

**BUREAU OF MARIJUANA CONTROL
PROPOSED TEXT OF REGULATIONS**

**CALIFORNIA CODE OF REGULATIONS
TITLE 16
DIVISION 42. BUREAU OF MARIJUANA CONTROL
CHAPTER 5. TESTING LABORATORIES**

Article 1. Chapter Definitions

§ 5237. Definitions

In addition to the definitions in the Medical Cannabis Regulation and Safety Act at Business and Professions Code section 19300.5 and section 5000 of this division, the following definitions apply to this chapter.

(a) “Acceptance criteria” is the specified limits placed on characteristics of an item or method that are used to determine data quality.

(b) “Accredited college or university” is a college or university accredited by a regional or national accrediting agency that is an accreditor recognized by the Secretary of the US Department of Education.

(c) “Action level” is the threshold value that provides the criterion for determining whether a sample passes or fails an analytical test.

(d) “Aliquot” is a portion of a sample that is used in an analysis.

(e) “Analyte” is a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

(f) “Analytical batch” is a group of samples that is prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and that have common analytical quality-control checks.

(g) “Analytical method” is a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

(h) “Batch” is a specific quantity of homogeneous medical cannabis goods and is one of the following types:

(1) “Harvest batch” is a specifically identified quantity of dried flower or trim, leaves, and other cannabis plant matter that is uniform in strain, harvested at the same time, and, if applicable, cultivated using the same pesticides and other agricultural chemicals.

(2) “Manufactured cannabis batch” is either:

(A) An amount of cannabis concentrate or extract produced in one production cycle using the same extraction methods and standard operating procedures, and is from the same harvest batch.

(B) An amount of a type of manufactured cannabis produced in one production cycle using the same formulation and standard operating procedures.

(i) “Cannabinoid” is a chemical compound that is unique to and derived from cannabis.

(j) “CAS number” is the unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service.

(k) “CBD” is cannabidiol, Chemical Abstracts Service number 13956-29-1.

(l) “CBDA” is cannabidiolic acid, Chemical Abstracts Service number 1244-58-2.

(m) “CBG” is cannabigerol, Chemical Abstracts Service number 25654-31-3.

(n) “CBN” is cannabinol, Chemical Abstracts Service number 521-35-7.

(o) “Certificate of analysis” is the report prepared for the requester and the bureau under section 5334 about the analytical testing performed and results obtained by the testing laboratory.

(p) “Certified reference material” is a reference material prepared by a certifying body.

(q) “Concentrate” is manufactured cannabis that has undergone a process to concentrate one or more active cannabinoids, thereby increasing the product’s potency. Resin from glandular trichomes from a cannabis plant (“kief”) is a concentrate for purposes of the Act. A cannabis concentrate is not considered food, as defined by Health and Safety Code section 109935, or a drug, as defined by Health and Safety Code section 109925.

(r) “Data-quality assessment” is a scientific and statistical process that establishes whether the collected data are of the right type, quality, and quantity to support the data’s intended use.

(s) “Field duplicate sample” is a sample that is taken in the identical manner and from the same cannabis batch being sampled as the primary sample. It is analyzed separately from the primary sample and is used for quality control only.

(t) “Frequency” is the number of items occurring in a given category. Frequency may be determined by analytical method or laboratory-specific requirements for the purpose of accuracy, precision of the analysis, or statistical calculation.

(u) “Hashish” is compressed kief, as that is defined in subsection (x).

(v) “Increment” or “sample increment” is a smaller sample that, together with other increments, makes up the primary sample.

(w) “ISO/IEC” or “ISO” is the joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission.

(x) “Kief” is a concentrate that is the resin from glandular trichomes from a cannabis plant.

(y) “Laboratory” is an entity that is a testing laboratory that is licensed by the bureau to conduct sampling and analyses of medical cannabis goods and includes the personnel, specialized apparatus, and instruments used to analyze medical cannabis goods.

(z) “Limit of detection” or “LOD” is the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

(aa) “Limit of quantitation” or “LOQ” is the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

(bb) “Matrix” is the component or substrate that contains the analyte of interest. “Matrices” is the plural.

(cc) “Matrix spike duplicate” is a duplicate sample prepared by adding a known quantity of a target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

(dd) “Matrix spike sample” is a sample prepared by adding a known quantity of the target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

(ee) “Medical cannabis goods” are medical cannabis, including dried flower, and manufactured medical cannabis products.

(ff) “Method blank” is an analyte-free matrix to which all reagents are added in the same volumes or proportions as are used in sample preparation.

(gg) “Moisture content” is the percentage of water in a dry sample, by weight.

(hh) “Non-target organism” is an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method.

(ii) “Percent recovery” is the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate.

(jj) “Practical experience” is hands-on post-secondary-education laboratory experience, using equipment, instruments, kits, and materials routinely found in a laboratory.

(kk) “Primary sample” is a portion of medical cannabis goods, or “sample,” collected from a medical cannabis batch for testing.

(ll) “Proficiency test” is an evaluation of a laboratory’s performance against pre-established criteria by means of interlaboratory comparisons of test measurements.

(mm) “Proficiency test sample” is a sample prepared by a party independent of the testing laboratory, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing laboratory and testing laboratory personnel.

(nn) “Quality assurance” is a set of operating principles that enable laboratories to produce defensible data of known accuracy and precision. Quality assurance encompasses employee training, equipment preventative maintenance procedures, calibration procedures, and quality-control testing, among other things.

(oo) “Quality control” is a set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control in which errors have been reduced to acceptable levels.

(pp) “Quality-control samples” are samples produced and used by a laboratory for the purpose of assuring quality control. Quality-control samples include but are not limited to blank samples, spike samples, duplicate samples, and reference material samples.

(qq) “Reagent” is a compound or mixture added to a system to cause a chemical reaction or test if a reaction occurs. A reagent may be used to tell whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.

(rr) “Reference material” is a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process.

(ss) “Reference method” is a method by which the performance of an alternate method is measured or evaluated.

(tt) “Relative percent difference” or “RPD” is a comparative statistic used to calculate precision or random error. RPD is calculated using the following equation:

$$\text{RPD} = \frac{|\text{(primary sample measurement} - \text{duplicate sample measurement)}|}{\frac{[\text{primary sample measurement} + \text{duplicate sample measurement}]}{2}} \times 100\%$$

(uu) “Relative standard deviation” or “RSD” is the standard deviation expressed as a percentage of the mean recovery. It is the coefficient of variation multiplied by 100. RSD is calculated using the following equation. If any results are less than the limit of quantitation, the absolute value of the limit of quantitation is used in the following equation:

$$\text{RSD} = (s / x) \times 100\%; \text{ where } s = \text{standard deviation and } x = \text{mean recovery}$$

(vv) “Requester” means a person who submits a request to a licensed testing laboratory for state-mandated testing of medical cannabis goods. The requester may be a licensed cultivator, licensed manufacturer, or licensed distributor.

(ww) “Sample” is a representative part of or a single item from a larger whole or group.

(xx) “Sample area” is the physical space within the distributor’s or laboratory’s premises in which sampling occurs.

(yy) “Sampler” is a testing laboratory employee who collects samples of medical cannabis goods for testing.

(zz) “Sanitize” is to sterilize, disinfect, or make hygienic.

(aaa) “Significant figures” are the number of digits used to express a measurement.

(bbb) “Standard operating procedure” is a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

(ccc) “Synthetic cannabinoid” is a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce psychoactive effects similar to those of cannabis.

(ddd) “Tamper evident” means that one or more one-time-use seals are affixed to the opening of a package, allowing a person to recognize whether or not the package has been opened.

(eee) “Target organism” is an organism that is being tested for in an analytical procedure or test method.

(fff) “Testing laboratory record” is information relating to the testing laboratory and the analyses it performs that is prepared, owned, used, or retained by the laboratory and includes electronic files and video footage.

(ggg) “THC” and “delta-9 THC” is tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3.

(hhh) “THCA” is tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0.

(iii) “Validation” is the confirmation by examination and objective evidence that the particular requirements for a specific intended use are fulfilled.

(jjj) “Water activity” is a measure of the quantity of water in a product that is available and therefore capable of supporting bacteria, yeasts, and fungi. Water activity is reported in the unit A_w .

Authority: Sections 19302.1, 19304, 19342, 19343, 19344, and 19345, Business and Professions Code. Reference: Sections 19300.5, 19342, 19343, 19344, and 19345, Business and Professions Code.

Article 2. License Application

§ 5238. Application

In addition to the information required by section 5006 in this division, an applicant for a testing laboratory license shall provide the following information:

- (a) Proof of ISO 17025 accreditation or proof that the applicant is in the process of applying or is preparing to apply for ISO 17025 accreditation;
- (b) Laboratory-employee qualifications; and
- (c) All required standard operating procedures.

Authority: Sections 19302, 19302.1, 19304, and 19322(a)(8), Business and Professions Code.
Reference: Section 2105, Corporations Code and Section 19322, Business and Professions Code.

§ 5239. [RESERVED]

§ 5240. [RESERVED]

§ 5241. Premises diagram

A testing laboratory applicant shall provide all information required under section 5012 of this division. A testing laboratory applicant's premises diagram shall include a brief statement of the principal activity to be conducted in each room or partitioned area, including activities related to sample receiving, sample storage, record storage, microbiology and chemistry analysis, and office space.

Authority: Sections 19302, 19302.1, 19304, 19320(c), 19322(a)(8), and Business and Professions Code. Reference: Sections 19320(c), Business and Professions Code.

§ 5242. [RESERVED]

§ 5243. [RESERVED]

§ 5244. Provisional Testing Laboratory License

(a) A testing laboratory applicant that meets all qualifications for licensing except for ISO accreditation may apply to the bureau for a provisional testing laboratory license.

(b) An applicant for a provisional license shall include the information and documentation required for a license as required under section 5006, except that documentation of the laboratory's ISO 17025 accreditation is not required. Instead, documentation required under section 5238(a) is required.

