Chapter 1. All Licensees

Article 1. Division Definitions and General Requirements

§ 15000. Definitions.

(a) [...]

(n) “CBD” means the compound cannabidiol, CAS number 13956-29-1. “Total CBD” is defined in section 15700(~~qqq~~yyy).

(o) [...]

(qqq) “THC” or “delta-9 THC” means the compound tetrahydrocannabinol, CAS number 1972-08-3. “Total THC” is defined in section 15700(~~rrr~~zzz).

(rrr) [...]

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Section 26013, Business and Professions Code.

Chapter 6. Testing Laboratories

Article 1. Chapter Definitions

§ 15700. Definitions.

In addition to the definitions in section 15000, the following definitions apply to this chapter.

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

(b) “Accreditation body” means an impartial non-profit organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.

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

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

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

(f) “Analytical batch” means a set of no more than 20 samples that is prepared together for the same analysis and are prepared with laboratory quality control (LQC) samples.

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

(h) “Analytical sequence” means a group of samples that are analyzed sequentially using the same instrument calibration curve.

(i) “Audit trail” means a secure, computer-generated, time-stamped electronic record that allows reconstruction of the events relating to the creation, modification, and deletion of any electronic record.

(~~i~~j) “Cannabinoid” means a class of diverse chemical compounds derived from a cannabis plant.

(~~j~~k) “CAS number” means the unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service, a division of the American Chemical Society.

(~~k~~l) “CBDA” means cannabidiolic acid, CAS number 1244-58-2.

(~~l~~m) “CBG” means cannabigerol, CAS number 25654-31-3.

(~~m~~n) “CBN” means cannabinol, CAS number 521-35-7.

(~~n~~o) “Certificate of accreditation” means a document issued by an accreditation body that attests to the laboratory's competence to carry out specific testing analysis.

(~~o~~p) “Certified reference material” (CRM) means a reference material in cannabis or similar non-cannabis matrix ~~prepared~~ spiked at a known concentration by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation. The laboratory will calculate the percent recovery of the certified reference material based on measured concentration relative to the known concentration.

(~~p~~q) “Chain of Custody” (COC) means the chronological documentation that records the sequence of custody, control, transfer, analysis, and disposal of a sample.

(~~q~~r) “Coefficient of Determination” (commonly denoted as “r^2”) means a statistical measure that determines how well the regression approximates the actual data points in the calibration curve, with a regression of 1 being a perfect fit.

(~~r~~s) “Continuing calibration verification” (CCV) means a type of quality control sample that includes each of the target method analytes that is a mid-range calibration standard which checks the continued validity of the initial calibration of the instrument.

(~~s~~t) “Corrective action” means an action taken by the laboratory to resolve, and prevent from recurrence, a problem with the technical operations of the laboratory.

(u) “Delta-8 THC” means the compound delta-8 tetrahydrocannabinol, CAS number 5957-75-5.

(v) “Delta-10 THC” means the compound delta-10 tetrahydrocannabinol, CAS numbers 95543-62-7 ((6aR,9R)-delta-10 tetrahydrocannabinol) and 95588-87-7 ((6aR,9S)-delta-10 tetrahydrocannabinol),

(~~t~~w) “Exclusivity” means the specificity of the test method for validating microbial testing methods. It evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms.

(~~u~~x) “Foreign material” means any filthy, putrid, or decomposed substance including hair, insects, excreta, or related adulterant that may be hazardous or cause illness or injury to the consumer.

(~~v~~y) “Frequency” means the number of items occurring in each category. Frequency may be determined by analytical method or laboratory specific requirements for accuracy, precision of the analysis, or statistical calculation.

(~~w~~z) “Good laboratory practice” (GLP) means a system of management controls for laboratories to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of analyses performed by the testing laboratory.

(~~x~~aa) “Inclusivity” means, related to microbiological method validation, 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.

(~~y~~bb) “Inhalable” means consumable through the lungs.

(~~z~~cc) “Initial Calibration Verification” (ICV) means a solution of each of the target method analytes of known concentration that is obtained from a source external to the laboratory and different from the source of calibration standards.

(~~aa~~dd) “ISO/IEC” means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

(~~bb~~ee) “ISO/IEC 17025” means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.

(~~cc~~ff) “ISO/IEC 17034” means the general requirements established by the ISO/IEC for the competence of reference material producers.

(~~dd~~gg) “ISO/IEC 17043” means the general requirements established by the ISO/IEC for proficiency testing.

(~~ee~~hh) “Laboratory” means “testing laboratory” as defined at Business and Professions Code section 26001(a~~v~~z).

(~~ff~~ii) “Laboratory Control Sample” (LCS) means a blank matrix to which known concentrations of each of the target method analytes are added. The spiked concentration must be at a mid-range concentration of the calibration curve for the target analytes. The LCS must be prepared and ~~is~~ analyzed in the ~~same~~ identical manner as the representative sample.

(~~gg~~jj) “Laboratory replicate sample” means a sub-sample taken of the representative sample used for laboratory quality control purposes to demonstrate reproducibility. It is prepared and analyzed in the identical manner as the representative sample. The results from replicate analyses are used to evaluate analytical precision.

(~~hh~~kk) “Laboratory employee” means any person directly employed by the laboratory for wages, salary, barter, or trade by the laboratory and who is not employed by any other licensee under the Act except for another testing laboratory. “Laboratory employee” does not mean an independent contractor, third party entity, or any other entity acting on behalf of the laboratory.

(~~ii~~ll) “Laboratory quality assurance” means the set of operating principles that enable laboratories to produce defensible data of known accuracy and precision and includes employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing, among other things.

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

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

(~~ll~~oo) “Linear regression” means the determination, in analytical chemistry, of the best linear equation for calibration data to generate a calibration curve. The concentrate of an analyte in a sample can then be determined by comparing a measurement of the unknown to the calibration curve. A linear regression uses the following equation:

y = mx + b; where m = slope, b = intercept

(~~mm~~pp) “Matrix” means the substances that are present in a sample except for the analyte(s) of interest.

(~~nn~~qq) “Matrix spike sample” means a sample prepared by adding a known quantity of each of the target analyte to an unknown sample from within the same analytical batch ~~a sample matrix or to a matrix that is as closely representative of the matrix~~

~~being analyzed as possible~~. The spiked concentration must be at a mid-range concentration of the calibration curve for the target analytes.

(~~oo~~rr) "Method Blank" means an analyte free matrix to which all reagents are added in the same volumes or proportions as used in the sample preparation and is processed in exactly the same manner as the samples.

(~~pp~~ss) "Moisture content" means the percentage of water in a sample, by weight.

(~~qq~~tt) "Non-target organism" means an organism that the test method or analytical procedure is not testing for and can be used in evaluating the specificity of a test method.

