Section I
Notice of Development of Proposed Rules and Negotiated Rulemaking

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Division of Consumer Services

RULE NOS.:	RULE TITLES:
5J-18.0012	Bureau of Fair Rides Inspection Forms
5J-18.002	Annual Permit or Temporary Amusement Ride Permit, Request for Re-Inspection, USAID Number
5J-18.003	Qualified Inspectors
5J-18.004	Nondestructive Testing of Amusement Rides
5J-18.0142	Reporting of Accidents and Mechanical, Structural or Electrical Defects

PURPOSE AND EFFECT: The purpose of this rulemaking is to modify an incorporated form and update material references in accordance with those changes. The amendments will also clarify language for permanent amusement ride permitting and align accident reporting and reinspection language with other reporting criteria outlined in statute.

SUBJECT AREA TO BE ADDRESSED: The Fair Rides Affidavit of Compliance and Non-destructive Testing (NDT) form is being modified to address public comments following statutory changes that took effect on July 1, 2023. Changes will also clarify the language regarding permitting of permanent amusement rides and further define requirements for amusement rides whereby an accident occurs due to a structural, mechanical or electrical defect.

RULEMAKING AUTHORITY: 616.165, 616.242(3)(p), (q), (4), (4)(b), (5), (6), (7), (8), (11)(a)1., (12), (15), (16), (17) FS.

LAW IMPLEMENTED: 616.242, (3)(p) and (q), (4), (4)(b), (5), (6), (7), (8), (11)(a)1., (12), (15), (16), (17) FS.

A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: May 21, 2025, 10:00 a.m.

PLACE: Andretti Indoor Karting & Games, 9299 Universal Blvd., Orlando, FL 32819

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 3 days before the workshop/meeting by contacting: Michelle Faulk at (850)410-3838. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Michelle Faulk, Bureau of Fair Rides Inspection, 2005 Apalachee Parkway, Tallahassee, Florida, 32399-6500, phone (850)410-3838.

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS AVAILABLE AT NO CHARGE FROM THE CONTACT PERSON LISTED ABOVE.

FISH AND WILDLIFE CONSERVATION COMMISSION

Marine Fisheries

RULE NO.:	RULE TITLE:
68B-2.012	Tagging of Marine Organisms

PURPOSE AND EFFECT: The purpose of this rulemaking is to update regulations related to the tagging of marine organisms and make them easier for the public to locate within the rule chapters related to marine fisheries. This rule development is linked to the rule development for the Marine Special Activities License (SAL) rule chapter (68B-8, F.A.C.). The effect of this rulemaking would be to move regulations related to the tagging of marine organisms from Marine SAL program rule 68B-8.003, F.A.C., into the general marine fisheries rule chapter, 68B-2, F.A.C.

SUBJECT AREA TO BE ADDRESSED: The subject areas addressed in the rule development notice include definitions, requirements, and exemptions related to the tagging of marine organisms.

RULEMAKING AUTHORITY: Art. IV, Sec. 9, Florida Constitution.

LAW IMPLEMENTED: Art. IV, Sec. 9, Florida Constitution.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Jessica McCawley, Director, Division of Marine Fisheries Management, Florida Fish and Wildlife Conservation Commission, 620 S. Meridian St., Tallahassee, Florida 32399, and (850)487-0554.

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS AVAILABLE AT NO CHARGE FROM THE CONTACT PERSON LISTED ABOVE.

FISH AND WILDLIFE CONSERVATION COMMISSION

Marine Fisheries

RULE NOS.:	RULE TITLES:
68B-8.001	Introduction and Scope
68B-8.002	Definitions
68B-8.003	General Conditions and Restrictions

68B-8.005	Third Party Contractors
68B-8.006	Scientific Research Special Activity License
68B-8.007	Education/Exhibition Special Activity License
68B-8.008	Florida Marine Science Educators Association Certification
68B-8.009	Prohibited Species Collection Criteria
68B-8.010	Stock Collection and Release Special Activity License
68B-8.011	Aquaculture Broodstock Collection Special Activity License
68B-8.012	Snook Special Activity License
68B-8.013	Non-Conforming Gear Special Activity Licenses and Exemptions
68B-8.014	Marine Chemical Special Activity License
68B-8.016	Commission Activities and Agreements

PURPOSE AND EFFECT: The purpose of this rulemaking is to improve the operation of the Marine Special Activity License (SAL) program, update and modernize rule language, meet evolving program needs, improve and streamline the licensing process, and provide greater transparency to applicants. The effect of these changes would be to reduce administrative burdens on applicants and license holders, provide additional information to increase transparency, implement changes to meet evolving program needs, and expand the types of activities that may be authorized through the SAL program.

SUBJECT AREA TO BE ADDRESSED: The subject areas addressed in the rule development notice include definitions, general conditions and restrictions, third party contractors, prohibited species, the Florida Marine Science Educators Association Certification, as well as eligibility requirements, evaluation criteria, license periods, and license conditions for several SAL types, and other subjects encompassed by the above-cited rules.

RULEMAKING AUTHORITY: Art. IV, Sec. 9, Florida Constitution.

LAW IMPLEMENTED: Art. IV, Sec. 9, Florida Constitution.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Jessica McCawley, Director, Division of Marine Fisheries Management, Florida Fish and Wildlife Conservation Commission, 620 S. Meridian St., Tallahassee, Florida 32399, and (850)487-0554.

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS AVAILABLE AT NO CHARGE FROM THE CONTACT PERSON LISTED ABOVE.

Section II
Proposed Rules

DEPARTMENT OF HEALTH

RULE NOS.:	RULE TITLES:
64-4.300	CMTL Definitions
64-4.301	Requirements for CMTL Certification and Application
64-4.302	Renewal Application Requirements for CMTLs
64-4.303	CMTL Testing
64-4.304	CMTL On-Site Inspection
64-4.305	CMTL Standard Operating Procedures
64-4.306	CMTL Testing Methods
64-4.307	CMTL Submission for Product Testing
64-4.308	CMTL Sample Testing
64-4.309	CMTL Quality Control Samples
64-4.310	CMTL Calibration Standards
64-4.311	CMTL Certificate of Analysis
64-4.312	CMTL Manual Integration
64-4.313	CMTL Waste Management and Disposal
64-4.314	CMTL Background Screening
64-4.315	CMTL Fines, Suspension, and Revocation

PURPOSE AND EFFECT: This rulemaking initiates nonemergency rulemaking to replace the emergency rules (64ER20-1, 64ER20-3, 64ER20-4, 64ER20-6, 64ER20-7, 64ER20-10, 64ER20-11, 64ER20-12, 64ER20-14, 64ER20-15, 64ER20-38, 64ER20-39, 64ER21-6, 64ER22-5, 64ER22-6) adopted by the Department to implement sections 381.986 and 381.988, Florida Statutes.

SUMMARY: Rule 64-4.300, F.A.C. supersedes and amends Emergency Rule 64ER20-1 by providing additional definitions necessary to clarify and interpret the rules relating to certified marijuana testing laboratories (CMTLs). Rule 64-4.301, F.A.C., supersedes and amends Emergency Rule 64ER20-14 by updating the CMTL initial application fee and providing additional requirements on a CMTL's Quality Assurance program and tracking system capabilities. Rule 64-4.302, F.A.C., supersedes and amends Emergency Rule 64ER22-6 by clarifying the requirements and process for the renewal of a CMTL certification. Rule 64-4.303, F.A.C., supersedes and amends Emergency Rule 64ER20-3 by updating the procedures and requirements for Proficiency Testing conducted by CMTLs. Rule 64-4.304, F.A.C., supersedes and amends Emergency Rule 64ER20-4 by clarifying procedures relating to the Department's inspections of a CMTL. Rule 64-4.305, F.A.C., supersedes and amends Emergency Rule 64ER20-6 by clarifying the requirements for Standard Operating Procedures created by CMTLs. Rule 64-4.306, F.A.C., supersedes and amends Emergency Rule 64ER20-7 by clarifying the permissible testing methods to be used by CMTLs. Rule 64-4.307, F.A.C., supersedes and amends Rule 64ER20-38 by

clarifying and adding requirements for the collecting, tracking, transporting, and storing samples of Final Products from medical marijuana treatment centers for Regulatory Compliance Testing by CMTLs. Rule 64-4.308, F.A.C., supersedes amends Emergency Rule 64ER20-39 by clarifying and updating requirements for sample testing of Final Products by CMTLs. Rule 64-4.309, F.A.C., supersedes and amends Emergency Rule 64ER20-10 by clarifying and updating requirements for quality control samples used by CMTLs. Rule 64-4.310, F.A.C., supersedes and amends Emergency Rule 64ER20-11 by clarifying the requirements for calibration standards and Limit of Detection determinations made by CMTLs. Rule 64-4.311, F.A.C., supersedes and amends Emergency Rule 64ER20-12 by enhancing and clarifying requirements for Certificates of Analysis generated by CMTLs. Rule 64-4.312, F.A.C., establishes guidelines and requirements for performing, documenting, and reviewing integrations and chromatography conducted by a CMTL. Rule 64-4.313, F.A.C., supersedes and amends Emergency Rule 64ER21-6 by clarifying procedures for managing and disposing of waste by CMTLs. Rule 64-4.314, F.A.C., supersedes and amends Emergency Rule 64ER20-15 by clarifying requirements for the level 2 background screenings of CMTL employees, owners, and managers as required by section 381.988, F.S. Rule 64-4.315, F.A.C., supersedes and amends Emergency Rule 64ER22-5 by establishing guidelines related to fines, suspension, and revocation imposed upon a CMTL for violations of rule and statute.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:

Pursuant to Chapter 2022-157, § 18 at 16, Laws of Florida, rules adopted under the nonemergency rulemaking procedures of the Administrative Procedures Act to replace emergency rules adopted by July 1, 2022, are exempt from ss. 120.54(3)(b) and 120.541, Florida Statutes. Rules 64-4.300-4.311 and 4.313-4.315, F.A.C. are subject to this provision.

The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: A SERC has not been prepared by the agency. For rules listed where no SERC was prepared, the Agency prepared a checklist for each rule to determine the necessity for a SERC. Based on this information at the time of the analysis and pursuant to section 120.541, Florida Statutes, the rule will not require legislative ratification.

Any person who wishes to provide information regarding a statement of estimated regulatory costs or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: Art. X, § 29, Fla. Const., 381.986(8)(e)11.d., 381.986(8)(k), 381.988(2), 381.988(3), 381.988(9), 943.05(2)(h)3., FS.

LAW IMPLEMENTED: Art. X, § 29, Fla. Const., 381.986, 381.988, 943.05, FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Office of Medical Marijuana Use at OMMURules@flhealth.gov.

THE FULL TEXT OF THE PROPOSED RULE IS:

64-4.300 CMTL Definitions.

The following words and phrases have the meanings provided below and apply to Rules 64-4.301-4.315, F.A.C.:

(1) Acceptable Limit – The maximum concentration allowed for a specified Target Analyte.

(2) AFRNP - The Applicant Fingerprint Retention and Notification Program authorized by section 943.05(2)(b), F.S., and established by the Florida Department of Law Enforcement, as provided in Rule 11C-6.010, F.A.C.

(3) Agricultural Agents – Any pesticide, herbicide, fungicide, fertilizer, synergist, or root stimulant applied to the plant or substrate, at any stage of cultivation or processing.

(4) Analyst – An Employee of an Applicant or CMTL whose duties include conducting analyses on analytical instrumentation, analyzing and recording results, maintaining testing-related workspaces and equipment, and maintaining marijuana Samples.

(5) Analytical Batch – A group of no more than 30 Analytical Samples, which behave similarly with respect to the sampling or the testing procedures being employed, that are prepared together by the same Analyst during the same work shift.

(6) Analytical Method – An approved method, as provided in Rule 64-4.306, F.A.C., that is used for the testing and analysis of Analytical Samples.

(7) Analytical Sample – A Testing Sample that has undergone all preparatory procedures specified within the Analytical Method and is in a form to be analyzed.

(8) Applicant – An individual or entity that seeks certification as a CMTL pursuant to s. 381.988(2), F.S., and Rule 64-4.301, F.A.C.

(9) Automatic Integration – The process used by chromatographic software using defined parameters for integration to determine peak area or height used for quantitation.

(10) Baseline – The recorded response in a chromatograph when only the mobile phase, background noise, and Matrix signal are detected.

(11) Baseline Resolution – The amount of resolution between adjacent peaks at which the detector signal will drop to the baseline.

(12) Calibration – The set of analyses that establish, under conditions specified in the analysis SOP, the relationship between values of quantities indicated by the measuring instrument or measuring system, or values represented by a material measure of a Certified Reference Material, and the corresponding values realized by standards.

(13) Calibration Curve – The mathematical relationship between the known values, such as the concentrations of a series of Calibration Standards, and their instrument response, prepared at multiple concentrations that cover the working range of the instrument.

(14) Calibration Drift – A calculation used to measure the change in accuracy of the Calibration Curve over time, calculated for the CCV as

$$\left(\frac{(CCV\ quantitative\ results\ -\ CCV\ known\ value)}{CCV\ known\ value}\right) x\ 100$$

and for the ICV as

$$\left(\frac{(ICV\ quantitative\ result\ -\ ICV\ known\ value)}{ICV\ known\ value}\right) x\ 100$$

(15) Calibration Standard – A Certified Reference Material used to calibrate an instrument.

(16) Cannabinoid Profile – An analysis conducted to determine the level of concentration of d9-THC, d8-THC, THCA, THCV, CBD, CBDA, CBDV, CBG, CBGA, CBN, and CBC in a Final Product.

(17) Certificate of Analysis (COA) – A document created by a CMTL that certifies the quality and purity of the tested Final Product and meets the requirements of the CMTL Certificate of Analysis rule.

(18) Certified Marijuana Testing Laboratory (CMTL) – A laboratory that has been certified by the department to collect and analyze marijuana samples from an MMTC pursuant to s. 381.988, F.S., and Rule 64-4.301, F.A.C.

(19) Certified Reference Material – A material characterized by a metrologically valid procedure performed by an ISO/IEC 17034:2017 accredited provider for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

(20) Contaminants Unsafe for Human Consumption – Any Microbe, Mycotoxin, Agricultural Agent, Residual Solvent, Heavy Metal, Moisture, Water Activity, or Filth and Foreign Material found in an amount that exceeds any of the department's Acceptable Limits.

(21) Continuing Calibration Verification (CCV) – A traceable standard solution from an ISO/IEC 17034:2017 accredited Certified Reference Material provider containing all Target Analytes in the Calibration Curve. These standards are used to check the drift of a Calibration Curve on a daily basis (before the analysis and every 12 hours thereafter or after every 10 Injections, whichever occurs first).

(22) Control – Voting power which includes the power to vote, or the power to direct the voting, of an Owner's interest.

(23) Cultivar – A variety, strain, or race that has originated and persisted under cultivation and has been developed through artificial selection for specific morphological, physiological, or chemical characteristics.

(24) Data Packages – Analytical testing data that is collected and prepared by a CMTL and contains information about the testing performed, Quality Assurance and Quality Control data, and the results of any tests performed.

(25) Data Reduction - The transformation of raw analytical results into corrected and ordered Target Analyte concentrations using Analytical Sample acceptance/rejection criteria, peak integration, Quality Control Samples, Calibration Curves, CCVs, ICVs, Surrogates, and Internal Standards.

(26) Derivative Batch – A portion of Derivative Product that contains the same product type and was processed using the same methods, SOPs, equipment, and ingredients.

(27) Derivative Product – Usable product created from marijuana, infused with marijuana, or that otherwise includes or contains marijuana.

(28) Dilution Factor – the ratio by which the concentration of an Analytical Sample is reduced by dilution with a Target-Analyte-free solvent.

(29) Duplicate – The second instance of the same Analytical Sample or Quality Control Sample being analyzed within one Analytical Batch.

(30) Edible – Derivative Product that is a commercially produced food item made with, or infused with, marijuana oil, but no other form of marijuana, that is produced and dispensed by an MMTC. The term "Edible" includes any Derivative Product made with, or infused with, marijuana oil that otherwise meets the definition of "food" in s. 500.03, F.S. and complies with the Standards for Production of Edibles rule. The term does not include pills, capsules, tinctures, topicals, and similar Derivative Products.

(31) Employee – Any person whose duties or activities involve any aspect of Regulatory Compliance Testing or research and development (R&D) testing of marijuana for a CMTL, whether or not they are compensated for their work.

(32) Environmental Contaminant Testing – Physical and chemical testing analyses, to include Heavy Metals, Agricultural Agents, Residual Solvents, Moisture, Water Activity, and Mycotoxins.

(33) Filth and Foreign Materials – Mold, mildew, hair, insects, feces, manufacturing waste, or marijuana cultivation and manufacturing by-products.

(34) Final Product – Any Usable Whole Flower Marijuana or Derivative Product in its receptacle and final, labeled form intended for use by a qualified patient, to include all parts consumed (i.e., gel-capsule, rolling papers) during administration.

(35) Flower Batch – A portion of Usable Whole Flower Marijuana of uniform Cultivar, cultivated with the same Agricultural Agents, and harvested at the same time.

(36) Formulation – The specific combination of ingredients combined to produce a Final Product.

(37) Gas Chromatography – An analytical technique used to separate and analyze the chemical components of a Sample mixture by vaporization.

(38) Heavy Metals – A metallic chemical element that has a relatively high density and is toxic or poisonous at low concentrations.

(39) Increment – A subsample taken from an Edible for the purposes of homogeneity testing.

(40) Initial Calibration Verification (ICV) – A traceable Calibration Standard from a second ISO/IEC 17034:2017 accredited Certified Reference Material provider or separate production lot from the same provider, different from the Calibration Curve lot, containing all Target Analytes in the Calibration Curve. These standards are used to check the Calibration Drift of a Calibration Curve.

(41) Initial Display of Competency (IDOC) – An assay used to determine whether an Employee can correctly, accurately, and repeatedly perform a specific analysis or preparation, or analyze a specific measurement.

(42) Injection – The introduction of an Analytical Sample or any other substance into an analytical instrument for the purposes of analysis, Calibration, or Quality Control.

(43) Interest – Any form of ownership in, or Control of, an Applicant, a CMTL, or MMTC. This includes, but is not limited to, ownership of stock, membership interests, partnership interests, a sole proprietorship, or that which otherwise conveys to the holder thereof an ownership right, interest in, or right to the profits, capital, or voting rights with respect to such Applicant, CMTL, or MMTC.

(44) Internal Audit - A review conducted by the CMTL to ensure the CMTL has the proper controls, governance, and risk management processes required for operation in accordance with ISO17025:2017 and sections 381.986 and 381.988, F.S., and department rules. This review should include, at a minimum, audits on SOPs, data retention and traceability, employee training, sampling, consumable handling, and security.

(45) Internal Standard – A pure Target Analyte of known concentration, not expected to be found in the Testing Samples, added to the Analytical Samples before analysis and used to measure the relative response of other Target Analytes and Surrogates to correct for variations.

(46) Investor – Any person who, directly or indirectly, owns a legal or equitable Interest (actually or beneficially), or Controls less than a 5% share of Interests of an Applicant or CMTL.

(47) Laboratory Batch – A series that includes the Analytical Batch as well as all applicable Quality Control Samples, to include one Method Blank, duplicate Laboratory Fortified Blanks, duplicate Matrix Spike Samples, and at least one duplicate Sample for Mycotoxins, Residual Solvents, Agricultural Agents, Cannabinoid Profile, and Heavy Metals.

(48) Laboratory Director – An individual who oversees all Analysts, Employees, Managers, and the functions of testing Usable Whole Flower Marijuana, Derivative Product, and Edibles at only one physically independent Testing Facility operated by the CMTL.

(49) Laboratory Fortified Blank – A Quality Control Sample, created using a Matrix similar to the Testing Sample Matrix, and initially without Target Analytes, prepared along with Testing Samples, that have been amended with a known concentration of a Target Analyte or analytes for competency assessment purposes.

(50) Limit of Detection (LOD) – The lowest quantity of a Target Analyte that can be distinguished from the absence of that Target Analyte within a stated confidence limit. The LOD must be $1/5^{th}$ of the Acceptable Limit or less with an instrument signal-to-noise ratio of 3:1 or greater for each Target Analyte tested.

(51) Limit of Quantitation (LOQ) – The minimum concentration of a Target Analyte in a specific Matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision. The LOQ must be equal to ½ the Acceptable Limit or less, with an instrument Signal-to-noise Ratio of 10:1 or greater for each Target Analyte tested.

(52) Liquid Chromatography – An analytical technique used to separate and analyze the chemical components of a Sample mixture that are dissolved in a solvent.

(53) Livescan Service Provider – A vendor, entity, or agency authorized by s. 943.053(13), F.S., that scans fingerprints electronically and submits them to FDLE.

(54) Manager – Any person with direct or indirect authority to exercise or contribute to the operational control, direction, or management of an Applicant or a CMTL or who has direct or indirect authority to supervise any Employee of an Applicant or

a CMTL. The term includes all officers, Laboratory Directors, and members of the board of directors, as well as any other person engaged to undertake management or Control of the Applicant or a CMTL, or any person in Control of an entity engaged to undertake management or Control of the Applicant or CMTL.

(55) Manual Integration - The process employed by the Analyst to integrate peak height or area by manually setting the baseline, splitting chromatographic peaks, or identifying a peak using chromatographic software.

(56) Matrix – The component or substrate containing a Target Analyte(s).

(57) Matrix Group – The components of a Testing Sample other than the Target Analytes.

(58) Matrix Spike Sample – An aliquot from a Testing Sample, which has been amended with a known concentration of a Target Analyte(s) to test for potential Matrix interference.

(59) Method Blank – A Target Analyte-free Matrix (e.g., plant material, oil, or food product similar to Edible being tested) which is carried through the complete preparation and analytical procedure, and measures no Target Analytes above the LOD, used to evaluate contamination resulting from the complete analytical procedure.

(60) Metered Dose Inhalers (MDI) – A pressurized canister of Derivative Product intended to be inhaled through the mouth that, when sprayed, gives a reliable, consistent dose.

(61) Microbe – Any microscopic organism, including bacteria and fungi.

(62) Microbiological Contaminant Testing – The analysis of microbes.

(63) Medical Marijuana Treatment Center (MMTC) – Any individual or entity licensed by the department pursuant to s. 381.986, F.S.

(64) Moisture – The total amount of water present in a Sample, calculated as a percentage of weight.

(65) Mycotoxins – Any toxin produced by a fungus.

(66) Non-Oral Transmucosal Product – A Derivative Product with routes of administration other than oral and heated inhalation, to include, but not limited to, nasal and throat sprays, MDI, suppositories, and similar transmucosal routes of administration.

(67) Owner – Any person who, directly or indirectly, owns a legal or equitable Interest (actually or beneficially), or otherwise Controls, any share of Interests of the Applicant or CMTL. In the event that one person owns a beneficial right to Interests and another person holds the voting rights with respect to such Interests, both persons are the Owner of such Interests. In determining who are Owners of the Applicant or a CMTL, the attribution of ownership rules set forth in the Treasury Regulations cited as 26 C.F.R. § 1.414(c)-4(b) and (c) (4-1-19 edition), incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX, apply with the following modifications:

(a) The use of the term "Option" in 26 C.F.R. § 1.414(c)-4(b) shall be interpreted broadly to include, without limitation, options, warrants, calls, rights of first refusal and any other right to acquire an Interest (as defined herein), whether such right is vested or unvested and regardless of whether such right is then exercisable or becomes exercisable at a future date or upon the occurrence of a future event.