(c) The bureau may grant the testing laboratory applicant a provisional license. The provisional license, if granted, expires 12 months from the date of issuance.

(d) The bureau has the discretion to renew a testing laboratory's provisional license. The bureau may renew a testing laboratory's provisional license if the laboratory has applied for ISO 17025 accreditation but has not yet been granted or denied accreditation. A testing laboratory shall provide evidence to the bureau of having submitted an application for ISO 17025 accreditation.

(e) If granted, a provisional license renewal expires after 180 calendar days.

(f) When a testing laboratory holding a provisional license receives ISO 17025 accreditation, the testing laboratory shall send proof of the accreditation to the bureau within five business days.

(g) When a laboratory holding a provisional license is denied ISO 17025 accreditation, the laboratory shall notify the bureau of the denial within 24 hours. The bureau shall revoke the provisional license when the laboratory is denied accreditation.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19341, 19342, and 19343, Business and Professions Code.

§ 5245. [RESERVED]

§ 5246. [RESERVED]

Article 3. Sampling Medical Cannabis Goods

§ 5247. Sampling Standard Operating Procedures

(a) A laboratory shall develop and implement sampling plans that are consistent with these regulations for obtaining samples of medical cannabis goods.

(b) A laboratory shall develop a separate sampling plan for each type of matrix. The sampling plan must be appropriate to the type of matrix to be analyzed such that a representative sample may be obtained.

(c) The sampling plans shall be signed and dated by the laboratory director and shall include the revision dates and authors. The laboratory director's signature denotes approval of the plan.

(d) The laboratory shall keep controlled copies of the sampling plans at the laboratory, and the sampling plans shall be available to laboratory personnel. Uncontrolled copies of the sampling plans shall be available to samplers in the field.

(e) The laboratory shall make the sampling plans available for inspection by the bureau if requested by the bureau.

Authority: Sections 19302.1, 19304, 19307, 19322, 19342, and 19343, Business and Professions Code. Reference: Sections 19307, 19327, 19322, 19342, 19343, and 19345, Business and Professions Code.

§ 5248. [RESERVED]

§ 5249. [RESERVED]

§ 5250. Sampling Requirements

(a) A laboratory shall obtain samples for the purposes of laboratory analyses for homogeneity; the presence or absence of various analytes, including cannabinoids, residual solvents, micro-organisms, pesticides, heavy metals, and mycotoxins; water activity and moisture content; and filth and foreign material, as required in this chapter. A laboratory may also obtain samples for an analysis for the presence and concentration of terpenes.

(b) Only the laboratory that collects samples shall be the laboratory that analyzes the collected samples.

(c) Only a trained sampler employed by the licensed testing laboratory may obtain samples for the laboratory.

(d) The sampler shall do the following when obtaining samples:

- (1) Ensure area is as clean and free from contaminants and filth as possible and sanitize tools;
- (2) Obtain both primary and duplicate samples from each batch;
- (3) Assign a unique sample identifier to each sample and sample increment;
- (4) Follow chain-of-custody protocols to ensure that sample integrity is such that it may be maintained from the point of collection to the receipt of the samples at the laboratory; and
- (5) Wear the equipment required under section 5253.

Authority: Sections 19302.1, 19304, 19326, 19327, 19343, 19344, and 19345, Business and Professions Code. Reference: Sections 19327, 19342, 19343, 19344, and 19345, Business and Professions Code.

§ 5251. [RESERVED]

§ 5252. [RESERVED]

§ 5253. Sampler Personal Equipment

(a) A sampler shall wear the following items during the entire sampling process:

- (1) Disposable protective coveralls or disposable lab coat or apron;
- (2) Disposable nitrile gloves;
- (3) Filtering dust mask;
- (4) Safety goggles; and
- (5) Hair net.

(b) The sampler shall change gloves between sampling different batches.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5254. [RESERVED]

§ 5255. [RESERVED]

§ 5256. Sampling Tools

(a) The sampler shall sanitize all tools and equipment used in the sampling process.

(b) Sampling tools may include the following:

- (1) Amber glass jars or containers with polytetrafluoroethylene (PTFE)-lined lids;
- (2) A cooler with ice or cold packs;
- (3) Cleaning supplies such as 10% bleach or 70% ethanol;

(4) Powder-free, nitrile, and sterile disposable gloves;

(5) A field balance capable of weighing material to within 1 gram of accuracy;

(6) Labels and permanent markers;

(7) Disinfecting wipes; and

(8) Spoons, spatulas, tongs, knives, pipettes, corers, and sampling thieves.

Authority: Sections 19302.1, 19304, 19343, and 19345, Business and Professions Code.

Reference: Sections 19342, 19343, and 19345, Business and Professions Code.

§ 5257. [RESERVED]

§ 5258. [RESERVED]

§ 5259. Field Duplicate Sampling

(a) A sampler shall collect a field duplicate sample. The sampler shall collect the field duplicate sample from the same batch, at the same time, and in the same manner as the sampler collects the field primary sample.

(b) The field duplicate sample shall be separately stored and separately analyzed from the primary sample.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5260. [RESERVED]

§ 5261. [RESERVED]

§ 5262. Storage and Handling of Samples

(a) Samplers shall place samples in tamper-evident containers as this is defined in section 5237(ddd).

(b) Samplers shall place samples in amber glass jars or containers with polytetrafluoroethylene (PTFE)-lined lids to avoid photo degradation of the sample. The sample shall be kept on ice in an ice chest, with a physical separation between the ice and the sample, and the temperature shall be maintained at 0 to 6 degrees Celsius.

Authority: Sections 19302.1, 19304, 19334, 19343, and 19345, and Business and Professions Code. Reference: Sections 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5263. [RESERVED]

§ 5264. [RESERVED]

§ 5265. Sample Field Log

The sampler shall use a sample field log to record the following information during each sampling event:

- (a) Laboratory's name and license number;
- (b) Sampler's name and title and the names of others onsite;
- (c) Date and time sampling began;
- (d) Distributor's name, address, and license number;
- (e) Name, business address, and license number of the person who transports the samples to the laboratory;
- (f) Sample matrix;
- (g) Requested analyses;
- (h) Total composite sample weight or count;
- (i) Date and time each sample was obtained;
- (j) Total batch size, by weight or count;
- (k) Problems encountered and corrective actions taken;
- (l) For each sample, the weight or count of each sample, the unique sample identification number, and the location within the batch from which the sample was taken;
- (m) Any other observations from sampling, including major inconsistencies in the medical cannabis goods' color, size, or smell;
- (n) Sampling conditions, including temperature; and
- (o) Batch or lot number of the matrix.

Authority: Sections 19302.1, 19304, 19327, 19334, 19342, 19343, and 19345, Business and Professions Code. Reference: Sections 19321, 19322, 19327, 19342, 19343, 19344, and 19345, Business and Professions Code.

§ 5266. [RESERVED]

§ 5267. [RESERVED]

§ 5268. Sampling Unpackaged Harvest Batches

- (a) Samples collected must be representative of the harvest batch being sampled.
- (b) The sampler may obtain samples from unpackaged (loose) harvest batches directly from the container or containers in which the batch is held.

(c) A sampler may not collect samples from a harvest batch weighing more than 10 pounds. Samples collected from batches weighing more than 10 pounds shall be deemed invalid.

(d) The sampler shall sample by performing all of the following tasks:

(1) Draw samples from varying locations of the container, both vertically and horizontally. The sampler may obtain the necessary increments by following different paths through the batch container or by drawing the increments systematically at well-separated points along a heptagonal pattern.

(2) Remove the dried flower and place into an air-tight, sterile sample container as described in section 5256 that is capable of protecting the sample from contamination and degradation.

(3) Immediately and completely seal the sample container. The sampler shall seal all openings of the container so that it is tamper evident. The sampler shall initial and date each seal.

(4) Place the sealed sample containers into a tamper-evident, portable storage unit for transport. The storage unit must be kept at 0 to 6 degrees Celsius.

(5) Repack the remaining portion of the batch and replace any lids; and

(6) Complete a chain-of-custody form and sample field log.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19334, 19342, 19343, and 19343, Business and Professions Code.

§ 5269. [RESERVED]

§ 5270. [RESERVED]

§ 5271. Minimum Unpackaged Harvest Batch Sample Size

The sampler shall collect 0.5% of the total batch size. A laboratory may obtain greater amounts if the amount in the table is insufficient for the testing required.

Sample Size Requirements Based on Size of Harvest Batch

<u>Batch size (pounds)</u>	<u>Required sample size (grams)</u>
<u>< 1.00</u>	<u>2.3</u>
<u>1.01 to 2.0</u>	<u>4.5</u>
<u>2.01 to 3.0</u>	<u>6.8</u>
<u>3.01 to 4.0</u>	<u>9.1</u>
<u>4.01 to 5.0</u>	<u>11.3</u>
<u>5.01 to 6.0</u>	<u>13.6</u>
<u>6.01 to 7.0</u>	<u>15.9</u>

<u>7.01 to 8.0</u>	<u>18.1</u>
<u>8.01 to 9.0</u>	<u>20.4</u>
<u>9.01 to 10.0</u>	<u>22.7</u>

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5272. [RESERVED]

§ 5273. [RESERVED]

§ 5274. Unpackaged harvest-batch sample increments

(a) The sampler shall collect a minimum of 7 and not more than 9 sample increments from each harvest batch. The table below shows the number of increments required for the primary sample, by batch size.

Number of Increments for the Primary Sample, Based on Batch Size

<u>Batch size, pounds</u>	<u>< 2.0</u>	<u>2.01 to 4.0</u>	<u>4.01 to 6.0</u>	<u>6.01 to 8.0</u>	<u>8.01 to 10.0</u>
<u>Number of increments</u>	<u>7</u>	<u>7</u>	<u>8</u>	<u>8</u>	<u>9</u>

(b) The sampler may collect more increments if doing so is required because of the analytical method or laboratory-specific procedures or to ensure that a sufficient quantity of material is available for all required tests. The sampler may collect only the amount necessary to conduct the required and requested testing.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5275. [RESERVED]

§ 5276. [RESERVED]

§ 5277. Sampling of Packaged Medical Cannabis Goods

(a) For packaged medical cannabis goods, the sampler shall store and secure the sample, taking all of the following steps:

(1) Place into an air-tight, sterile sample container that is capable of protecting the sample from contamination and degradation.

