	The Department disagrees in part with this comment. The regulation clearly indicates the sample size that shall be used for the method, irrespective of section 15724(a) which calls for 0.5 grams. Additionally, other validated methods, such as the AOAC standard method 2018.10, use 0.2 grams.

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		points in the calibration curve for compounds that have a high concentration in samples, i.e. delta-9 THC. Commenter asserters that there are concerns with interlaboratory consistency for every analysis presented, with the spread of THC content for Sample A ranging from 17.9% to 27.1% (40.9% RPD), and from 23.1% to 32.2% (32.9% RPD) for Sample B.	
15025.(a)(1)	2,4,6,8,10	Commenter would like a review of regulations for a pass-through window	While not on the proposed action, the Department notes commenter's recommendation and looks forward to working with stakeholders on future policy development.
15041.1(d)(5)	3,5, 7,9,11	Commenter would like a review of regulations for trade sample distribution.	While not on the proposed action, the Department notes commenter's recommendation and looks forward to working with stakeholders on future policy development.

Summary and Response to Comments Received During Second 15-Day Comment Period from October 4, 2022 to October 20, 2022

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15712.1(a)	42	Commenter asserts that by forcing laboratories to solely use this method for regulatory flower testing and not suggesting an equivalent for other matrices, the Department is effectively forcing all cannabis product manufacturers to require R&D testing on flowers in addition to regulatory testing in order to get results that correlate. Many clients care a great deal about trace cannabinoids that this method would not detect in source flower, but would be prevalent in extracts and therefore significant to the consumer. What that means is, regulatory COAs will be rendered meaningless for evaluating potency at the manufacturing level and R&D COAs will become the standard. Commenter does not think that is the intention of the Department.	The Department disagrees with this comment. This SOP includes all of the analytes required for regulatory compliance testing, as well as several additional analytes. If the laboratory makes the business decision to analyze and report additional cannabinoid analytes, the laboratory must validate the method to ensure accurate and scientifically valid testing, as required by section 15713. The test method developed by the Department has been validated as accurately and consistently capturing cannabinoid content in dried flower, including pre-rolls. COAs obtained outside the regulatory compliance process, such as those obtained for research and development, may not be used for regulatory compliance. The Department looks forward to working with stakeholders on the development of new test methods in the future.
15712.2(c)	12	Commenter asserts that clarity is needed on what a “sample matrices” is. Commenter also requests clarity regarding use of pseudo-matrices like MCT oil or cellulose powder.	The Department disagrees with this comment. The method stipulates that dried flower and pre-rolls are the matrices being tested. As provided in the SOP, pseudo-matrices such as

Section of Regulation	Comment Numbers	Summary of Comments Received During Second 15-Day Comment Period	Department Response
			cellulose powder are permitted.
15712.2(c)	13	Commenter requests clarity regarding quality control samples and asks what they must use for spike concentration levels. Commenter also requests clarity on ability to use post-extraction spikes.	The Department disagrees with this comment. SOP (VII)(B)(4) allows for use of Matrix Post-dilution spike. The Department has not proposed prescriptive levels for spiking, which allows the laboratory to establish an appropriate level for its operations while still producing accurate results.
SOP, Definition – Certified Reference Material	16	Commenter states that "CRM" is still listed as a definition and requests an updated definition for "standards".	The Department agrees in part with this comment. The Department has retained the definition for CRM as it is not interchangeable with “standards”. However, the Department has added a definition for “standard” to provide further clarity. CRM refers to Certified Reference Material and is a spiked matrix at a known analyte concentration level by a certified body. Standard refers to a reference standard at known analyte concentrations prepared by a certified body and is not prepared in a matrix.
SOP Definition – Laboratory Control Sample	14	Commenter asserts that under the proposed regulations, the LCS must be analyzed in the same manner as a representative sample and the spiked concentration must be at a mid-range concentration of the calibration curve for the target analytes. Commenter asserts this will be difficult to accomplish due to the sheer volume of standard that would be used for spiking.	The Department disagrees with this comment. The proposed regulation provides that the LCS can be spiked at any calibration level that does not correspond to the lowest or highest calibrant. Any calibrants between the lowest and highest calibrants are