(b) The exception for attribution of a spouse's interest, as set forth in 26 C.F.R. § 1.414(c)-4(b)(5)(ii), does not apply. The term "Interest" as used in 26 C.F.R. § 1.414(c)-4(b)(6) shall have the meaning as set forth in subsection (43) above.

(c) The age limitation contained in 26 C.F.R. § 1.414(c)-4(b)(6) applies only to children who have not attained the age of 18 years. The term "Interest" as used in 26 C.F.R. § 1.414(c)-4(b)(6) shall have the meaning as set forth in subsection (43) above.

(d) If a person under the age of 18 owns or is deemed an Owner of an Interest, such person must be disclosed to the department. Persons under the age of 18 must submit to a background screening only in the event that the Interest or ownership was not imputed to another family member or guardian.

(e) As used in 26 C.F.R. § 1.414(c)-4(b)(3), the term "Actuarial Interest" shall be interpreted broadly and shall include, but not be limited to, the right of a beneficiary of a trust or an estate to receive either income or principal distributions with respect to an Interest held by such trust or estate.

(f) With regard to publicly traded companies with ownership Interests in the Applicant or CMTL, any person who holds 5% or more Interest in the publicly traded company is an Owner.

(68) Peak Enhancement – The action of adding to the integrated peak area, usually by integrating along the baseline that is not part of the target peak or lowering the integrated area below the baseline.

(69) Peak Shaving – The action of removing area from the integrated peak area, usually by raising the integration area above the baseline, or not integrating the entire width of the peak.

(70) Percent Recovery – A calculation of the recovery of spiked analytes in Laboratory Fortified Blanks and Matrix Spike Quality Control Samples, calculated as:

$$Percent\ Recover = \left(\frac{|quantitative\ result - theoretical\ concentration|}{theoretical\ concentration}\right) x\ 100$$

(71) Potency Testing – The analysis of the relative strength of cannabinoids, and the total amount, in milligrams.

(72) Proficiency Testing – Testing by an Applicant or CMTL of unknown samples supplied to the Applicant or CMTL by an ISO/IEC 17043:2023 accredited body to determine the

accuracy of the analysis for specific Target Analytes and Matrix Groups.

(73) Quality Assurance – A set of procedures developed by an Applicant or CMTL to ensure that products and services delivered are as accurate and precise as possible.

(74) Quality Assurance Manual – A written collection of all Quality Assurance systems or protocols to include the management policies, objectives, principles, organizational structure and authority, responsibilities, and implementation of an Applicant or CMTL to ensure the quality and utility of the service rendered.

(75) Quality Control – A set of procedures developed in accordance with ISO/IEC 17025:2017 standards, to verify that the required level of quality in analyses are met and maintained, including determination that appropriate equipment and instruments are used, continued inspection and overview of all facets of the testing procedure, and undertaking corrective action as necessary.

(76) Quality Control Samples – Samples analyzed along with Analytical Samples to ensure accurate instrument analysis and proper Analytical Sample preparation, to include Method Blanks, Laboratory Fortified Blanks, Matrix Spikes, Duplicates, CCV, and ICV.

(77) Reagent – A compound or mixture used in a chemical analysis to cause a chemical reaction or test if a reaction occurs.

(78) Receptacle – The container, canister, or material that comes into direct contact with the usable product. In the case of some derivative products, "receptacle" means the container, canister, or material that comes into direct contact with the usable derivative product's immediate covering (e.g., a vape cartridge that contains derivative product). In the case of edibles, "receptacle" means the container, canister, or material that comes into direct contact with the individually wrapped edible. Where the usable product is dispensed inside of a marijuana delivery device (e.g., a vape pen that contains derivative product), the receptacle means the container, canister, or material that comes into direct contact with the delivery device.

(79) Regulatory Compliance Testing – The testing of a representative sample of Final Products in a Retail Batch for the required Cannabinoid Profile, Potency Testing, Microbiological Contaminant Testing, Mycotoxins, Heavy Metals, Residual Solvents, Agricultural Agents, Moisture, Water Activity, Homogeneity, and Filth and Foreign Material Testing Fields to comply with all requirements in Rule 64-4.308, F.A.C.

(80) Relative Percent Difference (RPD) – A calculation of the precision of the measured recovered concentration of duplicate Laboratory Fortified Blanks, duplicate Matrix Spike Samples, or duplicate Testing Samples, calculated as:

$$RPD = \left(\frac{|quantitative\ result\ A\ -\ quantitative\ result\ B|}{\frac{(quantitative\ result\ A\ +\ quantitative\ result\ B)}{2}} \right) x\ 100$$

(81) Remediation - Additional processing steps completed by an MMTC to transform a Retail Batch that has failed Regulatory Compliance Testing into new Final Product(s). The new Final Product(s) created from the failed Retail Batch must pass all required Regulatory Compliance Testing to be considered successfully remediated by the MMTC.

(82) Residual Solvents – Volatile chemicals used during the manufacturing of a Final Product, which have not been completely removed by practical manufacturing techniques.

(83) Retail Batch – A portion of one Flower Batch or one Derivative Batch that is used to create a Final Product that consists of one product type at one concentration and one volume or weight, is intended to have a defined and uniform character and quality, and is produced during the same cycle of manufacture.

(84) Retention Time – A measure of the time taken for a solute to pass through a chromatography column and be measured on the instrument detector.

(85) Retention Time Window – A specified amount of time variation from the expected retention time from a chromatographic peak, outside of which the identification of the peak, compared to a known standard, is brought into question.

(86) Sample – A group of individual Final Products collected by a CMTL from an MMTC for the purposes of Regulatory Compliance Testing by the CMTL.

(87) Sampler – An Employee of a CMTL who collects Samples of marijuana from an MMTC for testing and has undergone required training to fulfill this function.

(88) Secure Storage – The segregation of Usable Whole Flower Marijuana, Derivative Product, or Edibles in a manner that prevents access by unauthorized persons, compromise of the product's integrity, or premature spoilage.

(89) Signal-to-noise Ratio – The ratio of the power of a Target Analyte response to the power of background response.

(90) Spike Solution – A solution of Target Analytes of known concentrations that is used to fortify a Laboratory Fortified Blank or Matrix Spike Sample. For Analytical Methods with multiple Target Analytes, a representative number of Target Analytes may be chosen for the Spike Solution.

(91) Standard Operating Procedure (SOP) – Written documents that detail the techniques and procedures of methods of an operation, analysis, or action appropriate as a method of performing certain routine or repetitive tasks.

(92) Standard Solution – A solution created with a Certified Reference Material obtained from an ISO/IEC 17034:2017 accredited provider, containing a known concentration of a substance or substances that is used to

determine the concentration of that same substance or substances and used to create Standard Curves and Spike Solutions.

(93) Surrogate – A Target Analyte or mix of Target Analytes that behave similarly to the Target Analyte but are not expected in the Analytical Sample, may be added to all Testing and Quality Control samples before Testing Sample preparation to measure Analytical Method efficiency.

(94) Synthetic Derived Cannabinoids – Any Cannabinoid created by reacting an intermediate with solvent or acid to derive a new Cannabinoid. The only approved reactions are the use of heat to convert THCA to THC, THC to CBN, and CBDA to CBD.

(95) Tamper-evident Device – A mechanism that makes unauthorized access to protected objects easily detectable.

(96) Target Analyte – A substance or chemical constituent to be quantitatively measured in an Analytical Method.

(97) Testing Facility – The location of a real property or the area within a real property to be utilized as a CMTL.

(98) Testing Field – The suite of Target Analytes tested within a Matrix Group.

(99) Testing Sample – A homogenized sample for analysis created from a Sample.

(100) Total Active CBD - The concentration of CBD + (concentration of CBDA multiplied by 0.877) in milligrams per gram or milligrams per milliliter multiplied by the labeled size of the product in grams or milliliters.

(101) Total Active THC - The concentration of delta-9 THC + the concentration of delta-8 THC + the concentration of CBN + (concentration of THCA multiplied by 0.877) in milligrams per gram or milligrams per milliliter multiplied by the labeled weight of the product in grams or milliliters.

(102) Total Combined Yeast and Mold – The total detected yeast, mold, and other fungi in Final Products.

(103) Total Contaminant Load (TCL) – The sum of all Heavy Metals and Agricultural Agents present in an amount above the LOQ but below the Acceptable Limit.

(104) Unique Identifier – A string of alpha-numeric characters used to differentiate between different Samples during the Regulatory Compliance Testing process, including but not limited to during sampling, analysis, and reporting. A Unique Identifier cannot be used to identify more than one Sample.

(105) Usable Whole Flower Marijuana – The flowers of the female cannabis plant, including low-THC cannabis, that is suitable to be dispensed from an MMTC for use by a qualified patient. Usable Whole Flower Marijuana does not include seeds, stems, roots, leaves, resin extracted from any part of the plant, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. Usable Whole Flower Marijuana is not considered a Derivative Product. Products consisting of mechanically separated trichomes with no solvent extraction step (i.e., kief, bubble hash, pressed rosin) are to be sampled and tested to the same requirements as Usable Whole Flower Marijuana.

(106) Water Activity – The measure of the quantity of free water in a product that is available and, therefore, capable of supporting bacteria, yeasts, mold, and fungi.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(2), 381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const., 381.988, FS. History–New.

64-4.301 Requirements for CMTL Certification and Application.

(1) This rule establishes the application and ongoing certification requirements for CMTLs. Any Applicant seeking certification as a CMTL must apply for certification as provided for in this rule.

(2) Certification will be on a per-Testing Facility basis. Separate applications must be submitted for each Testing Facility.

(3) To apply for certification, an Applicant must submit a completed Form DH5062-OMMU-04/2025 (Eff. 4/2025), "Certified Marijuana Testing Laboratory Application Instructions, Requirements, and Forms," incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX, together with the application fee of $78,000.00.

(4) To become a CMTL, an Applicant must meet and maintain, and continue to maintain during certification, all of the following requirements pertaining to CMTLs:

(a) Accreditation. A CMTL must possess a separate ISO/IEC 17025:2017 accreditation for each Testing Facility, by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC). A CMTL must maintain compliance with all parts of ISO/IEC 17025:2017 and AOAC Laboratory Accreditation Guidelines (ALACC) at all times. The accreditation must establish that the CMTL is qualified to analyze all Testing Fields in one or more of the following Matrix groups:

1.Usable Whole Flower Marijuana

a. Microbes;

b. Mycotoxins;

c. Heavy Metals;

d. Agricultural Agents;

e. Water Activity;

f. Moisture;

g. Filth and Foreign Material; and

h. Cannabinoid Profile.

2. Derivative Products

a. Microbes;

b. Mycotoxins;

c. Residual Solvents;
d. Heavy Metals;
e. Agricultural Agents;
f. Water Activity;
g. Filth and Foreign Material; and
h. Cannabinoid Profile.
3. Edibles
a. Microbes;
b. Mycotoxins;
c. Residual Solvents;
d. Heavy Metals;
e. Agricultural Agents;
f. Water Activity;
g. Filth and Foreign Material; and
h. Cannabinoid Profile.

(b) Proficiency Testing. A CMTL must create, maintain, and submit a Proficiency Test plan and schedule that are a minimum of two years in duration to OMMULabs@flhealth.gov. A CMTL must have received satisfactory results a minimum of 80% of all analytes in each PT test and for each Target Analyte on two of the three most recent Proficiency Tests administered by an ISO/IEC 17043:2023 accredited body covering all Testing Fields within one or more of the following Matrix Groups:

1.Usable Whole Flower Marijuana
a. Microbes;
b. Mycotoxins;
c. Heavy Metals;
d. Agricultural Agents;
e. Water Activity;
f. Moisture; and
g. Cannabinoid Profile.
2. Derivative Products
a. Microbes;
b. Mycotoxins;
c. Residual Solvents;
d. Heavy Metals;
e. Agricultural Agents;
f. Water Activity; and
g. Cannabinoid Profile.
3. Edibles
a. Microbes;
b. Mycotoxins;
c. Residual Solvents;
d. Heavy Metals;
e. Agricultural Agents;
f. Water Activity;
g. Cannabinoid Profile.

(c) Personnel:

1. Employees:

a. All CMTL Employees must be 21 years of age or older.

b. All CMTL Employees must have, at a minimum, a high school diploma from a state-approved and accredited public or private school, or secondary school equivalent.

c. CMTL Employees must not work for an MMTC, regardless of whether compensation is received from the MMTC; nor shall CMTL Employees receive any form of compensation, gratuity, benefit, or gift of any kind, from an MMTC while employed by a CMTL.

2. Samplers:

a. All CMTL Samplers must meet the requirements for an Employee of a CMTL.

b. All CMTL Samplers must be trained by the CMTL on the minimum requirements for sampling and the SOPs for sampling and security.

3. Analysts:

a. All CMTL Analysts must meet the requirements for an Employee of a CMTL.

b. All CMTL Analysts must be trained by the CMTL on the minimum requirements for sampling and the SOPs for sampling and security.

c. All CMTL Analysts must have, at a minimum, a bachelor's degree in a natural science, to include, but not be limited to, biology, chemistry, physics, engineering, or environmental sciences; or hold a current license as a Clinical Laboratory Personnel, as defined in s. 483.803, F.S., from the Florida Board of Clinical Laboratory Personnel.

4. Laboratory Directors:

a. All Laboratory Directors must meet the requirements for an Employee and for an Analyst of a CMTL.

b. A CMTL must employ a Laboratory Director for each Testing Facility operated by the CMTL.

c. All Laboratory Directors must have a minimum of three (3) years of experience in an International Standards Organization (ISO), College American Pathologists (CAP), or The NELAC Institute (TNI) accredited laboratory environment.

(d) Infrastructure and Security. A CMTL must have the ability to maintain adequate controls against the diversion, theft, or other loss of marijuana, the tampering or compromise of samples, and the tampering or compromise of testing equipment and materials. A CMTL must have documented security controls together with written SOPs, in accordance with any accreditation required by this rule, and must comply with the following security requirements to ensure the safety and security of all proposed Testing Facilities and Secure Storage areas:

1. A fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detector and duress, panic, and hold-up alarms.

2. A fully operational video surveillance system that records continuously 24 hours a day, and meets the following criteria:

a. Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of any Testing Facility and Secure Storage areas;

b. Cameras are fixed at entrances and exits to the premises, record from both indoor and outdoor, or ingress and egress, vantage points;

c. Records images legibly and accurately displays the time and date; and

d. Video surveillance recordings are retained for at least 45 days.

3. Fully operational dusk-to-dawn safety lighting on the exterior of the Testing Facility that provides illumination to the areas directly around the premises, including all points of ingress and egress.

4. All marijuana and marijuana samples are safely stored in a Secure Storage area under sanitary conditions and temperatures to protect against Contaminants Unsafe for Human Consumption as defined by Rule 64-4.300, F.A.C.

5. At least two Employees are on the Testing Facility premises when marijuana is received, when marijuana is tested, when marijuana is disposed of, and during the CMTL's normal business hours.

6. Each Employee must wear a legible photo identification badge visible at all times while on the premises.

7. Any non-Employee persons with access to the premises of the CMTL must prominently display an identification badge clearly indicating their visitor status, and be accompanied by an Employee;

8. Each Employee has training in and access to the CMTL's alcohol and drug-free workplace policy.

9. Each Employee has training in and access to the CMTL's theft and diversion policies and procedures which must require reporting to local law enforcement within 24 hours of notification or knowledge of any apparent theft, diversion, or loss of marijuana.

(e) Operations and Accountability. A CMTL must have written Quality Assurance and Quality Control procedures. Quality Assurance and Quality Controls must be contained within written SOPs and be in accordance with any accreditation required by this rule.

1. A CMTL's written Quality Assurance Manual must address every aspect of its Quality Assurance program, including without limitation:

a. Quality Control procedures;

b. Organizational structure, to include all Employees

c. Employee training and IDOCs;

d. Employee responsibilities;

e. Objectives for measurement data;

f. Testing Sample preparation for each Testing Field;

g. Testing Sample analysis for each Testing Field;

h. Data and result traceability;

i. Data Reduction;

j. Chromatography and Manual Integration;

k. Preventative maintenance and calibration of equipment;

l. Performance audits, to include internal and external auditing;

m. Corrective action;

n. Recordation and maintenance of Quality Assurance records; and

o. Transport, receiving, handling, destruction, and Secure Storage of samples.

2. At least once a calendar year, or whenever a change of method, equipment, or Laboratory Director occurs, the Laboratory Director or authorized Employee must review, amend as necessary, and approve the Testing Facility's Quality Assurance Manual and Quality Assurance program.

3. Internal Quality Assurance and Quality Control audits must occur at least once every calendar year. Internal audit results, including any and all remedial actions, must be provided to the department via email to OMMUlabs@flhealth.gov, by the internal auditor that conducted the audit within five (5) business days of the completion of the audit.

4. A CMTL must use testing equipment that satisfies the requirements of any accreditation required by this rule.

a. Equipment that is not suitable for a specific method must not be used for that purpose.

b. Testing equipment must be used and maintained according to the manufacturer's instructions and must be calibrated pursuant to the requirements of any accreditation under which it is operated. CMTLs must retain records of all equipment repairs, maintenance, and Calibrations.

5. Internal audits of all CMTL equipment, facilities, personnel, and security must occur at least once every calendar year. Audit results must be provided to the department via email to OMMUlabs@flhealth.gov, by the internal auditor that conducted the audit within seven (7) calendar days of the completion of the audit.

6. A CMTL must have a tracking system to document the complete chain of custody of marijuana samples, and all testing data attributed to those samples, from receipt through disposal. The CMTL's tracking system will be required to be integrated with the department's seed-to-sale tracking system.

a. The CMTL's tracking system must have the following capabilities:

(I) Traceability of all sample data and metadata;

(II) Protection of all calculations used to report data and the reported data;

(III) Calculation of the final Testing Sample concentration, LOD, and LOQ;

(IV) Automatic flagging of all results above the Acceptable Limit for the purposes of internal sample management and COA generation; and

(V) Automatic flagging of a Retail Batch which has already been sampled for Regulatory Compliance Testing by the CMTL.

b. The CMTL's tracking system must contain the following information:

(I) Date, time, and name of Employees handing the samples;

(II) The condition of the samples;

(III) The condition of any container or packaging the samples were transported or stored in;

(IV) The location of the samples;

(V) The Unique Identifier assigned to each sample; and

(VI) The seed-to-sale information from the MMTC.

(f) Background Screening. A CMTL's Employees, Owners, and Managers must pass background screening in accordance with Rule 64-4.314, F.A.C.

(g) Ownership. A CMTL must not be owned or Controlled by an MMTC, and must provide to the department the following:

1. A fully diluted capitalization table that must:

a. List all share types and the aggregate sum of shares associated with any natural persons, whether considered Owners or Investors;

b. Sum to one hundred percent (100%) of all shares issued and outstanding; and

c. List only natural persons as Owners and Investors.

2. A CMTL must notify the department in writing of all contractual relationships to change Control of the entity holding the certification, or to change its Managers, Owners, or Investors prior to the execution of the change. Such contractual relationships, along with an updated fully diluted capitalization table, must be provided to the department for approval before the change of Control.

3. Publicly-traded companies are not exempt from any requirements of this rule and must maintain documentation identifying all Owners and Investors that are considered Non-Objecting Beneficial Owners ("NOBOs").

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(2), 381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const., 381.988 FS. History–New.

64-4.302 Renewal Application Requirements for CMTLs.

(1) Each CMTL seeking renewal of its certification for a Testing Facility must submit a renewal application to the department in compliance with Form DH5063-OMMU-04/2025 (Eff. 4/2025), "Certified Marijuana Testing Laboratory Renewal Application Instructions, Requirements, and Forms," herein incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. A CMTL must also submit a non-refundable renewal fee of $78,000 by cashier's check made payable to the "Florida Department of Health" before the renewal application is deemed submitted.

(2) Renewal certification will be on a per-Testing Facility basis. A separate renewal application and renewal fee must be submitted for each Testing Facility.

(3) The following are grounds for denial of a renewal application:

(a) Failure to submit the $78,000 renewal fee within 120 days of the CMTL's renewal application submission date;

(b) Failure to timely provide the information and documentation required by the "Certified Marijuana Testing Laboratory Renewal Application Instructions, Requirements, and Forms" after an opportunity to correct errors and omissions within 120 days of the CMTL's renewal application submission date;

(c) Failure to meet the requirements of section 381.988, F.S., or any rules adopted thereunder; and

(d) Submission of information in the renewal application that would constitute a deficiency or violation that is grounds for revocation, suspension, or denial of certification pursuant to sections 381.986 or 381.988, F.S., or department rules.

(e) Any outstanding enforcement actions, including but not limited to, fines and notices of violation, with the department or the CMTL's ISO 17025:2017 accrediting body.

(4) The renewal application must be received by the department no later than 90 days, but no earlier than 120 days, before the end of the effective certification period. The effective certification period is a two-year period measured from the date the CMTL certification was initially issued; after the initial effective certification period, the two-year period is measured from the effective date of CMTL certification renewal as indicated on the renewal certificate.

(5) A CMTL's renewal application, renewal fee, and supporting documentation must be delivered to the department's Agency Clerk, at the address provided in the "Certified Marijuana Testing Laboratory Renewal Application Instructions, Requirements, and Forms," no later than 5:00 p.m. ET on the deadline established in subsection (4). If the deadline falls on a Saturday, Sunday, or legal holiday, then the deadline shall roll to the next day which is not a Saturday, Sunday, or legal holiday.

(6) Renewal applications that are not received by the department's Agency Clerk, at the address provided in the "Certified Marijuana Testing Laboratory Renewal Application Instructions, Requirements, and Forms" on or before the date and time set forth in this rule will not be considered and the cashier's check will be returned to the renewal applicant.

(7) A CMTL that is denied renewal, does not timely renew its certification, or elects to voluntarily relinquish its certification during the eligible renewal application submission window set forth in subsection (4) must cease operations as a CMTL on or before the expiration of the effective certification period. The CMTL must dispose of all Marijuana Waste in accordance with Rule 64-4.313, F.A.C. The CMTL must also return any Final Product that has not been removed from its original packaging to the originating MMTC. The CMTL must comply with the requirements of this subsection on or before the expiration of the effective certification period. The department will conduct a final on-site inspection of the CMTL Testing Facility to confirm the CMTL's compliance with this subsection.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(2), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const., 381.988, FS. History – New.

64-4.303 CMTL Testing.

(1) A CMTL may only perform analyses of Testing Fields within Matrix Groups under the following conditions:

(a) Analyses of Testing Fields within Matrix Groups must have been previously approved by the department pursuant to the application process set forth in Rule 64-4.301, F.A.C., or subsection (3) of this rule;

(b) Analyses of Testing Fields within Matrix Groups must be covered by the CMTL's ISO/IEC 17025:2017 accreditation that is compliant with Rule 64-4.301, F.A.C. All ISO/IEC 17025:2017 inspection results must be provided directly to the department by the ISO/IEC 17025:2017 via email to OMMUlabs@flhealth.gov.

(c) Analyses of Testing Fields within Matrix Groups must be supported by documentation of two (2) satisfactory analyses of the three (3) most recent Proficiency Tests administered by an ISO/IEC 17043:2023 accreditation that is compliant with Rule 64-4.301, F.A.C. Proficiency Test results that are within the Acceptable Limits established by the contracted ISO/IEC 17043:2023 accredited body are satisfactory.