(2) The sampler shall seal all openings of the container so that it is tamper evident. The sampler shall initial and date each seal.

(3) Place the sealed sample containers into a tamper-evident, portable storage unit for transport to the testing laboratory.

(4) Complete a chain-of-custody form and a field sample log.

Authority: Sections 19302.1, 19304, 19334, 19342, and 19343, Business and Professions Code. Reference: Sections 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5278. [RESERVED]

§ 5279. [RESERVED]

§ 5280. Sample Increments for Packaged Medical Cannabis Goods

(a) For batches that are packaged for retail sale, the minimum number of required sample increments required, by size of the batch, is in the table below. Each increment consists of 1 prepackaged unit.

<u>Units in Batch</u>	<u>Number of Increments</u>
<u>2 – 15</u>	<u>2</u>
<u>16 – 50</u>	<u>3</u>
<u>51 – 150</u>	<u>5</u>
<u>151 – 500</u>	<u>8</u>
<u>501 – 3200</u>	<u>13</u>
<u>3201 – 35,000</u>	<u>20</u>
<u>35,001 – 500,000</u>	<u>32</u>
<u>500,001 and above</u>	<u>50</u>

(b) The sampler may collect a greater number of increments if required because of an analytical method or laboratory-specific procedures or to ensure that a sufficient quantity of material is available for all required tests. The sampler may only collect the amount necessary to conduct the required and requested testing. A sampler may not collect samples from a harvest batch weighing more than 10 pounds.

(c) If an entire unit for sale is an insufficient quantity of material available for all required tests, multiple units for sale may be combined to create a single increment.

(d) The sampler or testing laboratory shall combine all primary sample increments to constitute one primary sample.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5281. [RESERVED]

§ 5282. [RESERVED]

§ 5283. Homogeneity Tests for Edible Cannabis Products

(a) A laboratory shall perform a homogeneity test for THC or CBD, whichever is purported by the manufacturer to be the largest ingredient content, for each batch of edible medical cannabis product. If the amounts of THC and CBD are very similar (near 1:1), the laboratory shall test for homogeneity of THC.

(b) A homogeneity test requires at least 10 increments, collected separately than those collected for the field primary sample, from different regions of the manufactured cannabis batch, following procedures in sampling section 5277 and the laboratory's standard operating procedure for sampling. The laboratory shall determine the relative standard deviation of THC or CBD content between the 10 or more increments.

(c) The batch is homogeneous and "passes" homogeneity testing if the relative standard deviation, with no outliers, as assessed using the Grubb's outlier test with a significance level of 0.05, is less than 15% on average. If the relative standard deviation is greater than 15%, the batch "fails" the homogeneity test.

(d) If a homogeneity test is not performed or if a batch fails homogeneity testing, the batch fails and shall be destroyed.

(e) If the product batch passes homogeneity testing, the laboratory shall perform all other analyses required under this chapter.

Authority: Sections 19302.1, 19304, 19342, and 19343, Business and Professions Code.

Reference: Sections 19326, 19342, and 19343, Business and Professions Code.

§ 5284. [RESERVED]

§ 5285. [RESERVED]

§ 5286. Chain-of-Custody Protocol

(a) Laboratories shall develop and implement a chain-of-custody protocol to ensure accurate documentation of the transport, handling, storage, and destruction of cannabis samples.

(b) The chain-of-custody protocol shall require the use of a chain-of-custody form that contains, at minimum, the following:

(1) Laboratory licensee's name, physical address, and license number of the laboratory collecting and analyzing the sample;

(2) Distributor licensee's name, physical address, and license number; and

(3) Information regarding each sample increment as follows:

(A) Unique sample-increment identifier as indicated on the sample container;

(B) Date and time of the sample-increment collection;

(C) The printed names and signatures of the laboratory samplers;

(D) All conditions, including sample temperature at time of collection and temperature of the cooler used for transport;

(E) The printed and signed name and signature of the person at the testing laboratory that received the samples; and

(F) The location of the sample within the testing laboratory storage area.

(c) Each time the sample changes custody between licensees, is transported, is removed from storage at the laboratory, or is destroyed, the date, time, and the names and signatures of persons involved in these activities shall be recorded on the chain-of-custody form.

Authority: Sections 19302.1, 19304, 19334, 19343, and 19345, Business and Professions Code.

Reference: Sections 19327, 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5287. [RESERVED]

§ 5288. [RESERVED]

§ 5289. Sample Rejection

(a) When samples are received by a laboratory, the laboratory shall check whether the integrity of the samples has been maintained. The laboratory shall deem a sample compromised if one or more of the following has occurred. This list is not a comprehensive list of reasons for which a sample may be deemed compromised:

(1) Broken shipping container;

(2) Evidence that the sample has been tampered with, manipulated, adulterated, or contaminated;

(3) Evidence that the sample was not collected in the manner required by this chapter or the laboratory's sampling standard operating procedures;

(4) Missing or incomplete chain-of-custody form or sampling field log;

(5) The temperature of the sample is out of the required range; and

(6) Any other factor that may have negatively impacted the integrity of the sample since its collection.

(b) If the sample is rejected, the laboratory shall document the sampling or handling errors and shall re-sample.

Authority: Sections 19302.1, 19304, 19334, 19343, and 19345, Business and Professions Code.

Reference: Sections 19327, 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5290. [RESERVED]

§ 5291. [RESERVED]

Article 4. Standard Operating Procedures

§ 5292. Standard Operating Procedures for Laboratory Processes

(a) A laboratory shall develop, implement, and maintain written standard operating procedures in accordance with the requirements of this chapter for the following testing laboratory functions and responsibilities:

- (1) Calibration and maintenance of equipment and instruments;
- (2) Chain-of-custody protocols;
- (3) Data review and internal review processes;
- (4) Analytical methods;
- (5) Employee training;
- (6) Premises and sample security;
- (7) Quality-assurance and quality-control procedures;
- (8) Recordkeeping and record retention;
- (9) Sample preparation;
- (10) Sample storage;
- (11) Schedule and process for internal audits and corrective actions; and
- (12) Disposal of cannabis-sample waste or leftover material.

(b) The laboratory director shall review, approve, sign, and date each standard operating procedure and each revision to a standard operating procedure. The standard operating procedures shall include the dates of issue and dates of revision, if any.

(c) A laboratory shall keep all standard operating procedures on the laboratory premises and in the field, as necessary, and shall ensure that each standard operating procedure is accessible to laboratory personnel during operating hours. A laboratory shall make the standard operating procedures accessible to the bureau upon request.

(d) A standard operating procedure is a “testing laboratory record” for purposes of the Act and these regulations.

Authority: Sections 19302.1, 19304, 19322, 19327, 19343, and 19345, Business and Professions Code. Reference: Sections 19322, 19327, 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5293. [RESERVED]

§ 5294. [RESERVED]

§ 5295. Standard Operating Procedures for Analytical Methods

(a) The testing laboratory shall take analytical measurements using methods and equipment that have been tested to ensure they are fit for the purpose of the required test.

(b) The analytical method standard operating procedure for each required test shall describe how the laboratory performs each method. At a minimum, the method standard operating procedure shall include the following elements:

(1) Identification (name) of the test method;

(2) List of analytes;

(3) Applicable matrices;

(4) Method sensitivity;

(5) Potential interferences;

(6) Analytical instruments;

(7) Consumable supplies, reagents, and standards;

(8) Sample preservation, storage, and hold time;

(9) Types, frequency, and acceptance criteria for quality-control samples;

(10) Types, frequency, and acceptance criteria for calibration standards;

(11) Procedure for analyzing analytical batch samples and frequency of quality-control samples;

(12) Data-quality assessment and acceptance criteria;

(13) Calculation of results; and

(14) Reagent, solution, and reference-material preparation.

Authority: Sections 19302.1, 19304, 19322, 19327, 19342, 19343, and 19344, Business and Professions Code. Reference: Sections 19322, 19326, 19327, 19342, 19343, and 19344, Business and Professions Code.

§ 5296. [RESERVED]

§ 5297. [RESERVED]

§ 5298. Testing Methodologies

(a) Laboratories shall develop and implement scientifically valid testing methodologies for the chemical, physical, and microbial analysis of medical cannabis goods. A method validated in

accordance with this section is deemed a scientifically valid testing methodology. A laboratory shall not perform testing using a method that has not been validated.

(b) To the extent practicable, the testing laboratory's testing methodologies shall comport with the following guidelines, which are incorporated herein by reference:

(1) US Food and Drug Administration's *Bacterial Analytical Manual*, 2016;

(2) AOAC International's *Official Methods of Analysis for Contaminant Testing of AOAC International*, 20th Edition, 2016;

(3) Methods of analysis for contaminant testing published in the 2016 *United States Pharmacopeia and the National Formulary (USP-NF)*; or

(4) If a laboratory wants to use an alternative scientifically valid testing methodology, the laboratory shall validate the methodology and submit the standard operating procedure for the new methodology to the bureau.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.

Reference: Sections 19322, 19326, and 19343, Business and Professions Code.

§ 5299. [RESERVED]

§ 5300. [RESERVED]

§ 5301. Validation of Non-Standard Test Methods and Modified Standard Test Methods

(a) A laboratory may use a nonstandard method; a laboratory-designed or -developed method; a standard method used outside its intended scope; or an amplification or a modified standard method for the analysis of samples.

(b) A laboratory shall validate a method it wants to use for the analysis of samples, for each matrix. The laboratory shall use one of the following guidelines, which are incorporated here by reference, for validating a method, depending on the type of method:

(1) US Food and Drug Administration's *Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition, 2015; or

(2) US Food and Drug Administration's *Guidelines for the Validation of Chemical Methods for the FDA FVM Program*, 2nd Edition, 2015.