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			considered mid-range.
SOP Definition – Laboratory Control Sample	15	Commenter recommends that the requirement of targeting the middle of the calibration curve be removed and that the Department allow a target a lower level calibrator.	The Department disagrees with this comment. The regulation allows for lower calibration points. The middle of the calibration curve is considered any point that is not the lowest or the highest calibration level.
SOP (II)(T)	43	Commenter suggests strictly prohibiting the use of a cryomill on all sample types including flowers. Although the Department removed the requirement of a cryomill from this SOP, it did not prohibit its use in regulated laboratories. A cryomill could be classified as "size reduction equipment capable of grinding samples to less than 1 mm", which would be allowed by this definition. Especially when considering that on January 26, 2022 the Department issued a mandatory recall of Claybourne Co. Head Banger cannabis flower due to aspergillus contamination. Fungal cells are much larger and more prone to lysis in a cryomill than smaller prokaryotic cells. DNA from a lysed cell would likely not be amplified using most PCR platforms. Therefore, the root cause of the false-negative in this case might have been caused by the use of cryomills. Commenter strongly urges the Department to take action on this issue as it is a public health concern and many other states have banned their use specifically for this reason or similarly flawed technologies, which there currently is no restriction against in California.	The Department disagrees with this comment. Sample preparation for microbial contaminants, such as aspergillus, is not part of this SOP and separate from sample preparation for testing cannabinoids. The Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
SOP (IV)	31	Commenter requests an accepted vendors list for standards be	The Department disagrees with this

Section of Regulation	Comment Numbers	Summary of Comments Received During Second 15-Day Comment Period	Department Response
		provided by the Department.	comment. Rather than providing a prescriptive list of approved vendors, the SOP lists standard requirements and allows laboratories to determine how they will meet these requirements.
SOP (IV)(B)	22	Commenter requests clarity regarding requirements for the preparation of standards. Commenter asks why they are not permitted to make one set of 100 ug/mL for the calibration curve and another for ICV, instead of preparing 4 standards.	The Department disagrees with this comment. The SOP contains a prescriptive standard preparation to for consistency between laboratories. The preparation of standards is a critical step that influences the outcome of the results, and the intent of BPC section 26100(f)(2) is to reduce interlaboratory variation. These steps are required to ensure laboratories have a common method of standardization and preparation of standards.
SOP (IV)(B)(3)	18	Commenter requests clarity regarding whether a separate lot of calibration standard from the same vendor is acceptable, and proposes rewording the SOP to: “a different source of calibration standard meaning either a standard obtained from a different source than that used for the working standard (A) or from the same source but a different lot.”	The Department disagrees with this comment. The SOP clearly states that the ICV is a solution of each of the target method analytes of known concentration that is obtained from a source external to the laboratory and different from the source of calibration standards.
SOP (IV)(B)(5)	63	Commenter asserts the 20C criteria for the standards is too restrictive. Commenter suggests that laboratories who have seen stability with their prepared standards at different temperature ranges should be able to set their own criteria in their SOPs or follow manufacturers	The Department disagrees with this comment. The -20C criteria is based on specific requirements for storing of standards from suppliers. This is applied to both standards and

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		guidelines. Alternatively, the temperature criteria should be range, such as: -10 C to -25C	samples to be consistent. A -20 freezer is not too restrictive as it is common in laboratories for storage of samples, standards, solvents and should be readily available. The Department has modified the requirement to allow laboratories to store working standards per the manufacturer's specifications as an alternative.
SOP (IV)(C)(1)	23	Commenter asserts that the 100 ppm calibration standard solutions listed in SOP (IV)(C)(1) does not need any further dilution.	While not on the proposed action, the Department notes commenter's statement and agrees that further dilution is not needed nor required.
SOP (IV)(C)(2)	24	Commenter asserts that the 10 ppm calibration standards listed in SOP (IV)(C)(2) does not need any further dilution.	While not on the proposed action, the Department notes commenter's statement and agrees that further dilution is not needed nor required.
SOP (IV)(C)(1-3)	37, 48	Commenter requests that the Department share any method validation data that demonstrates acceptable quantitation of the required cannabinoid analytes at 0.5 ppm. At 0.5 ppm, commenter finds it difficult to distinguish a pure D9-THC CRM peak from the instrument baseline at the 220 nm wavelength. Most standards provided by third party vendors are available at 1 mg/mL. The procedure described in C1 and C2 would require an initial 10x dilution (1 mg/mL > 100 ppm) followed by a series of serial dilutions. This creates several opportunities to introduce error. Extending the calibration curve to top out at 1000 ppm (1 mg/mL) would create a shared calibration curve target for	The Department disagrees with this comment. The 0.5 ppm standard concentration is a typical concentration used in HPLC, its use was validated by the Department and UCSD laboratories, and it is used as part of the AOAC Official Method 2018.10 as well. The second part of the comment about errors introduced in serial dilution of samples is not correct. The error in dilution is insignificant for this step. The point of using a 1000 ppm standard is already allowed in SOP (IV)(C)(3).