(uu) "Percent accuracy" means the measurement of how close a measured value is to the true or accepted value. Percent accuracy is calculated using the following equation:

Percent Accuracy = 100 - [(True value – measured value)/true value *100]

(~~rr~~vv) "Percent recovery" means the percentage of a measured concentration relative to the added (spiked) concentration in a reference material or matrix spike sample. A laboratory shall calculate the percent recovery by dividing the sample result by the expected result then multiplying the quotient by 100.

(~~ss~~ww) "Practical experience" means experience performing scientific analytical tests in a laboratory setting using equipment, instruments, kits, and materials routinely found in a laboratory. "Practical experience" includes experience in any type of laboratory setting and is not limited to cannabis-specific laboratories.

(~~tt~~xx) "Proficiency test" means an evaluation of a laboratory's performance against pre-established criteria by means of interlaboratory comparisons of test measurements.

(~~uu~~yy) "Proficiency test sample" means a sample that is prepared by a party independent of the testing laboratory with the ISO/IEC 17043 accreditation, where the concentration and identity of an analyte is known to the independent party, but is unknown to the testing laboratory and testing laboratory employees.

(~~vv~~zz) "Quadratic regression" means the determination, in analytical chemistry, of the best parabola equation for calibration data to generate a calibration curve. The concentrate of an analyte in a sample can then be determined by comparing a measurement of the unknown to the calibration curve. A quadratic regression uses the following equation:

$y = ax^2 + bx + c$; where a, b, and c are numerical coefficients

(aaa) “Qualified Reviewer” means a Research Scientist, Environmental Scientist, Senior Environmental Scientist, or Environmental Program Manager employed in the Department’s Laboratory Services Division.

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

(~~xx~~ccc) “Quality control sample” means a sample that is produced and used by a laboratory for the purpose of assuring the quality of the data and results. Quality control samples include blank samples, matrix spike samples, laboratory control samples, replicate samples, and reference material samples.

(~~yy~~ddd) “Reagent” means 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 a specific chemical substance is present by causing a reaction to occur with the chemical substance.

(eee) “Reference laboratory” means the Department’s cannabis testing laboratory or other laboratory contracted with the Department to conduct cannabis testing.

(~~zz~~fff) “Reference material” means material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix.

(~~aaa~~ggg) “Reference method” means the method by which the performance of an alternate method is measured or evaluated.

(~~bbb~~hhh) “Relative percent difference” (RPD) means the comparative statistic that is used to calculate precision or random error. RPD is calculated using the following equation:

> RPD = | (representative sample measurement - replicate sample measurement) / ([representative sample measurement + replicate sample measurement] / 2) x 100%

(~~ccc~~iii) “Relative standard deviation” (RSD) means the standard deviation expressed as a percentage of the means recovery. RSD is calculated using the following equation:

> RSD = (s / x) x 100%; where s = standard deviation and x = mean

(~~ddd~~jjj) “Representative” means a small quantity of the batch whose characteristics represent, as accurately as possible, the entire batch, thus allowing the results to be generalized.

(~~eee~~kkk) “Representative sample” means a sample that is comprised of several sample increments of cannabis or cannabis products that are collected from random and varying locations within a batch for testing.

(~~fff~~ lll) “Requester” means the person who submits a request to the laboratory for testing of cannabis or cannabis products from an entity licensed under the Act.

(~~ggg~~mmm) “Reserve sample” means any portion of a representative sample that was not used in the testing process.

(~~hhh~~nnn) “Sample” means a representative part of, or a single item from, a batch which is comprised of several sample increments.

(~~jjj~~ooo) “Sample increment” means a portion of a batch that, together with other increments, makes up the sample.

(ppp) “Sample injection” means the prepared or diluted sample physically inserted into analytical instrumentation.

(~~kkk~~qqq) “Sampler” means the laboratory employee responsible for obtaining samples of cannabis or cannabis products from a licensed distributor or licensed microbusiness authorized to engage in distribution.

(~~##~~rrr) “Sanitize” means to sterilize, disinfect, or make hygienic.

(~~mmm~~sss) “Scope of accreditation” means the tests or types of tests performed, materials or products tested, and the methods used for testing cannabis or cannabis products for which the accreditation has been granted.

(~~nnn~~ttt) “Standard operating procedure” (SOP) means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

(~~ooo~~uuu) “Target organism” means an organism that is being tested for in an analytical procedure or test method.

(~~ppp~~vvv) “THCA” means tetrahydrocannabinolic acid, CAS number 23978-85-0.

(www) “THCV” means the compound tetrahydrocannabivarin, CAS number 31262-37-0.

(xxx) “THCVA” means the compound tetrahydrocannabivarin acid, CAS number 39986-26-0.

(~~qqq~~yyy) “Total CBD” means the ~~sum~~ calculated amount of CBD and CBDA. Total CBD is calculated using the following equation:

Total CBD concentration (mg/g) = (CBDA concentration (mg/g) x 0.877) + CBD concentration (mg/g)

(~~rrr~~zzz) “Total THC” means the ~~sum~~ calculated amount of THC, THCA, THCV, THCVA, delta-8 THC, and ~~THCA~~ delta-10 THC. Total THC is calculated using the following equations.

> ~~Total THC (mg/g) = [(delta 8-THCA concentration (mg/g) + delta 9-THCA concentration (mg/g)) x 0.877] + [delta 8-THC concentration (mg/g) + delta 9-THC concentration (mg/g)]~~

For concentration expressed in weight:

> Total THC (mg/g) = (THCA concentration (mg/g) x 0.877) + (THCVA concentration (mg/g) x 0.867) + [(THC concentration (mg/g) + delta-8 THC concentration (mg/g) + delta-10 THC concentration (mg/g) + THCV concentration (mg/g)]

For concentration expressed in volume:

> Total THC is calculated using the following equation: Total THC (mg/mL) = (THCA concentration (mg/mL) x 0.877) + (THCVA concentration (mg/mL) x 0.867) + [(THC concentration (mg/mL) + delta-8 THC concentration (mg/mL) + delta-10 THC concentration (mg/mL) + THCV concentration (mg/mL)]

(~~sss~~aaaa) “Validation” means the confirmation by examination and objective evidence that the requirements for a specific intended use or analytical method are fulfilled.

(~~ttt~~bbbb) “Water activity” means the measure of the quantity of water in a product that is available and therefore capable of supporting bacteria, yeasts, and fungi and which is reported in units Aw.

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26013 and 26100, Business and Professions Code.

Article 2. Laboratory License

§ 15701. General Laboratory License Requirements.

(a) A licensed laboratory shall maintain ISO/IEC 17025 accreditation for the testing of the following:

(1) Cannabinoids;

(2) Heavy metals;

(3) Microbial impurities;

(4) Mycotoxins;

(5) Residual pesticides;

(6) Residual solvents and processing chemicals; ~~and~~

(7) If tested, terpenoids; and

(8) Beginning six months after the effective date of this subsection, vitamin E acetate.