1. Proficiency Testing for Usable Whole Flower Matrix Group must be performed using cannabis flower or hemp flower Proficiency Test samples.

2. Proficiency Testing for Derivative Product Matrix Group (excluding Edibles) must be performed in a Matrix containing hemp or cannabis oil.

3. Proficiency Testing for Edibles Matrix Group must be performed using food, as defined in s. 500.03, F.S., containing hemp oil.

4. A CMTL must participate in at least two (2) Proficiency Testing rounds from an ISO/IEC 17043:2023 accredited body for each Target Analyte in a Testing Field per calendar year beginning on the date of issuance or renewal of certification.

a. One (1) Proficiency Test for each Target Analyte per Matrix Group must be completed per calendar year beginning on the date of issuance or renewal of certification; and

b. Each Target Analyte in all Testing Fields must have at least one Proficiency Testing result above the CMTL's LOD per effective certification period, as described in section 64-4.302(4), F.A.C., beginning on the date of issuance or renewal of certification.

c. All Target Analytes testing below the LOD must be reported as less than the calculated LOD.

d. Any Target Analyte testing within the Calibration Curve must be reported at the specific value.

e. Any Target Analyte testing above the Acceptable Limit for Derivative Product not meant for inhalation may be reported at greater than the Acceptable Limit for Derivative Product not meant for inhalation.

f. Any Target Analyte testing between the highest Calibration Curve point and the Acceptable Limit for Derivative Product not meant for inhalation must be diluted to be within the Calibration Curve and reported as the specific value.

g. If a Target Analyte fails in a round of Proficiency Testing, the next round must contain a result above the LOD for that Target Analyte.

h. Proficiency Tests for Microbiological Testing must contain at least one positive sample in the set for each Target Analyte.

i. A minimum of 80% of all Target Analytes in each Proficiency Test Testing Field must have satisfactory results.

j. Analyses performed with multiple types of techniques must have passing Proficiency Testing results for each technique.

k. Proficiency Testing of the same Matrix Group and Testing Field must be conducted at a minimum interval of one (1) day between each Proficiency Test to ensure accuracy and integrity of the test.

l. A Proficiency Testing round must be completed no less than five (5) months and no more than seven (7) months after the previous round. Proficiency Testing used to correct unsatisfactory Proficiency Testing results or to validate new testing methods does not have to comply with this sub-subparagraph.

m. All Proficiency Testing results performed by the ISO/IEC 17043:2023 accredited Proficiency Testing provider must be provided directly to the department by the Proficiency Testing provider via email to OMMUlabs@flhealth.gov.

(2) A CMTL shall only conduct Final Product testing, R&D testing, and Proficiency Testing at its department-approved Testing Facility.

(3) A CMTL seeking to add Testing Fields within Matrix Groups must request approval from the department via email to OMMUlabs@flhealth.gov.

(a) With its request, the CMTL must submit the following:

1. Documentation demonstrating the additional Testing Fields within Matrix Groups have been added to the scope of their ISO/IEC 17025:2017 accreditation;

2. Documentation demonstrating the LOD of all Target Analytes in each additional Testing Field added to the scope of their ISO/IEC 17025:2017 accreditation complies with the requirements set forth in Rule 64-4.310, F.A.C.;

3. Documentation of the satisfactory completion of two (2) consecutive Proficiency Test results conducted within the last 18 months and administered by an ISO/IEC 17043:2023 accredited body for the additional Testing Field; and

4. An SOP evidencing the use of a validated Analytical Method, as identified in Rule 64-4.306, F.A.C., for each requested Testing Field.

(b) A CMTL must direct the ISO/IEC 17025:2017 accredited body to deliver the results of this accreditation directly to the department by email to OMMUlabs@flhealth.gov.

(c) Upon receipt of the request, the department will review the request and notify the CMTL in writing if its request is approved or if additional documentation is required.

(4) A CMTL that fails to satisfactorily complete two (2) of the three (3) most recent Proficiency Testing rounds must not test or provide results to MMTCs for any Target Analyte, Matrix, or other measurement for which its analysis was unsatisfactory, for a minimum of seven (7) days after generating such results.

(a) The CMTL must undertake an internal investigation to determine the reason(s) for the unsatisfactory Proficiency Test result and must obtain satisfactory results on additional Proficiency Testing for any Target Analyte, Matrix, or other failed measurement.

(b) Before the CMTL may resume testing for any Target Analyte, Matrix, or other failed measurement, the CMTL must pass at least two (2) of the three (3) most recent Proficiency Tests. Proficiency Tests in response to a failure must be amended to contain the failed Target Analyte above the CMTL's LOD.

(5) Additional Proficiency Tests conducted for internal purposes are exempt from the requirements of this rule. However, a CMTL must notify the department in writing prior to conducting the additional Proficiency Tests.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const., 381.988, FS. History–New.

64-4.304 CMTL On-Site Inspection.

(1) The department may conduct announced or unannounced inspections of any CMTL Testing Facility, including any vehicle utilized by a CMTL, to determine compliance with ss. 381.986 and 381.988, F.S. and department rules. All inspections will be initiated during a CMTL's normal business hours. A CMTL's refusal to allow entry for inspection is grounds for disciplinary action pursuant to Rule 64-4.315, F.A.C.

(2) A CMTL must allow department personnel complete, immediate, and unrestricted access to enter, inspect, monitor, and observe all areas and operations of a CMTL Testing Facility, including, without limitation, areas where marijuana, records, or equipment are located, or where CMTL business is conducted, and any vehicles utilized by a CMTL. During an inspection, the CMTL must provide responses to oral inquiries from the department.

(3) A CMTL must maintain at its Testing Facility all records necessary to substantiate its compliance with ss. 381.986 and 381.988, F.S., and department rules. The CMTL must make such records available to the department for review during any inspection or within 48 hours the department's request for such records.

(4) If during any inspection, the department identifies any deficiencies or violations of ss. 381.986 or 381.988, F.S., or department rules, the department will send a written notice of violation to the CMTL identifying the deficiencies or violations. The notice of violation may include disciplinary action in accordance with Rule 64-4.315, F.A.C.

(5) The department may review COAs and Data Packages at any time for completeness, accuracy, and compliance with ss. 381.986 and 381.988, F.S., and department rules. A CMTL must comply with all requests for data pursuant to Rule 64-4.311, F.A.C.

(6) A CMTL must submit all responses to requests for documents and records by the department electronically by email to OMMUlabs@flhealth.gov or the department's licensing portal at https://fldohommu.force.com/cmtl. A CMTL may not submit physical copies of documents and records to the department for the purpose of responding to such a request.

(7) Notwithstanding any disciplinary action included in a notice of violation, within seven (7) calendar days of receipt of a written notice of violation, the CMTL must provide the department a written corrective action plan to resolve the identified deficiencies or violation(s) pursuant to subsection 64-4.315(4), F.A.C.

(8) Upon review of the corrective action plan by the department, the CMTL may be required to take specific additional action to cure the deficiencies or violations in the timeframe required by the department. The CMTL must comply

with and perform all such additional steps as directed by the department.

(9) Notwithstanding any corrective action taken by a CMTL, the department may take disciplinary action against the CMTL in accordance with s. 381.988(8), F.S., and Rule 64-4.315, F.A.C.

(10) A CMTL is subject to additional inspections, including but not limited to data audits, by the department to confirm that the deficiency or violation has been resolved and that the corrective action plan has been implemented.

(11) A CMTL's failure to resolve any deficiencies or violations identified during an inspection in the timeframe required by the department or specified in a corrective action plan is an additional ground for disciplinary action pursuant to s. 381.988(8), F.S., and Rule 64-4.315, F.A.C.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const., 381.988, FS. History-New.

64-4.305 CMTL Standard Operating Procedures.

(1) CMTLs must develop, maintain, and implement testing methods and a corresponding written Quality Assurance Manual in conformity with this rule and any required accreditation pursuant to Rule 64-4.301, F.A.C.

(2) A CMTL must create and maintain SOPs compliant with s. 381.988, F.S., and department rules that address the following testing functions and responsibilities:

(a) Identification, Calibration, and maintenance of equipment and instruments;

(b) Chain of custody protocols;

(c) Data review and internal review processes;

(d) Sample preparation methods;

(e) Sample preparation method development and validation;

(f) Analytical Methods;

(g) Analytical Method development and validation;

(h) Chromatographic peak identification and integration;

(i) Data Reduction;

(j) Cleaning procedures for equipment, workspaces, and Secure Storage;

(k) Balance and pipette verification, calibration, and maintenance;

(l) Temperature calibration and monitoring;

(m) Contingency plans for data that are not within the parameters set forth in Rules 64-4.309 and 64-4.310, F.A.C., or are otherwise unacceptable for analysis;

(n) Employee training;

(o) IDOC;

(p) Premises and sample security;

(q) Proficiency Testing instructions provided with Proficiency Testing samples;

(r) Quality Assurance and Quality Control procedures;

(s) LOD and LOQ determination;

(t) Quality Control and Quality Assurance standard preparation and documentation, to include the creation of:

1. Calibration Standards;

2. Spike Solutions;

3. ICV solutions;

4. CCV solutions; and

5. Internal Standards solution.

(u) Recordkeeping and record retention;

(v) Sample collection;

(w) Sample preparation;

(x) Sample homogenization;

(y) Sample identification;

(z) Sample transportation;

(aa) Sample rejection;

(bb) Sample destruction;

(cc) Sample disposal;

(dd) Disposal of non-marijuana waste;

(ee) Sample Secure Storage;

(ff) Schedule and process for internal audits and corrective actions;

(gg) Disposal of Marijuana Waste; and

(hh) Disposal of hazardous waste.

(3) A CMTL's SOP for Analytical Methods as required by paragraph (2)(f) must include:

(a) The name of the Analytical Method;

(b) Definitions of terms and acronyms used therein;

(c) A list of all Target Analytes tested for using the Analytical Method;

(d) LODs and LOQs of all Target Analytes in Matrix and on column;

(e) The applicable Matrix or Matrices;

(f) Method sensitivity;

(g) Common potential interferences;

(h) The equipment and instruments used;

(i) Consumable supplies and Calibration Standards;

(j) Sample collection, preservation and hold time;

(k) Type, frequency, and acceptable criteria for Quality Control samples;

(l) Type, frequency, and acceptable criteria for Calibration Standards;

(m) Procedures for analyzing Analytical Batch samples;

(n) Data Quality Control and acceptance criteria;

(o) Calibration of results;

(p) Reagent and Certified Reference Material preparation;

(q) Reference method the SOP is based on; and

(r) Dates and narrative of authorized changes.

(4) Laboratory Directors must review, approve, sign, and date each SOP and each revision to an SOP. All SOPs must include issue dates and revision dates.

(5) The latest revised SOP must be kept on Testing Facility premises and be accessible to all Employees during all hours of operation.

(6) Upon request by the department, a CMTL must provide the department with a current copy of the CMTL's SOPs to substantiate compliance with ss. 381.986 and 381.988, F.S., and department rules, within 48 hours of the request. A CMTL must submit responses to the department's requests for the CMTL's SOPs electronically by email to ommulabs@flhealth.gov or the department's licensing portal at https://fldohommu.force.com/cmtl. A CMTL may not submit physical copies of documents and records to the department for the purpose of responding to such a request. Failure to provide the department with a current copy of the CMTL's SOPs in a timely manner may be grounds for disciplinary action in accordance with s. 381.988(8), F.S., and Rule 64-4.315, F.A.C.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const.,381.988, FS. History-New.

64-4.306 CMTL Testing Methods.

(1) Approved Analytical Methods. A CMTL must use approved Analytical Methods, as provided in this rule.

(a) A CMTL must follow any cannabis-specific Analytical Methods published by the following entities:

1. United State Pharmacopeia (USP) that is validated or verified with cannabis or cannabis product as a sample Matrix;

2. American Society for Testing and Materials (ASTM) that is validated or verified with cannabis or cannabis products as a sample Matrix;

3. US Food and Drug Administration (FDA) that is validated or verified with cannabis or cannabis products as a sample Matrix;

4. US Environmental Protection Agency (EPA) that is validated or verified with cannabis or cannabis products as a sample Matrix; or

5. US Department of Agriculture (USDA) that is validated or verified with cannabis or cannabis products as a sample Matrix.

(b) A Testing Field that does not currently have a cannabis-specific method listed in paragraph (1)(a) may use the following:

1. Approved Analytical Methods applicable to Microbiological Testing include:

a. FDA Bacterial Analytical Manual (BAM), Chapter 1 (eff. 04/2022), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

b. FDA BAM Chapter 2 (eff. 11/2000), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

c. FDA BAM, Chapter 4 (eff. 10/2020), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

d. FDA BAM, Chapter 5 (eff. 03/2022), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

e. FDA BAM, Chapter 18 (eff. 04/2001), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

f. Official Methods of Analysis of AOAC INTERNATIONAL (2023) 22nd Ed., AOAC INTERNATIONAL, Official Method. 2000.06. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

g. International Standards Organization (ISO). ISO 6579-1:2017 Microbiology of the Food Chain – Horizontal Method for the Detection, Enumeration, and serotyping of Salmonella. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

h. ISO. ISO/TS 13136:2012 Microbiology of Food and Animal Feed. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

i. USDA: Food Safety and Inspection Services (FSIS). Microbiology Laboratory Guidebook, Method Number 4.11 (eff. 08/16/2021), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

j. USDA: FSIS. Microbiology Laboratory Guidebook, Method Number 5C.02 (eff. 08/16/2021), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

k. Official Methods of Analysis of AOAC INTERNATIONAL (2023) 22nd Ed., AOAC INTERNATIONAL, Official Method. 997.02. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

l. Official Methods of Analysis of AOAC INTERNATIONAL (2023) 22nd Ed., AOAC INTERNATIONAL, Official Method. 2002.11. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

2. Approved Analytical Methods applicable to Residual Solvent testing include:

a. EPA, 624.1 Purgeable by GC/MS (eff. 12/2016), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

b. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3500 Series, Method 3500C (eff. 02/2007), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

c. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3500 Series, Method 3535A (eff. 02/2007), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

d. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3500 Series, Method 3550C (eff. 02/2007), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

e. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3500 Series, Method 3580A (eff. 07/1992), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

f. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3500 Series, Method 3585 (eff. 12/1996), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

g. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3600 Series, Method 3600C (eff. 12/1996), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

h. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 8000 Series, Method 8000D (eff. 03/2018), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

i. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 8000 Series, Method 8260D (eff. 06/2018), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

3. Approved Analytical Methods applicable to Heavy Metals testing include:

a. FDA, Elemental Analysis Manual for Food and Related Products, (eff. 02/2020), Method 4.7, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

b. USDA: FSIS, Chemistry Laboratory Guidebook, Method Number CLG-TM3 (eff. 11/05/2018), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

c. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3000 Series, Method 3005A (eff. 07/1992), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

d. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3000 Series, Method 3015A (eff. 02/2007), incorporated by reference

herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

e. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3000 Series, Method 3031 (eff. 12/1996), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

f. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3000 Series, Method 3040A (eff. 12/1996), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

g. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3000 Series, Method 3050B (eff. 12/1996), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

h. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 6000 Series, Method 6010D (eff. 07/2018), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

i. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 6000 Series, Method 6020B (eff. 07/2014), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

j. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 7000 Series, Method 7000B (eff. 02/2007), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

k. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 7000 Series, Method 7010 (eff. 02/2007), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

l. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 7000 Series, Method 7061A (eff. 07/1992), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

m. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 7000 Series, Method 7470A (eff. 09/1994), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

n. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 7000 Series, Method 7471B (eff. 02/2007), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

4. Approved Analytical Methods applicable to Agricultural Agent testing include:

a. Official Methods of Analysis of AOAC INTERNATIONAL (2023) 22nd Ed., AOAC INTERNATIONAL, Official Method. 2007.01. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

b. FDA Pesticide Analytical Manual (PAM), Volume 1, 3rd Edition, Chapter 2 (eff. 10/1999), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

c. FDA PAM, Volume 1, 3rd Edition, Chapter 3 (eff. 10/1999), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

d. FDA PAM, Volume 1, 3rd Edition, Chapter 4 (eff. 09/1996), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

e. FDA PAM, Volume 1, 3rd Edition, Chapter 5 (eff. 09/1996), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

f. FDA PAM, Volume 1, 3rd Edition, Chapter 6 (eff. 09/1996), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

g. USDA: FSIS. Chemistry Laboratory Guidebook, Method Number CLG-PST5 (eff. 04/01/2022), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

h. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3500 Series, Method 3500C (eff. 02/2007).

i. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3500 Series, Method 3535A (eff. 02/2007).

j. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3500 Series, Method 3550C (eff. 02/2007).

k. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3500 Series, Method 3580A (eff. 07/1992).

l. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 3600 Series, Method 3600C (eff. 12/1996).

m. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 8000 Series, Method 8270E (eff. 07/2018), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

n. EPA Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 8000 Series, Method 8275A (eff. 12/1996), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

5. Approved Analytical Methods applicable to Water Activity, and Moisture testing include:

a. FDA, Water Activity (Aw) in Foods (eff. 04/16/1984), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

b. USDA:FSIS, Chemistry Laboratory Guidebook, Method Number CLG-MOI (eff. 05/18/2018), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

c Official Methods of Analysis of AOAC INTERNATIONAL (2023) 22nd Ed., AOAC INTERNATIONAL, Official Method 934.01 Loss on Drying. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

d. ASTM Method D8493-23 Standard Guide for Sample Preparation of Cannabis and Hemp Inflorescence for Laboratory Analysis. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

6. Approved Analytical Methods Applicable to Cannabinoid Profile testing include:

a. Gambaro, V., Dell'Acqua, L., Farè, F., Froldi, R., Saligari, E., & Tassoni, G. (2002). Determination of primary active constituents in cannabis preparations by high-resolution gas chromatography/flame ionization detection and high-performance liquid chromatography/UV detection. Analytica Chimica Acta, 468(2), 245–254. https://doi.org/10.1016/s0003-2670(02)00660-8. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

b. Stolker, A. A., van Schoonhoven, J., de Vries, A. J., Bobeldijk-Pastorova, I., Vaes, W. H., & van den Berg, R. (2004). Determination of cannabinoids in cannabis products using liquid chromatography-ion trap mass spectrometry. Journal of chromatography. A, 1058(1-2), 143–151. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

c. Upton, R., Craker, L., ElSohly, M., Romm, A., Russo, E., & Sexton, M. (2014). Cannabis inflorescence: Cannabis spp.; Standards of Identity, Analysis, and Quality Control. American Herbal Pharmacopoeia. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee, Florida 32399-02506.

(2) A CMTL may request approval from the department to use an alternative, scientifically validated testing methodology

not listed under paragraph (1)(b) only if there are no existing cannabis-specific methods published by the entities listed in paragraph (1)(a). All requests for alternative, scientifically validated testing methodologies must be made in writing via email to OMMUlabs@flhealth.gov and are subject to the department's written approval. With its request, the CMTL must submit documentation evidencing that the alternative, scientifically validated testing methodologies have been validated in accordance with one of the methods listed under this subsection. Upon receipt of the request, SOP, validation study result, passing PT result, updated ISO/IEC 17025 accreditation, and any supporting documentation, the department will review the request and supporting documentation and notify the CMTL in writing whether use of the alternative, scientifically valid testing methodology is approved.

(a) FDA, Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds. Edition 3.0 (eff. 10/2019), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(b) FDA, Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products 3rd Edition (eff. 10/2019), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(c) AOAC. Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces (eff. 2012), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(d) AOAC. Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals (eff. 2019), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(e) FDA. Analytical Procedures and Methods Validation for Drugs and Biologics (eff. 07/2015), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(f) International Conference on Harmonization (ICH), Harmonized Tripartite Guideline Validation of Analytical Procedures: Text and Methodology (eff. 11/2005), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(g) USDA: FSIS. Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods (eff. 10/2010) incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(3) Competency. An Analyst must demonstrate an IDOC for a testing method prior to analyzing any Analytical Sample using that method. An IDOC is comprised of one (1) Method Blank and four (4) Laboratory Fortified Blanks amended with the method-specified Spike Solution, and prepared and analyzed according to the same SOPs as Testing Samples. If applicable for the analysis, the acceptable calculated relative standard deviation must be less than or equal to 20 percent; the recovery of each Target Analyte in each Laboratory Fortified Blank must be within the CMTL's acceptable range for Laboratory Fortified Blanks for all analytes for the amended concentration; and the Method Blank must not have any Target Analytes test above the LOD. The IDOC must be repeated every time there is a substantive change in the method, or when the method has not been performed by the Analyst within a 12-month period.

(4) Equipment. CMTLs must use testing equipment that satisfies the requirements of all required accreditation pursuant to Chapter 64-4, F.A.C. If any piece of equipment is not suitable for a specific method, it must not be engaged for that method or purpose. Testing equipment must be used and maintained according to the manufacturer's instructions and must be calibrated pursuant to the requirements of all accreditations under which the CMTL is operating. CMTLs must retain records of all equipment repairs, maintenance, and Calibrations for a minimum of three (3) years.

(5) Proficiency Testing. A CMTL must authorize any contracted ISO/IEC 17043:2023 accredited Proficiency Test provider to submit all Proficiency Testing results to the department and the CMTL concurrently. After the Proficiency Testing data are submitted, no modification to any aspect of the reported results, method/technology, measurement units, or the associated report information shall be made unless it is necessary due to a documented error made by the accredited Proficiency Testing provider.

(a) CMTLs must manage, analyze, and report all Proficiency Testing samples in the same manner as MMTC Testing Samples, including adherence to the same sample tracking, sample preparation, analysis methods, SOPs, Calibrations, Quality Control, and Acceptance criteria used in testing MMTC Testing Samples. CMTLs must analyze received Proficiency Testing samples as a mixture of Analytes in a solvent, using the samples' entire preparation and analytical process. If required by the Proficiency Test provider, the CMTL

must add the Proficiency Testing mixture to a clean Matrix before extracting and preparing the sample for analysis.

(b) The Matrix of the Proficiency Testing sample must be of the same complexity as the Matrix type designated in the SOPs being used to prepare and analyze the Proficiency Testing sample. The same Proficiency Testing sample may be used for multiple methods if those methods are within the same Testing Field and Matrix Group.

(c) Rounds of Proficiency Testing may not occur at greater than six-month intervals, as determined by the closing dates of each Proficiency Testing round. If a CMTL reports more than one result for a field of accreditation (Matrix Group-Testing Field-Target Analyte combination) from a Proficiency Testing round, any unsatisfactory result constitutes a failed testing attempt for the corresponding approved or pending field of accreditation. The results of all Proficiency Testing must be sent from the ISO/IEC 17043:2023 accredited body directly to the department. The CMTL must direct the ISO/IEC 17043:2023 accredited body to deliver the results directly to the department via email at OMMUlabs@flhealth.gov.

(d) To contest the results of a Proficiency Test, the CMTL must submit to the department, within seven (7) days of the CMTL's receipt of the results, the name of the Proficiency Test provider, the method and Target Analyte(s) in question, a detailed description of the discrepancy, and any supporting documentation.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const., 381.988 FS. History–New.

64-4.307 CMTL Submission for Product Testing.

(1) A CMTL must collect from an MMTC a random and representative Sample of Final Product from every Retail Batch for Regulatory Compliance Testing. The CMTL must follow its field sampling protocol approved under its scope of ISO/IEC 17025:2017 accreditation.

(2) At the time of selection, the CMTL must confirm within the MMTC's seed-to-sale system that the total quantity of Final Products in the Retail Batch from which a Sample is being selected matches the total quantity of Final Products in the Retail Batch denoted in the system. The CMTL must sample from the entire Retail Batch for Regulatory Compliance Testing.