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		laboratories to use. This would also create a simpler dilution scheme and help reduce potential dilution/calibration errors and satisfy the cannabinoid LOQ requirements detailed in VI Method Limit of Quantitation of this SOP. Commenter proposes as an optional change that the cannabinoid calibration curve requirements be increased to include 1000 ppm (1 mg/mL).	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.
SOP (V)(B)(1)	32	Commenter requests that the SOP provide picture references of final homogenized flower and inside of centrifuge tube	The Department disagrees with this comment. The SOP provides in Section (II) Apparatus and Materials, that flower must be homogenized to less than 1 mm. The Department has determined that the information contained in the SOP provides sufficient guidance and direction for the laboratories.
SOP (V)(B)(2)	25	Commenter requests confirmation that their calculation of Dilution Fact 200 to start in SOP (V)(B)(2) is accurate.	While not on the proposed action, the commenter's calculation is accurate.
SOP (V)(B)(2)	33	Commenter requests that the test method require at least 500 mg of sample to be extracted. This allows the Department to spot check from retention to see if values can be repeated when properly homogenized sample is used during an on-site audit.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
SOP (V)(B)(2)	34	Commenter recommends reducing solvent to 20 mL, especially if extraction mass is only 250 mg. There isn't enough mass for proper consistency, but laboratories must use more solvent than needed to properly dissolve. This is irresponsible for the business, employee safety, and environment.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.

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SOP (V)(C)	40, 49	Commenter suggests allowing any effective extraction solvent to be permitted, provided recoveries of the analytes and efficiency of the extraction step can be proven and validated effectively. Commenter states they hope the use of a sonicator would be eliminated and believe the Department can appreciate how cumbersome this step as drafted would be when the draft regulations state it is required to use ice within a bath that will continuously get warmed by its operation. Commenter asserts that Section V(C). Sample Extraction of the SOP requires the use of an 80:20 ratio of acetonitrile:methanol as the extraction solvent. Acetonitrile is the worst solvent for extraction of very non-polar and fatty cannabinoids. In fact, acetonitrile is preferred as the extraction solvent for pesticide analysis because this leave most of the cannabinoids behind on the plant, which thus favors the pesticides being extracted and making for pesticide analysis more simplified and more effective within the mass detector. This effectively allows for better detection of the pesticides with less hindrance from the cannabinoids. As currently drafted, the proposed regulations would force laboratories to use a more expensive and less effective solvent for the extraction of cannabinoids from flower and trim. Methanol or ethyl acetate are far better solvents for extracting cannabinoids, and this has been proven by many laboratories. In fact, with the use of ethyl acetate a sonication step is not even required for optimal cannabinoid extraction.	The Department disagrees with this comment. The Department determined through method validation that the extraction solvent and sonication steps outlined in the SOP provided optimal results.