(b) Each testing laboratory licensed premises shall have ISO/IEC 17025 accreditation.

(c) A licensed laboratory shall retain, and make available to the Department upon request, all records associated with the licensee's ISO/IEC 17025 certificate of accreditation.

(d) A licensed testing laboratory may test items not regulated by this division if they comply with the laws governing the testing of such items. A licensed testing laboratory shall maintain separate and distinct records of their activities regulated by this division and their activities that are subject to other laws.

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26012 and 26100, Business and Professions Code.

§ 15702. Laboratory License Application.

In addition to the information required in section 15002, an application for a testing laboratory license includes the following:

(a) A valid certificate of accreditation, issued by an accreditation body, that attests to the laboratory's competence to perform testing, including all the required analytes for the following test methods:

(1) Cannabinoids;

(2) Heavy metals;

(3) Microbial impurities;

(4) Mycotoxins;

(5) Residual pesticides;

(6) Residual solvents and processing chemicals; ~~and~~

(7) If tested, terpenoids; and~~.~~

(8) Beginning six months after the effective date of this subsection, vitamin E acetate.

(b) Standard operating procedures that meet the criteria in section 15711 for the following testing methods:

(1) Cannabinoids;

(2) Foreign material;

(3) Heavy metals;

(4) Microbial impurities;

(5) Moisture content and water activity;

(6) Mycotoxins;

(7) Residual pesticides;

(8) Residual solvents and processing chemicals; ~~and~~

(9) If tested, terpenoids; and

(10) Beginning six months after the effective date of this subsection, vitamin E acetate.

(c) Method validation reports that meet the criteria in section 15713 for the following testing methods:

(1) Cannabinoids;

(2) Heavy metals;

(3) Microbial impurities;

(4) Mycotoxins;

(5) Residual pesticides;

(6) Residual solvents~~;~~ and processing chemicals; ~~and~~

(7) If tested, terpenoids; and

(8) Beginning six months after the effective date of this subsection, vitamin E acetate.

(d) Standard operating procedures that meet the criteria in section 15704 for the sampling of cannabis or cannabis products.

(e) Records demonstrating that each supervisory or management-level employee meets the required qualifications in section 15737(b).

Note: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26012, 26050, 26055, 26102 and 26104, Business and Professions Code.

Article 3. Sampling Cannabis and Cannabis Products

§15706. Chain of Custody (COC)

(a) The licensed laboratory shall develop and implement a COC protocol to ensure accurate documentation is recorded for the transport, handling, storage, and destruction of samples.

(b) The COC protocol shall require the use of a COC form. The sampler shall use a COC form to record the following information for each sampled batch:

(1) Laboratory's name, licensed premises address, and license number;

(2) Date and time sampling started and ended;

(3) Licensed distributor or licensed microbusiness' name, licensed premises address, and license number;

(4) Licensed cultivator's, licensed manufacturer's, licensed distributor's, or licensed microbusiness' name, licensed premises address, and license number;

(5) Batch number of the batch from which the representative sample was obtained and assigned unique sample identifier;

(6) Sample matrix;

(7) Total batch size, by weight, or unit count;

(8) Total weight, or unit count of the representative sample;

(9) Sampling conditions or problems encountered during the sampling process, if any;

(10) Printed name and signature of the licensed distributor or licensed microbusiness' authorized to engage in distribution employee; and

(11) Printed name and signature of the sampler.

(c) The sampler must affix the associated package tag for each representative sample to the COC form obtained at the time the batch is sampled by the licensed laboratory for regulatory compliance testing.

(d) The sampler must affix the associated package tag to the physical package or container holding the representative sample(s).

~~(c)~~ (e) Each time a sample changes custody between licensees, is transported, or is destroyed, the date, time, and the names and signatures of persons involved in these activities shall be recorded on the COC form.

~~(d)~~ (f) Once the custody of the sample changes between licensees, the COC form for that change of custody may not be altered.

NOTE: Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26102, 26104 and 26110, Business and Professions Code.

§15708. Cannabis Product Batch and Pre-Roll Sampling.

(a) The sampler shall obtain a representative sample from each cannabis product batch or pre-roll batch.

(b) The sampler may collect a greater number of sample increments if necessary to perform the required testing or to ensure that the samples obtained are representative.

(c) The cannabis product batch or pre-roll batch from which a representative sample is obtained shall contain no more than 150,000 units. Laboratory analyses of a sample collected from a cannabis product batch containing more than 150,000 units shall be deemed invalid and the cannabis product batch or pre-roll batch from which the representative sample was obtained shall not be released for retail sale.

(d) The sampler shall obtain a representative sample of a cannabis product or pre-roll batch by collecting, at minimum, the number of sample increments relative to the

batch size as listed in the following table. Each sample increment consists of one (1) packaged unit in its final form.

Cannabis Product or Pre-roll Batch Size (units)	Number of Sample Increments (per sample)
≤ 50	2
51 – 150	3
151 – 500	5
501 – 1,200	8
1,201 – 3,200	13
3,201 – 10,000	20
10,001 – 35,000	32
35,001 – 150,000	50

NOTE: Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

Article 4. Standard Operating Procedures

§15713. Validation of Test Methods.

(a) The licensed laboratory may use a nonstandard (i.e., not recognized by an established authority in the field of analytical chemistry, such as the United States Environmental Protection Agency), amplified (i.e., enhanced to increase sensitivity or specificity), or modified (i.e., adapted from a standard method to suit specific sample conditions) test method; or a test method that is designed or developed by the licensed laboratory, provided the licensed laboratory ~~to~~ validates that~~the~~ method~~s~~ for ~~analyses~~ analysis of samples.

(b) The licensed laboratory shall follow the guidelines set forth in the US Food and Drug Administration's *Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds*, ~~2nd~~ Third Edition, ~~April 2015~~ October 2019, incorporated herein by reference, to validate test methods for the microbial analysis of samples. The licensed laboratory shall include and address the criteria listed in the following table when validating test methods for microbial ~~analyses~~ analysis of samples.

Criteria	Requirement
Number of target organisms; inclusivity	5 per species reported
Number of non-target organisms; exclusivity	5 per species reported
Number of analyte levels per matrix: Qualitative methods (limit of detection)	3 levels: high and low inoculum levels and 1 uninoculated level
Number of analyte levels per matrix: Quantitative methods	4 levels: low, medium and high inoculum levels and 1 uninoculated level
Replicates per food at each level tested	2 or more replicates per level
Accuracy	Include a comparison of assay results to a known reference standard or method
Reproducibility and Robustness	Consistent results across multiple operators, instruments, and days

(c) The licensed laboratory shall follow the guidelines set forth in the US Food and Drug Administration's *Guidelines for the Validation of Chemical Methods for the FDA FVM Program*, ~~2nd~~ Third Edition, ~~April 2015~~ October 2019, incorporated herein by reference, to validate test methods for chemical ~~analyses~~ analysis of samples.