(3) A CMTL must develop and implement a chain of custody protocol to ensure accurate documentation is recorded for the transport, handling, storage, and destruction of Samples. The protocol must include use of a log form developed by the CMTL. The CMTL must use the CMTL's chain of custody log to record the following information for each Retail Batch sampled:

(a) CMTL's name and address;

(b) Date and time sampling started and ended;

(c) MMTC's name and address where the Sample was collected;

(d) The Retail Batch number of the batch from which the Sample was obtained and the assigned Unique Sample Identifier;

(e) Sample Matrix;

(f) Total Retail Batch size, by weight or volume;

(g) Total quantity of Final Products in the Retail Batch;

(h) Total weight or volume of the Sample;

(i) Total Quantity of Final Products in the Sample;

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

(k) Identification of which, if any, Usable Whole Flower Products which were treated with a sterilization step before testing;

(l) Printed name and signature of the MMTC representative who was present and granted access to the Final Products for sampling;

(m) Printed CMTL Employee ID number and signature of the CMTL Sampler; and

(n) The date and time the Sample departed from the MMTC's premises and date and time when the Sample arrived at the CMTL, along with the names and signatures of the CMTL Employees involved in the transport of the Samples.

(4) The CMTL must ensure that each Retail Batch is sampled only once unless being resampled and retested pursuant the MMTC Regulatory Compliance Testing rule.

(5) The CMTL must homogenize all Final Products into one (1) Testing Sample for each Retail Batch sampled, except in the case of homogeneity testing of Edibles. All homogenization processes undertaken must not impact the Testing Sample in a way which would affect the accuracy and/or precision of any testing results, including but not limited to, additional trimming of Usable Whole Flower, additional drying steps, or the removal of an Edible's sugar coating.

(a) A CMTL must use no less than three (3) cartridges for testing vaporizer products for Residual Solvents and Microbes. A CMTL may open and heat, to a maximum of 50° C, the remaining cartridges to remove the marijuana oil.

(b) A CMTL must initially homogenize Usable Whole Flower Marijuana before taking a microbiological aliquot from the Sample.

(c) A CMTL must homogenize Usable Whole Flower Marijuana and Edible products to a standard particle size of 0.1mm or less prior to conducting Environmental Contaminant Testing and Potency Testing.

(d) A CMTL must mix ground samples to ensure no stratification exists before taking an aliquot of the Testing Sample to perform individual analyses.

(e) A minimum of three (3) Final Products must be sampled from each Retail Batch. The number of Final Products chosen for testing from a Retail Batch must be enough total weight or volume to satisfy the following: if all Regulatory Compliance Testing of a Retail Batch is to be performed by one (1) CMTL, 0.35% of the total volume or weight of the Retail Batch must be collected by the CMTL. In no event, however, may the CMTL collect less than a 15g or 15ml sample of Derivative Products and Edibles, and 25g of Usable Whole Flower Marijuana.

(6) The CMTL may, if necessary, collect more Final Product to ensure all tests are completed accurately.

(7) The CMTL must ensure that samples are transported and stored in a manner that prevents degradation, contamination, comingling, and tampering. The CMTL's original chain of custody log must accompany the samples at all times during transport. Samples must be packaged by the CMTL at the MMTC facility where the sampling takes place, and the package must be sealed in or with a Tamper-evident Device.

(8) For Microbiological Testing, Moisture, Water Activity, and Filth and Foreign Material tests, a CMTL must begin preparation of Testing Samples within 72 hours of collection as reflected in the CMTL's chain of custody log. For all other required tests, a CMTL must begin preparation of Testing Samples within seven (7) days of the Sample's collection as documented in the CMTL's chain of custody log.

(9) If a CMTL is unable to complete Regulatory Compliance Testing for one or more Testing Field(s) within the required timeframe, the CMTL may have a secondary CMTL complete the analysis of the remaining Testing Field(s).

(a) Samples prepared for the purpose of Regulatory Compliance Testing must be homogenized by the primary CMTL. The aliquot of the homogenized sample must be transported to the secondary CMTL for sample preparation and analysis. The secondary CMTL must take the aliquot from the Testing Sample created by the primary CMTL.

(b) A completed chain of custody form must document the transport of the aliquot collected from the primary CMTL to the secondary CMTL. The primary CMTL must notify the department of the primary CMTL's inability to complete full Regulatory Compliance Testing via email at OMMULabs@flhealth.gov, and provide to the department a corrective action plan in accordance with Rule 64-4.315, F.A.C.

(c) The primary CMTL must receive a full data package for the analysis from the secondary CMTL in compliance with Rule 64-4.311, F.A.C.

(d) The primary CMTL must report the Regulatory Compliance Testing COA with the data required in Rule 64-4.311, F.A.C., for the test(s) completed by the secondary CMTL along with a statement identifying the secondary CMTL performing that portion of testing.

(10) A CMTL may resample and retest a previously failed Retail Batch as permitted by the MMTC Regulatory Compliance Testing rule. A previously failed Retail Batch is subject to the same sampling requirements as the initial Sample and must undergo complete Regulatory Compliance Testing in accordance with Rule 64-4.308, F.A.C.

(11) While transporting Samples collected from an MMTC or Testing Samples to another CMTL, the CMTL must ensure samples are not visible to the public. All samples must be locked in a fully enclosed box, container, or cage that is secured to the inside of the vehicle used for transport. The enclosed box, container, or cage must be separate and distinct from any part of the body of the vehicle. For the purposes of this subsection, the inside of a vehicle includes the trunk. Vehicles used for transporting samples must be equipped with an operational alarm system.

(a) The CMTL must require at least two (2) Employees to be in a vehicle when transporting samples.

(b) The CMTL must not leave a vehicle containing samples unattended. One (1) Employee shall remain with the vehicle transporting samples at all times.

(c) The CMTL must ensure that packages or containers holding samples are neither tampered with, nor opened, during transport.

(d) The CMTL must ensure that all vehicles used to transport samples are in good working order and receive regular maintenance.

(e) A CMTL must not deviate from the travel requirements described herein, except for necessary rest, fuel, or vehicle repair stops. The CMTL transporting samples must only travel between:

1. The MMTC for whom the CMTL is conducting Regulatory Compliance Testing or R&D testing and the CMTL's Testing Facility; or

2. The CMTL Testing Facility and another CMTL.

(f) The CMTL may simultaneously transport multiple Samples obtained from different MMTCs.

(g) No person under the age of 21 years old may be in a vehicle transporting samples.

(h) Only CMTL Employees may be in a vehicle while transporting samples.

(i) For any vehicle that will be utilized to transport samples that was not approved as part of the CMTL's initial application, the CMTL must submit completed Form DH5060-OMMU-04/2025 (Eff. 4/2025), "Certified Marijuana Testing Laboratory Vehicle Notification," incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX, to the department via email at

OMMULabs@flhealth.gov or the department's licensing portal at https://fldohommu.force.com/cmtl, prior to using such vehicle.

(j) If a CMTL decommissions any vehicle that was utilized to transport samples, the CMTL must submit a completed "Certified Marijuana Testing Laboratory Vehicle Notification" to the department via email at OMMULabs@flhealth.gov or the department's licensing portal at https://fldohommu.force.com/cmtl.

(k) Vehicles transporting samples are subject to inspection by the department at any time in accordance with Rule 64-4.304, F.A.C.

(12) Any Final Product collected by the CMTL, whether used or unused for any testing purposes, must be disposed of by the CMTL in compliance with Rule 64-4.313, F.A.C.

Rulemaking Authority 381.986(8)(k), 381.988(3), 381.988(9), FS. Law Implemented 381.986, 381.988, FS. History-New.

64-4.308 CMTL Sample Testing.

(1) CMTLs shall test Final Products for the following as specified in Rule 64-4.301 F.A.C.: tetrahydrocannabinol (THC) potency, concentration of cannabidiol (CBD), Cannabinoid Profile, Contaminants Unsafe for Human Consumption, Moisture, and Water Activity.

(a) Notwithstanding the Acceptable Limits associated with paragraphs (2)(a)-(h), results must be reported accurately to three (3) significant figures as the concentration in parts per million (ppm) or parts per billion (ppb) for Usable Whole Flower Marijuana, Derivative Products, and Edibles. Microbial Testing must be reported as presence/absence for Aspergillus spp., E. coli, Salmonella, Listeria spp., Staphylococcus aureus, and bile-tolerant, Gram-negative bacteria. Microbial Testing must be reported accurately to three (3) significant figures as CFU/g for total aerobic count and Total Combined Yeast and Mold.

1. All Usable Whole Flower Marijuana analyses except Potency Testing and Terpene Analysis must be dry weight corrected using the CMTL-tested Moisture content. Usable Whole Flower Marijuana Potency and Terpene Analysis must be tested as received and not corrected to dry weight.

2. All Derivative and Edible products are assumed to be 100% solid and no dry weight corrections are permitted.

(b) Any test result that exceeds enumerated Acceptable Limits constitutes a failure.

1. All failures for Microbes, Mycotoxins, Residual Solvents, Heavy Metals, and Agricultural Agents must be confirmed by the CMTL through reanalysis of the failed Target Analyte using a portion of stored sample equal in size to the portion of the sample used in the first test.

2. Reanalysis of a failed Target Analyte must occur after the first test that registered the initial failure is completed. If reanalysis results are below the Acceptable Limit, the CMTL must perform a second reanalysis using a portion of the stored sample, equal in size to the first sample, to determine the final test result and document the cause of the inconsistent results.

3. Failure confirmations must be analyzed within 48 hours. If a failure is confirmed, the highest value must be reported on the COA. If failure is overturned, the highest value which is below the Acceptable Limit must be reported.

4. A CMTL must reanalyze any Target Analyte with results less than 10% below the Acceptable Limit. If the reanalysis fails, the laboratory must follow the above procedure for confirmation of a failed Target Analyte.

(c) Analytical Batches which include a previously failed sample being retested, either for reanalysis of a failed Target Analyte, or resampling and retesting of a previously failed Retail Batch, must include the failing Target Analyte in the Spike Solution for Laboratory Fortified Blanks and Matrix Spikes at a concentration between the Acceptable Limit and the instrument LOQ of the failing analyte.

(d) Any test result that meets the requirements of an enumerated Acceptable Limit is satisfactory. Any product that may be administered via multiple routes of administration is subject to the more stringent Acceptable Limit contained herein. A Retail Batch that meets the requirements of all enumerated Acceptable Limits may not be resampled and retested after the COA is generated and verified. All resampling and retesting must meet the requirements in the MMTC Regulatory Compliance Testing rule.

(e) All testing results must be verified and reported on a COA. A CMTL must not conduct additional analytical testing of the Testing Sample after the CMTL verifies the testing results on the COA. However, if Quality Control criteria is found to be outside of documented limits, a CMTL may continue analytical testing after verifying the testing results on the COA. A CMTL must notify the department in writing at OMMULabs@flhealth.gov before any Retail Batch can be tested after the CMTL verifies the testing results on the COA.

1. The written notification must include:

a. The original COA;

b. Testing Field(s) which require reanalysis;

c. Reason for resuming testing; and

d. Documentation of the Quality Control outside of criteria requiring resuming analytical testing.

2. All COAs reporting a testing failure must clearly show the Target Analyte which failed and its concentration.

3. Testing results must be reported by the CMTL to the MMTC by providing the COA for the Retail Batch within 24 hours of verification of the COA. All failures must be reported to the department by providing the COA for the failed Retail Batch via the online licensing portal at https://fldohommu.force.com/cmtl or by email to

OMMUlabs@flhealth.gov within 24 hours of verification of the COA and concurrently or before providing results to the MMTC for the failed Retail Batch.

4. Passing results must be uploaded to the department's seed-to-sale system in accordance with department rules and emergency rules. For the purposes of this rule, a test result is considered verified when the Laboratory Director, or other qualified and authorized Employee, confirms the accuracy of the results in the COA. If a CMTL makes any updates or corrections to a COA after the COA has been reported to the MMTC and the department, the updated or corrected COA must be provided to the Department via email to OMMULabs@flhealth.gov or the department's licensing portal within 24 hours of the update or correction and in accordance Rule 64-4.311, F.A.C.

(f) After resampling and retesting a previously failed Retail Batch, the CMTL must provide the following to the department via email to OMMULabs@flhealth.gov or the department's licensing portal within 24 hours of verification of the COA:

1. The COA (whether passing or failing) of the previously failed Retail Batch; and

2. The Data Package (whether passing or failing) for the failed Testing Field(s).

(2) The following are Acceptable Limits:

(a) Microbes; Acceptable Limits for Usable Whole Flower Marijuana and Derivative Products including Edibles with a minimum sample size of 1 gram:

1. Shiga toxin producing Escherichia coli, none present;

2. Any Salmonella species, none present;

3. Aspergillus species:

a. A. niger, none present;

b. A. fumigatus, none present;

c. A. flavus, none present; and

d. A. terreus, none present.

4. Listeria monocytogenes, none present,

5. Total Aerobic microbial count, less than 100 CFU/g in Non-Oral Transmucosal Products only.

6. Staphylococcus aureus, none present in Non-Oral Transmucosal Products only.

7. Bile tolerant gram-negative bacteria, none present in Non-Oral Transmucosal Products only.

8. Total Combined Yeast and Mold; Acceptable Limits for Usable Whole Flower Marijuana and Derivative Products including Edibles:

a. Less than 100,000 CFU/g.

b. Less than 10 CFU/g in Non-Oral Transmucosal Products only.

(b) Mycotoxins; Acceptable Limits for Usable Whole Flower Marijuana and Derivative Products including Edibles:

1. Aflatoxins:

a. B1 (CAS No. 1162-65-8), less than 20 ppb.

b. B2 (CAS No. 7220-81-7), less than 20 ppb.

c. G1 (CAS No. 1165-39-5), less than 20 ppb.

d. G2 (CAS No. 7241-98-7), less than 20 ppb.

e. Sum of all Aflatoxins, less than 20 ppb.

2. Ochratoxin A (CAS No. 303-47-9), less than 20 ppb.

(c) Residual Solvents; Acceptable Limits:

	Analyte	CAS No.	Acceptable Limit for Derivative Product Meant for inhalation	Acceptable Limit for Derivative Product not meant for inhalation
1.	Acetone	67-64-1	less than 750 ppm	less than 5,000 ppm
2.	Acetonitrile	75-05-8	less than 60 ppm	less than 410 ppm
3.	Benzene	71-43-3	less than 1 ppm	less than 1 ppm
4.	Butane	106-97-8	less than 5,000 ppm	less than 5,000 ppm
5.	Chloroform	67-66-3	less than 2 ppm	less than 2 ppm
6.	1,2-dichloroethane	107-06-2	less than 2 ppm	less than 2 ppm
7.	1,10dichloroethene	76-35-4	less than 8 ppm	less than 8 ppm
8.	Ethanol	64-17-5	less than 5,000 ppm	less than 5,000 ppm
9.	Ethyl acetate	141-78-6	less than 400 ppm	less than 5,000 ppm
10.	Ethyl ether	60-29-7	less than 500 ppm	less than 5,000 ppm
11.	Ethylene oxide	75-21-8	less than 5 ppm	less than 5 ppm
12.	Heptane	142-82-5	less than 5,000 ppm	less than 5,000 ppm
13.	Hexane	110-54-3	less than 250 ppm	less than 250 ppm
14.	Isopropyl alcohol	67-63-0	less than 500 ppm	less than 5,000 ppm

15.	Methanol	67-56-1	less than 250 ppm	less than 3,000 ppm
16.	Methylene chloride	75-09-2	less than 125 ppm	less than 125 ppm
17.	Pentane	106-66-0	less than 750 ppm	less than 5,000 ppm
18.	Propane	74-98-6	less than 5,000 ppm	less than 5,000 ppm
19.	Trichloroethylene	79-01-6	less than 25 ppm	less than 25 ppm
20.	Toluene	108-88-3	less than 150 ppm	less than 890 ppm
21.	Total xylenes (m-, p-, o-xylenes	1330-20-7	less than 150 ppm	less than 2170 ppm

22. Products for topical administration, oral administration, and MDIs are exempt from the ethanol Acceptable Limit. The CMTL must report the testing concentration of ethanol on the COA.

(d) Heavy Metals; Acceptable Limits:

	Analyte	CAS No.	Acceptable Limit for Derivative Product Meant for inhalation	Acceptable Limit for Derivative Product not meant for inhalation
1.	Lead	7439-92-1	less than 500 ppb	less than 500 ppb
2.	Arsenic	7440-38-2	less than 200 ppb	less than 1500 ppb
3.	Cadmium	7440-43-9	less than 200 ppb	less than 500 ppb
4.	Mercury	7439-97-6	less than 200 ppb	less than 3000 ppb
5.	Nickel	7440-50-8	less than 500 ppb	less than 3000 ppb
6.	Tin	7440-31-5	less than 4000 ppb	less than 4000 ppb

(e) Agricultural Agents; Acceptable Limits using Liquid Chromatography:

	Analyte	CAS No.	Acceptable Limit for Derivative Product Meant for inhalation	Acceptable Limit for Derivative Product not meant for inhalation
1.	Abamectin, sum of isomers B1a and B1b	71751-41-2	less than 100 ppb	less than 300 ppb
2.	Acephate	30560-19-1	less than 100 ppb	less than 3000 ppb
3.	Acequinocyl	57960-19-7	less than 100 ppb	less than 2000 ppb
4.	Acetamiprid	135410-20-7	less than 100 ppb	less than 3000 ppb
5.	Aldicarb	116-06-3	less than 100 ppb	less than 100 ppb
6.	Azoxystrobin	131860-33-8	less than 100 ppb	less than 3000 ppb
7.	Bifenazate	149877-41-8	less than 100 ppb	less than 3000 ppb
8.	Bifenthrin	82657-04-3	less than 100 ppb	less than 500 ppb
9.	Boscalid	188425-85-6	less than 100 ppb	less than 3000 ppb
10.	Carbaryl	63-25-2	less than 500 ppb	less than 500 ppb
11.	Carbofuran	1563-6-2	less than 100 ppb	less than 100 ppb
12.	Chlorantraniliprole	500008-45-7	less than 1000 ppb	less than 3000 ppb
13.	Chlormequat chloride	999-81-5	less than 1000 ppb	less than 3000 ppb
14.	Chlorpyrifos	2921-88-2	less than 100 ppb	less than 100 ppb
15.	Clofentezine	74115-24-5	less than 200 ppb	less than 500 ppb
16.	Coumaphos	56-72-4 100	less than 100 ppb	less than 100 ppb
17.	Cyfluthrin	68359-37-5	less than 500 ppb	less than 1000 ppb
18.	Cypermethrin	52315-07-8	less than 500 ppb	less than 1000 ppb
19.	Daminozide	1596-84-5	less than 100 ppb	less than 100 ppb
20.	Diazinon	333-41-5	less than 100 ppb	less than 200 ppb
21.	Dichlorvos	62-73-7	less than 100 ppb	less than 100 ppb
22.	Dimethoate	60-51-5	less than 100 ppb	less than 100 ppb
23.	Dimethomorph, sum of isomer E and Z	11321-97-2	less than 200 ppb	less than 3000 ppb

		11321-98-3		
24.	Ethoprophos	13194-48-4	less than 100 ppb	less than 100 ppb
25.	Etofenprox	80844-07-1	less than 100 ppb	less than 100 ppb
26.	Etoxazole	153233-91-1	less than 100 ppb	less than 1500 ppb
27.	Fenhexamid	126833-17-8	less than 100 ppb	less than 3000 ppb
28.	Fenoxycarb	72440-01-8	less than 100 ppb	less than 100 ppb
29.	Fenpyroximate	134098-61-6	less than 100 ppb	less than 2000 ppb
30.	Fipronil	120068-37-3	less than 100 ppb	less than 100 ppb
31.	Flonicamid	158062-67-0	less than 100 ppb	less than 2000 ppb
32.	Fludioxonil	131341-86-1	less than 100 ppb	less than 3000 ppb
33.	Hexythiazox	78587-05-0	less than 100 ppb	less than 2000 ppb
34.	Imazalil	35554-44-0	less than 100 ppb	less than 100 ppb
35.	Imidacolprid	138261-41-3	less than 400 ppb	less than 3000 ppb
36.	Kresoxim-methyl	143390-89-0	less than 100 ppb	less than 1000 ppb
37.	Malathion	121-75-5	less than 200 ppb	less than 2000 ppb
38.	Metalxyl	57837-19-1	less than 100 ppb	less than 3000 ppb
39.	Methiocarb	2032-65-7	less than 100 ppb	less than 100 ppb
40.	Methomyl	16752-77-5	less than 100 ppb	less than 100 ppb
41.	Mevinphos	7786-34-7	less than 100 ppb	less than 100 ppb
42.	Mycobutanil	88671-89-0	less than 100 ppb	less than 3000 ppb
43.	Naled	300-76-5	less than 250 ppb	less than 500 ppb
44.	Oxamyl	23135-22-0	less than 500 ppb	less than 500 ppb
45.	Paclobutrazol	76738-62-0	less than 100 ppb	less than 100 ppb
46.	Permethrin, sum of isomers cis- and trans-permethrin	52645-53-1	less than 100 ppb	less than 1000 ppb
47.	Phosmet	732-11-6	less than 100 ppb	less than 200 ppb
48.	Piperonyl Butoxide	51-03-6	less than 3000 ppb	less than 3000 ppb
49.	Prallethrin	23031-36-9	less than 100 ppb	less than 400 ppb
50.	Propiconazole	60207-90-1	less than 100 ppb	less than 1000 ppb
51.	Propoxur	144-26-1	less than 100 ppb	less than 100 ppb
52	Pyrethrins, sum of compounds Pyrethrin I and II, Cinerin I and II, Jasmolin I and II	8003-34-7	less than 500 ppb	less than 1000 ppb
53.	Pyridaben	96489-71-3	less than 200 ppb	less than 3000 ppb
54.	Spinetoram, sum of isomers J and L	187166-40-1 187166-15-0	less than 200 ppb	less than 3000 ppb
55.	Spinosad, sum of ismers A and D	168316-95-8 131929-60-7	less than 100 ppb	less than 3000 ppb
56.	Spiromesifen	283594-90-1	less than 100 ppb	less than 3000 ppb
57.	Spirotetramat	203313-25-1	less than 100 ppb	less than 3000 ppb
58.	Spiroxamine	118134-30-8	less than 100 ppb	less than 100 ppb
59.	Tebuconazole	107534-96-3	less than 100 ppb	less than 1000 ppb
60.	Thiacloprid	111988-49-9	less than 100 ppb	less than 100 ppb
61.	Thiamethoxam	153719-23-4	less than 500 ppb	less than 1000 ppb
62.	Trifloxystrobin	141517-21-7	less than 100 ppb	less than 3000 ppb

The list above of Agricultural Agents does not constitute authorization to use or apply any of those Agricultural Agents during the cultivation or processing of marijuana.