(c) At minimum, the testing laboratory shall conduct a level-one (emergency-use) single-laboratory validation study for all methods for testing for microbiological impurities and comply with subsections (b) and (e)(1).

(d) At minimum, the laboratory shall conduct a level-one (emergency-use) single-laboratory validation study for all methods for testing for chemicals and shall comply with subsections (b) and (e)(2).

(e) In addition to following the Food and Drug Administration guidelines listed in subsection (b), a laboratory shall also include and address the following in the laboratory’s level-one validation study.

(1) Microbiological-analysis method-validation studies.

<u>Criteria</u>	<u>Requirement</u>
<u>Number of target organisms; inclusivity</u>	<u>5</u>
<u>Number of non-target organisms; exclusivity</u>	<u>5</u>
<u>Number of analyte levels per matrix: Qualitative methods</u>	<u>3 levels: high and low inoculum levels and 1 uninoculated level</u>
<u>Number of analyte levels per matrix: Quantitative methods</u>	<u>4 levels: low, medium and high inoculum levels and 1 uninoculated level</u>
<u>Replicates per food at each level tested</u>	<u>2 or more replicates per level</u>
<u>Reference method comparison</u>	<u>No</u>

(A) For purposes of validating standards for microbiological analysis, the following definitions apply:

(i) “Exclusivity” is the specificity of the test method. It evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms.

(ii) “Inclusivity” is the sensitivity of the test method. It evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness.

(2) Chemical-analysis method validation studies.

(A) Matrix spike samples (laboratory-fortified matrix). When high-concentration standards for matrix spiking are unavailable, matrix spikes may be made through post-processing and -dilution spiking of samples before analysis, rather than direct sample-matrix spike. When high-concentration reference standards are available, laboratories shall employ direct spiking of the sample matrix.

(B) Reference materials and certified reference materials. Laboratories shall use reference materials validation studies when cannabis reference materials become available.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.

Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5302. [RESERVED]

§ 5303. [RESERVED]

Article 5. Laboratory Analyses and Reporting

§ 5304. Required Analyses

(a) At minimum, a laboratory shall develop and implement test methods and corresponding standard operating procedures following the requirements in sections 5298 and 5301 for the analyses of cannabinoids; residual solvents and processing chemicals; pesticides; microbiological impurities; mycotoxins; water activity and moisture content; filth and foreign material; and heavy metals.

(b) A laboratory shall develop and implement test methods and corresponding standard operating procedures for the analysis of terpenes. Terpenes need only be tested for if the cultivator, manufacturer, or distributor desires to claim on the labeling that the medical cannabis goods contain terpenes or if the cultivator, manufacturer, or distributor desires an analysis of terpenes for any other reason.

Authority: Sections 19302.1, 19304, 19322, 19327, 19342, 19343, and 19344, Business and Professions Code. Reference: Sections 19322, 19326, 19327, 19342, 19343, and 19344, Business and Professions Code.

§ 5305. [RESERVED]

§ 5306. [RESERVED]

§ 5307. Cannabinoids

(a) A laboratory shall test for and report measurements for the following cannabinoids:

(1) THC;

(2) THCA;

(3) CBD;

(4) CBDA;

(5) CBG; and

(6) CBN.

(b) For harvest-batch samples, a laboratory shall report, to 3 significant figures, the concentration in milligrams per gram (mg/g) dry-weight sample of the cannabinoids listed in subsection (a). The laboratory shall report this information in the certificate of analysis.

(c) For harvest-batch samples, a laboratory shall also calculate the dry-weight percent of cannabinoids listed in subsection (a) that are detected in the sample in the following way:

(1) Dry-weight percent THC = wet-weight percent THC / (1 – percent moisture / 100).

(2) Dry-weight percent CBD = wet-weight percent CBD / (1 – percent moisture / 100).

(3) Dry-weight percent THCA = wet-weight percent THCA / (1 – percent moisture / 100).

(4) Dry-weight percent CBDA = wet-weight percent CBDA / (1 – percent moisture / 100).

(5) Dry-weight percent CBG = wet-weight percent CBG / (1 – percent moisture / 100).

(6) Dry-weight percent CBN = wet-weight percent CBN / (1 – percent moisture / 100).

(d) For samples from manufactured cannabis batches, a laboratory shall report, to 3 significant figures, the concentration in milligrams per gram (mg/g) of the cannabinoids listed in subsection (a). The laboratory shall report this information in the certificate of analysis.

(e) A laboratory may test for and provide test results for additional cannabinoids if requested to do so by the requester of the laboratory testing.

(f) For the purposes of cannabinoid potency testing of manufactured cannabis products, the laboratory shall report that the sample “passed” cannabinoid potency testing if the concentration of THC does not exceed the labeled potency of THC, plus or minus 15 percent. A cannabis product fails potency testing if the amount or percentage of THC exceeds the labeled concentration of THC, plus or minus 15 percent.

(g) For the purposes of cannabinoid potency testing of manufactured cannabis products, the laboratory shall report that the sample “passed” cannabinoid potency testing if the concentration of CBD does not exceed the labeled concentration of CBD, plus or minus 15 percent. A cannabis product fails potency testing if the amount or percentage of CBD exceeds the labeled concentration of CBD, plus or minus 15 percent.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.

Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5308. [RESERVED]

§ 5309. [RESERVED]

§ 5310. Residual Solvents and Processing Chemicals

(a) A laboratory shall analyze samples of manufactured cannabis batches for residual solvents and processing chemicals. A laboratory does not need to analyze for residual solvents and processing chemicals in dried flower, kief, and hashish samples.

(b) The laboratory shall analyze the concentration of residual solvents present in each sample of manufactured cannabis batches in accordance with the table in subsection (c).

(c) For the purposes of residual-solvent testing, the laboratory shall report that the sample “passed” residual-solvent testing if the concentrations of residual solvents are at or below the following residual solvents and processing chemicals action levels:

<u>Chemical Name</u>	<u>CAS No.</u>	<u>Action Level for Medical Cannabis Goods Meant for Inhalation (ppm)</u>	<u>Action Level for All Other Medical Cannabis-Infused Goods (ppm)</u>
<u>1,2-Dichloroethane</u>	<u>107-06-2</u>	<u>2</u>	<u>5</u>
<u>Acetone</u>	<u>67-64-1</u>	<u>750</u>	<u>5000</u>
<u>Acetonitrile</u>	<u>75-05-8</u>	<u>60</u>	<u>410</u>
<u>Benzene</u>	<u>71-43-2</u>	<u>1</u>	<u>2</u>
<u>Butane</u>	<u>106-97-8</u>	<u>800</u>	<u>5000</u>
<u>Chloroform</u>	<u>67-66-3</u>	<u>2</u>	<u>60</u>
<u>Ethanol</u>	<u>64-17-5</u>	<u>1000</u>	<u>5000</u>
<u>Ethyl acetate</u>	<u>141-78-6</u>	<u>400</u>	<u>5000</u>
<u>Ethyl ether</u>	<u>60-29-7</u>	<u>500</u>	<u>5000</u>
<u>Ethylene oxide</u>	<u>75-21-8</u>	<u>5</u>	<u>50</u>
<u>Heptane</u>	<u>142-82-5</u>	<u>500</u>	<u>5000</u>
<u>Hexane</u>	<u>110-54-3</u>	<u>50</u>	<u>290</u>
<u>Isopropyl alcohol</u>	<u>67-63-0</u>	<u>500</u>	<u>5000</u>
<u>Methanol</u>	<u>67-56-1</u>	<u>250</u>	<u>3000</u>
<u>Methylene chloride</u>	<u>75-09-2</u>	<u>125</u>	<u>600</u>
<u>Naphtha</u>	<u>8030-30-6</u>	<u>400</u>	<u>400</u>
<u>Pentane</u>	<u>109-66-0</u>	<u>750</u>	<u>5000</u>
<u>Petroleum ether</u>	<u>8032-32-4</u>	<u>400</u>	<u>400</u>
<u>Propane</u>	<u>74-98-6</u>	<u>2100</u>	<u>5000</u>
<u>Trichloroethylene</u>	<u>79-01-6</u>	<u>25</u>	<u>80</u>
<u>Toluene</u>	<u>108-88-3</u>	<u>150</u>	<u>890</u>
<u>Total xylenes (ortho-, meta-, para-)</u>	<u>1330-20-7</u>	<u>150</u>	<u>2170</u>

(d) The testing laboratory shall report the solvents and processing chemicals listed in this section in parts per million (ppm) to 3 significant figures. The laboratory shall report this information in the certificate of analysis.

(e) The laboratory shall include in the certificate of analysis both the concentrations of solvents and processing chemicals in the sample and whether the sample “passed” or “failed” residual solvent and processing-chemicals testing.

(f) If the sample fails residual solvent testing, the batch fails laboratory testing.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.

Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5311. [RESERVED]

§ 5312. [RESERVED]

§ 5313. Residual Pesticides

(a) A testing laboratory shall test all samples for residual pesticides.