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SOP (V)(C)(1)	26	Commenter requests clarity on the sample types and asks if 0.5 g is not for dried flower and pre-rolls and if it is 0.5 g just for all others.	The Department disagrees with this comment. The regulation clearly indicates the sample size that shall be used, irrespective of section 15724(a). The test method has been limited to dried flower, including pre-rolls, and has removed references to cannabis products. For cannabis products, laboratories are to utilize the sample mass requirement in section 15724(a).
SOP (V)(C)(3)	17	Commenter requests clarity regarding how using ice water sonication is more beneficial for extraction as opposed to regular sonication at room temperature.	The Department disagrees with this comment. The Department determined through method validation that the extraction solvent and dilution provided optimal results. Ice water sonication is used to avoid any THCA and CBDA degradation due to heat generated by sonication.
SOP (V)(C)(3)	35	Commenter asserts that an ice bath is unnecessary to extract cannabinoids and the definition will lead to various practices. Recommend removing or placing a temperature requirement on sonication bath. Most cannabis laboratories use a warm bath currently and placing ice in there could potentially meet this requirement while surely violating the intent.	The Department disagrees with this comment. The Department determined through method validation that the extraction solvent and dilution provided optimal results. Ice water sonication is used to avoid any THCA and CBDA degradation due to heat generated by sonication.
SOP (V)(C)(3)	50	Commenter requests the Department share any method validation data (or technical references) that comparatively evaluated the significance of using an ice-cold water bath during	The Department disagrees with this comment. The Department determined through method validation that the extraction solvent

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		extract sonication. Commenter proposes an optional change to require method users to maintain a temperature range during this 30-minute sonication period.	and dilution provided optimal results. Ice water sonication is used to avoid any THCA and CBDA degradation due to heat generated by sonication. 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.
SOP (V)(C)(6)	27	Commenter requests clarity on dilution and asks if further dilution of DF 20 is accurate and if this means the Final DF= 4000.	The Department agrees with this comment. Commenter is correct regarding the calculation.
SOP (V)(D)(1)	39	Commenter asserts that Section (V)(D)(1) of the SOP states that instrumental parameters that are recommended are based on a Raptor Arc-18 column and that other C18 and columns can be used, however, the mobile phase and buffers are specific to acetonitrile and water with only 0.05% formic acid. Often a higher amount of formic acid is needed to maintain proper pH and buffering of the mobile phase. Often ammonium formate is added with formic acid to create a salt complex that allows for both better maintenance of the pH of the buffer as well as aid in better separation of peaks on the column. With the very low concentration of formic acid the pH of the buffer is likely to fluctuate more frequently leading to change in peak shapes and shifting of peaks, which will ultimately lead to more errors, exactly the opposite of the intent of the Department. Commenter suggests permitting the use of ammonium formate as needed as well, to eliminate these concerns and operational challenges.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.

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SOP (V)(D)(1)	51	Commenter requests the Department share any method validation data (or technical references) that comparatively evaluated various mobile phases. Often a higher amount of formic acid is needed to maintain proper pH and buffering of the mobile phase. Ammonium formate is often added with formic acid to create a salt complex that allows for both better maintenance of the pH of the buffer as well as aid in better separation of peaks on the column. With the very low concentration of formic acid currently being required for use, the pH of the buffer is likely to fluctuate more frequently leading to change in peak shapes and shifting of peaks leading to more errors. Commenter proposes as an optional change allowing for modification of the buffer for the mobile phase.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development. 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.
SOP (V)(D)(2)	38, 52	Commenter states that as provided in Section (V)(D)(2) of the SOP, quantification must be at 220 nm. Every double bond or carbonyl absorbs at 220 nm. At 220 nm the interference from the matrix, the background as well as the change in gradient from the mobile phase will be absorbed thus reducing the sensitivity and selectivity of detection. Allowing for quantification to be at 270 nm of the non-acids and 301 for the acids allows for less interference from background and matrix, thus allowing for better selectivity and sensitivity.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
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	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.

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		of acidic cannabinoids.	
SOP (V)(D)(2)	60	Commenter request that the Department replace wavelength for detection with 228 nm.	While not on the proposed action, the Department notes commenter's suggestion. The SOP already allows this alternate wavelength. In SOP (V)(D) Instrumental Parameters are column and system specific and will vary according to the specific HPLC column and system used.
SOP (V)(E)	61	Commenter states that cellulose powder is cheaper than hemp matrix, but it is harmful to the instruments and produces inconsistent results.	The Department disagrees with this comment. The Department is not aware of any evidence that cellulose powder can be harmful to instruments or produce inconsistent results. Cellulose powder has been proved to be appropriate through multi-laboratory validation to generate consistent results.
SOP (V)(E)(3)	28	Commenter asserts that spiking with the 1000 ug/mL standards in 40 mL extraction solvent, LCS concentration will be 25 ug/mL. Further dilutions to DF 20 will make the in-vial concentration to 1.25 ug/mL.	The Department agrees with this comment. Commenter's calculation is correct.
SOP (V)(E)(3)	29	Commenter asserts that per the Department regulations, LQC is either LRS or Matrix Spike. As per SOP, LRS AND Matrix Spike. Is this just for cannabis flower and pre-roll?	The Department agrees with this comment. Current regulations, specifically section 15730(d)(3), require the use of a LRS or Matrix spike sample for all chemical methods. However, the cannabinoids method for flower and pre-rolls requires the use of both LQC type samples – LRS