(f) Agricultural Agents; Acceptable Limits using Gas Chromatography:

	Analyte	CAS No.	Acceptable Limit for Derivative	Acceptable Limit for Derivative

			Product Meant for inhalation	Product not meant for inhalation
2.	Chlordane, sum of isomers cis- and trans- Chlordane in a mix of isomers	57-74-9	less than 100 ppb	less than 100 ppb
3.	Chlofenapyr	122453-73-0	less than 100 ppb	less than 100 ppb
4.	Methyl Parathion	289-00-0	less than 100 ppb	less than 100 ppb
5.	Pentachloronitrobenzene	82-68-8	less than 150 ppb	less than 200 ppb

The list above of Agricultural Agents does not constitute authorization to use or apply any of those Agricultural Agents during the cultivation or processing of marijuana. Agricultural Agents not required to be analyzed by Gas Chromatography may be analyzed by Gas Chromatography if all Acceptable Limit and Quality Control requirements are met and the analytes are listed on the CMTLs ISO/IEC 17025:2017 scope of accreditation as being tested by Gas Chromatography. When reporting the concentration of Chlordane in a mix of isomers, the response sum of cis- and trans-chlordane peaks must be used.

(g) Total Contaminant Load; Acceptable Limits for:

1. Usable Whole Flower Marijuana and Derivative Product meant for inhalation, five (5) ppm or less;

2. Derivative Product, not meant for inhalation, including Edibles, 30 parts per million or less; and

(h) A Testing Sample containing levels of any Microbe, Residual Solvent, Heavy Metal, or Agricultural Agent, that is not otherwise enumerated in this rule and that could be toxic if consumed or applied by a qualified patient, may be deemed to fail testing for Acceptable Limits by the department.

(i) Water Activity; Acceptable Limits for Usable Whole Flower Marijuana, Derivative Product, and Edibles:

1. Usable Whole Flower Marijuana, Water Activity 0.65 Aw or less. A testing result of greater than 0.65 Aw in Usable Whole Flower Marijuana constitutes a failure for Water Activity.

2. Derivative Product or Edible, Water Activity of 0.85 Aw or less, with the exception of products with water listed as an ingredient, which are exempt from Water Activity testing. A testing result of greater than 0.85 Aw in a solid and semi-solid derivative product or edible constitutes a failure for Water Activity.

3. Results must be reported accurately to two (2) significant figures.

(j) CMTLs must test Usable Whole Flower Marijuana for Moisture content. Usable Whole Flower Marijuana that has a Moisture content below 15.0% is acceptable for Moisture content testing. A testing result of greater than or equal to 15.0% in Usable Whole Flower Marijuana constitutes a failure for Moisture. Results must be reported to the nearest tenth of a percent.

(k) Filth and Foreign Materials. Each Final Product sampled must be visually inspected by the CMTL for Filth and Foreign Materials before being used to create a Testing Sample. Usable Whole Flower Marijuana must have both the interior and exterior of flower buds inspected. A testing result greater than the Acceptable Limit constitutes a failure for Filth and Foreign Material. Acceptable Limits for Usable Whole Flower Marijuana and Derivative Product, including Edibles:

1. Filth and Foreign Material (to include hair, insects, packaging contaminants, manufacturing waste, or other similar marijuana cultivation and manufacturing by-products), not more than an average of 1% by weight, or cover more than 10% of the total sample area.

2. Any visible feces; and

3. Any visible mold, mildew, and/or fungus.

(3) Potency Testing. Potency Testing must include the amount, in milligrams, accurate to three (3) significant figures of Total Active THC and Total Active CBD in the Final Product. A CMTL must only report Usable Whole Flower Marijuana potency at the CMTL-tested Moisture content. Usable Whole Flower Marijuana potency percentage must be calculated as follows: Usable Whole Flower Marijuana Potency percentage = (mg Total Active THC/Total Active CBD ÷ product weight in mg) x 100. All potency calculations for Usable Whole Flower Marijuana and Derivative Products must use the labeled weight of the Final Product. All Usable Whole Flower potency results greater than 32% must be confirmed by repreparation and reanalyzing of a portion of the homogenized Testing Sample. Confirmation test must meet requirements of paragraph 64-4.309(1)(d) to confirm potency. Usable Whole Flower Results confirmed to be above 32% must be reported to the department via email to OMMULabs@flhealth.gov, to include the passing COA and Data Package for the Potency Testing Field. Edibles must use the measured weight of the Final Product for potency calculations.

(4) Cannabinoid Profile. The Cannabinoid Profile results for each cannabinoid must be reported as concentration in mg/g, accurate to three (3) significant figures, and percent, accurate to three (3) significant figures relative to the total weight or volume of the product. A CMTL must only report Usable Whole Flower Cannabinoid Profile at the CMTL-tested Moisture content. A CMTL must utilize the homogenized

Testing Sample when conducting Cannabinoid Profile Regulatory Compliance Testing of Edibles. The CMTL must test for the following cannabinoids:

(a) d9-Tetrahydrocannabinoid (d9-THC), CAS No. 1972-08-3.

(b) d8-Tetrahydrocannabinoid (d8-THC), CAS No. 5957-75-5.

(c) d9-Tetrahydrocannabinolic acid (THCA), CAS No. 23978-85-0.

(d) Tetrahydrocannabivarin (THCV), CAS No. 31262-37-0.

(e) Cannabidiol (CBD), CAS No. 13956-29-1.

(f) Cannabidiolic acid (CBDA), CAS No. 1244-58-2.

(g) Cannabidivarin (CBDV), CAS No. 24274-48-4.

(h) Cannabigerol (CBG), CAS No. 25654-31-3.

(i) Cannabigerolic acid (CBGA), CAS No. 25555-57-1.

(j) Cannabinol (CBN), CAS No. 521-35-7.

(k) Cannabichromene (CBC), CAS No. 20675-51-8.

(5) Samples are not required to be labeled for potency at the time of testing. If included on the Sample label and/or packaging by an MMTC at the time of testing, potency concentrations and ratios must meet the following criteria:

(a) For Usable Whole Flower Marijuana and Derivative Products, if the tested concentration per Final Product of total active THC, total active CBD, or any individual cannabinoid is greater than 25 milligrams, the tested concentration may vary by no more than 10% from the concentration printed on the Final Product packaging.

(b) For Usable Whole Flower Marijuana and Derivative Products, if the tested concentration per Final Product of Total Active THC, Total Active CBD, or any individual cannabinoid is 25 milligrams or less, the tested concentration may vary by no more than 50% from the concentration printed on the Final Product packaging

(c) For Usable Whole Flower Marijuana and Derivative Products, if the tested concentration per Final Product of Total Active THC, Total Active CBD, or any individual cannabinoid is 10 milligrams or less, the tested concentration printed on the Final Product packaging must also be 10 milligrams or less.

(d) For Edibles, the tested concentration for Total Active THC, Total Active CBD, and any other labeled cannabinoid may vary by no more than 15% from the concentration printed on the Final Product packaging.

(e) Labeled potency concentrations that fall outside of these specifications result in a failure for labeled potency.

(f) Usable Whole Flower Marijuana labeled potency will be compared to the potency at the CMTL tested moisture content in order to determine a failure for labeled potency.

(g) For all Usable Product. If a cannabinoid ratio is claimed on the packaging or product label, the following equation must be used, $(\text{larger cannabinoid result}/y) * x$, where the ratio labeled on the Final Product packaging is x:y and x<y, and the percent difference between the smaller cannabinoid result and the result of the equation must be less than or equal to 10%.

(h) CMTLs must receive evidence of the corrected potency label prior to amending the COA to reflect a passing result. The CMTL must provide the department with the new COA as amended with an updated image of the corrected label before the product can be transported to an MMTC's department-approved dispensing facility.

(6) When conducting Regulatory Compliance Testing for Edibles, CMTLs must test for potency and must perform homogeneity testing for multi-serving edibles.

(a) A multi-serving edible may not contain more than 200 milligrams of Total Active THC. A single serving edible or a single serving portion of a multi-serving edible may not exceed 10 milligrams of THC. Edibles may have a potency variance of up to 15% from the 200 milligram and 10 milligram THC thresholds. An edible that exceeds the allowable variance constitutes a failure.

(b) Homogeneity sampling and testing of multi-serving Edibles, shall be in accordance with the following table.

TOTAL NUMBER OF FINAL PRODUCTS IN THE RETAIL BATCH	NUMBER OF FINAL PRODUCTS TO BE SAMPLED	SINGLE SERVINGS TESTED PER FINAL PRODUCT	TOTAL NUMBER OF SINGLE SERVINGS TESTED
1-249	1	3	3
250-499	2	3	6
500-749	3	3	9
750-999	4	3	12
1,000-1,249	6	2	12
1,250-1,499	7	2	14
1,500-1,749	8	2	16
1,750-1,999	9	2	18
2,000-2,499	10	2	20
2,500-2,999	11	2	22
3,000-3,999	12	2	24
4,000-4,999	13	2	26
5,000-7,499	14	2	28
7,500-9,999	15	2	30
10,000-14,999	16	2	32
15,000-19,999	17	2	34
20,000-29,999	18	2	36
30,000-39,999	19	2	38

40,000-49,999	20	2	40
50,000-59,999	21	2	42
60,000-69,999	22	2	44
70,000-79,999	23	2	46
80,000-89,999	24	2	48
90,000-100,000	25	2	50

(c) For batches over 100,000 units, the Retail Batch may be sampled as a 100,000-unit Retail Batch for every 100,000 units. Any remaining units under 100,000 will need to be tested again using the chart in paragraph (7)(b) above.

(d) The percent relative standard deviation of each Retail Batch of Edibles must be calculated using Total Active THC and Total Active CBD values from all servings tested using the following formula:

Percent Relative Standard Deviation = (Standard Deviation of Sample / Average of Sample) x 100.

A percent relative standard deviation greater than 25% and/or a single serving deviation of more than 50% from the average constitutes a failure of homogeneity testing.

(e) For the purposes of homogeneity testing only, each Retail Batch may be run as one Analytical Batch. Homogeneity testing must still adhere to all requirements in Rule 64-4.309, F.A.C., to include a final CCV at the end of the analysis.

(7) CMTLs must report any Testing Sample that is found to contain a significant level of any contaminant not listed in this rule. The CMTL must report such findings to the MMTC from which the sample was collected and to the department at OMMUlabs@flhealth.gov within 24 hours of the finding. Test results of samples tested for research and development purposes only are not required to be reported to the department.

(a) Any COA generated for research and development samples must be clearly labeled "R&D ONLY NOT FOR RETAIL." A Retail Batch that has already been sampled for Regulatory Compliance Testing cannot be sampled as R&D.

(b) Any COA generated by the testing of non-marijuana products (water, growth medium, nutrients, product ingredient, product packaging) must accurately describe the material tested.

(c) Final Products submitted for Regulatory Compliance Testing cannot also be submitted as R&D or amended to be classified as R&D.

(8) Any analyte tested at multiple dilutions must be reported to the lowest dilution factor still within the calibration curve. If samples are run at duplicate dilutions, the highest in-matrix concentration value is reported.

(9) CMTLs must maintain at least two untested portions of each Testing Sample, whether having passed or failed any testing, one of which must be in unopened Final Product packaging to maintain sterility. These Testing Samples must be securely stored for a minimum of 45 days before being destroyed. Every Testing Sample that is destroyed must be logged by the CMTL. Testing Samples that have been stored a minimum of 45 days may be used by the CMTL for in-house method development and validation prior to being destroyed. Stored Testing Samples may be collected by the department for testing purposes.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.986(8)(k), 381.986(8)(e)11.d., 381.988(3), 381.988(9) FS. Law Implemented Art. X, § 29, Fla. Const., 381.986, 381.988, FS. History—New.

64-4.309 CMTL Quality Control Samples.

(1) CMTLs must use Quality Control Samples in each analysis, where applicable. Quality Control Samples must be prepared and analyzed in the same manner as Testing Samples. The following Quality Control Samples must be in each analysis for Mycotoxins, Residual Solvents, Heavy Metals, Agricultural Agents, and Cannabinoid Profile:

(a) Method Blanks. CMTLs must prepare at least one Method Blank sample per Laboratory Batch according to the following:

1. The Method Blank must be analyzed after the Calibration Curve, ICV, and CCV.

2. Method Blanks that contain Target Analytes above the LOD must be reanalyzed.

a. Upon reanalysis, if the Method Blank is again above the LOD, the CMTL must determine and correct the source of the contamination, repeat preparation of the Laboratory Batch, and reanalyze the Testing Samples. If Method Blank results continue to read above the LOD, the CMTL must discontinue the analysis until such time as it is able to test at or below the LOD.

b. All analytes in the Method Blank above the LOD must be integrated and quantified. A CMTL may not subtract any result above the LOD in the Method Blank from any Quality Control Sample or Analytical Sample.

(b) Laboratory Fortified Blanks. CMTLs must prepare and analyze Laboratory Fortified Blanks for each Laboratory Batch according to the following:

1. Laboratory Fortified Blanks must be analyzed after the Method Blank.

2. The CMTL must record the Percent Recovery for all Target Analytes within each Laboratory Fortified Blank.

a. The CMTL must determine acceptable ranges of recovery in Laboratory Fortified Blanks, which must be

approved within the scope of the CMTL's ISO/IEC 17025:2017 accreditation.

b. The range of recovery for Agricultural Agents, Mycotoxins, Residual Solvents, and Cannabinoid Profile Laboratory Fortified Blanks and Laboratory Fortified Blank duplicates must be calculated as three (3) times the standard deviation from the mean of no less than 20 replicates, updated a minimum of every six (6) months.

c. The limit for recovery of Agricultural Agents, Mycotoxins, Residual Solvents, and Cannabinoid Profile cannot be below 45% or above 130%.

d. The range of recovery deviations for Agricultural Agents, Mycotoxins, Residual Solvents, and Cannabinoid Profile can be no greater than 20% from the average recovery of no less than 20 replicates, updated a minimum of every six (6) months.

e. The range of recovery for Heavy Metals must be between 80% and 120%.

3. All analytes in the Laboratory Fortified Blanks above the LOD must be integrated and quantified.

4. The Laboratory Fortified Blanks must represent each matrix type present in the Analytical Batch. The CMTL may only spike post dilution for cannabinoid analysis.

(c) Matrix Spike Samples. CMTLs must prepare and analyze Matrix Spike Samples for each Laboratory Batch according to the following:

1. Matrix Spike Samples must be analyzed after the Laboratory Fortified Blanks.

2. The CMTL must record the Percent Recovery for any Target Analyte within each Matrix Spike Sample.

a. The CMTL must determine acceptable ranges of recovery in Matrix Spike Samples, which must be approved within the scope of the CMTL's ISO/IEC 17025:2017 accreditation.

b. The range of recovery for Agricultural Agents, Mycotoxins, Residual Solvents, and Cannabinoid Profile Matrix Spike Samples and Matrix Spike Sample duplicates is calculated as three (3) times the standard deviation from the mean of no less than 20 replicates, updated a minimum every six (6) months.

c. The limit for recovery Agricultural Agents, Mycotoxins, Residual Solvents, and Cannabinoid Profile cannot calculate to be below 45% or above 130%.

d. The range of recovery deviations for Agricultural Agents, Mycotoxins, Residual Solvents, and Cannabinoid Profile can be no greater than 30% from the average recovery of no less than 20 replicates, updated a minimum of every six (6) months.

e. The range of recovery for Heavy Metals must be between 80% and 120%.

3. All analytes in the Matrix Spikes above the LOD must be integrated and quantified.

4. A Matrix Spike sample must be present for each matrix type in the Analytical Batch. The CMTL may only spike post dilution for cannabinoid analysis.

(d) For Analytical Samples with an analyte response above the LOD and greater than 30% analyte recovery below the average analyte recovery, the CMTL must perform standard addition to correct for Matrix effect. The standard addition regression must have an r^2 value of 0.99 or greater. The concentration of the analyte is calculated as: Concentration of analyte on column = (response of analyte on column / regression slope).

1. For analyte recoveries of 50%-70% of the average recovery with an analyte response above the CMTL LOQ, the CMTL must perform a standard addition for the analyte with a minimum of four (4) levels.

2. For analyte recoveries of less than 50% of the average recovery with an analyte response above the CMTL LOD, the CMTL must perform a standard addition for the analyte with a minimum of four (4) levels.

(e) CMTLs must run duplicate Testing Samples, Laboratory Fortified Blanks and Matrix Spike Samples and must calculate their RPD. The RPD between duplicates must be as follows:

1. Mycotoxins: 20% or less;

2. Residual Solvents: 30% or less;

3. Heavy Metals: 20% or less;

4. Agricultural Agents: 20% or less;

5. Cannabinoids: 15% or less; and

(f) CMTLs shall run Quality Control Samples after the Calibration Curve in the following order: ICV first, then CCV.

(g) After the initial CCV, the CMTL must run subsequent CCVs once every 12 hours, or at a minimum, every 10 injections, and after all Analytical Batch injections. The CMTL shall calculate the Calibration Drift between the ICV and the corresponding Calibration Curve level. The CMTL shall also calculate the Calibration Drift between the CCV and the corresponding Calibration Curve level. The Calibration Drift must be no more than 20%. The ICV and CCV must contain all required Target Analytes. All Target Analytes must have Calibration Drift calculated and evaluated. An ICV must be analyzed a minimum of every 3 months or with every new Calibration.

1. If one or both of the CCV results bracketing a group of 10 injections are greater than 20% but less than 50% Calibration Drift above the corresponding Calibration Curve level concentration, the CMTL may report any Target Analyte result below the LOD. A CCV may be reinjected immediately after a failed CCV, and if passing the run can continue using the results from the second CCV injection. Otherwise, the CMTL must

reanalyze the samples affected by the failed CCV after a new Calibration Curve has been established and accepted. If a CCV result is greater than 50% Calibration Drift above the corresponding Calibration Curve level concentration, the CMTL must reanalyze the Analytical Batch for the failed Target Analyte. CCV results may only be reported from one (1) CCV injection.

2. If one or both of the CCV results bracketing a group of 10 injections are greater than 20% Calibration Drift below the corresponding Calibration Curve level concentration, the CMTL may report any Target Analyte result above the Acceptable Limits. Otherwise, the samples affected by the failed CCV shall be reanalyzed for the failing Target Analyte.

3. If a CCV's Calibration Drift is greater than 20% for Target Analyte results below the LOD for 5% or more of the Target Analytes, the CMTL must reanalyze the portion of the Analytical Batch tested before and after the failing CCV.

(h) Analytical Methods containing fewer than 11 Spike Solution Target Analytes in a Laboratory Fortified Blank and Matrix Spike Sample may not have any RPD measurements outside of the accepted range. All Target Analytes present in the Spike Solution must be fully analyzed and conform to all Quality Control requirements. Analytical Methods for each instrument containing greater than or equal to 11 Spike Solution Target Analytes may have the following number of Target Analytes outside of the accepted range for RPD based on the following schedule:

1. Analytical Methods for each instrument containing 11 to 30 Target Analytes may have one (1) Target Analyte per Quality Control Sample outside the accepted range.

2. Analytical Methods for each instrument containing 31 to 50 Target Analytes may have two (2) Target Analytes per Quality Control Sample outside the accepted range.

3. Analytical Methods for each instrument containing 51 to 70 Target Analytes may have three (3) Target Analytes per Quality Control Sample outside the accepted range.

4. Analytical Methods for each instrument containing 71 or more Target Analytes may have four (4) Target Analytes per Quality Control Sample outside the accepted range.

(i) Analytical Methods for each instrument containing multiple Target Analytes may have a representative number of Target Analytes chosen for the required Spike Solution. All analytes present in the Spike Solution must be fully analyzed and conform to all Quality Control requirements. A CMTL must include all Heavy Metal Target Analytes in the Spike Solution.

1. Analytical Methods for each instrument that include one (1) to 10 Target Analytes, the Spike Solution must contain all Target Analytes.

2. Analytical Methods for each instrument that include 11 to 30 Target Analytes, the Spike Solution must contain 50% of the Analytical Method Target Analytes, with a minimum of five (5) Target Analytes.

3. Analytical Methods for each instrument that include more than 30 Target Analytes, the Spike Solution must contain at least 35% of the Analytical Method Target Analytes, with a minimum of 11 Target Analytes.

4. The CMTL must ensure all Target Analytes are included in the Spike Solution at least once in a two-year period.

(j) In Heavy Metals analysis, three (3) replicates of each injection are required with a relative standard deviation less than 15% if above the LOD. The CMTL must calculate the relative standard deviation as:

(standard deviation of the sample replicate values / mean sample value) x 100.

The CMTL must report the average value of the three (3) replicates.

(k) An analysis will be deemed satisfactory when all Quality Control Sample measurements meet the accepted criteria. If any Quality Control Sample measurements fall outside the accepted criteria, the failing Quality Control Sample may be reanalyzed once before any Testing Samples to confirm the failure. If the Quality Control Sample failure is confirmed, the Laboratory Batch must be reanalyzed. If after reanalysis the same Quality Control Sample falls outside the accepted criteria, the CMTL must repeat the preparation of the Analytical Batch and reanalyze as a new Laboratory Batch. If the Quality Control Sample continues to fall outside the accepted criteria, the CMTL must discontinue conducting the analysis until the CMTL is able to correct the cause of the unsatisfactory Quality Control Sample measurement. All spiked Target Analytes must be integrated and evaluated against the criteria set forth in paragraphs (1)(a)-(j) above.

(l) CMTLs must generate Quality Control Sample reports that contain the date of the analysis, the parameters of the analysis, the Matrix or Matrices used, the Target Analytes tested for, the instrument of analysis, and the results of all Quality Control Samples.

(m) Internal Standards must be used during Residual Solvent, Agricultural Agent, and Heavy Metals testing for all Target Analytes.

1. Internal Standard recovery for Calibration Standards, CCVs, and ICVs must be 70%-130%;

2. Internal Standards recovery for Analytical Samples and Quality Control Samples listed in paragraphs (1)(a) - (e) in the Agricultural Agents and Residual Solvents Testing Fields must be 50%-150%; and

3. Internal Standards recovery for Analytical Samples and Quality Control Samples listed in paragraphs (1)(a) -(e) in the Heavy Metals Testing Field must be 70%-130%.

4. Every Residual Solvent and Agricultural Agent Target Analyte must be compared to an internal standard with a

Retention Time difference between the Internal Standard and the assigned Target Analyte less than 2.5 minutes.

5. Every Heavy Metal Target Analyte must be compared to an Internal Standard no more than 50 atomic mass units from the assigned analyte.

(n) If using Surrogates in an Analytical Method, CMTLs must determine recovery criteria. The recovery window for Surrogates is calculated as three (3) times the standard deviation from the mean of no less than 20 replicates, updated on a continuous basis. The limit for recovery cannot be below 45% or above 130%. The recovery window deviations can be no greater than 20% from the average recovery of no less than 20 replicates, updated on a continuous basis.

(o) If the number of Analytical Samples in an Analytical Batch for Mycotoxins, Residual Solvents, Heavy Metals, Agricultural Agents, or Cannabinoid Profile is greater than 30, the Analytical Batch must be split between multiple Laboratory Batches such that the Quality Control Samples in each Laboratory Batch correspond to a maximum of 30 Analytical Samples.

(p) Analytes with multiple isomers must follow QC requirements for each individual isomer. Sum of isomers must meet LOD and LOQ requirements.

(2) Microbiological Testing by polymerase chain reaction (PCR).

(a) For PCR Microbiological Testing, the Laboratory Batch must include:

1. One positive Quality Control Sample able to detect Microbe presence in a minimum of one gram;

2. One negative Quality Control Sample; and

3. One Duplicate Testing Sample per well plate.

(b) Microbes with an Acceptable Limit of none present in a minimum of one gram must undergo a 24-hour enrichment before testing.

(c) PCR testing protocols may not utilize any extracellular DNA denaturing enzymes. Plating Aspergillus spp. samples is not permitted.