(1) The licensed laboratory shall include and address the following criteria to validate test methods for ~~analyses~~ analysis of samples:

(A) Accuracy;

(B) Precision;

(C) Linearity and range;

(i) The Coefficient of Determination (r2) for all calibration curves shall be greater than or equal to 0.99.

(ii) Linear regression or quadratic regression shall only be used for calibration curves. Curves shall not be weighted at all or only weighted at $^{1}/x$.

(iii) LOQ for analytes tested shall be within the range of the calibration curve.

(D) Calibration standard;

(i) For calibration curves, there shall be a minimum of five calibration standards, not including zero; ~~and~~

(ii) For each calibration curve point, the percent recovery must be 70-130%, except the lowest calibration point, for which the percent recovery must be 50-150%; and

(iii) Each calibration curve must include an Initial Calibration Verification (ICV). The percent recovery must be between 70% to 130%.

(E) Sensitivity and selectivity;

(F) ~~Limit of detection~~ LOD and ~~limit of quantitation~~ LOQ;

(G) Recovery;

(H) Reproducibility; and

(I) Robustness.

(2) The licensed laboratory must include and address the criteria listed in the following table when validating test methods for chemical analyses of samples.

Criteria	**Requirement**
Number of analyte spike levels per matrix	2 levels: low, medium
Number of method blanks	≥1
Replicates required at each spike level per matrix	≥2

(3) The licensed laboratory must use a minimum of one (1) representative matrix each for dried flower, inhalable cannabis concentrates, and edible cannabis products when validating test methods for chemical analysis of samples.

(4) The licensed laboratory must analyze all required Laboratory Quality Control (LQC) samples specified in section 15730 with each analytical batch when validating test methods for chemical analysis of samples.

(5) The licensed laboratory shall use certified reference materials to validate the following chemical analyses. The test method used for analysis is valid if the percent recovery of the certified reference material is between 80% to 120% for all required analytes.

(A) Cannabinoids~~, if available~~;

(B) Heavy metals;

~~(C) Microbial impurities;~~

(~~D~~C) Mycotoxins;

(~~E~~D) Residual pesticides;

(~~F~~E) Residual solvents and processing chemicals; ~~and~~

(~~G~~F) Terpenoids, if ~~available~~ tested; and

(G) Vitamin E and Vitamin E acetate.

(d) ~~The licensed laboratory shall generate~~ Before using a chemical or microbiological test method, the licensee or applicant laboratory must submit a complete method validation report for ~~each~~that test method to the Department for review and approval. Incomplete method validation reports will not be reviewed. The Department will notify submitting laboratories of incomplete reports by email. Each validation report ~~shall~~must include the following information:

(1) A written narrative describing:

(A) The intended purpose and scope of the test method;

(B) A description of the test method;

(C) The validation procedures, techniques, and experimental design used to demonstrate the performance of the test method for each characteristic listed in subsection (b) for microbiological test methods or subsection (c) for chemical test methods;

(D) Acceptance criteria; and

(E) A summary of the results and conclusions of the validation study.

(2) Instrument calibration data, if ~~any~~ applicable;

~~(2)~~ (3) Raw data~~, including instrument raw data,~~ necessary for recalculating sample results for each test method~~, if any~~. Raw data includes instrument output and is printed directly from the instrument.

(A) The following raw data is required for all chemical test methods:

(i) Analytical sequences showing the order, date, and times of sample analysis.

(ii) Sample and LQC sample results.

(iii) Instrument parameters.

(iv) Calibration curve graphs with r2 values, regression equations, and regression type.

(v) Instrument summary concentration reports with units of measurement.

(B) For test methods using chromatography, the following raw data is required in addition to the raw data in subsection (d)(3)(A):

(i) Chromatograms with discernible integrations. A discernible integration has a visible start and end point.

(ii) Detector response including peak areas or peak area counts for analytes; and for internal standards, if used.

(iii) Retention times.

(C) For test methods using chromatography–mass spectrometry, including tandem mass spectrometry, the following raw data is required in addition to the raw data in subsections (d)(3)(A) and (B):

(i) Quantifier and Qualifier Ion identities, mass to charge ratio (m/z) values, and abundances.

(ii) Ion transitions, ratios, and ranges, if used.

(iii) Mass spectral library match scores, if used.

(D) For test methods using inductively coupled plasma-mass spectrometry, the following raw data is required in addition to the raw data in subsection (d)(3)(A):

(i) Detector response, including ion abundances, net intensities, and counts per second (CPS) for analytes; and for internal standards, if used.

(ii) Ion identities and masses, mass to charge ratio (m/z) values.

(iii) Ion ratios, if used.

(iv) Tune reports.

(E) The following raw data is required for all microbiological test methods:

(i) Analytical sequences showing the order, date, and times of sample analysis.

(ii) Sample and LQC sample results.

(F) For microbiological test methods using enrichment and plate culture, the following raw data is required in addition to the raw data in subsection (d)(3)(E):

(i) Images with and without microbial growth.

(ii) Negative and positive control cultures.

(iii) Target microbial cultures.

(G) For microbiological test methods using Quantitative Polymerase Chain Reaction (qPCR) or Polymerase Chain Reaction (PCR), the following raw data is required in addition to the raw data in subsection (d)(3)(E):

(i) Amplification curves or plots.

(ii) Cycle threshold (Ct) values.

(iii) Information regarding reaction fluorescence for qPCR or PCR.

~~(3)~~ (4) Cannabis reference materials or ~~certified reference material~~CRM results in accordance with subsection (c)(5), if applicable;

(5) Certificates of Analysis for reagents and chemical standards used;

(6) Certificates of Analysis for bacterial and fungal strains used, if applicable;

~~(4)~~ (7) For quantitative methods, d~~D~~ata and calculations pertaining to the reported results and LOD and LOQ determinations~~, if any~~;

~~(5)~~ (8) LQC report, as described in this chapter, for the validation of each method; ~~and~~

~~(6)~~ (9) Worksheets, bench sheets, forms, pictures, or copies of laboratory notebook pages and any other documentation necessary to meet the requirements described in subsections (b) and (c).

~~(7)~~ (10) The dated signature of the ~~The~~ supervisory or management-level laboratory employee ~~shall~~ who reviewed~~,~~ and approved~~, sign, and date~~ the validation report ~~for each test method~~.