(b) Medical cannabis goods must not contain levels of pesticides above those listed in the following table:

	<u>Edible Cannabis Products (ppm)</u>	<u>Dried Cannabis Flowers (ppm)</u>	<u>All Other Processed Cannabis (ppm)</u>
<u>Abamectin</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>
<u>Acephate</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>
<u>Acequinocyl</u>	<u>0.27</u>	<u>0.1</u>	<u>0.02</u>
<u>Acetamiprid</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Aldicarb</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Azoxystrobin</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Bifenazate</u>	<u>1.0</u>	<u>0.1</u>	<u>0.1</u>
<u>Bifenthrin</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Boscalid</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Captan</u>	<u>1.0</u>	<u>0.7</u>	<u>0.05</u>

<u>Carbaryl</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Carbofuran</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Chlorantraniliprole</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>
<u>Chlordane</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Chlorfenapyr</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Chlorpyrifos</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>
<u>Clofentezine</u>	<u>1.3</u>	<u>0.1</u>	<u>0.04</u>
<u>Coumaphos</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Cyfluthrin</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Cypermethrin</u>	<u>1.0</u>	<u>1.0</u>	<u>0.5</u>
<u>Daminozide</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>DDVP (Dichlorvos)</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>
<u>Diazinon</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Dimethoate</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Dimethomorph</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Ethoprop(hos)</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Etofenprox</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Etoxazole</u>	<u>0.46</u>	<u>0.1</u>	<u>0.05</u>
<u>Fenhexamid</u>	<u>1.7</u>	<u>0.1</u>	<u>0.08</u>
<u>Fenoxycarb</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Fenpyroximate</u>	<u>0.5</u>	<u>0.1</u>	<u>0.1</u>
<u>Fipronil</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Flonicamid</u>	<u>0.4</u>	<u>0.1</u>	<u>0.1</u>
<u>Fludioxonil</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>

<u>Hexythiazox</u>	<u>0.25</u>	<u>0.1</u>	<u>0.1</u>
<u>Imazalil</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Imidacloprid</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>
<u>Kresoxim-methyl</u>	<u>3.6</u>	<u>0.1</u>	<u>0.02</u>
<u>Malathion</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Metalaxyl</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Methiocarb</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Methomyl</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Methyl parathion</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Mevinphos</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Myclobutanil</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>
<u>Naled</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Oxamyl</u>	<u>0.026</u>	<u>0.5</u>	<u>0.2</u>
<u>Paclobutrazol</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Pentachloronitrobenzene</u>	<u>0.03</u>	<u>0.1</u>	<u>0.1</u>
<u>Permethrin</u>	<u>2.5</u>	<u>0.5</u>	<u>0.02</u>
<u>Phosmet</u>	<u>0.12</u>	<u>0.1</u>	<u>0.02</u>
<u>Piperonyl butoxide</u>	<u>63.0</u>	<u>3.0</u>	<u>3.0</u>
<u>Prallethrin</u>	<u>0.5</u>	<u>0.1</u>	<u>0.02</u>
<u>Propiconazole</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>
<u>Propoxur</u>	<u>0.02</u>	<u>0.02</u>	<u>0.02</u>
<u>Pyrethrins</u>	<u>0.7</u>	<u>0.5</u>	<u>0.5</u>
<u>Pyridaben</u>	<u>4.4</u>	<u>0.1</u>	<u>0.02</u>
<u>Spinetoram</u>	<u>0.5</u>	<u>0.1</u>	<u>0.04</u>

<u>Spinosad</u>	<u>0.29</u>	<u>0.1</u>	<u>0.02</u>
<u>Spiromesifen</u>	<u>20.0</u>	<u>0.1</u>	<u>0.1</u>
<u>Spirotetramat</u>	<u>10.0</u>	<u>0.1</u>	<u>0.1</u>
<u>Spiroxamine</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Tebuconazole</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Thiacloprid</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Thiamethoxam</u>	<u>0.01</u>	<u>0.01</u>	<u>0.01</u>
<u>Trifloxystrobin</u>	<u>25.0</u>	<u>0.1</u>	<u>0.02</u>

(c) The laboratory shall report the levels detected in parts per million (ppm) to 3 significant figures in the certificate of analysis. If a sample is found to contain pesticides above the allowable amount listed in the tables in subsection (b), the sample “fails” pesticide testing. If the sample fails pesticide testing, the batch fails laboratory testing and may not be released for retail sale.

Authority: Sections 19302.1, 19304, 19342, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19331, 19332, 19343, and 19344, Business and Professions Code.

§ 5314. [RESERVED]

§ 5315. [RESERVED]

§ 5316. Microbiological Impurities

(a) A testing laboratory shall test all samples for microbiological impurities. For the purposes of microbiological testing, the laboratory shall report that the sample “passed” microbiological-impurity testing if the following are not detected:

(1) Shiga toxin-producing *Escherichia coli*: not detected in 1 gram;

(2) *Salmonella* spp.: not detected in 1 gram.

(b) The laboratory shall report whether the strains listed in subsection (a) are detected or are not detected in 1 gram. The laboratory shall report this information in the certificate of analysis. If the strains are detected, the batch fails laboratory testing and may not be released for retail sale.

(c) A laboratory is also required to test for the pathogenic *Aspergillus* species *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus* in all medical cannabis goods intended for consumption by inhalation, including but not limited to dried flower, kief, hashish, oil, and waxes.

(1) For the purposes of pathogenic *Aspergillus*-species testing, the laboratory shall report that the sample “passed” if the concentrations of the following *Aspergillus* species are not detected:

(A) *Aspergillus fumigatus*: not detected in 1 gram;

(B) *Aspergillus flavus*: not detected in 1 gram;

(C) *Aspergillus niger*: not detected in 1 gram; and

(D) *Aspergillus terreus*: not detected in 1 gram.

(2) If a pathogenic *Aspergillus* species is detected in a sample under (c)(1), the sample fails microbiological-impurity testing, and the batch fails laboratory testing and may not be released for sale. The laboratory shall report the results in the certificate of analysis.

(d) The laboratory may test for and provide test results for additional microorganisms if requested by the requester of the laboratory testing.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.

Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5317. [RESERVED]

§ 5318. [RESERVED]

§ 5319. Mycotoxins

(a) A laboratory shall analyze all samples for mycotoxins. The laboratory shall report that the sample “passed” mycotoxins testing if the concentration of mycotoxins is below the following standards:

(1) The total of aflatoxin B1, B2, G1, and G2: < 20 µg/kg of substance.

(2) Ochratoxin A: < 20 µg/kg of substance.

(b) The laboratory shall report, to 3 significant figures, in micrograms per kilograms (µg/kg), the mycotoxins listed in subsection (a) that are detected in the sample. The laboratory shall report this information in the certificate of analysis.

(c) The laboratory shall indicate in the certificate of analysis whether the concentrations of mycotoxins detected in the sample meets or exceeds the action levels established by this section and whether the sample “passed” or “failed” mycotoxin testing. If the sample fails mycotoxin testing, the batch fails laboratory testing and may not be released for retail sale.

(d) The laboratory may test for and provide test results for additional microorganisms if requested by the requester of the laboratory testing.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.

Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5320. [RESERVED]

§ 5321. [RESERVED]

§ 5322. Water Activity and Moisture Content

(a) A laboratory shall analyze a dried flower harvest-batch sample to determine its water-activity level. If the water activity is at or below 0.65 A_w , the sample “passes” water-activity testing.

(b) A laboratory shall analyze solid and semi-solid edible cannabis products to determine its water-activity level. If the water activity is at or below 0.85 A_w , the sample “passes” water-activity testing.

(c) The laboratory shall report the water-activity level of the sample in A_w to 2 significant figures. The laboratory shall report this information in the certificate of analysis.

(d) A laboratory shall analyze a dried flower harvest-batch sample to determine its moisture content. If the moisture content is at 5.0% to 13.0%, the sample “passes” moisture-content testing.

(e) The laboratory shall report the moisture content in percentage to the nearest tenth of one percent, by weight, of the dry sample. The laboratory shall report this information in the certificate of analysis.

(f) The laboratory may provide additional information on moisture content and water activity results if the laboratory determines it is important or if requested by the requester of the laboratory testing.

(g) If a harvest-batch sample “fails” water-activity or moisture-content testing, the harvest batch may be returned to the cultivator or person holding title for further drying and curing unless prohibited by these regulations. The harvest batch will then need to be retested for all tests required in this chapter.

Authority: Sections 19302.1, 19304, 19342, 19343, and 19344, Business and Professions Code.
Reference: Sections 19326, 19342, 19343, and 19344, Business and Professions Code.

§ 5323. [RESERVED]

§ 5324. [RESERVED]

§ 5325. Filth and Foreign Material

(a) A laboratory shall analyze all samples for filth and foreign material present in the sample. “Filth and foreign material” includes but is not limited to hair, insects, feces, packaging contaminants, and manufacturing waste and by-products.

(b) The laboratory shall report that the sample “passed” filth and foreign material testing if the concentration of filth and foreign material is at or below the filth and foreign material action levels in the following table:

<u>Defect</u>	<u>Action Level</u>
<u>Mold or foreign material</u>	<u>Average of 5% or more, by weight</u>
<u>Mammalian excreta</u>	<u>Average of 1 mg or more per pound</u>

(c) The laboratory shall report in the certificate of analysis whether the sample “passed” or “failed” filth and foreign-material testing. If it fails filth and foreign-material testing, the batch fails laboratory testing. A harvest batch that fails must be destroyed unless it can be remediated. Failed manufactured cannabis batches must be destroyed.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.

Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5326. [RESERVED]

§ 5327. [RESERVED]

§ 5328. Heavy Metals

(a) The laboratory shall analyze all samples for concentrations of the following heavy metals:

(1) Arsenic (As);

(2) Cadmium (Cd);

(3) Lead (Pb); and

(4) Mercury (Hg).

(b) The laboratory shall report the concentration of each heavy metal listed in subsection (a) in micrograms per gram (µg/g) in the certificate of analysis. The laboratory shall report that the sample “passed” heavy-metal testing if the concentrations of heavy metals listed in subsection (a) are below the following heavy metal action levels:

<u>Heavy Metal</u>	<u>Action Level for Medical Edible Cannabis Products, Suppositories, Sublingual Products, and Other Manufactured Products (µg/g)</u>	<u>Action Level for All Inhaled Medical Cannabis Goods (µg/g)</u>	<u>Action Level for Topical and Transdermal Medical Cannabis Goods (µg/g)</u>
<u>Cadmium</u>	<u>0.5</u>	<u>0.2</u>	<u>5.0</u>
<u>Lead</u>	<u>0.5</u>	<u>0.5</u>	<u>10.0</u>

<u>Arsenic</u>	<u>1.5</u>	<u>0.2</u>	<u>3.0</u>
<u>Mercury</u>	<u>3.0</u>	<u>0.1</u>	<u>1.0</u>

(c) The laboratory may test for and may provide test results for additional metals if the instrumentation detects additional metals in the samples or if requested by the requester of the laboratory testing.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.
Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5329. [RESERVED]

§ 5330. [RESERVED]

§ 5331. Terpenes

(a) If the cultivator's, manufacturer's, or distributor's product labeling says that the sample contains discrete terpenes, the laboratory shall test for those terpenes. The testing laboratory shall report to one-hundredth of a percent the concentration in percentage in the certificate of analysis.