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			+ matrix spike sample, as written in (V)(E)(3) of the SOP.
SOP (V)(E)(6)	45	Commenter asserts the SOP does not account for how long samples spend on the autosampler, account for if the autosampler is temperature-controlled or provide guidance on how long after the run completes before the samples must be transferred to a freezer. It reads as though someone must be present after each run finishes to immediately transfer samples to a freezer. The Department should either add acceptance criteria for how long a sample can be stored at above -20°C or reword this section so it's not as prescriptive.	The Department disagrees with this comment in part. Samples should be removed after the run to -20C storage if needed for further dilution or testing. The Department disagrees in being prescriptive in the acceptance criteria for how long a sample can be stored above -20°C. The minimal amount of time that the samples are being run will not affect the samples while outside of the freezer.
SOP (V)(E)(6)	44	Commenter identified a typographical error. There is an “en” dash instead of the hyphen-minus.	The Department agrees with this comment and has corrected the typographical error.
SOP (V)(E)(6)	53	Commenter asserts that sample degradation is expedited once the septum of a sample injection vial has been punctured. What exactly is the Department trying to promote with the emphasis of post run sampling requirements? How long are sample vials to remain in storage for?	The Department disagrees with this comment. The Department has determined that these are common practices for testing laboratories, thus the Department has determined it is appropriate to allow laboratories to establish their own sample retention practices rather than imposing a prescriptive standard.
SOP (V)(E)(6)	62	Commenter states that in the current regulations there is no requirement for storing sample vials and there is no need to be added as a requirement since the sample vials will not be re-used. The space requirement for this would be an issue for the laboratory. Commenter	The Department disagrees with this comment. The SOP does not require storing of samples. This is optional in case of the need for dilution, samples being outside of the range of the

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		suggests that the Department remove this requirement.	calibration curve, or reanalysis of a batch.
SOP (VI)	30	Commenter requests clarity regarding whether the LOQ will be the reporting limit. Commenter asserts the dilutions would increase the reporting limit.	The Department agrees with this comment. The reporting limit was removed from the SOP.
SOP(VII)	46	Commenter asserts that including both the symbol and word for "percent" is redundant. Commenter requests that either the symbol or word be deleted in all instances such as in (A)(2)&(3) "+/- 30% percent recovery".	The Department disagrees with this comment as it believes the use of % and percent recovery is necessary for clarity.
SOP (VII)(A)(1)	19	Commenter asserts the wording in the SOP regarding the solvent blank acceptance is such that it sounds acceptable to keep rerunning the blank until it passes. Commenter recommends rewording the second sentence to "If the target analytes are present over the LOQ, rerun to verify the result. If the problem is still present, take corrective action to eliminate the source of contamination before proceeding with analysis of samples."	The Department disagrees with this comment. The SOP clearly indicates that the solvent blank should be rerun until the system shows it is free from contamination or system carryover.
SOP (VII)(A)(2)	20	Commenter requests clarity regarding the rewording in the SOP regarding a "source external to the laboratory and different from the source of the calibration standards". Commenter recommends that if a separate lot of calibration standard from the same vendor is acceptable, rewording to: "a different source of calibration standard meaning either a standard obtained from a different source than that used for the calibration curve standards or from the same source but a different lot."	The Department disagrees with this comment. The SOP clearly indicates that the ICV is a solution of each of the target method analytes of known concentration that is obtained from a source external to the laboratory and different from the source of calibration standards.
SOP (VII)(A)(2-3)	21	Commenter recommends changing "percent recovery" to "accuracy" which is a more appropriate term for an ICV & CCV.	The Department disagrees with this comment. Recovery means the measured