(e) After receiving a complete method validation report for a chemical test method, a Qualified Reviewer will conduct a substantive review to evaluate whether the submitting laboratory validated the test method for its intended use. The Qualified Reviewer will consider the chemical test method validated and approve the test method for use if they determine, based on the information provided in the method validation report and using their scientific judgment, that all of the following conditions are met:

(1) The report demonstrates the accuracy of the test method within the defined acceptance criteria for the target analytes in the required matrices, using an experimental design and acceptance criteria that are scientifically sound.

(2) The report demonstrates the precision of the test method within the defined acceptance criteria for the target analytes in the required matrices, using an experimental design and acceptance criteria that are scientifically sound.

(3) The report demonstrates the linearity and range for the target analytes with the following acceptance criteria for calibration curves:

(A) The coefficient of determination (r2) is greater than or equal to 0.99.

(B) Shall use either linear regression or quadratic regression.

(C) Shall be unweighted, or if weighted, shall only be weighted at 1/x.

(D) LOQ for target analytes are within the range of the calibration curve.

(E) Shall include a minimum of five calibration points, not including zero.

(F) For each calibration curve point the percent recovery must be 70-130%, except the lowest calibration point whereby the percent recovery must be 50-150%; and

(G) includes an Initial Calibration Verification with 70-130% recovery.

(4) The report demonstrates the sensitivity and selectivity of the test method within the defined acceptance criteria for the target analytes in the required matrices, using an experimental design and acceptance criteria that are scientifically sound.

(5) The report demonstrates that the laboratory has established Limits of Detection and Limits of Quantitation using the method listed in section 15731 and in accordance with the respective action limits and limits of quantitation for each test method.

(6) The report demonstrates the recovery of the test method within the defined acceptance criteria for the target analytes in the required matrices, using an experimental design and acceptance criteria that are scientifically sound.

(7) The report demonstrates the reproducibility of the test method within the defined acceptance criteria for the target analytes in the required matrices, using an experimental design and acceptance criteria that are scientifically sound.

(8) The report demonstrates the robustness of the test method within the defined acceptance criteria for the target analytes in the required matrices, using an experimental design and acceptance criteria that are scientifically sound.

(9) The report demonstrates that for the following chemical analyses, the CRM analysis results indicate 80-120% recovery for all required analytes:

(A) Cannabinoids.

(B) Heavy Metals.

(C) Mycotoxins.

(D) Residual Pesticides.

(E) Residual Solvents.

(F) Terpenoids.

(f) If the Qualified Reviewer determines, on a case-by-case basis and using their scientific judgment, that supplemental information is required to complete their review of a method validation report for a chemical test method, they will notify the submitting laboratory and request the information by email.

(g) Upon receipt of a complete method validation report for a microbiological test method, a Qualified Reviewer will conduct a substantive review to evaluate whether the submitting laboratory validated the test method for its intended use. The Qualified Reviewer will consider the microbiological test method validated and approve the test method for use if they determine, based on the information provided in the method validation report and using their scientific judgment, that all of the following conditions are met:

(1) The report demonstrates the inclusivity of the test method within the defined acceptance criteria for the target species in the required matrices, using an experimental design and acceptance criteria that are scientifically sound.

(2) The report demonstrates the exclusivity of the test method within the defined acceptance criteria for the target species in the required matrices, using an experimental design and acceptance criteria that are scientifically sound.

(3) The report demonstrates the extraction and detection of the target species in the required matrices, using an experimental design and acceptance criteria that are scientifically sound.

(h) If the Qualified Reviewer determines, on a case-by-case basis and using their scientific judgment, that supplemental information is required to complete their review of a method validation report for a microbiological test method, they will notify the submitting laboratory and request the information by email.

(i) Upon completion of the review of a method validation report for a chemical or microbiological test method, the Department will notify the submitting laboratory by email that the test method is either approved or not approved for use.

(j) Before a licensed laboratory begins using any altered or updated version of a previously approved test method, the laboratory must request Department approval to use the revised method by submitting a description of the alterations or updates, using the Licensee Notification and Request Form, Notifications and Requests Regarding Testing Laboratories, DCC-LIC-029 (Rev. XX/25), incorporated by reference herein, to testinglabs@cannabis.ca.gov. A Qualified Reviewer will evaluate the information provided, on a case-by-case basis and using their scientific judgment, to determine whether the test method has been altered or updated to an extent requiring re-demonstration of the method validation characteristics listed in subsection (b) or (c), as applicable.

(k) Within 30 calendar days after receipt of a request for approval submitted pursuant to subsection (j), the Qualified Reviewer will provide one of the following notifications to the submitting laboratory by email:

(1) The altered or updated test method is approved for use.

(2) The altered or updated test method is not approved for use and a new method validation report must be submitted pursuant to subsection (d).

(3) The altered or updated test method is not approved for use because a determination cannot be made based on the description provided, and the laboratory may restart the review process by submitting a new request for approval pursuant to subsection (j) if desired.

(l) If the Qualified Reviewer does not respond to the submitting laboratory within 30 calendar days in accordance with subsection (k), then the altered or updated test method will be deemed approved for use.

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26012, 26100, 26104 and 26110, Business and Professions Code.

Article 5. Laboratory Testing and Reporting

§ 15715. Vitamin E Acetate Testing.

(a) Beginning six months after the effective date of this section, licensed laboratories must analyze at minimum 0.25 grams of the representative sample of an inhalable cannabis product to determine whether vitamin E acetate is present.

(b) Licensed laboratories must report the results of vitamin E acetate testing in unit micrograms per gram (µg/g) and indicate "pass" or "fail" on the COA.

(c) The sample passes vitamin E acetate testing if the presence of each chemical listed in the following table does not exceed the indicated action levels.

Chemical	***CAS No.***	***Inhalable Cannabis Product***
		Action Level (µg/g)
α-Tocopherol acetate (vitamin E acetate)	58-95-7	1.0

(d) If the sample fails vitamin E acetate testing, the batch from which the sample was collected fails vitamin E acetate testing and may not be released for retail sale.

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

§ 15719. Residual Pesticides Testing.

*[**PLACEHOLDER--NOTE:** The Department of Pesticide Regulation (DPR) is finalizing recommendations to DCC regarding pesticide residues pursuant to Business and Professions Code section 26060(c). Upon receipt from DPR, DCC will review the recommendations in accordance with Business and Professions Code section 26100(d)(2) and propose any amendments to section 15719 that are determined to be necessary for consistency.]*

§ 15720. Microbial Impurities Testing.

(a) The licensed laboratory shall analyze at minimum 1.0 grams of the representative sample of cannabis or cannabis products to determine whether microbial impurities are present.

(b) The licensed laboratory must ensure that sterile sample preparation techniques are used and that each sample has a minimum incubation time of 24 hours.

~~(b)~~ (c) The licensed laboratory shall report the result of the microbial impurities testing by indicating "pass" or "fail" on the COA.