(b) The laboratory shall also report a terpene measurement for a terpene requested to be tested for by the requester of the laboratory test.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.
Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5332. [RESERVED]

§ 5333. [RESERVED]

§ 5334. Certificate of Analysis

(a) The laboratory shall generate a certificate of analysis for each primary sample of a batch that it tests and provide the certificate of analysis to the distributor, the licensee who holds title to the batch, and the bureau within 2 business days of the completion of the analyses.

(b) The certificate of analysis shall, at a minimum, contain the following information:

- (1) Licensed laboratory's name, mailing address, and physical address;
- (2) Sample-identifying information, including matrix type and unique sample identifiers;
- (3) Sample history, including date collected, date received by laboratory, and date or dates of sample preparations and analyses;
- (4) The identity of the test methods used to analyze cannabinoids, residual solvents, pesticides, microbiological contaminants, mycotoxins, heavy metals, and, if applicable, terpenes;

- (5) Test results for sample homogeneity, if applicable; cannabinoids; residual solvents; pesticides; microbiological contamination; mycotoxins; and, if applicable, terpenes;
- (6) Test results for moisture content and water activity, and filth and foreign material;
- (7) The reporting limit for each analyte tested;
- (8) The total primary sample weight in grams, reported to 3 significant figures;
- (9) Whether the primary sample and batch “passed” or “failed” laboratory testing; and
- (10) The licensee for whom the testing was done, including license number, name, and batch number.

(c) The laboratory shall also report any other claim made by the manufacturer regarding any other cannabinoids present in the sample.

(d) The laboratory shall validate the accuracy of the information contained in the certificate of analysis, and the laboratory director shall sign and date the certificate of analysis.

(e) Failure to provide timely and accurate data is grounds for discipline.

Authority: Sections 19302.1, 19304, 19323, 19342, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19342, 19343, and 19344, Business and Professions Code.

§ 5335. [RESERVED]

§ 5336. [RESERVED]

§ 5337. General Reporting Requirements

(a) A laboratory shall report on the certificate of analysis unknown or unidentified substances or materials detected during the analysis of the sample. A laboratory shall, within 24 hours, notify the bureau if a sample is found to contain levels of a contaminant not listed in these regulations that could be injurious to human health if consumed.

(b) If a sample’s result exceeds an action level in this chapter, the laboratory shall report that the sample failed the particular test for which the result exceeds the action level, and the laboratory shall report that the sample failed testing in general unless otherwise provided for in these regulations.

(c) A laboratory shall report a sample containing synthetic cannabinoids as “failed.”

(d) If a sample fails laboratory testing, the laboratory shall, within 2 business days, upload copies of the certificate of analysis to the track and trace system.

(e) If a sample passes testing, the laboratory shall, within 24 hours, enter “pass” into the track and trace system for the batch from which the sample came. The batch is then released for retail sale.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.
Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5338. [RESERVED]

§ 5339. [RESERVED]

Article 6. Post-Testing Procedures

§ 5340. No Retesting Without Remediation

A batch may not be retested following a failed testing unless it has gone through a remediation process. Prior to retesting, the distributor shall provide to the testing laboratory a document specifying how the product was remediated. This document shall be kept by the laboratory and be available for inspection by the bureau.

Authority: Sections 19302.1, 19304, 19343, and 19345, Business and Professions Code.
Reference: Sections 19326, 19343, and 19345, Business and Professions Code.

§ 5341. [RESERVED]

§ 5342. [RESERVED]

§ 5343. Test-Sample Waste Disposal

(a) A laboratory shall destroy nonhazardous used or unused medical cannabis test samples in accordance with section 5080 of this division.

(b) A laboratory shall discard hazardous waste, including hazardous waste containing cannabis, in accordance with federal and state hazardous waste laws.

(c) The testing laboratory shall document the waste disposal procedures followed for each sample.

Authority: Sections 19302.1, 19304, 19327, 19343, and 19345, Business and Professions Code.
Reference: Sections 19326, 19327, 19343, and 19345, Business and Professions Code.

§ 5344. [RESERVED]

§ 5345. [RESERVED]

Article 7. Quality Assurance and Quality Control

§ 5346. Quality-Assurance Program

(a) A laboratory shall develop and implement a quality-assurance program that is sufficient to ensure the reliability and validity of the analytical data produced by the laboratory.

(b) A laboratory shall develop and maintain a written quality-assurance program manual that addresses all aspects of the laboratory's quality-assurance program, including but not limited to the following:

- (1) Quality-control procedures;
- (2) Laboratory organization and personnel training and responsibilities;
- (3) Quality-assurance objectives for measurement data;
- (4) Traceability of all data and analytical results;
- (5) Equipment preventative maintenance;
- (6) Equipment-calibration procedures and frequency;
- (7) Performance and system audits;
- (8) Corrective action;
- (9) The keeping of quality-assurance records;
- (10) Standardization of testing procedures; and
- (11) Method validation.

(c) The laboratory director and quality-assurance manager, if there is one, shall review, amend if necessary, and approve the quality-assurance program and manual at least annually. The laboratory director shall also review and amend the quality-assurance program and manual whenever there is a change in methods, laboratory equipment, or laboratory director.

Authority: Sections 19302.1, 19304, 19322, and 19343, Business and Professions Code.
Reference: Sections 19326, 19322, and 19343, Business and Professions Code.

§ 5347. [RESERVED]

§ 5348. [RESERVED]

§ 5349. Quality-Control Elements

(a) A laboratory shall run quality-control samples with every analytical batch of samples for chemical analysis. Of samples for chemical analysis, 10% to 20% must be quality-control samples. For microbiological analysis, quality-control samples shall be run as needed.

(b) A laboratory shall use quality-control samples in the performance of each assay for chemical and microbiological analyses.

(c) A laboratory shall analyze the quality-control samples in the exact same manner as the test samples to validate the laboratory testing results.

(d) Method blank sample for chemical analysis.

(1) A laboratory shall prepare and run one or more method blank sample for each analytical batch.

(2) A laboratory shall process a method blank sample with a batch of 10 to 20 samples along with and under the same conditions, including all sample-preparation steps, as the other samples in the analytical batch, to demonstrate that the analytical process did not introduce contamination.

(3) Whenever a method blank contains analytes of interest above the limit of detection (LOD) for that analysis, the laboratory shall run another re-prepared method blank and then subtract the average of the 2 method blanks from the results.

(4) If the method blank contains analytes of interest above the limit of quantitation (LOQ), it should be reanalyzed once. If the method blank is still above the limit of quantification, the laboratory should seek to locate and reduce the source of the contamination, and then the entire batch should be re-prepared and reanalyzed. If the method blank results still do not meet the acceptance criteria and reanalysis is not practical, then the laboratory cannot do the analysis until resolution of the issue. Resolution of the issue is the reduction of method blank measurements below the limit of quantification.

(e) Duplicate sample.

(1) The laboratory shall prepare and run a duplicate sample with every 10 to 20 samples for each analytical method.

(2) The acceptance criteria between the primary sample and the duplicate sample is less than 20% relative percent difference, as defined and calculated in section 5237(vv).

(f) Matrix spike samples.

(1) The laboratory shall prepare and run 1 or more matrix spike samples for each analytical batch.

(2) A laboratory shall calculate the percent recovery for quantitative chemical analysis by dividing the sample result by the expected result and multiplying that by 100. If interferences are present in the sample, results will be significantly higher or lower than the actual concentration contained in the sample. The acceptable percent recovery is 70% to 130%.

(3) If the percent recovery is outside of the range in (e)(2), the laboratory must investigate the cause, correct the problem, and re-run the batch of samples. If the problem persists, the laboratory must re-prepare the samples and run the analysis again if possible.

(g) Reference material and certified reference material for chemical analysis.

(1) The laboratory shall use a reference material for each analytical batch. It should be certified and obtained from an outside source if possible.

(2) If a reference material is not available from an outside source, the laboratory shall make its own in-house reference material. Reference material made in-house should be made from a different source of standards than what the calibration standards are made from. The test results

for the reference material must fall within the quality-control acceptance criteria. If it does not, the laboratory shall document and correct the problem and, if necessary, run the batch again.

(h) Calibration standards. The laboratory shall prepare calibration standards by serially diluting a standard solution to produce working standards used for calibration of the instrument and quantitation of analyses in samples.

(i) The laboratory shall generate a quality-control-sample report that includes quality-control parameters and measurements, analysis date, and matrix.

Authority: Sections 19302.1, 19304, 19322, and 19343, Business and Professions Code.

Reference: Sections 19326, 19322, and 19343, Business and Professions Code.

§ 5350. [RESERVED]

§ 5351. [RESERVED]

§ 5352. Limits-of-Detection and Limits-of-Quantitation Calculations for Quantitative Analyses

(a) For chemical method analysis, the laboratory shall calculate the limit of detection using one of the following:

(1) Based on signal-to-noise ratio. The determination of the signal-to-noise ratio is performed by comparing measured signals from samples with known low concentrations of analytes with those of method blank samples and establishing the minimum concentration at which the analyte can be reliably detected. A signal-to-noise ratio of between 3:1 and 2:1 is acceptable for estimating the limit of detection.

(2) Based on the standard deviation of the response and the slope of calibration curve. Standard deviation of the response can be determined using 7 blank samples. The limit of detection for chemical methods must be less than one-tenth of the action level for each analyte. The limit of detection may be calculated as follows:

$3.3 \times \text{standard deviation of the response} / \text{slope of the calibration curve}$

(3) Other methods published by the US Food and Drug Administration or the US Environmental Protection Agency.