(3) For Total Combined Yeast and Mold analysis, each Testing Sample must be prepared and analyzed in duplicate with a maximum calculated RPD of 40% between duplicate Testing Samples.

(a) Analysis for Total Combined Yeast and Mold must use a culture based method.

(b) The higher of the Duplicate Total Combined Yeast and Mold value must be reported on the COA. If one Duplicate passes and one Duplicate fails, a third must be prepared and reanalyzed to confirm the result.

(c) A minimum of 10 grams must be prepared for Total Combined Yeast and Mold analysis.

(d) Confirmation of failed results must use the same method as the original analysis.

(e) Total Combined Yeast and Mold analyzed by plate count must be serially diluted to obtain a CFU count of 10 to 150 CFU per plate at a dilution of 100x or greater and must have a minimum of one (1) microbe specific positive plate, one (1) negative plate, and one (1) Duplicate Testing Sample plate per day.

(f) Total Combined Yeast and Mold analysis using most probable number must be visually inspected to ensure the wells have not been compromised, resulting in a non-detectable result due to oversaturation.

(g) Total Combined Yeast and Mold culture-based protocols must incubate for a minimum 60 hours. If an irradiative sterilization step is used on Whole Flower Usable Product during processing, Total Combined Yeast and Mold Samples must be incubated for an additional 48 hours if no growth is visible after 60 hours.

(4) For Moisture and Water Activity analysis, the equipment must be verified daily, and a duplicate sample measured every 30 samples.

(a) RPD between duplicate samples must be 15% or below.

(b) Moisture analysis temperature may not exceed 90° Celsius.

(c) A daily record must be kept detailing each sample analyzed, the analyst who performed the test, and the time the test was performed.

(5) All reagents and solutions used to prepare and analyze Quality Control samples and Testing Samples must be used within their manufacturer or CMTL determined expiration date.

(6) Data must be reported once all Quality Control Samples pass the requirements stated in this rule. Retesting of a Testing Sample may only be performed to confirm a failing result or if one or more Quality Control Samples does not meet one or more of the Quality Control Sample requirements stated in this rule.

Rulemaking Authority Art. X, § 29, Fla. Const.,381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const., 381.988, FS. History–New.

64-4.310 CMTL Calibration Standards.

(1) Calibration Standards must be prepared by diluting Certified Reference Materials to produce working standards to be used in the Calibration of instruments, the quantitation of Analytical Samples, and for use in Laboratory Fortified Blanks and Matrix Spike Samples. CMTLs must prepare Calibrations for Agricultural Agents and Mycotoxins in a Matrix that matches the Analytical Batch being tested. Certified Reference Materials must be:

(a) Obtained from an independent body that holds ISO/IEC 17034:2017 accreditation; or

(b) Created by the CMTL, if the CMTL holds ISO/IEC 17034:2017 accreditation; and

(c) Within the manufacturer's or CMTL-determined expiration date.

(2) The LOD must be calculated for Mycotoxins, Heavy Metals, Residual Solvents, Agricultural Agents, and Cannabinoid Profile. In the determination of the LOD, the CMTL must follow the U.S. Environmental Protection Agency, "Definition and Procedure for the Determination of the Method Detection Limit," Revision 2, December 2016, which is incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. The LOD for chemical methods must be 1/5 of the Acceptable Limit or less with an instrument signal to noise ratio of 3:1 or greater for each Target Analyte, including all isomers and compounds thereof, as calculated in the Analytical Sample after correction for all Dilution Factors and sample weights or volumes.

(3) The LOQ must be calculated for Mycotoxins, Heavy Metals, Residual Solvents, Agricultural Agents, and Cannabinoid Profile. The LOQ for chemical methods must be no lower than the lowest Calibration Standard, and a maximum of ½ of the Target Analyte's Acceptable Limit as calculated in the Analytical Sample after correction for all Dilution Factors and sample weights or volumes. The LOQ must have a Signal-to-noise Ratio of 10:1 or greater.

(4) For Heavy Metals analysis, the instrument detection limit must be measured as the concentration equivalent to the Target Analyte signal which is equal to the average blank result plus three (3) times the standard deviation of a series of 10 replicate measurements of the calibration blank signal at the selected analytical mass(es). The instrument detection limit cannot be greater than the LOD. The instrument detection limit samples must be run in three (3) separate batches over three (3) separate days.

(5) The Calibration Curve must:

(a) Use the concentration and percentage for each analyte and isomer identified in the Certificate of Analysis from the ISO/IEC 17034:2017 accredited Certified Reference Material provider to calculate the concentration of all standard curve points.

(b) Consist of a minimum of five (5) consecutive points with a known concentration above zero if utilizing a linear correlation with no non-consecutive points added;

(c) Consist of a minimum of six (6) consecutive points with a known concentration above zero if utilizing a non-linear correlation with no non-consecutive points added;

(d) Consist of a minimum of six (6) consecutive points with known concentrations above zero and utilize a quadratic correlation for Cannabinoid analysis;

(e) Have a response and be integrated in accordance with Rule 64-4.312, F.A.C.; and

(f) Have a correlation of determination (r^2) using all standard curve points equal or greater to 0.99.

1. A CMTL may only use non-linear correlations if linear correlations do not meet the 0.99 r^2 requirement.

2. A CMTL may only use weighted correlations if non-weighted correlations do not me the 0.99 r^2 requirement.

(g) Use calibration table values corresponding with on-instrument concentrations excluding calculations and Dilution Factors;

(h) Have an in-Matrix concentration spanning from, at a minimum, the LOQ to the inhalation limit, no more than three (3) times the inhalation Acceptable Limit for each individual Target Analyte, and a maximum dilution factor of 20 for non-inhalation Target Analytes;

(i) Use the same instrument method for all Injections of Calibration Standards, Quality Control Samples, and Analytical Samples;

(j) Have all calibration point be from the same run sequence;

(k) Not have multiple calibration points at the same concentration averaged to create one calibration point at that concentration;

(l) Not be used for samples which were injected before the Calibration Standards used in the Calibration Curve were injected; and

(m) Be the most recently established Calibration Curve used for sample analysis. Quality Control Samples and Analytical Samples may not be analyzed with a previous Calibration Curve once a new Calibration Curve has been established.

(6) The highest level on the Calibration Curve shall be the highest reportable value. Any subsequent results greater than the highest level on the Calibration Curve must be diluted and reanalyzed or reported as greater than the highest level on the Calibration Curve.

(7) A Calibration Curve is deemed established when the regression is analyzed and compared to the requirements set forth in this rule.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const., 381.988, FS. History–New.

64-4.311 CMTL Certificate of Analysis.

(1) A CMTL must generate a COA containing the results from each Final Product tested, containing all the information required in paragraph (1)(a) below, and all the information required in paragraphs (1)(b) and (1)(c) below, as applicable. Additional information, analysis, or graphics not expressly required by paragraphs (1)(a) through (1)(c) may be included on any COA required by this rule. All Target Analyte concentrations must be reported on and labeled in the units

specified in Rule 64-4.308, F.A.C. All COAs must be delivered to the MMTC as a portable document format ("PDF") and must be locked to prohibit unauthorized editing.

(a) COAs for Environmental Testing, Microbiological Testing, and Cannabinoid Profile testing must contain:

1. The name of the MMTC from which the Sample was collected;

2. The cultivation facility or facilities which cultivated the marijuana from which the Sample was collected;

3. The processing facility or facilities which processed the marijuana from which the Sample was collected;

4. The facility from which the Sample was collected;

5. The Cultivar or Cultivars making up the Sample – if the Retail Batch is comprised of more than two Cultivars, the Testing Sample can be referred to as "mixed Cultivar";

6. The Sample's Retail Batch and harvest batch number(s) and date the Retail Batch and harvest batch were created;

7. The Sample's batch number and date any Laboratory Batch was created;

8. The total units of the Sample's Final Product received for testing;

9. Sample's Total Retail Batch weight or volume;

10. Total number of units in the Sample's Retail Batch;

11. The Sample's Testing Sample Matrix as one of the following:

a. Usable Whole Flower Marijuana;

b. Derivative Product intended for inhalation;

c. Derivative Product not intended for inhalation; or

d. Edible.

12. The internal Employee identification number of any person who performed the Sample preparation;

13. The date and time of the Sample's preparation;

14. The title or number of the SOP used to prepare the Sample;

15. The title or number of the SOP used to analyze the Sample;

16. The date and time Sample injection occurred;

17. The expiration date of the COA results for the retail product. The expiration date of the COA results must be one (1) year or less from the sample date;

18. A narrative outlining all COA changes resulting in the issuance of a revised COA for the Sample;

19. The internal Employee identification number of any person who performed the Sample analysis; and

20. A statement in bolded 14-point font size identifying a retested or amended COA for the Sample. All amended or corrected COAs must be reported to the department with a written narrative as indicated in subparagraph (1)(a)18. above.

21. All failed COAs must be accompanied by a photographic image of the product label and packaging of the product being tested.

(b) COAs for Environmental Testing and Cannabinoid Profile testing must contain:

1. The type of instrument used to analyze the Sample;

2. The initial weight or volume of the aliquot used to prepare the Testing Sample for analysis;

3. The final weight or volume of the Analytical Sample used in the analysis;

4. The Target Analytes measured in the test;

5. The numerical concentration for each Target Analyte measured in the Testing Sample above the LOD and the LOQ. The LOD and LOQ must be calculated with respect to changes including but not limited to Standard Curves, dilutions, injection volume, and Analytical Sample weights. The CMTL must reflect these changes on the COA;

6. The Target Analytes reported and qualified as follows:

a. Analytical values reported to three (3) significant figures as <[LOD value] if the concertation falls below the LOD;

b. Analytical values reported to three (3) significant figures and marked with a qualifier if the concentration falls between the LOQ and LOD;

c. Analytical values reported to three (3) significant figures if the concentration falls within the Calibration Curve; or

d. Analytical values reported to three (3) significant figures as >[highest Calibration Curve point concentration] if the concentration falls above the Calibration Curve.

7. The Dilution Factor of each Target Analyte reported to no more than three (3) significant figures;

8. The percentage of each cannabinoid and the total percentage of all cannabinoids within the Sample at the CMTL-tested Moisture content reported to three (3) significant figures;

9. The total concentration in milligrams per Final Product of Total THC and Total CBD calculated at the CMTL-tested Moisture content reported to three (3) significant figures;

10. The percent relative standard deviation measured for all Edibles reported to 3 significant figures; and

11. The package label deviation for Total THC and Total CBD using the following formula: Percent Deviation = ((Tested Total THC or Total CBD concentration – Labeled Total THC or Total CBD)/ Labeled Total THC or Total CBD) x 100, and the packaging label deviation for cannabinoid ratio as defined in paragraph 64-4.308(6)(g), F.A.C., reported to no more than three (3) significant figures.

12. The Acceptable Limit for the analysis conducted.

13. A statement (i.e., "PASS" or "FAIL") indicating whether the Sample has passed or failed any and all Acceptable Limits for individual Target Analytes. The indicator statement must be in bolded 14-point font size or larger and must be displayed in a manner that is visually distinct from the information outlined in subparagraphs (1)(b)1.-12. above.

(c) COAs for Microbiological Testing must contain:

1. The presence or absence of Microbes present in 1 gram;

2. The Target Analytes measured in the test;

3. The Acceptable Limit for the analysis conducted;

4. Total Yeast and Mold numerical concentration reported as CFU per gram reported to three (3) significant figures.

5. A statement (i.e., "PASS" or "FAIL") indicating whether the Sample has passed or failed any and all Acceptable Limits for Microbes. The indicator statement must be in bolded 14-point font size or larger and must be displayed in a manner that is visually distinct from the information outlined in subparagraphs (1)(c)1.-4. above.

(d) If a Final Product can be administered through multiple routes of administration, the CMTL must use the more stringent Acceptable Limits.

(e) COAs generated by the CMTL must be delivered to the MMTC and the department within 14 days of the Sample departure date noted on the chain of custody documentation. A CMTL may withhold testing results if payment for services has not been received.

(f) The following actions performed by a CMTL constitute an invalidation of the COA:

1. Using a method not covered in Rule 64-4.306, F.A.C., or approved by the department;

2. Sampling not in accordance with Rule 64-4.307, F.A.C.;

3. Generating Quality Control Sample results not in accordance with Rule 64-4.309, F.A.C.;

4. Generating standard curve results not in accordance with Rule 64-4.310, F.A.C.;

5. Performing Manual Integrations not in accordance with Rule 64-4.312, F.A.C; and

6. Using an SOP for analysis and preparation of samples not included in the CMTL's ISO/IEC 17025:2017 accreditation.

(2) Data Packages. All Target Analyte concentrations must be labeled. CMTLs must create and maintain Data Packages for every analyzed Laboratory Batch. Data Packages must contain:

(a) All COAs for the Retail Batch as required by subsection (1);

(b) Laboratory Batch Quality Control Sample reports;

(c) Unique instrument identifier;

(d) Raw data for each Sample with analysis date stamp. If the failure is for Filth and Foreign Material, the CMTL must include a photograph of the Testing Sample. If the failure is for a Microbial analyte using plating, the CMTL must include a photograph of the plates;

(e) Instrument raw data with injection date and time stamp, if any;

(f) All Standard Curve, Quality Control, and Analytical Sample chromatographic raw data including clear depictions of integrations, if any;

(g) Instrument test method with parameters;

(h) Instrument tune reports, where applicable;

(i) All instrument Calibration and/or tune data;

(j) Internal Standard report;

(k) ICV Report;

(l) CCV Report;

(m) Sample preparation worksheets;

(n) Employee workbook sheets relevant to the analysis run;

(o) Analytical Batch Sample sequence;

(p) Internal laboratory sample chain of custody documentation as described in Rule 64-4.301, F.A.C.; and

(q) Chain of custody documentation as described in Rule 64-4.307, F.A.C.

(3) Prior to the dissemination of any documentation contemplated by subsections (1) and (2) to the department or an MMTC, the CMTL's Laboratory Director, or designee, must:

(a) Review the quantitative analytical results for technical correctness, clarity, and completeness;

(b) Verify that the results of each analysis are accurately reported, and that the results can be traced back to the specific Laboratory Batch; and

(c) Approve the results by signing and dating the Data Package.

(4) CMTLs must maintain Data Packages for three (3) years from the date created. Chain of custody documentation, IDOC documentation, CMTL audit reports, and CMTL on-site inspection reports must be retained for a minimum of three (3) years from the date created. Quality Control reports and Proficiency Testing results must be retained for a minimum of two (2) years from the date of receipt by the CMTL. Video surveillance recordings must be maintained for a minimum of 45 days or longer upon the request of a law enforcement agency, the department, or as ordered by any court of competent jurisdiction.

(5) Supporting documentation. Upon request by the department, a CMTL must provide the department copies of the following within 48 hours of the department's request:

(a) Proof of accreditation required by department rules;

(b) All materials and documents submitted for the most recent ISO/IEC 17025:2017 accreditation audit;

(c) SOPs;

(d) Analytical Methods;

(e) Equipment logs;

(f) Raw analytical data;

(g) Initial Display of Competency documentation;

(h) Chain of custody documentation;

(i) Sample rejection logs;

(j) Quality Assurance reports;

(k) Proficiency Testing results;

(l) Quality Assurance Manual;

(m) Personnel qualification, training, and competency documentation;

(n) Purchasing and supply records;

(o) Method verification and validation records;

(p) Quality Assurance and Quality Control records;

(q) Equipment service records;

(r) Non-conforming work and corrective action records;

(s) Internal and external audit records;

(t) Testing Facility and Secure Storage area security records;

(u) Data Packages;

(v) Data backup records;

(w) Data reports, data review, and data approval records;

(x) Any report or COA created for an MMTC;

(y) Any analytical testing data:

(z) Traceability records;

(aa) Standards records;

(bb) Calibration records;

(cc) Extraction logs and Certified Reference Materials records;

(dd) Analyst notebooks and logbooks;

(ee) Sample analysis reports;

(ff) Contamination records;

(gg) Cleaning records;

(hh) Safety and chemical-hygiene records;

(ii) R&D testing results;

(jj) Any other generated report related to the testing of marijuana;

(kk) Any other generated report related to the audit or on-site inspection of MMTCs, to include any materials used in the creation of such report; and

(ll) Any other document or record necessary to substantiate compliance with sections 381.986 and 381.988, F.S., and department rules.

(6) A CMTL must provide the requested records to the department electronically in an accessible format. If the CMTL provides such records in a protected format (i.e., a locked PDF), the CMTL must simultaneously provide the department with a password to unlock the record for access and analysis.

Rulemaking Authority Art. X, § 29, Fla. Const.,381.988(3), 381.988 (9), FS. Law Implemented Art. X, § 29, Fla. Const., 381.988, FS. History–New.

64-4.312 CMTL Manual Integration.

(1) CMTLs must create and maintain Retention Time Windows for each Target Analyte, Surrogate, and Internal Standard for each Testing Field in which chromatography is used for analysis.

(a) The Retention Time Window is calculated by multiplying three (3) times the standard deviation of the Retention Times of no less than seven (7) injections of a standard containing the same concentration of the Target Analyte. The result is then added to and subtracted by the expected Retention Time to create the Retention Time Window. The Retention Time Window cannot be less than the expected Retention Time of the peak plus or minus 0.03 minutes. The expected Retention Time must be updated at the time of Calibration. If a Calibration is not performed, the CMTL must update the expected Retention Time when a shift in Retention Times is observed at the beginning of each analytical run using the first injection of a CCV standard.

(b) Identification of a Target Analyte peak outside of its established Retention Time Window is treated as a Manual Integration as described in subsection (5). A CMTL may choose to not allow identification outside of a Retention Time Window as part of the SOP required by subsection (6).

(2) The resolution between a Target Analyte's chromatographic peak and an adjacent peak, whether an interferent peak or a preceding or succeeding Target Analyte, must be greater than or equal to 1.0 using the equation:

$$R = 1.18\left(\frac{(RT_2 - RT_1)}{(W_{1/2h1} + W_{1/2h2})}\right),$$

where R is the resolution, RT is the Retention Time of the peaks, and W is the width of the peaks at one half the height of the peaks.

(a) This calculation must be performed under the following circumstances:

1. During validation of the instrument method for any Target Analyte whose chromatographic peak and an adjacent peak, whether an interferent peak or a preceding or succeeding Target Analyte does not achieve Baseline Resolution.

2. During review of analytical data in which the resolution between any Target Analyte whose chromatographic peak and an adjacent peak does not achieve Baseline Resolution.

3. During review of analytical data in which the resolution between a Target Analyte and an adjacent peak that has shifted Retention Times and appears to not have a resolution greater or equal to 1.0.

(b) If upon calculation, the resolution is less than 1.0, the CMTL must discontinue conducting the analysis until the CMTL is able to achieve a resolution of greater than or equal to 1.0. Target Analytes with a resolution from adjacent peaks less than 1.0 is not reportable.

(3) Integration parameters for Automatic Integration must be set at time of Calibration and not changed until the next Calibration.

(4) All peaks that meet criteria identified in the CMTL's Quality Assurance Manual and SOPs, which include but are not limited to Retention Time, Signal-to-noise Ratio, and ion ratios, must be integrated and uploaded to the CMTL's tracking system to determine if the instrument response equates to a concentration of greater than the LOD.

(5) CMTLs may perform Manual Integrations when the Automatic Integration performed by the chromatographic software is in error.

(a) CMTLs must maintain the original Automatic Integration performed by the chromatographic software and the final Manual Integration performed by the Analyst as part of the Data Package in Rule 64-4.311, F.A.C.

(b) CMTLs must utilize the audit trail functionality of all chromatographic software. This functionality must also be used in the annual review required by subsection (8).

(c) All Manual Integrations must have a record of the Analyst who performed them, the date they were performed, and the reason for manually integrating the peak.

(d) Raw data resulting from a manually integrated peak must be automatically identified by the chromatographic software.

(e) All Manual Integrations must be reviewed by a second Analyst before reporting the data and have a record of the name of the reviewer and date of the review. The reviewer must be an Analyst trained on the CMTL's Manual Integration policies and have a valid IDOC for the Testing Field being reviewed.

(f) Manual Integrations must never be used to force a Calibration or Quality Control Sample to pass method and/or regulatory criteria. Manual integrations must not be used to force a client sample to calculate below the Acceptable Limit. Manual integrations may not be performed where there are no errors present in either the Automatic Integration performed by the chromatographic software or a previous Manual Integration. This includes, but is not limited to, Peak Shaving and Peak Enhancement.

(g) All integrations, whether automatic, manual, or both, across all Calibration Standards, calibration verification standards, batch Quality Control Samples, and client samples must be consistently integrated.

(h) A CMTL may not use Manual Integrations to replace proper instrument maintenance or other corrective or preventative actions to improve chromatographic performance.

(i) All automatically integrated and manually integrated peaks must meet a Signal-to-noise Ratio of at least three (3) in order to be reported.

(6) CMTLs must create, maintain, and follow an SOP for chromatography and Manual Integration standards. The SOP must include but is not limited to the following topics:

(a) A CMTL must not establish a policy prohibiting Manual Integrations;

(b) All previously mentioned requirements in this rule;

(c) Definition of Peak Shaving and an explanation of its prohibition;

(d) Definition of Peak Enhancement and an explanation of its prohibition;

(e) Definition of consistent integrations and how to perform them in difficult Matrices, including interference peaks, fronting, tailing, and fluctuating baselines; and

(f) Excessive Manual Integrations on a single peak and proper corrective measures.

(7) CMTLs must have annual training on Manual Integration policies and procedures for all Analysts that perform analyses in a Testing Field utilizing chromatography. All Analysts must be trained in the CMTL's Manual Integration policies and procedures as part of their IDOC in a Testing Field utilizing chromatography. This annual training should include but is not limited to all topics in subsection (6).

(8) The Laboratory Director, or their designee, must perform an annual review of at least three (3) analytical runs of each Testing Field utilizing chromatography and at least three (3) analytical runs for each Analyst across all Testing Fields in which the Analyst performs analyses utilizing chromatography.

(a) The Laboratory Director, or their designee, must not be the original Analyst or the original reviewer of the data as required in paragraph (5)(e).

(b) A report must be generated after the review is completed and be sent to the department at OMMULabs@flhealth.gov within five (5) business days of completion. The report must contain:

1. The CMTL's name and address;

2. The Testing Field that was reviewed;

3. The Analyst that was reviewed;

4. A copy of all Automatic Integrations and Manual Integrations reviewed;

5. A narrative of all observations and conclusions based on the review;

6. Any corrective action plans as a result of the review; and

7. The name and signature of the Laboratory Director, or their designee, who performed the review.

Rulemaking Authority Art. X, § 29, Fla. Const.,381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const.,381.988, FS. History–New.

64-4.313 CMTL Waste Management and Disposal.

(1) As used in this rule, the term "Marijuana Waste" includes the following materials:

(a) Testing Waste, which means spent solvents, lab wastes, and similar materials used in the testing of Usable Whole Flower Marijuana or Derivative Product ready for disposal;

(b) Product Waste, which means Usable Whole Flower Marijuana or Derivative Product ready for disposal, regardless of whether or not it has been analyzed or removed from the Package;

(c) Other contaminated materials ready for disposal. "Contaminated Materials" means any item, object, utensil, or

tool that came in contact with marijuana or usable product and has trace residuals of marijuana thereon.

(d) Notwithstanding the foregoing, Marijuana Waste does not include hazardous waste or universal waste, as those terms are defined in Rule 62-730.020, F.A.C., which is incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX, or biomedical waste as defined in s. 381.0098(2)(a), F.S.