~~(c)~~ (d) The sample of inhalable cannabis and cannabis products shall be deemed to have passed the microbial impurities testing if all of the following conditions are met:

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

(2) Salmonella spp. is not detected in 1 gram; and

(3) Pathogenic Aspergillus species A. fumigatus, A. flavus, A. niger, and A. terreus are not detected in 1 gram.

~~(d)~~ (e) The sample of non-inhalable cannabis and cannabis products shall be deemed to have passed the microbial impurities testing if both the following conditions are met:

(1) Shiga toxin-producing Escherichia coli is not detected in 1 gram~~,~~; and

(2) Salmonella spp. is not detected in 1 gram.

(f) The licensed laboratory must report detection of any pathogenic Aspergillus in a sample, identifying each particular species detected, on the COA.

~~(e)~~ (g) If the sample fails microbial impurities testing, the batch from which the sample was collected fails microbial impurities testing and shall not be released for retail sale.

Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

§15724. Cannabinoid Testing.

(a) The licensed laboratory shall analyze at minimum 0.5 grams of the representative sample of cannabis ~~and~~ or cannabis products to determine the cannabinoid profile of the batch. The cannabinoid profile must include, at minimum, the following cannabinoids: ~~such as THC; THCA; CBD; CBDA; CBG; and CBN~~ CBDA, CBD, CBG, CBN, THC, delta-8 THC, delta-10 THC, THCA, THCV, and CBC. A licensed laboratory may test for additional cannabinoids provided that the cannabinoid testing method approved by the Department under section 15713 includes the additional cannabinoid to be tested.

(b) The licensed laboratory shall establish a limit of quantitation (LOQ) of 1.0 mg/g or lower for all cannabinoids analyzed and reported.

(c) The licensed laboratory shall report the result of the cannabinoid testing on the COA, including, at minimum:

(1) A percentage for ~~THC, THCA, CBD, and CBDA,~~ each tested cannabinoid;

(A) When the licensed laboratory reports the result of the cannabinoid testing for harvest batch representative samples on the COA in dry-weight percent, they shall use the following equation:

Dry-weight percent cannabinoid = wet-weight percent cannabinoid /

(1 – percent moisture / 100)

(2) A percentage for Total THC and Total CBD~~, if applicable~~;

(3) Milligrams per gram (mg/g) if by dry-weight or milligrams per milliliter (mg/mL) if by volume for ~~THC, THCA, CBD, and CBDA,~~ each tested cannabinoid.

(4) Milligrams per gram (mg/g) if by dry-weight or milligrams per milliliter (mg/mL) if by volume for Total THC and Total CBD~~, if applicable~~;

~~(A) The licensed laboratory shall calculate the total cannabinoid concentration as follows:~~

~~(i) For concentration expressed in weight:~~

~~Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g)~~

~~(ii) For concentration expressed in volume:~~

~~Total cannabinoid concentration (mg/mL) = (cannabinoid acid form concentration (mg/mL) x 0.877) + cannabinoid concentration (mg/mL)~~

(5) Milligrams per package for THC and CBD;

(6) Milligrams per package for Total THC and Total CBD, if applicable;

(7) Milligrams per serving for THC and CBD, if any; and

(8) Milligrams per serving for Total THC and Total CBD, if any and if applicable.~~; and~~

~~(9) The licensed laboratory shall report the results of all other cannabinoids analyzed on the COA both as a percentage and in either milligrams per gram (mg/g) if by weight or milligrams per milliliter (mg/mL) if by volume.~~

(d) The sample shall be deemed to have passed the cannabinoid testing if the amount of THC does not exceed the limits established in section 17304.

(e) The licensed laboratory shall report the test results and indicate an overall “pass” or “fail” for the cannabinoid testing on the COA.

(f) Any cannabinoids found to be less than the LOQ shall be reported on the COA as “<1mg/g” if by dry-weight or “<1 mg/mL” if by volume.

(g) If the sample fails cannabinoid testing, the batch from which the sample was collected fails cannabinoid testing and shall not be released for retail sale.

(h) For purposes of this division, any one cannabinoid, Total THC, and/or Total CBD claimed to be present on a label shall not be considered inaccurate if the difference in percentage on the certificate of analysis is plus or minus 10.0%.

(i) A cannabinoid, Total THC, or Total CBD result reported on the COA will be considered inaccurate if the difference in percent, calculated as follows, is greater than 10.0% when compared to the Department's reference laboratory measurement.

Difference in percent = |(Reference laboratory measurement – Licensed laboratory COA result)| / (Licensed laboratory COA result) x 100%

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

§ 15726. Certificate of Analysis (COA).

(a) The licensed laboratory shall generate a COA for each representative sample that the laboratory analyzes.

(b) The licensed laboratory shall ensure that the COA contains the results of all required analyses performed for the representative sample.

(c) The licensed laboratory ~~shall~~ must, within 1 business day of completing all analyses of a sample, ~~both~~ upload the COA into the track and trace system ~~and simultaneously provide a copy of the COA to the Department via email at testinglabs@cannabis.ca.gov with a file name of "METRC UID Number and Test Sample ID" and "Passed" or "Failed" in the subject heading of the email~~.

(d) The licensed laboratory shall not release to any person any cumulative or individual test results prior to completing all analyses and providing the COA to the Department.

(e) The COA shall contain, at minimum, the following information:

(1) The term "Regulatory Compliance Testing" in font no smaller than 14-point, which shall appear in the upper-right corner of each page of the COA. No text or images shall appear above the term "Regulatory Compliance Testing" on any page of the COA.

(2) Laboratory's name~~, licensed premises address,~~ and license number;

(3) Licensed distributor's or licensed microbusiness authorized to engage in distribution's name~~, licensed premises address,~~ and license number;

(4) Licensed cultivator's, licensed manufacturer's, or licensed microbusiness' name~~, licensed premises address,~~ and license number;

(5) Batch number of the batch from which the sample was obtained. For cannabis and cannabis products that are already packaged at the time of sampling, the labeled batch number on the packaged cannabis and cannabis products shall match the batch number on the COA;

(6) Sample identifying information, including matrix type and ~~unique sample identifiers~~UID assigned to the test sample;

(7) Sample history, including the date collected, the date received by the laboratory, and the date(s) of sample analyses and corresponding testing results;

(8) A picture of the sample of cannabis and cannabis products. If the sample is pre-packaged, the picture must include an unobstructed image of the packaging;

(9) For dried flower samples, the total weight of the batch, in grams or pounds, and the total weight, of the representative sample in grams;

(10) For cannabis product or pre-rolls samples, the total unit count of both the representative sample and the total batch size;

(11) Measured density of the cannabis and cannabis products, if applicable;

(12) The analytical methods, analytical instrumentation used, and corresponding Limits of Detection (LOD) and Limits of Quantitation (LOQ);

(13) An attestation on the COA from the laboratory supervisory or management-level employee that all LQC samples required by section 15730 were performed and met the acceptance criteria; and

(14) Analytes detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed, if any.