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			concentration relative to the added spike concentration in a reference material or matrix spike sample. ICVs and CCVs are considered reference materials.
15730	47	Commenter asserts proposed changes to section 15730 do not address a component of the rule set that allows for intentional calibration curve manipulation to achieve desirable analyte quantitation. Currently, the broad CCV recovery range of 70%-130% has created a situation where a “compliant” calibration curve can be leveraged to produce cannabinoid results that are favorable for a client. Until the CCV recoveries requirements are tightened, laboratories will still be able to compliantly apply a markup of 30% due to acceptable margin of error. The potency inflation in the cannabis industry is a direct result of this allowed error.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
15730	36	Commenter asserts that the biggest issue that still has not been addressed is section 15730 relating to the recoveries on all quality samples regardless of matrix or detection method. All CCV recoveries are allowed to be within 70-130% meaning that a continuing calibration verification sample can have an error of 30% and still pass. This error is passed on to the potency results which are reported with a +/- of 30%. The potency inflation we are seeing run rampart in the industry today is a direct result of this allowed error. We suggest making this 85-115%, for PDA and FID detection only (a 30% error for mass spectroscopy detection is acceptable), which will allow laboratories to be easily effective, and greatly curtail the	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.

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		current THC inflation reporting we are all witnessing today.	
ASTM Standard Test Method	41	ASTM International Technical Committee D37 on Cannabis has developed D8375-22 Standard Test Method for Determination of Cannabinoid Concentration in Dried Cannabis and Hemp Raw Materials using Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) which allows for the determination of a wide-range of sample; concentrations by using a 1000-fold calibration range and the option to perform multiple levels of sample dilution. The calibration curve is prepared in methanol over a range of 10 ng/mL to 10 000 ng/mL for all seventeen cannabinoids, or a subset of cannabinoids if desired, while the sample extracts are diluted in methanol into the calibration range. The test method shall apply to any dried raw material from a cannabis plant regardless of the type of cannabis plant from which it was derived. The procedure includes sub-sampling a ground, homogeneous sample, extraction with methanol:water (80:20, v:v),dilution in methanol and analysis by liquid chromatography tandem mass spectrometry (LC-MS/MS). The method was validated with quality control samples prepared in methanol, a candidate certified reference material (CRM), and repeat analysis of cannabinoid samples.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
General Question	1	Does the regulation only affect marijuana testing laboratories in CA?	While not on the proposed action, the Department notes commenter's question. The proposed regulations apply to testing laboratories licensed in California by the Department.

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General Comment	54	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	55	Commenter states that laboratories will be commenting on the most recent round of modifications commenting directly to the Department on the technical aspects of the language for which they are most ably qualified to address. Commenter asks Department to continue treating these comments with the gravity they deserve, coming from industry experts with decades of experience and innovation in laboratory testing.	The Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
General Comment	56	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 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	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 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

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		in addressing the most glaring performance issues in the process.	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.
15025.(a)(1)	2,4,6,8,10	Commenter would like a review of regulations for a pass-through window	While not on the proposed action, the Department notes commenter's recommendation
15041.1(d)(5)	3,5, 7,9,11	Commenter would like a review of regulations for trade sample distribution.	While not on the proposed action, the Department notes commenter's recommendation

Summary and Response to Comments Received During Third 15-Day Comment Period from May 8, 2022 to May 23, 2022

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SOP	1	Commenter asserts that laboratories must have the ability to modify or provide a fully validated equivalent method in order to provide the most accurate results. Commenter states they have found performance issues with the method. Commenter states without a proper understanding of method performance metrics, the Department cannot know what constitutes acceptable results. Multi-lab validation is required to ensure appropriately published data reduction and performance evaluation, otherwise DCC will have no basis for accurately determining underperforming labs, and thus no basis to discipline these labs. ACIL encourages DCC to perform a thorough multi-lab validation of its method. The validation provided by the DCC for the method does not even meet the U.S. Food and Drug Administration's standards for method validation (Please see the referenced: Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products 3rd Edition, page 8-10).	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
SOP (VII) (E)	2	Commenter states that the only way to deconvolve a cannabinoid from any potential interference including other cannabinoids, is to modify the sample preparation or chromatographic conditions, however taking such actions violates the section 15712.1(c). Commenter states they have run this proposed method in their lab and identified a co-elution of CBNA with d9-THC and have submitted feedback and data showing this co-	The Department disagrees with this comment. Deconvolution of peaks is not a modification of the method, but an allowed mathematical practice to separate peaks in the method as provided in SOP section (VII)(E), if it follows the requirements for review by management contained in