(b) For chemical method analysis, the laboratory shall calculate the limit of quantitation using one of the following:

(1) Based on signal-to-noise ratio. The determination of the signal-to-noise ratio is performed by comparing measured signals from samples with known low concentrations of analyte with those of blank samples and establishing the minimum concentration at which the analyte can be reliably quantified. A signal-to-noise ratio of 10:1 is the minimum for reliable quantitation.

(2) Based on the standard deviation of the response and the slope. Standard deviation of the response can be determined from seven blank samples. The limit of detection may be calculated as follows:

10 × standard deviation of the response / slope of the calibration curve

(3) Other methods published by the federal US Food and Drug Administration or the US Environmental Protection Agency.

Authority: Sections 19302.1, 19304, 19322, 19342, and 19343, Business and Professions Code.

Reference: Sections 19326, 19322, 19342, and 19343, Business and Professions Code.

§ 5353. [RESERVED]

§ 5354. [RESERVED]

§ 5355. Data Package

(a) The laboratory shall create a data package for each batch of samples a laboratory analyzes. The data package shall contain at minimum the following information:

(1) The name and address of the laboratory that performed the analytical procedures;

(2) The names, functions, and signatures of the laboratory personnel that performed sample preparation, analyses, and reviewed and approved the data;

(3) All sample and the batch quality-control sample results;

(4) Raw data for each sample

(5) Instrument raw data, if any;

(6) Instrument test method with parameters;

(7) Instrument tune report;

(8) All instrument-calibration data;

(9) Test-method worksheets or forms used for sample identification, characterization, and calculations, including chromatograms, sample-preparation worksheets, and final datasheets;

(10) Quality-control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;

(11) Analytical batch sample sequence;

(12) The field sample log and the chain-of-custody form; and

(13) The certificate of analysis created as required under this chapter.

(b) Analytical results reported for dried flower samples must be reported on a dry-weight basis with the percent moisture also reported on the certificate of analyses, to allow back calculation of the result to a wet-weight basis.

(c) After the data package has been compiled, the laboratory director shall do the following:

- (1) Review the analytical results for technical correctness and completeness;
- (2) Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively and that the measurements can be traced back;
- (3) Approve the measurement results by signing and dating the data package prior to release of the data by the laboratory.
- (d) The entire data package shall be kept for a minimum of 7 years and shall be made available upon request by the bureau or the requester of the laboratory testing.

Authority: Sections 19302.1, 19304, 19327, 19343, and 19345, Business and Professions Code. Reference: Sections 19326, 19327, 19343, and 19345, Business and Professions Code.

§ 5356. [RESERVED]

§ 5357. [RESERVED]

§ 5358. Required Proficiency Testing

- (a) A laboratory shall participate in a proficiency-testing program provided by an ISO 17043 accredited proficiency-test provider, or a laboratory similar to one, at least once every six months.
- (b) Laboratories shall rotate the proficiency tests among their analytical tests and among the staff in the laboratory so that all methods and all staff performing the methods have participated in proficiency tests over a reasonable planned period as defined in the laboratory quality-assurance manual.
- (c) The laboratory shall participate in a proficiency-testing program and analyze the proficiency-test samples following the approved laboratory standard operating procedures and the same equipment that are used for testing of commercial medical cannabis goods.
- (d) Laboratory employees who participate in a proficiency test shall sign corresponding analytical reports or attestation statements to certify that the proficiency test was conducted in the same manner as the laboratory ordinarily conducts testing of medical cannabis goods.
- (e) The laboratory director shall review and approve all proficiency-test samples analyzed and results reported.
- (f) The laboratory shall authorize the proficiency-test provider to release the results of the proficiency test to the bureau at the same time that the results are submitted to the laboratory. The laboratory shall also provide the results to the bureau within three business days of the laboratory receiving the results of the proficiency test.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19326, 19327, and 19343, Business and Professions Code.

§ 5359. [RESERVED]

§ 5360. [RESERVED]

§ 5361. Successful Performance in a Proficiency Test

(a) A laboratory shall be found to have successfully participated in a proficiency test if test results were considered “satisfactory” for an analyte tested in a specific method or if the results demonstrate a positive identification of an analyte tested in a specific method, including quantitative results when applicable. Test results demonstrating a positive identification of 80% of the analytes, including quantitative results when applicable, are proof of a successful participation in a proficiency test. The reporting of a false-positive result is an “unsatisfactory” score for the proficiency test.

(b) A laboratory shall take corrective action and document corrective action when the laboratory meets the standards of subsection (a) but fails to score 100% on a proficiency test. A laboratory may not continue to report results for analytes that were deemed “unacceptable,” “questionable,” or “unsatisfactory.”

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19326, 19327, and 19343, Business and Professions Code.

§ 5362. [RESERVED]

§ 5363. [RESERVED]

§ 5364. No Participation or Unsatisfactory Performance in a Proficiency Test

(a) Failure to participate in a proficiency test required in section 5358 may result in disciplinary action against the testing laboratory license.

(b) The repeated failure of proficiency tests may also subject the testing laboratory to disciplinary action against the testing laboratory license. For the purpose of this subsection, “repeated” means twice or more often in a three-year period and “failure” means anything other than successful performance as defined in section 5361 of this division.

(c) Within 30 days of receiving an “unacceptable,” “questionable,” or “unsatisfactory” proficiency test result, the laboratory shall submit to the bureau the proficiency-test results and detailed corrective action responses, which must include root-cause analysis and remedial action plans.

(d) Within 180 days of an unsatisfactory proficiency test result, the laboratory shall submit to the accrediting body and the bureau a written report showing whether the laboratory successfully implemented the corrective action.

(e) The laboratory shall not report analytes for which the laboratory failed the proficiency test unless and until the laboratory satisfactorily remedies the cause of the failure for that analyte, as proven to the bureau by the report required under subsection (d).

(f) The laboratory shall analyze only the analytes for which proficiency-test results were considered “satisfactory.”

(g) The laboratory shall not accept samples or analyze the analytes for which proficiency test results were considered “unacceptable,” “questionable,” or “unsatisfactory” until the corrective

action has been taken and the problem resolved. The testing laboratory shall enroll in the next available round of proficiency tests. Such enrollment should be documented in the corrective action plan initiated in response to a proficiency-test failure as defined in section 5361 of this division.

Authority: Sections 19302.1, 19304, 19311, 19312, 19327, and 19343, Business and Professions Code. Reference: Sections 19311, 19312, 19327, and 19343, Business and Professions Code.

§ 5365. [RESERVED]

§ 5366. [RESERVED]

§ 5367. Internal audit

(a) A laboratory shall conduct an internal audit at least once per year or according to the ISO accrediting body's requirement, whichever is more frequent.

(b) The internal audit must cover everything required to be covered by ISO 17025 internal-audit standards.

(c) Within three business days of completing the internal audit, the laboratory shall submit the results of the internal audit to the bureau.

(d) Failure to conduct an internal audit or failure to submit the results of an internal audit to the bureau may subject the laboratory to a citation or disciplinary action against the testing laboratory license.

Authority: Sections 19302.1, 19304, 19311, 19312, 19327, and 19343, Business and Professions Code. Reference: Sections 19311, 19312, 19327, and 19343, Business and Professions Code.

§ 5368. [RESERVED]

§ 5369. [RESERVED]

§ 5370. Additional Testing Laboratory Recordkeeping Requirements

(a) A laboratory shall maintain analytical testing laboratory records in such a manner that the analyst, date the analysis was performed, the approver of the certificate of analysis and data package, test method, and materials used can be determined by the bureau. Testing laboratory recordkeeping may be on paper or on electronic, magnetic, or optical media and shall be stored in such a way that the data are readily retrieved when requested by the bureau. If the testing laboratory recordkeeping is not on paper, the laboratory must be able to produce them in hard copy for the bureau upon request. All testing laboratory records must be kept for a minimum of 7 years. The bureau shall be allowed access to all electronic data, including standards records, calibration records, extraction logs, laboratory notebooks, and all other laboratory-related documents listed below.

(b) A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the laboratory's methods as they relate to medical cannabis testing.

(c) A laboratory shall keep and make available to the bureau the following records:

(1) Personnel qualification, training, and competency documentation, including but not limited to resumes, training records or a training database, continuing education records, analytical proficiency testing records, and demonstration of competency records or attestations for laboratory work. These records shall be kept current.

(2) Method verification and validation records, including method modification records, method detection limit and quantitation limit determination records, ongoing verification records such as proficiency test records, and reference material analysis records.

(3) Quality-control and quality-assurance records, including the laboratory's quality-assurance manual and control charts with control limits.

(4) Chain-of-custody records, including chain-of-custody forms, field sample logs, sample-receipt records, sample-description records, sample-rejection records, laboratory information management system (LIMS) records, sample-storage records, sample-retention records, and disposal records.

(5) Purchasing and supply records, equipment-services records, and other equipment records, including purchase requisition records, packing slips, supplier records, and certificates of analysis.

(6) Laboratory equipment installation records, maintenance records, and calibration records. These shall include the date and name of the person performing the installation of, calibration of, or maintenance on the equipment, with a description of the work performed, maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records, and daily verification-of-calibration records.

(7) Customer service records. These include contracts with customers; customer request records; certificates of analyses; customer-transaction records; customer-feedback records; records related to the handling of complaints and nonconformities; and corrective-action records pertaining to complaints.

(8) Nonconforming work and corrective action records. These include corrective-action reports, nonconformance records, nonconformities-resolved-by-correction records, customer-notification records of nonconformities, internal-investigation records, and implementation of corrective action and resumption of work records.

(9) Internal- and external-audit records. These records include audit checklists, standard operating procedures, and audit observation and findings reports. These records must include the date and name of the person or persons performing the audit.