(f) The licensed laboratory shall report test results for each representative sample on the COA as follows:

(1) Indicate an overall “pass” or “fail” for the entire batch;

(2) When reporting qualitative results for each analyte, the licensed laboratory shall indicate “pass” or “fail”;

(3) When reporting quantitative results for each analyte, the licensed laboratory shall use the appropriate units of measurement as required under this chapter;

(4) When reporting results for each test method, the licensed laboratory shall indicate “pass” or “fail”;

(5) When reporting results for any analytes that were detected below the analytical method LOQ, indicate “<LOQ”, notwithstanding cannabinoid results;

(6) When reporting results for any analytes that were not detected or detected below the LOD, indicate “ND”; and

(7) Indicate “NT” for any test that the licensed laboratory did not perform.

(g) The licensed laboratory may not calculate or report cannabinoid content in any manner other than as described in this chapter.

~~(g)~~ (h) The licensed laboratory supervisory or management-level employee shall validate the accuracy of the information contained on the COA and sign and date the COA.

~~(h)~~ (i) The laboratory supervisory or management-level employee may request to amend a COA to correct minor errors. Requests must be emailed to the Department at testinglabs@cannabis.ca.gov for approval prior to making any corrections. Errors in results required to be reported pursuant to subsection (f) are not minor errors.

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

Article 6. Post Testing Procedures

§15728. Post Testing Sample Retention.

(a) The licensed laboratory shall retain the reserve sample, consisting of any portion of a sample that was not used in the testing process. The reserve sample shall be kept, at minimum, for ~~45~~ 60 business days after the analyses, after which time it may be destroyed and denatured to the point the material is rendered unrecognizable and unusable.

(b) The licensed laboratory shall securely store the reserve sample in a manner that prohibits sample degradation, contamination, and tampering.

(c) The licensed laboratory shall provide the reserve sample to the Department upon request.

Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

Article 7. Laboratory Quality Assurance and Quality Control

§ 15729. Laboratory Quality Assurance (LQA) Program.

(a) The licensed laboratory shall develop and implement an LQA program to assure the reliability and validity of the analytical data produced by the laboratory. The LQA program shall, at minimum, include a written LQA manual that addresses the following:

(1) Quality control procedures, including all standard operating procedures (SOPs) developed in accordance with section 15711;

(2) Laboratory organization and employee training and responsibilities, including good laboratory practice (GLP) and integration training;

(3) LQA objectives for measurement data;

(4) Traceability of data and analytical results. To ensure traceability of data:~~;~~

(A) Each analytical instrument must provide an audit trail that independently records all changes to electronic records, without obscuring the previous data;

(B) Each user of an analytical instrument must have their own unique username and password. Usernames and passwords may not be shared between laboratory employees; and

(C) If any paper records are created during testing, the transcription of those records must be reviewed by another laboratory employee and approved by a supervisory or management-level employee;

(5) Instrument maintenance, calibration procedures, and frequency;

(6) Reagent preparation, use, and storage;

~~(6)~~ (7) Performance and system audits;

~~(7)~~ (8) Corrective action procedures;

~~(8)~~ (9) Steps to change processes when necessary;

~~(9)~~ (10) Record retention and document control;

~~(10)~~ (11) Test procedure standardization; and

~~(11)~~ (12) Method validation.

(b) The supervisory or management-level laboratory employee shall annually review, amend if necessary, and approve the LQA program and manual both when they are created and when there is a change in methods, laboratory equipment, or the supervisory or management-level laboratory employee.

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

§ 15730. Laboratory Quality Control (LQC) Samples.

The licensed laboratory shall use LQC samples and adhere to good laboratory practice (GLP) in the performance of each analysis according to the following specifications.

(a) The licensed laboratory shall analyze LQC samples in the same manner as the laboratory analyzes cannabis and cannabis products samples.

(b) The licensed laboratory shall use at least one negative control, one positive control, and one laboratory replicate sample in each analytical batch for each target organism during microbial testing. If one of the controls produces unexpected results, the samples shall be re-prepped and reanalyzed with a new set of controls.

(c) If the result of the microbial analyses is outside the specified acceptance criteria in the following table, the licensed laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

Laboratory Quality Control Sample	*Acceptance Criteria*	*Corrective Action*
Positive control	Produces expected result, positive result	Re-prep and reanalyze the entire analytical batch, once. If problem persists, locate and remedy the source of unexpected result, then re-prep samples and reanalyze with a new set of controls.
Negative control	Produces expected result, negative result	Re-prep and reanalyze the entire analytical batch, once. If problem persists, locate and remedy the source of unexpected result, then re-prep samples and reanalyze with a new set of controls.
Laboratory replicate sample	Sample results must concur	Reanalyze sample and associated replicate sample once. If problem persists, re-prep samples and reanalyze.

(d) For each chemical analysis, the laboratory must have a valid calibration curve that meets the requirements of section 15713.

~~(d)~~ (e) The licensed laboratory shall prepare and analyze at least one of each of the following LQC samples for each analytical batch:

(1) Method blank;

(2) Laboratory control sample (LCS); and

(3) Laboratory replicate sample or matrix spike sample.

~~(e)~~(f) The laboratory shall analyze, at minimum, a continuing calibration verification (CCV) sample at the beginning of each analytical sequence, ~~and~~at every 10 sample~~s~~ injections thereafter, and at the end of each analytical sequence.

~~(f)~~ (g) If the result of the chemical analyses is outside the specified acceptance criteria in the following table, the laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

Laboratory Quality Control Sample	*Acceptance Criteria*	*Corrective Action*
Method blank sample	Not to exceed LOQ	Reanalyze entire analytical batch once. If method blank is still greater than the LOQ for any analyte, locate the source of contamination then re-prep samples and reanalyze.
LCS	Percent recovery 70% to 130%	Reanalyze the entire analytical batch, once. If problem persists, re-prep samples and reanalyze or re-run the initial calibration curve.
Laboratory replicate sample	RPD ≤30%	Reanalyze sample and associated replicate sample once. If problem persists, re-prep samples and reanalyze.
Matrix spike sample	Percent recovery ~~between~~ 70% to 130%	Reanalyze sample and associated matrix spike sample once. If problem persists, re-prep samples and reanalyze.
CCV	Percent recovery ~~between~~ 70% to 130%	Reanalyze all samples that followed the last CCV that met the acceptance criteria. If CCV still fails, re-run the initial calibration curve and all samples in the analytical sequence.
ICV	Percent recovery 70% to 130%	Reanalyze the ICV one time. If problem persists, re-run the initial calibration curve and ICV.

Calibration curve point	Percent accuracy 70% to 130%	Reanalyze the initial calibration curve.