Section of Regulation	Comment Numbers	Summary of Comments Received During Third 15-Day Comment Period	Department Response
		elution. Commenter asserts they are submitting data showing evidence of this co-elution. CBNA is not included in the proposed Cannabinoid Test Method so they do understand how this co-elution may not have been identified upon validation. The co-elution of CBNA with d9-THC results in inflation of d9-THC values, which is the precise problem this prescribed method intends to solve. Commenter states that while CBNA is absent from many cannabinoid standard mixtures, they have found CBNA to be universally present in cannabis samples containing other cannabinoid acids. These samples include all cannabis flower samples and most cannabis concentrates. This proposed method is applicable to all dried flower, including non-infused pre-rolls. Due to CBNA's high absorbance in the wavelength range of 200 -350 nm, its inflating effect when co-eluting with d9-THC is disproportionate to its concentration when measured at all common detection wavelengths, including the proposed measurement wavelength of 220 nm.	SOP section (VII)(C). Further, CBNA is not included in the method as laboratories are only required to test for the cannabinoids listed in section 15724.
SOP (IX) (B)	3	Commenter states that reporting with 3 significant figures should not be deleted. Commenter states they have seen COAs that list cannabinoid concentrations up to 6 significant figures into the 4th decimal place, but the measurement of uncertainty for a cannabinoid test method is definitely greater than the 4th decimal place. Commenter states that they believe it is scientifically correct to limit the number of significant figures on a COA. Reporting results with 6 significant	The Department disagrees with this comment. The Department's regulations stipulate reporting requirements for cannabinoids testing in sections 15724 and 15726.

Section of Regulation	Comment Numbers	Summary of Comments Received During Third 15-Day Comment Period	Department Response
		figures and/or to the 4th decimal place can be misleading to the consumer.	
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.	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 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.
SOP (V) (C)	5	Commenter states that requiring centrifuge of 3900 rpm for 15 minutes creates a significant upfront cost burden to laboratories that are using standardized laboratory grade centrifuges that run at 3000 rpm. Commenter request requirement be reduced to require 3000 rpm or grandfathering of laboratories that are in operation currently using centrifuges that operate at 3000 rpm.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
SOP Definitions	6	Commenter states it is unclear what "sample" means in this context and whether this refers to spiking an actual client sample, such as a flower or pre-roll, or refers to spiking blank matrix. Additionally, it is unclear if this requires a separate preparation or if the preparation of an LQC or client sample could be split into two dilutions.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.

Section of Regulation	Comment Numbers	Summary of Comments Received During Third 15-Day Comment Period	Department Response
		Recommends further defining "Post-Dilution Spike" to include exactly what the department intends this LQC to be.	
SOP (V)	7	Commenter states the sample preparation procedures in the proposed method would require laboratories to purchase new equipment for homogenization, sample extraction, and sample cleanup steps. This would be a financial burden to many labs and result in testing prices increasing. Some of the required equipment is estimated to cost around $50,000. Commenter recommends the department remove the requirement for centrifugation since accurate and repeatable results can be produced without it; especially considering filtration is required at a later step. Additionally, the department should allow alternative techniques to vortexing/sonication that might be equivalently effective, but quicker and more affordable for laboratories.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
SOP (V)	8	Commenter states the department allows for significant flexibility in the instrument parameters but does not allow for similar flexibility in the sample preparation scheme. This method would greatly increase the cost per sample due to the required reagents and additional preparation time yet not increase any scientific accuracy. Commenter recommends the department allow for alternative extraction solvents so long as the method verification still yields acceptable results. Although it might increase the longevity of instrumentation, the Department should remove the requirement of filtration since accurate and repeatable cannabinoid results can be obtained without this expensive step.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.