(e) Once the CMTL is in possession of the marijuana, the CMTL is prohibited from returning any marijuana, including Marijuana Waste, to the MMTC.

(2) A CMTL may clean Contaminated Material using any method that completely eliminates any trace marijuana residuals from the material. Once the material has been cleaned of all trace marijuana residuals, the material may be recycled or disposed of like any other non-marijuana waste that falls outside the scope of this rule.

(3) A CMTL shall comply with all applicable federal and state laws and regulations for solid and liquid wastes and any applicable local regulations or ordinances.

(4) Marijuana Waste must be rendered unusable and unrecognizable or irretrievable Onsite at the CMTL's department-approved Testing Facility before it is transported offsite as provided for in paragraphs (7)(a) and (b). For the purposes of this rule, "Onsite" means within the secured building or adjoining secured fenced-in area controlled by the CMTL at their department-approved Testing Facility.

(a) Marijuana Waste is unusable and unrecognizable if it is incapable of being salvaged and consumed through any means and all components are homogenous and indistinguishable.

(b) Marijuana Waste is irretrievable if it cannot be transformed to a physical or chemical condition or state as marijuana or a substance with a chemical structure or effect that is similar to marijuana.

(c) At least two employees of the CMTL, one of whom must be a Manager, shall be present when rendering the Marijuana Waste unusable and unrecognizable or irretrievable. Steps taken to render Marijuana Waste unusable and unrecognizable or irretrievable shall be conducted under video surveillance.

(d) Until such time that the Marijuana Waste is rendered unusable and unrecognizable or irretrievable, the Marijuana Waste shall be stored in a waste receptacle(s) that is:

1. A securely locked, enclosed container; and

2. Located in a secured area of the facility.

(5) Prior to disposal, in accordance with subsection (7), Marijuana Waste shall be:

(a) Rendered unusable and unrecognizable by grinding and mixing the compostable Marijuana Waste with at least an equal amount of other compostable materials (e.g., food waste, yard waste, vegetable-based grease or oils);

(b) Rendered unusable and unrecognizable by grinding the Marijuana Waste with at least an equal amount of other compostable materials (e.g., food waste, yard waste, vegetable-based grease or oils) or non-compostable materials (e.g., paper waste, cardboard waste, plastic waste, or oil), or both; or

(c) Rendered irretrievable by permanently altering the physical or chemical condition through irreversible means.

(6) After being rendered unusable and unrecognizable or irretrievable, the CMTL must securely lock the Marijuana Waste in an enclosed container.

(7) After Marijuana Waste is rendered unusable and unrecognizable or irretrievable, any remaining Marijuana Waste shall be disposed of via one of the following methods:

(a) Delivered to an appropriate solid waste management facility, as that term is defined in subsection 62-701.200(112), F.A.C., which is incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

(b) Delivered to a composting facility that is registered with or permitted by the Department of Environmental Protection pursuant to chapter 62-709, F.A.C., which is incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX; or

(c) Composted Onsite by the CMTL in accordance with chapter 62-709, F.A.C.

(8) A CMTL must maintain a waste management plan that will be provided to the department upon request and is subject to the department's approval. A waste management plan must include, at a minimum:

(a) The identity of all CMTL employees with access to the Marijuana Waste storage area(s) of its Testing Facility;

(b) Procedures for rendering Marijuana Waste unusable and unrecognizable or irretrievable, as required by this rule;

(c) Procedures for storing Marijuana Waste before it is rendered unusable and unrecognizable or irretrievable;

(d) The manner of disposing of Marijuana Waste after it is rendered unusable and unrecognizable or irretrievable;

(e) Procedures for ensuring that the disposal of Marijuana Waste is properly documented on the CMTL's chain of custody logs;

(f) Employee training materials and exercises concerning the CMTL's Marijuana Waste management procedures; and

(g) Record maintenance and retention procedures for Marijuana Waste records.

(9) A CMTL must maintain accurate records of the Marijuana Waste it generates. Such records must account for all activity related to the disposal of the Marijuana Waste, including:

(a) The date, time, and manner of rendering the Marijuana Waste unusable and unrecognizable or irretrievable, along with the legible names and signatures of the persons who rendered the Marijuana Waste unusable and unrecognizable or irretrievable;

(b) The video recording of the persons and process of rendering the Marijuana Waste unusable and unrecognizable or irretrievable;

(c) The name of the entity(ies) hauling the Marijuana Waste, if any, and documentation that evidences the CMTL's subscription to waste collection services from that entity; and

(d) The date, time, and manner of disposing of the Marijuana Waste, including whether the Marijuana Waste was disposed of via delivery to a solid waste management facility, delivery to a registered or permitted composting facility, or composted Onsite by the CMTL.

(e) Video surveillance recordings must be retained for at least 45 days. All other Marijuana Waste records must be retained for at least two years.

(f) A CMTL's chain of custody log must reflect the CMTL's disposal of samples.

(10) Prior to disposal, non-hazardous waste that does not meet the definition of "Marijuana Waste," but displays an MMTC's or CMTL's identifying information, (e.g., packaging materials for Usable Whole Flower Marijuana or Derivative Product) must be rendered unusable and unrecognizable, or irretrievable by defacing, grinding, or shredding.

(11) After being rendered unusable and unrecognizable or irretrievable the CMTL must securely lock the non-hazardous waste in an enclosed container.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(3), 381.988(9), FS. Law Implemented Art. X, § 29, Fla. Const.,381.988, FS. History—New .

64-4.314 CMTL Background Screening.

(1) Required Background Screening.

(a) No person may serve as an Employee, Owner, or Manager, as those terms are defined in Rule 64-4.300, F.A.C., until the person has passed a level 2 background screening as required by section 381.988, F.S.

(b) A CMTL that allows a person to serve as an employee, owner, or manager before passing background screening will be subject to discipline pursuant to Rule 64-4.315, F.A.C.

(2) Background Screening Procedures.

(a) A CMTL or Applicant must request and obtain written notice from the department that a prospective owner, employee, or manager has passed background screening before allowing any such individual to serve as an employee, owner, or manager of the CMTL.

(b) A CMTL or Applicant must request that the department process the prospective employee, owner, or manager's background report. The request must be submitted by email to OMMUBGS@flhealth.gov and include the full name of the person(s) submitting to background screening together with Form DH5061-OMMU-04/2025 (Eff. 4/2025), "Certified Marijuana Testing Laboratory Background Screening Acknowledgment and Information," incorporated by reference and available at https://knowthefactsmmj.com/rules-and-regulations and at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. Form DH5061-OMMU-04/2025 must be completed, signed, and dated by the prospective employee, owner, or manager prior to the submission of fingerprints. If Form DH5061-OMMU-04/2025 is signed and dated after the submission of fingerprints to the Livescan Provider, the department will not process the background report.

(c) Persons required to undergo background screening must submit a full set of fingerprints to a Livescan Service Provider and, at the time of submission, give to the Livescan Service Provider the department's ORI number. Prospective employees, owners, and managers may request the department's ORI number by sending an email to OMMUBGS@flhealth.gov. If a person's fingerprints are rejected twice for image quality, the person must participate in the Federal Bureau of Investigation's (FBI) name check procedure for fingerprint submissions rejected twice due to image quality.

(d) After successful submission of fingerprints or successful compliance with FBI name check procedure, FDLE will send a background report to the department. The department will not process the background screening report unless it has received a request from a CMTL or Applicant pursuant to paragraph (2)(b). If the request is not received by the department within 150 days from the date the prospective employee, owner, or manager submitted fingerprints to a Livescan Service Provider, the department will not process the background report and the individual will be required to resubmit fingerprints to a Livescan Service Provider pursuant to paragraph (2)(c).

(e) After receipt of the background report, the department may issue to the prospective employee, owner, or manager requests for additional information or clarification necessary to complete the background screening process. After assessing the background report and any additional information received from the prospective employee, owner, or manager, the department will issue notice in writing to that individual stating whether the individual has passed background screening and is therefore eligible pursuant to section 381.986, F.S. The department will also issue written notice to the CMTL or Applicant advising whether the prospective employee, owner, or manager has passed background screening.

(f) A CMTL must retain, in its records, the written background screening notices from the department for all employees, owners, and managers currently serving the CMTL and must retain the written notices for at least seven (7) years after an employee, owner, or manager is terminated, removed, or otherwise separated from the CMTL. Upon request from the department, the CMTL must provide copies of written notices of background screening for the CMTL's current employees, owners, or managers. Copies of such notices must be provided within 48 hours of the department's request.

(3) Fingerprint Retention Fees and Notifications.

(a) The annual fee for participation in the AFRNP is $6.00 per individual fingerprint record retained. There is no fee for the initial year of participation. The CMTL must pay the annual fee for all its active employees, owners, and managers in the AFRNP.

(b) CMTLs must provide written notice to the department within 30 calendar days of the termination or separation of any employee, owner, or manager so that the individual's fingerprints may be removed from the AFRNP.

(c) The department will provide a CMTL written notice of the AFRNP annual retentions fees the CMTL must pay. Upon receipt of the department's written notice, a CMTL must confirm the status (i.e., "separated" or "retained") of its employees, owners, and managers by submitting such confirmation in an Excel file format to the department by email at OMMUBGS@flhealth.gov. The Excel file must contain the following information for each employee, owner, or manager:

1.Name;

2. Date of birth;

3.Fingerprint retention date;

4. Separated or retained; and

5. Employment location.

(d) If the department determines that the fingerprints of a CMTL employee, owner, or manager have not been retained in the AFRNP, the employee, owner, or manager must be rescreened in accordance with subsection (2). The department will send written notice to the CMTL informing the CMTL that the employee, owner, or manager must be rescreened pursuant to this rule. The rescreening must be completed within 30 calendar days of the date of the written notice.

(4) Disclosure of Arrest Reports and Continuing Background Screening.

(a) After becoming aware of the arrest of any CMTL employee, owner, or manager for any of the disqualifying offenses as provided in section 435.04, F.S., or for an offense under Chapters 837, 895, and 896, F.S., or similar law of another jurisdiction, the CMTL must provide written notice to the department. Such notice must be provided to the department within 48 hours of becoming aware of the individual's arrest and must include the following information:

1. Name of the arrested individual;

2. Position or job title of the arrested individual;

3. A copy of the arrest report, if available; and

4. Date of birth of the arrested individual.

(b) If the department receives an arrest notification concerning a CMTL employee, owner, or manager that makes them ineligible for employment by a CMTL under the requirements of section 381.988, F.S., the department will provide written notice to the CMTL. Within 24 hours of receiving written notice from the department, the CMTL must ensure that such employee, manager, or owner is terminated or removed as an employee, owner, or manager.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(3), 381.988(9), 943.05(2)(h)3., FS. Law Implemented Art. X, § 29, Fla. Const., 381.988, 943.05, FS. History–New.

64-4.315 CMTL Fines, Suspension, and Revocation.

(1) The department may suspend or revoke a CMTL's certification, or refuse to renew a CMTL's certification, if the department finds that the CMTL committed a violation of s. 381.986, F.S., s. 381.988, F.S., or department rules.

(2) The department will provide to the CMTL a written notice of violation. If a violation of department rules is also a violation of ISO/IEC 17025:2017 standards, the department will also provide the notice of violation to the CMTL's ISO/IEC 17025:2017 accrediting body. A CMTL must provide a proposed corrective action plan to the department within seven (7) calendar days of receipt of a notice of violation. The corrective action plan must conform to the ASTM D8229-19 Standard Guide for Corrective Action and Preventative Action (CAPA) for the Cannabis Industry incorporated by reference and available at: https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. The department may extend the timeframe for submittal of a corrective action plan for good cause (e.g., untimely delivery of notice of violation) shown. Upon review of the corrective action plan by the department, the CMTL may be required to take specific additional actions to cure the violation. The CMTL must comply with and perform all such additional curative actions as directed by the department. A CMTL is subject to discipline notwithstanding the implementation of a corrective action plan.

(3) A CMTL that loses or has its required accreditation suspended must report the loss or suspension within 24 hours of its occurrence to the department via email to OMMUlabs@flhealth.gov.

(a) Within seven (7) calendar days of receiving notice of the loss or suspension of its required accreditation, a CMTL must provide the following to the department:

1. Documentation identifying the cause of the loss or suspension of accreditation; and

2. Documentation evidencing that written notice of the loss or suspension of accreditation has been provided to each MMTC for which the CMTL conducts testing.

(b) A CMTL is prohibited from testing marijuana product or providing results to an MMTC during the time that its accreditation is lost or suspended.

(c) A CMTL must reestablish accreditation within 180 days of the effective date of the loss or suspension of accreditation. If a CMTL fails to reestablish its accreditation within 180 days of its loss or suspension, the CMTL's certification will be subject to revocation.

(4) The department may, in addition to or in lieu of suspension or revocation, impose a fine of up to $10,000 per violation, as set forth in the schedule provided in subsection (13). The schedule of fines is meant to serve as a guideline. The maximum fines listed in the schedule reflect the maximum fines that the department may impose per violation. Where there are multiple incidents resulting in more than one violation of the same provision, the department may impose a fine, up to the maximum, for each incident. For violations that are ongoing and continuous in nature, each day a violation continues constitutes a distinct violation.

(5) The department will use the factors set forth in s. 381.988(8)(a)-(d), F.S., to determine what discipline will be imposed, including suspension or revocation. The department will also consider the following in determining the severity of the violation and the amount of the fine to be imposed, if applicable:

(a) Frequency or number of occurrences of the violation;

(b) Potential for rehabilitation through department-approved corrective action;

(c) Impact on the department;

(d) Impact on an MMTC's business practices;

(e) Potential and/or actual harm to a qualified patient or a member of the public;

(f) Willfulness and deliberateness of the violation;

(g) Severity of noncompliance;

(h) Length of noncompliance;

(i) Any good faith effort to prevent a violation; and

(j) Any corrective action taken by the CMTL related to the current violation or prior violations.

(6) The department may immediately suspend, for a period of up to three (3) weeks, the testing operations of a CMTL that has received three (3) written notices of violation in a twelve-month time-period for the same violation.

(7) The issuance of a suspension under this part does not relieve the CMTL of the obligation to timely comply with all license renewal requirements. A license suspension does not toll the CMTL's license renewal deadline.

(8) No CMTL, including its owners and controlling interests, whose license has been revoked may apply for licensure under s. 381.988, F.S., and department rules, for at least five (5) years from the date of such revocation. However, if a CMTL's violation of statute or rule is a substantial contributing factor to the death of a patient, the CMTL, including its owners and controlling interests will be permanently barred from applying for licensure.

(9) If a CMTL's license is suspended, revoked, or relinquished, no part of any application fee or renewal fee will be returned.

(10) A CMTL whose license is revoked must cease operations as a CMTL on or before the effective date of the revocation. All Testing Samples, Analytical Samples, and retained samples are deemed Marijuana Waste once a CMTL's license is revoked. The CMTL must dispose of all Marijuana Waste in accordance with Rule 64-4.313, F.A.C. The CMTL must also return any Final Product that has not been removed from its original packaging to the originating MMTC. The CMTL must comply fully with the requirements of this subsection within seven (7) calendar days of the effective date of the revocation.

(11) A CMTL whose license is suspended must cease operations in accordance with any suspension order issued by the Department, pursuant to this rule.

(12) A CMTL that relinquishes its license must cease operations as a CMTL on or before the effective date of the relinquishment. All Testing Samples, Analytical Samples, and retained samples are deemed Marijuana Waste once a CMTL relinquishes its license. The CMTL must dispose of all Marijuana Waste in accordance with Rule 64-4.313, F.A.C. The CMTL must also return any Final Product that has not been removed from its original packaging to the originating MMTC. The CMTL must comply fully with the requirements of this subsection within seven (7) calendar days of the effective date of the relinquishment. For the purposes of this subsection, the effective date of relinquishment is the date the department sends written notice to the CMTL approving the CMTL's request to relinquish its license.

(13) For the purposes of the following schedule of fines, the descriptions of the violations are abbreviated, and the full statute or rule may be found by referring to the cited statutory or rule provision.

	VIOLATION	MINIMUM FINE PER VIOLATION	MAXIMUM FINE PER VIOLATION
(a)	Failing to retain copies of all marijuana transportation	$1,000	$2,000

	manifests for at least three years. (Section 381.986(8)(g)1.g.(III), F.S.)		
(b)	Employing a qualified physician. (Section 381.986(3)(b), F.S.)	$500	$1,000
(c)	Granting a direct or indirect economic interest to a qualified physician. (Section 381.986(3)(b), F.S.)	$500	$1,000
(d)	Illegally acquiring marijuana from an entity other than a medical marijuana treatment center or another CMTL. (Section 381.988(4), F.S.)	$5,000	$10,000
(e)	Selling, distributing, or transferring marijuana, except to transfer a sample to another CMTL or the department. (Section 381.988(4), F.S.)	$5,000	$10,000
(f)	Failing to properly dispose of a received Sample. (Section 381.988(5), F.S.) (Rule 64-4.313, F.A.C.)	$1,000	$2,000
(g)	Being owned or controlled by an MMTC. (Section 381.988(1)(a), F.S.) (Rule 64-4.301, F.A.C.)	$5,000	$10,000
(h)	Permitting unauthorized persons to perform technical procedures or issue reports. (Section 381.988(7)(a), F.S.)	$2,500	$5,000
(i)	Demonstrating incompetence or making consistent errors in the performance of testing or erroneous reporting. (Section 381.988(7)(b), F.S.)	$5,000	$10,000
(j)	Performing a test and rendering a report thereon to a person or entity not authorized by law to receive such services. (Section 381.988(7)(c), F.S.)	$5,000	$10,000
(k)	Failing to file any report required under s. 381.986, F.S., s. 381.988, F.S., or department rules.	$500	$1,000

	(Section 381.988(7)(d), F.S.)		
(l)	Reporting a test result if the test was not performed. (Section 381.988(7)(e), F.S.)	$5,000	$10,000
(m)	Violating or aiding and abetting in the violation of any provision of s. 381.986, F.S., s. 381.988, F.S., or department rules. (Section 381.988(7)(g), F.S.)	$5,000	$10,000
(n)	Testing marijuana, or providing testing results to an MMTC, while required accreditation is lost or suspended.(Rule 64-4.315, F.A.C.)	$5,000	$10,000
(o)	Failing to maintain required accreditation. (Rule 64-4.301, F.A.C.)	$5,000	$10,000
(p)	Failing to report loss or suspension of required accreditation or to provide required documentation upon such loss or suspension. (Rule 64-4.315, F.A.C.)	$1,000	$2,000
(q)	Failing to comply with Proficiency Testing requirements. (Rules 64-4.301, 64-4.303, and 64-4.306, F.A.C.)	$1,000	$2,000
(r)	Employing unqualified personnel. (Rule 64-4.301, F.A.C.)	$1,000	$2,000
(s)	Failing to train employees on the requirements in 381.988, F.S., or department rules. (Rules 64-4.301, 64-4.312, and 64-4.313, F.A.C.)	$1,000	$2,000
(t)	Failing to maintain adequate controls against the diversion, theft, or other loss of marijuana, the tampering or compromise of samples, and the tampering or compromise of testing equipment and materials. (Rule 64-4.301 F.A.C.)	$5,000	$10,000
(u)	Failing to comply with the security requirements listed under Rule 64-4.301, F.A.C. (Rule 64-4.301, F.A.C.)	$1,000	$5,000
(v)	Failing to create, maintain, and utilize Standard	$2,000	$4,000

	Operating Procedures, including a Quality Assurance Manual addressing every aspect of its Quality Assurance program. (Rules 64-4.301, 64-4.305, and 64-4.312, F.A.C.)		
(w)	Failing to have the Laboratory Director or authorized Employee review, amend as necessary, and approve the Testing Facility's Quality Assurance Manual and Quality Assurance program at least once per calendar year, or whenever a change of method, equipment, or Laboratory Director occurs. (Rule 64-4.301, F.A.C.)	$500	$2,000
(x)	Failing to notify and request approval from the department in writing of all contractual relationships to change Control of the entity holding the certification, or to change its Managers, Owners, or Investors, prior to the execution of the change. (64-4.301, F.A.C.)	$5,000	$10,000
(y)	Failing to have a Laboratory Director review, approve, sign, and date each Standard Operating Procedure and each revision thereto. (Rule 64-4.305, F.A.C.)	$500	$1,000
(z)	Failing to keep the latest revised Standard Operating Procedures on Testing Facility premises or accessible to all Employees during all hours of operation. (Rule 64-4.305, F.A.C.)	$500	$1,000
(aa)	Failing to use or properly maintain testing equipment when testing Final Product. (Rules 64-4.301 and 64-4.306, F.A.C.)	$1,000	$2,000
(bb)	Failing to maintain records in accordance with department rules. (Rules 64-4.304 and 64-4.311, F.A.C.)	$1,000	$2,000
(cc)	Failing to perform internal audits. (Rule 64-4.301, F.A.C.)	$1,000	$2,000

(dd)	Utilizing a tracking system that does not have the capabilities specified in Rules 64-4.301 and 64-4.312, F.A.C. (Rules 64-4.301 and 64-4.312, F.A.C.)	$1,000	$10,000
(ee)	Failing to maintain or utilize an operational tracking system. (Rule 64-4.301, F.A.C.)	$5,000	$10,000
(ff)	Failing to obtain required background screenings. (Section 381.988(1)(d), F.S.) (Rules 64-4.301 and 64-4.314, F.A.C.)	$500	$1,000
(gg)	Failing to notify the department after becoming aware of any of the disqualifying offenses as provided in Rule 64-4.314, F.A.C. (Rule 64-4.314, F.A.C.)	$1,000	$2,000
(hh)	Failing to terminate an Employee or Manager or remove the Owner from his or her position after receiving written notice from the department that CMTL Owner, Manager, or Employee is ineligible to serve as a CMTL Owner, Manager, or Employee. (Rule 64-4.314, F.A.C.)	$1,000	$2,000
(ii)	Performing Testing Fields within Matrix Groups for which the CMTL is not approved to perform. (Rule 64-4.303, F.A.C.)	$1,000	$2,000
(jj)	Testing and providing results to an MMTC for any Target Analyte, Matrix, or other measurement for which its analysis was unsatisfactory when the CMTL has failed to satisfactorily complete two of the three most recent Proficiency Testing rounds, prior to providing the department with satisfactory Proficiency Testing Results from the required accredited body and receiving department approval to resume testing. (Rule 64-4.303, F.A.C.)	$2,000	$5,000

(kk)	Refusing to allow entry or inspection of a CMTL Testing Facility, including any vehicle utilized by a CMTL. (Rule 64-4.304, F.A.C.)	$5,000	$10,000
(ll)	Failing to cooperate or provide responses in a timely manner to the department's inquiries during an inspection or data audit. (Rule 64-4.304, F.A.C.)	$2,500	$5,000
(mm)	Failing to resolve a deficiency or violation in the time period specified by the department or specified in a corrective action plan. (Section 381.988(7)(f), F.S.) (Rules 64-4.304 and 64-4.315, F.A.C.)	$5,000	$10,000
(nn)	Using an unapproved Analytical Method. (Rule 64-4.306, F.A.C.)	$2,000	$4,000
(oo)	Failing to demonstrate an Initial Display of Competency for a testing method prior to analyzing an Analytical Sample using the method. (Rule 64-4.306, F.A.C.)	$2,000	$4,000
(pp)	Failing to follow required field sampling protocols when sampling Final Product for testing. (Rule 64-4.307, F.A.C.)	$500	$1,000
(qq)	Failing to maintain and implement a chain of custody protocol. (Rule 64-4.307, F.A.C.)	$1,000	$2,000
(rr)	Failing to obtain an adequate number of Final Products for testing. (Rule 64-4.307, F.A.C.)	$500	$1,000
(ss)	Failing to transport samples in a manner that prevents degradation, contamination, commingling, and tampering. (Rule 64-4.307, F.A.C.)	$1,000	$2,000
(tt)	Failing to prepare Testing Samples within established timeframes. (Rule 64-4.307, F.A.C.)	$500	$1,000