~~(g)~~(h) If any analyte is detected above any action level, as described in this chapter, the sample shall be re-prepped and reanalyzed in replicate within another analytical batch.

(1) For quantitative analyses, the original sample, the re-prepped sample, and ~~its~~ the re-prepped sample's associated replicate must meet the acceptance criteria of RPD ≤30%. If the acceptance criteria are not met, then the licensed laboratory must request resampling as prescribed in section 15705(g).

(2) For qualitative analyses, the original sample, the re-prepped sample, and ~~its~~ the re-prepped sample's associated replicate results must concur. If the results do not concur, then the licensed laboratory must request resampling as prescribed in section 15705(g).

~~(h)~~(i) If any LQC sample produces a result outside of the acceptance criteria, the laboratory cannot report the result and the entire batch cannot be released for retail sale. The laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

~~(i)~~(j) If the licensed laboratory determines that the result is a false-positive or a false-negative, the Department may ask for the laboratory to re-sample or retest.

~~(j)~~(k) The licensed laboratory shall compile and generate one LQC sample report for each analytical batch that includes LQC acceptance criteria, measurements, analysis date, and matrix.

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

§15731. Limits of Detection (LOD) and Limits of Quantification (LOQ) for Quantitative Analyses.

(a) The licensed laboratory shall calculate the LOD for chemical method analyses ~~according to any of the following methods:~~ using the standard

~~(1) Signal-to-noise ratio of between 3:1 and 2:1;~~

~~(2) Standard~~ deviation of the response and the slope of calibration curve using a minimum of 7 spiked blank samples calculated as follows; LOD = (3.3 x standard deviation of the response) / slope of the calibration curve.~~;~~ ~~or~~

~~(3) A method published by the United States Food and Drug Administration (USFDA) or the United States Environmental Protection Agency (USEPA).~~

(b) For chromatographic analyses, the LOD must have a minimum signal-to-noise ratio of 3:1, which must be verified by visual inspection. For non-chromatographic analyses, the LOD must have a minimum signal-to-noise ratio of 3:1, which must be verified by software analysis or mathematical calculation.

(c) The licensed laboratory shall calculate the LOQ for chemical method analyses ~~according to any of the following methods:~~ using the standard

~~(1) Signal-to-noise ratio of 10:1, at minimum;~~

~~(2) Standard~~ deviation of the response and the slope using a minimum of 7 spiked blank samples calculated as follows:

LOQ = (10 x standard deviation of the response) / slope of the calibration curve.~~;~~ ~~or~~

~~(3) A method published by the USFDA or the USEPA.~~

(d) For chromatographic analyses, the LOQ must have a minimum signal-to-noise ratio of 10:1, which must be verified by visual inspection. For non-chromatographic analyses, the LOQ must have a minimum signal-to-noise ratio of 10:1, which must be verified by software analysis or mathematical calculation.

(e) If the LOD or LOQ is outside the specified acceptance criteria, then the laboratory must take corrective action to bring the result within the specific acceptance criteria.

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

§15733. Required Proficiency Testing.

(a) ~~The~~Each licensed laboratory shall annually, successfully participate in a proficiency testing program, provided by an organization that ~~operates in conformance~~ complies with the requirements of ISO/IEC 17043, for the following test methods: ~~at least once every six months.~~

~~(b) The licensed laboratory shall annually, successfully participate in a proficiency testing program for each of the following test methods:~~

(1) Cannabinoids;

(2) Heavy metals;

(3) Microbial impurities;

(4) Mycotoxins;

(5) Residual pesticides;

(6) Residual solvents and processing chemicals; ~~and~~

(7) If tested, terpenoids~~.~~; and

(8) Vitamin E acetate.

(b) For purposes of this section, “annually” means:

(1) Licensed laboratories are required to participate in a program described in subsection (a) each calendar year, and

(2) All required proficiency program tests initiated by a licensed laboratory during a given calendar year must be completed within that same calendar year.

(c) The licensed laboratory shall report all analytes ~~available by the proficiency testing program provider and~~ for which the licensee is required to test~~, as required~~ under this chapter.

(d) The licensed laboratory shall participate in the proficiency testing program by following the laboratory’s existing SOPs for testing cannabis and cannabis products.

(e) The licensed laboratory shall rotate the responsibility for participating in the proficiency testing program among ~~the~~ laboratory employees who are trained to perform one or more ~~the~~ test methods to ensure that they remain proficient. The licensed laboratory shall also rotate proficiency testing across different testing equipment and methodologies to ensure comprehensive validation of all testing platforms and techniques.

(f) Laboratory employees who participate in a proficiency testing program shall sign the corresponding analytical reports or attestation statements to certify that the proficiency testing ~~program~~ was conducted in the same manner as the regular laboratory testing~~s~~ of cannabis and cannabis products.

(g) A supervisory or management-level laboratory employee shall review and verify the accuracy of results reported for all proficiency testing ~~program~~ samples analyzed.

(h) The licensed laboratory shall request that the proficiency testing program providers send results ~~concurrently~~ to the Department, in addition to the laboratory. ~~if available, or the laboratory shall provide the proficiency testing program results to the Department within 3 business days after the laboratory receives notification of their test results from the proficiency testing program provider. Any results shall be reported by submitting the Licensee Notification and Request Form, Notifications and Requests Regarding Testing Laboratories, DCC-LIC-029 (New 2/22), which is incorporated herein by reference.~~

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26100 and 26110, Business and Professions Code.

Article 8. Laboratory Employee Qualifications

§ 15737. Supervisory or Management-level Employee Responsibilities and Qualifications.

(a) ~~The~~Each licensed laboratory ~~shall~~must employ a supervisory or management-level employee who ~~must~~will be responsible for:

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

(2) Ensuring that the licensed laboratory achieves and maintains a laboratory quality assurance program as required by section 15729; ~~and~~

(3) Reviewing, approving, and signing COAs; and

~~(3)~~ (4) Providing ongoing and appropriate training to laboratory employees.

(b) To be considered qualified, the supervisory or management-level employee must have, at minimum:

(1) A doctoral degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university;

(2) A master's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least 2 years of full-time practical experience;

(3) A bachelor's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least 4 years of full-time practical experience; or

(4) A bachelor's degree in any field from an accredited college or university, plus at least 8 years of full-time practical experience, 4 years of which must have been in a supervisory or management-level position.

(c) Within five business days after hiring a new supervisory or management-level employee, the licensed laboratory must submit records satisfactorily demonstrating that individual's qualifications to the Department at testinglabs@cannabis.ca.gov, along with a completed Licensee Notification and Request Form, Notifications and Requests Regarding Testing Laboratories, DCC-LIC-029 (Rev. XX/25), which is incorporated herein by reference.

NOTE: Authority cited: Section 26013, Business and Professions Code. Reference: Sections 26102 and 26104, Business and Professions Code.