(10) Management review records. These records include technical data review reports and final management-review reports. They must include review date and the identity of the reviewer.

(11) Laboratory data reports, data review, and data approval records, which must include the analysis date and the name of the analysts. These records include instrument and equipment identification records, records with unique sample identifiers, analysts' laboratory notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data, and test-method raw data.

(12) Proficiency testing records, including the proficiency test schedule, proficiency test reports, data-review records, data-reporting records, nonconforming work and corrective action records, and quality-control and quality-assurance records related to proficiency testing.

(13) Electronic data, backed-up data, records regarding the protection of data, and laboratory-security records. These records include raw unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, authorized personnel records and laboratory-access records, and surveillance- and security-equipment records.

(14) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' laboratory notebooks and logbooks, supplier records, and certificates of analysis, and all other data-related records.

(15) Laboratory contamination and cleaning records, including autoclave records, acid-wash logs and records, and general laboratory-safety and chemical-hygiene protocols.

(d) If the records are missing or incomplete, or if a laboratory does not produce the records for the bureau upon request, the bureau may take disciplinary action against the licensee.

Authority: Sections 19302.1, 19304, 19311, 19312, 19327, and 19343, Business and Professions Code. Reference: Sections 19311, 19312, 19327, and 19343, Business and Professions Code.

§ 5371. [RESERVED]

§ 5372. [RESERVED]

Article 8. Employee Education and Experience Requirements

§ 5373. Personnel Qualifications

(a) Laboratory employees shall meet the experience and education requirements specified by this section. For an employee who attended a college or university not located in the United States or its territories, the requirement that the college or university be accredited is satisfied if the educational credentials of the employee are found, by a credential evaluation service, to be equivalent to those of a person who attended an accredited US college or university.

(b) A person who performs analytical tasks shall meet the experience and educational requirements of a testing analyst and be able to demonstrate proper performance of the analytical tasks.

(c) Laboratory director. To be a laboratory director of a licensed testing laboratory under the Act, a person must satisfy one of the following:

(1) Hold a doctoral degree in a chemical or biological science from an accredited college or university and have completed 3 years of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body;

(2) Hold a master's degree in a chemical or biological science from an accredited college or university and have completed 5 years of full-time practical experience in a post-education laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body; or

(3) Hold a bachelor's of science degree in a chemical or biological science from an accredited college or university and have completed 7 years of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body.

(d) In addition to meeting the educational requirements, the laboratory director shall be capable of satisfactorily fulfilling all of the following core responsibilities:

(1) Overseeing and directing the scientific methods of the laboratory;

(2) Ensuring that the testing laboratory achieves and maintains quality standards of practice; and

(3) Supervising all testing laboratory personnel.

(e) Supervisory analyst. To be a supervisory analyst of a licensed testing laboratory under the Act, a person must satisfy one of the following

(1) Satisfy the laboratory-director qualification criteria;

(2) Hold a doctoral degree and have completed at least 1 year of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body;

(3) Hold a master's degree and have completed 2 years of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body; or

(4) Hold a bachelor's of science degree in a chemical or biological science from an accredited college or university and have completed 3 years of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body.

(f) Laboratory testing analyst. To be a laboratory testing analyst of a licensed testing laboratory under the Act, a person must satisfy one of the following:

(1) Satisfy the qualification criteria required for a laboratory director;

(2) Satisfy the qualification criteria required for supervisory analyst; or

(3) Hold a bachelor's degree in one of the chemical or biological sciences from an accredited college or university; or

(4) Have completed at least 2 years of college coursework from an accredited college or university and at least 1 year of full-time, non-education-related practical experience in a

laboratory performing analytical scientific testing in which the testing methods are or were recognized by an accrediting body.

(g) Sampler. To be a sampler at a licensed testing laboratory under this Act, a person must satisfy all of the following:

- (1) Be 21 years old or older;
- (2) Have completed at least 2 years of college coursework; and
- (3) Have completed the minimum training requirements set forth in section 5376(a).

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Section 19343, Business and Professions Code.

§ 5374. [RESERVED]

§ 5375. [RESERVED]

§ 5376. Training Requirements for Samplers

(a) The testing laboratory shall ensure that a sampler is trained in the following areas:

- (1) The scientific basis of cannabis sampling for chemical and microbiological tests;
- (2) Theory of sampling, including common sampling errors and ways to identify and minimize errors;
- (3) Maintenance of sample integrity;
- (4) The proper completion of chain-of-custody forms;
- (5) Sample-collection procedures for each medical cannabis goods matrix;
- (6) An overview of relevant statutes and regulations;
- (7) The proper selection, use, and maintenance of sampling tools and equipment;
- (8) Practical, hands-on application with representative samples; and
- (9) Sample observations that should be recorded and how to record those observations during sampling.

(b) The laboratory shall maintain documentation proving that the training required under subsection (a) has been given to and completed by the sampler.

(c) A laboratory shall retain training records for samplers for 7 years, whether or not the sampler remains employed by the laboratory.

Authority: Sections 19302.1, 19304, 19327, 19342, and 19343, Business and Professions Code. Reference: Sections 19327, 19342, and 19343, Business and Professions Code.

§ 5377. [RESERVED]

§ 5378. [RESERVED]

§ 5379. Verification of Personnel Qualifications

(a) A laboratory shall verify and maintain documentation of qualifications of its employees. A laboratory shall maintain records that show the following:

(1) The colleges and universities attended by the employee and the names and addresses of the colleges and universities, the major course of study, dates of attendance, degrees conferred, and completion date;

(2) Official transcripts from the registrar of the colleges and universities attended by the employee showing all courses, course credits, degrees conferred, and dates degrees were conferred and;

(3) Records from credential evaluation services, including translations of transcripts from non-English-language colleges and universities.

(b) Documentation of a person's experience includes the following:

(1) Laboratory name and address, dates of employment, number of hours per week employed, and a description of the laboratory testing performed by the person; and

(2) Signed documentation of such experience from the facility's laboratory director or equivalent.

Authority: Sections 19302.1, 19304, 19327, and 19343, Business and Professions Code.

Reference: Sections 19327 and 19343, Business and Professions Code.

§ 5380. [RESERVED]

§ 5381. [RESERVED]

Article 9. Laboratory Security

§ 5382. Premises Security

(a) A laboratory shall develop and implement security protocols that are capable of preventing diversion, theft, and loss of medical cannabis samples.

(b) The security protocol shall be documented in writing and available to all laboratory personnel during normal business hours.

Authority: Sections 19302.1, 19304, 19322, 19323, 19327, 19334, and 19343, Business and Professions Code. Reference: Sections 19322, 19323, 19327, 19334, and 19343, Business and Professions Code.

§ 5383. [RESERVED]

§ 5384. [RESERVED]

§ 5385. [RESERVED]

§ 5386. [RESERVED]

§ 5387. [RESERVED]

§ 5388. Access Control

(a) A laboratory shall deter the unauthorized entrance into areas within the laboratory where medical cannabis is present by controlling access to those areas through doing all of the following:

(1) Limiting access to only certain personnel and for the sole purpose of executing their specific job function and duties;

(2) Implementing an access-control-card system capable of preventing unauthorized access through access control points. The system must record the transaction history of all entrants;

(3) Using a security alarm system as required in section 5074 of this division; and

(4) Maintaining a visitor arrival and departure log, which must contain, at minimum, the name of the visitor, date and time of arrival and departure, and the purpose of the visit.

Authority: Sections 19302.1, 19304, 19322, 19323, 19327, and 19334, Business and Professions Code. Reference: Sections 19322, 19323, 19327, and 19334, Business and Professions Code.

§ 5389. [RESERVED]

§ 5390. [RESERVED]

§ 5391. [RESERVED]

§ 5392. [RESERVED]

§ 5393. [RESERVED]

§ 5394. [RESERVED]

§ 5395. [RESERVED]

§ 5396. [RESERVED]

§ 5397. Storage Areas

(a) A laboratory shall store cannabis secured with a commercial-grade lock in a room or cabinet capable of preventing diversion, theft, and loss. Secured areas must be locked at all times except when managing or retrieving a secured item or items. A laboratory shall store medical cannabis samples and items apart and away from non-medical-cannabis samples and items. The testing laboratory shall designate secured areas for storage of the following:

- (1) Test samples of medical cannabis goods;
- (2) Waste containing cannabis;
- (3) Reference standards for analysis of cannabinoids;
- (4) Any controlled substances related to cannabinoids; and
- (5) Records of analytical tests, including certificates of analyses and data packages.

Authority: Sections 19302.1, 19304, 19322, 19323, 19327, 19334, 19343, and 19345, Business and Professions Code. Reference: Sections 19322, 19323, 19327, 19334, 19343, and 19345, Business and Professions Code.

§ 5398. [RESERVED]

§ 5399. [RESERVED]

§ 5400. Electronic Data

(a) Laboratories shall store all raw unprocessed instrument output data files and processed quantitation output files at the laboratory on some form of electronic, magnetic, or optical media. A laboratory shall allow access to these records for inspection and audit.

(b) Laboratories shall install, manage, and maintain password-protection for electronically stored data, including the data listed in subsection (a).

Authority: Sections 19302.1, 19304, 19327, 19334, and 19343, Business and Professions Code. Reference: Sections 19327, 19334, and 19343, Business and Professions Code.

§ 5401. [RESERVED]

§ 5402. [RESERVED]

§ 5403. Notification of Discrepancy

(a) Laboratories shall notify the bureau within 24 hours of discovering any of the following:

(1) An unexplained loss of 5% or more of the inventory of unpackaged and unused harvest-batch samples held at the laboratory;

(2) An unexplained loss of 1 or more units of packaged medical cannabis batch samples held at the laboratory; or

(3) Diversion or theft of medical cannabis or any other criminal activity pertaining to the operation of the laboratory.

Authority: Sections 19302.1, 19304, 19334, and 19343, Business and Professions Code. Reference: Sections 19334 and 19343, Business and Professions Code.

§ 5404. through 5499. [RESERVED]