Section of Regulation	Comment Numbers	Summary of Comments Received During Third 15-Day Comment Period	Department Response
SOP (V)	9	Commenter states the standardized method requires both an LCS and a Matrix Post-Dilution Spike, yet these LQCs serve the same purpose and both only evaluate analyte recovery in the presence of a matrix. Since the LCS involves spiking analytes in solution onto a blank matrix, it does not truly evaluate the extraction process because analytes are not extracted from the matrix. Considering that the volume of the Matrix Post-Dilution Spike can be scaled down, the LCS preparation would require significantly more cannabinoid standard than the Matrix-Post Extraction Spike. Recommends the department only require a post-dilution spike for this assay since the LCS would not provide any unique information to further validate the associated data and a Matrix-Post Dilution Spike is significantly cheaper for the laboratory to prepare.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
SOP (V) (B)(1)	10	Commenter states it is unclear if the laboratory must homogenize the entire representative sample to less than 1 mm or if only the aliquot for cannabinoid analysis required homogenization to this extent. Additionally, it is unclear if the laboratory is required to verify particle size (by use of screen or similar means) if the manufacturer's instructions do not indicate the size reduction capabilities of < 1 mm for plant tissue samples. Recommends the department clarify whether this homogenization of sample to 1 mm needs to occur to the entire representative sample prior to analysis for any assay, or if it is specific to cannabinoids. Additionally, the department should indicate acceptable homogenization techniques & equipment or require	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.

Section of Regulation	Comment Numbers	Summary of Comments Received During Third 15-Day Comment Period	Department Response
		the verification of particle size.	
SOP (V)(B)(2)	11	Commenter states 200 mg prep mass deviates away from the 0.5 g minimum required in regulations and will be less representative of the true potency of the sample when compared to a 0.5 g prep mass. Additionally, it is unclear if “200 mg” represents a minimum mass of sample and whether the laboratory would be allowed to continue preparing 0.5 g - 0.6 g of sample. Recommends the department provide an acceptable range for the preparation of mass of flower samples in accordance with the standardized method.	While not on the proposed action, the Department notes commenter's suggestion and looks forward to working with stakeholders on future policy development.
SOP (VII)(E)	12	Commenter states the additional language regarding deconvolving does not provide significant guidance. DCC method does not consider CBGa, which is a cannabinoid prevalent in all cannabis flower, so it will frequently cause interference unless significant changes are made to instrumentation. Commenter states the department should provide guidance on how to address co-elution when the laboratory is unable to deconvolve the cannabinoid upon reanalysis. Additionally, the DCC should include CBGa into the standardized method for flower since it will be expected at some level in all samples and there is a strong consumer demand for this analyte. If the Department were to include CBGa in the standardized method, it would save laboratories from requiring an entire method validation (as opposed to a verification) for just one additional analyte. This would prevent adding further cost increases associated with this regulatory change for laboratories that would like to	The Department disagrees with this comment Deconvolution of peaks is not a modification of the method, but an allowed mathematical practice to separate peaks in the method as provided in SOP section (VII)(E), if it follows the requirements for review by management contained in SOP section (VII)(C). Further, CBGa is not included in the method as laboratories are only required to test for the cannabinoids listed in section 15724.

Section of Regulation	Comment Numbers	Summary of Comments Received During Third 15-Day Comment Period	Department Response
		provide clients with CBGa results for flower samples.	

Alternatives That Would Lessen the Adverse Economic Impact on Small Business

No alternative proposed to the Department that would lessen any adverse economic impact on small businesses were rejected by the Department.

Alternatives Determination

The Department determined that no alternatives it considered or that was otherwise identified and brought to its attention would be more effective in carrying out the purpose for which the regulation is proposed, nor would be as effective and less burdensome to affected private persons and equally effective in implanting the statutory policy or other provision of law.

The amendments adopted by the Department are the only regulatory provisions identified by the Department that would accomplish the goal of implementing a standard cannabinoids test method. The final regulations are organized in a manner that allows licensees to implement the Standardized Operating Procedures in their own laboratories ensuring clarity and consistency in the standard cannabinoids test method.