(uu)	Failing to notify the department if the CMTL is unable to complete regulatory compliance testing after sampling. (Rule 64-4.307, F.A.C.)	$500	$1,000
(vv)	Failing to comply with the MMTC Regulatory Compliance Testing rule when resampling and retesting a previously failed Retail Batch. (Rule 64-4.307, F.A.C.)	$500	$5,000
(ww)	Failing to transport samples in accordance with Rule 64-4.307, F.A.C. (Rule 64-4.307, F.A.C.)	$500	$1,000
(xx)	Failing to generate a Certificate of Analysis for each Final Product tested that contains all required information as enumerated in Rule 64-4.311, F.A.C. (Rule 64-4.311, F.A.C.)	$500	$1,000
(yy)	Reporting false or inaccurate information on a Certificate of Analysis. (Rule 64-4.311, F.A.C.)	$1,000	$10,000
(zz)	Reporting Usable Whole Flower Potency at a Moisture content other than the CMTL tested Moisture content. (Rule 64-4.308, F.A.C.)	$1,000	$10,000
(aaa)	Failing to create and maintain Data Packages for every analyzed Laboratory Batch. (Rule 64-4.311, F.A.C.)	$2,000	$4,000
(bbb)	Failing to include the required information enumerated in Rule 64-4.311, F.A.C., for each Data Package. (Rule 64-4.311, F.A.C.)	$1,000	$2,000
(ccc)	Failing to have a Certificate of Analysis and Data Package reviewed by the CMTL's Laboratory Director, or designee, prior to dissemination. (Rule 64-4.311, F.A.C.)	$500	$1,000
(ddd)	Failing to provide requested documentation to the department within the timeframe required by Rule 64-4.311, F.A.C.	$500	$2,000

	(Rule 64-4.311, F.A.C.)		
(eee)	Failing to perform reanalysis of a failed Target Analyte in accordance with Rule 64-4.308, F.A.C. (Rule 64-4.308, F.A.C.)	$1,000	$2,000
(fff)	Failing to report testing failures to the department. (Rule 64-4.308, F.A.C.)	$5,000	$10,000
(ggg)	Failing to provide the information required under Rule 64-4.308 F.A.C., to the department after resampling and retesting a previously failed Retail Batch. (Rule 64-4.308, F.A.C.)	$1,000	$2,000
(hhh)	Failing to report Testing Samples found to contain a contaminant that could be injurious to human health. (Rule 64-4.308, F.A.C.)	$1,000	$5,000
(iii)	Failing to maintain at least one sterile untested portion of each Testing Sample in accordance with Rule 64-4.308, F.A.C.	$500	$1,000
	(Rule 64-4.308, F.A.C.)		
(jjj)	Failing to prepare required Quality Control samples in accordance with Rules 64-4.308 and 64-4.309, F.A.C. (Rules 64-4.308 and 64-4.309, F.A.C.)	$1,000	$2,000
(kkk)	Failing to analyze required Quality Control samples within an Analytical Batch. (Rule 64-4.309, F.A.C.)	$2,500	$10,000
(lll)	Failing to evaluate Quality Control samples to the required criteria. (Rule 64-4.309, F.A.C.)	$1,000	$5,000
(mmm)	Continuing to conduct an analysis of a Quality Control sample that repeatedly falls outside of accepted criteria after reanalysis and being tested as a new Laboratory Batch. (Rule 64-4.309, F.A.C.)	$1,000	$2,000
(nnn)	Failing to generate Quality Control sample reports in accordance with Rule 64-4.309, F.A.C.	$1,000	$5,000

	(Rule 64-4.309, F.A.C.)		
(ooo)	Failing to prepare required Calibration Standards in compliance with Rule 64-4.310, F.A.C. (Rule 64-4.310, F.A.C.)	$2,500	$5,000
(ppp)	Failing to analyze required Calibration Standards to quantitate an Analytical Batch. (Rule 64-4.310, F.A.C.)	$2,500	$5,000
(qqq)	Failing to evaluate Calibration Standards to the required criteria. (Rule 64-4.310, F.A.C.)	$2,500	$5,000
(rrr)	Using a Calibration Curve which does not meet LOD and/or LOQ requirements. (Rule 64-4.310, F.A.C.)	$2,500	$5,000
(sss)	Failing to determine the LOD in compliance with Rule 64-4.310, F.A.C. (64-4.310, F.A.C.)	$2,500	$5,000
(ttt)	Failing to manually integrate analytical peaks in compliance with 64-4.312, F.A.C. (Rule 64-4.312, F.A.C.)	$2,500	$5,000
(uuu)	Failing to create and maintain retention time windows. (Rule 64-4.312, F.A.C.)	$2,500	$5,000
(vvv)	Failing to maintain proper resolution between the chromatographic peak of interest and adjacent peak(s) whether target or non-target peak(s). (Rule 64-4.312, F.A.C.)	$2,500	$5,000
(www)	Changing the Automatic Integration parameters after the Calibration Curve is established. (Rule 64-4.312, F.A.C.)	$2,500	$5,000
(xxx)	Failure to maintain integration documentation in accordance with Rule 64-4.312, F.A.C. (Rule 64-4.312, F.A.C.)	$2,500	$5,000
(yyy)	Failure to perform an annual review for all Testing Fields utilizing chromatography.	$2,500	$10,000

	(Rule 64-4.312 F.A.C.)		
(zzz)	Failing to comply with all applicable federal and state laws and regulations for solid and liquid wastes and any applicable local regulations or ordinances. (Rule 64-4.313, F.A.C.)	$1,000	$2,000
(aaaa)	Failing to render marijuana waste unusable and unrecognizable or irretrievable in accordance with Rule 64-4.313, F.A.C. (Rule 64-4.313, F.A.C.)	$1,000	$5,000
(bbbb)	Failing to render non-hazardous waste that doesn't meet the definition of "Marijuana Waste" unusable, unrecognizable, and unidentifiable. (Rule 64-4.313, F.A.C)	$1,000	$2,000
(cccc)	Failing to dispose of unusable and unrecognizable or irretrievable marijuana waste in accordance with Rule 64-4.313, F.A.C. (Rule 64-4.313, F.A.C.)	$1,000	$5,000
(dddd)	Failing to maintain and comply with a waste management plan in accordance with Rule 64-4.313, F.A.C. (Rule 64-4.313, F.A.C.)	$1,000	$2,000
(eeee)	Failing to maintain accurate records of generated marijuana waste in accordance with Rule 64-4.313, F.A.C. (Rule 64-4.313, F.A.C.)	$500	$1,000
(ffff)	Failing to maintain compliance with all parts of ISO/IEC 17025:2017 accreditation. (Rule 64-.301, F.A.C.)	$1,000	$5,000
(gggg)	A violation of any other provision of s. 381.986, F.S., s. 381.988, F.S., or department rule or emergency rule. (Section 381.988(8), F.S.) (Rule 64-4.315, F.A.C.)	$100	$10,000

(14) This rule shall be reviewed, and if necessary, repealed, modified, or renewed through the rulemaking process five years from the effective date.

Rulemaking Authority Art. X, § 29, Fla. Const., 381.988(8), 381.988(9), FS; Law Implemented Art. X, § 29, Fla. Const., 381.986, 381.988, FS. History—New.

NAME OF PERSON ORIGINATING PROPOSED RULE: Christopher Kimball

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Joseph A. Ladapo, MD, PhD, State Surgeon General
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: April 23, 2025
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: July 1, 2022

Section III
Notice of Changes, Corrections and Withdrawals

NONE

Section IV
Emergency Rules

NONE

Section V
Petitions and Dispositions Regarding Rule Variance or Waiver

WATER MANAGEMENT DISTRICTS
Southwest Florida Water Management District
RULE NO.: RULE TITLE:
40D-22.201 Year-Round Water Conservation Measures
NOTICE IS HEREBY GIVEN that on April 28, 2025, the Southwest Florida Water Management District, received a petition for a variance or waiver.
Petitioner's Name: Talavera Community Development District
Rule No.: 40D-22.201
Nature of the rule for which variance or waiver is sought: Lawn and landscape irrigation
The Petition has been assigned tracking No. 25-4406.
A copy of the Petition for Variance or Waiver may be obtained by contacting: Camille Mourant, 7601 US Highway 301, Tampa, Florida 33637, (813)367-4906, water.variances@watermatters.org. Any interested person or other agency may submit written comments within 14 days after the publication of this notice. (T101283)

WATER MANAGEMENT DISTRICTS
Southwest Florida Water Management District
RULE NO.: RULE TITLE:
40D-22.201 Year-Round Water Conservation Measures
NOTICE IS HEREBY GIVEN that on April 28, 2025, the Southwest Florida Water Management District, received a petition for a variance or waiver.
Petitioner's Name: 25-4407 (Edgewater Place Homeowners Association, Inc.)
Rule No.: 40D-22.201
Nature of the rule for which variance or waiver is sought: Lawn and Landscape Irrigation
The Petition has been assigned tracking No. 25-4407.
A copy of the Petition for Variance or Waiver may be obtained by contacting: Camille R. Mourant, 7601 US Highway 301, Tampa, Florida 33637, (813)438-4906, water.variances@watermatters.org. Any interested person or other agency may submit written comments within 14 days after the publication of this notice (S101285)

DEPARTMENT OF ENVIRONMENTAL PROTECTION
Beaches and Coastal Systems
RULE NOS.:RULE TITLES:
62B-33.002 Definitions
62B-33.0051 Coastal Armoring and Related Structures
NOTICE IS HEREBY GIVEN that on April 23, 2025, the Department of Environmental Protection, received a petition for variance or waiver pursuant to section 120.542, F.S., from Michael and Gaelynn McGavick. The petition requested a variance from 62B-33.002(12)(b)1.; 62B-33.002(39); and 62B-33.0051(1)(a)l., F.A.C., for proposed armoring to protect eligible structures. The facility is located at 4500 Gordon Drive, Naples, FL. The petition has been assigned OGC #25-0652.
A copy of the Petition for Variance or Waiver may be obtained by contacting: Douglas Aarons, Florida Department of Environmental Protection, 2600 Blair Stone Road, Mail Station 3522, Tallahassee, Florida 32399-2400; telephone (850)245-7672; e-mail Douglas.Aarons@floridadep.gov, during normal business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday, except legal holidays. If you have any questions, please call the Coastal Construction Line Program Office at (850)245-2094.
Written comments must be received by the Department of Environmental Protection no later than 14 days from the date of publication of this notice.

DEPARTMENT OF HEALTH
Division of Environmental Health
RULE NO.: RULE TITLE:
64E-16.007 Treatment
NOTICE IS HEREBY GIVEN that on April 21, 2025, the Department of Health, received a petition for permanent Variance from subparagraph 64E-16.007(4)(c)1, Florida Administrative Code, from Gregg Short, Petitioner, President/CEO of Waste and Compliance Management Inc, 6054 Carte Del Cedro, Carlsbad, CA 90211. This rule requires that for disinfection, a minimum Log 6 kill for the vegetative organisms listed in Table 1 and a minimum Log 4 kill against Bacillus stearothermophilus spores utilizing steam or a minimum Log 4 kill against Bacillus subtilis spores using dry

heat, chemicals or microwave shredding. The Petitioner requests a variance from the testing requirements found in 64E-16.007(4)(c)1, of the Florida Administrative Code through a process that encapsulates sharps biomedical waste to prevent exposure of infectious disease.

Comments on this petition should be filed with the Agency Clerk, Department of Health, Office of General Counsel, 4052 Bald Cypress Way, BIN A02, Tallahassee, Florida 32399-1703.

A copy of the Petition for Variance or Waiver may be obtained by contacting: Justin R. Saukko, Bureau of Environmental Health, Facility Programs Section, 4052 Bald Cypress Way, BIN A08, Tallahassee, Florida 32399-1710, or by calling (850)274-2906.

DEPARTMENT OF HEALTH

Division of Environmental Health

RULE NO.: RULE TITLE:

64E-11.003 Food Hygiene Standards

The Department of Health hereby gives notice: On March 3, 2025, the Department of Health issued an order in response to a petition for a variance filed on July 21, 2024, by Sharonlea Wright, representing Advance Fresh Concepts, d/b/a AFC Sushi. Petitioner sought a variance from Rule subsections 64E-11.003(2), Florida Administrative Code referencing 2013 Food and Drug Code paragraph 3-502.11(C) which a variance from the regulatory authority, as specified in section 8-103.10 and 8-103.11 before using food additives or adding components such as vinegar as a method of food preservation rather than as a method of flavor enhancement, or to render a food so that it is not a time temperature control for safety food. The variance is valid for the following location: AFC Sushi at University of Florida, Turlington Hall, 330 Newell Drive, Gainesville, Florida using Food Facility Units 1404, 1405 and 1406. Notice of the petition was published November 25, 2024, in Volume 50, Number 230, of the Florida Administrative Register.

The Department found that the Petitioner demonstrated that the underlying intent of the statute. Therefore, pursuant to the requirements of section 120.542(2), Florida Statutes, the Department GRANTED w/CONDITIONS the Petitioner's request for a permanent variance.

A copy of the Order or additional information may be obtained by contacting: A copy of the petition and final order may be obtained by contacting: Agency Clerk, Department of Health, Office of the General Counsel, 4052 Bald Cypress Way, Bin A02, Tallahassee, Florida 32399-1703.

Section VI
Notice of Meetings, Workshops and Public Hearings

DEPARTMENT OF STATE

Division of Historical Resources

The Department of State announces a public meeting to which all persons are invited.

DATE AND TIME: May 7, 2025, 1:00 p.m. to 3:00 p.m.

PLACE: Via webinar: https://attendee.gotowebinar.com/register/3698874110854868317

Meeting ID: 844-980-331 / Call-in only: 213-929-4212

GENERAL SUBJECT MATTER TO BE CONSIDERED: Meeting of Florida Semiquincentennial Commission

A copy of the agenda may be obtained by contacting: Khara Fleming at (850)245-6302 or khara.fleming@dos.fl.gov.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 48 hours before the workshop/meeting by contacting: Khara Fleming at (850)245-6302 or khara.fleming@dos.fl.gov. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Khara Fleming at (850)245-6302 or khara.fleming@dos.fl.gov.

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Division of Administration

The CRAFT Foundation, Inc., Board of Directors announces a public meeting to which all persons are invited.

DATE AND TIME: Wednesday, May 14, 2025, 10:00 a.m.

PLACE: Attendees may attend the meeting at 600 N. Broadway Avenue, Suite 101, Bartow, FL 33830 or join the meeting online at: https://us02web.zoom.us/j/85388899799?pwd=o5H3sswiSqaHBjn4xVoQoF4HVMaLzr.1

GENERAL SUBJECT MATTER TO BE CONSIDERED: The CRAFT Board of Directors will meet to discuss and execute matters of the Board including, but not limited to, approval of previous meeting minutes, financial reports, requests for project amendments, an update on CRAFT Cycle Six and ETT Round Three projects, and other matters of the Board.

A copy of the agenda may be obtained by contacting: Steven Hall, Executive Director of CRAFT, at Steven@CRAFTFDN.org.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to

participate in this workshop/meeting is asked to advise the agency at least 2 days before the workshop/meeting by contacting: Steven Hall, Executive Director of CRAFT, at Steven@CRAFTFDN.org. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Steven Hall, Executive Director of CRAFT, at Steven@CRAFTFDN.org.

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Division of Administration

The Florida Agricultural Legacy Learning Center announces a public meeting to which all persons are invited.

DATE AND TIME: Wednesday, May 14, 2025, 1:00 p.m.

PLACE: 7900 Old Kings Road N, Palm Coast, FL 32137

GENERAL SUBJECT MATTER TO BE CONSIDERED: This meeting is to discuss general business.

A copy of the agenda may be obtained by contacting: Kara Hoblick O: (386)446-7630 C: (386)527-1467

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 2 days before the workshop/meeting by contacting: Kara Hoblick O: (386)446-7630 C: (386)527-1467. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Kara Hoblick O: (386)446-7630 C: (386)527-1467

DEPARTMENT OF HIGHWAY SAFETY AND MOTOR VEHICLES

The Department of Highway Safety and Motor Vehicles announces a public meeting to which all persons are invited.

DATE AND TIME: May 13, 2025, 2:30 p.m. – 4:00 p.m., ET

PLACE: THIS MEETING WILL BE HELD VIA MICROSOFT TEAMS. PLEASE SEE DIAL-IN INFO BELOW.

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Motorist Modernization Advisory Board is meeting to discuss and provide guidance & recommendations on Phase 2 of the Motorist Modernization Program.

AGENDA

• Roll Call
• Welcome
• Review and Approval of Last Meeting Minutes
• Phase II IV&V Update
• MM Phase II Program Update
• Financial Review
• Phase II Pilot/Implementation Readiness
• Stakeholder Outreach Update
• Q&A
• Adjourn

Microsoft Teams meeting

Join on your computer or mobile app:

https://teams.microsoft.com/l/meetup-join/19%3ameeting_MmFlYmMwYjgtZjRkYS00ZWRiLTlkOTUtYTI3MGNlZDE1ODBm%40thread.v2/0?context=%7b%22Tid%22%3a%2225c7bf74-6ed1-4f3c-af88-d6c3933606ca%22%2c%22Oid%22%3a%22f12acde9-abbd-45e0-93b8-12e80c44c029%22%7d

Or call in (audio only):

+1(850)583-5466,,362353834# United States, Tallahassee

Phone Conference ID: 362 353 834#

A copy of the agenda may be obtained by contacting: The agenda is included above.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Kristin Green, 2900 Apalachee Parkway, Room D313, Tallahassee, FL 32399, (850)617-2880. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

REGIONAL PLANNING COUNCILS

East Central Florida Regional Planning Council

The Local Emergency Planning Committee announces a public meeting to which all persons are invited.

DATE AND TIME: May 29, 2025 10:00 a.m.

PLACE: Marion County EOC at 692 NW 30th Ave, Ocala, FL 34475

GENERAL SUBJECT MATTER TO BE CONSIDERED: Emergency Planning and Community Right-To-Know Act Quarterly Meeting and TTF.

A copy of the agenda may be obtained by contacting: Kurt Brothers at kbrothers@ecfrpc.org or (407)245-0300 ext. 338

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least two (2) days before the workshop/meeting by contacting: Kurt Brothers at kbrothers@ecfrpc.org or (407)245-0300 ext. 338. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Kurt Brothers at kbrothers@ecfrpc.org or (407)245-0300 ext. 338

DEPARTMENT OF ELDER AFFAIRS

Office of Public and Professional Guardians

The Foundation for Indigent Guardianship announces a public meeting to which all persons are invited.

DATE AND TIME: May 21, 2025, 10:00 a.m.
PLACE: Microsoft Teams Join on your computer, mobile app or room device by copying and pasting the link below: https://teams.microsoft.com/l/meetup-join/19%3ameeting_MGJkMGNjZDEtMjU5OS00M2NkLTk4NTgtODg1OTg3ODZlMWIy%40thread.v2/0?context=%7b%22Tid%22%3a%22f75a7744-d4bf-4623-8660-bcfa3569c2a0%22%2c%22Oid%22%3a%228af789f9-7136-4fff-b856-14d30236d98c%22%7d
GENERAL SUBJECT MATTER TO BE CONSIDERED: Board of Directors updates relative to the Foundation for Indigent Guardianship.
A copy of the agenda may be obtained by contacting: Vicki B. Simmons via email at: simmons.vickib@gmail.com.
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 2 days before the workshop/meeting by contacting: OPPG Information at: (850)414-2381. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
For more information, you may contact: OPPG Information at: (850)414-2381.

DEPARTMENT OF HEALTH
Board of Medicine
The (Cancelled) Board of Pharmacy Joint Rules Committee in consultation with Members of the Boards of Medicine and Osteopathic Medicine announces a announces a public meeting to which all persons are invited.
DATE AND TIME: (Cancelled) May 6, 2025, 12:00 noon, E.T., or soon thereafter
PLACE: 1(888)585-9008, Participant Code: 599-196-982(#)
GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Joint Rules Committee
A copy of the agenda may be obtained by contacting: Floridaspharmacy.gov
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: Floridaspharmacy.gov. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.
For more information, you may contact: (850)245-4474.

DEPARTMENT OF HEALTH
Board of Medicine
The Florida Board of Medicine Surgical Care/Quality Assurance Committee announces announces a public meeting to which all persons are invited.
DATE AND TIME: Thursday, June 5, 2025, 1:00 p.m., ET, or soon thereafter.
PLACE: AC Hotel Tallahassee Universities at the Capitol, 801 S. Gadsden Street, Tallahassee, FL 32301. Phone: (850)392-7700. Tallahassee Hotel Downtown | AC Hotel Tallahassee
GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information.
A copy of the agenda may be obtained by contacting: https://flboardofmedicine.gov/meeting- information.
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.
For more information, you may contact: the Board by email at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131

DEPARTMENT OF HEALTH
Board of Medicine
The Florida Board of Medicine's Rules/Legislative Committee announces a announces a public meeting to which all persons are invited.
DATE AND TIME: Thursday, June 5, 2025, 3:00 p.m., ET, or soon thereafter.
PLACE: AC Hotel Tallahassee Universities at the Capitol, 801 S. Gadsden Street, Tallahassee, FL 32301. Phone: (850)392-7700. Tallahassee Hotel Downtown | AC Hotel Tallahassee
GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the Committee. Committee meetings may be canceled prior to the meeting date. Please check the Board's website at https://flboardofmedicine.gov/meeting-information

for cancellations or changes to the meeting date or time or call the Board at (850)245-4131 for more information

A copy of the agenda may be obtained by contacting: the Board of Medicine at https://flboardofmedicine.gov/meeting-information

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: the Board at BOM.MeetingMaterials@flhealth.gov or by calling the Board at (850)245-4131.

DEPARTMENT OF HEALTH

Board of Pharmacy

The Florida Board of Pharmacy announces a public meeting to which all persons are invited.

DATE AND TIME: May 06, 2025, 12:00 noon, E.T. CANCELLED

PLACE: CANCELLED

GENERAL SUBJECT MATTER TO BE CONSIDERED: This is a notice that meeting notice ID #29503634 has been CANCELLED.

A copy of the agenda may be obtained by contacting: CANCELLED

For more information, you may contact: (850)245-4474.

DEPARTMENT OF HEALTH

Division of Environmental Health

RULE NO.: RULE TITLE:

64E-18.003 Requirements for Certification

The Department of Health announces a public meeting to which all persons are invited.

DATE AND TIME: May 7, 2025, 11:00 a.m. – 12:00 noon

PLACE: Microsoft Teams Meeting https://teams.microsoft.com/l/meetup-join/19%3ameeting_

Open Voice Conference: 1(850)792-1375, Access Code: 883 238 073#

GENERAL SUBJECT MATTER TO BE CONSIDERED: This is a biannual general meeting of the Environmental Health Professional Advisory Board.

A copy of the agenda may be obtained by contacting: Michael Lawhorn, FL Dept. of Health, Bureau of Environmental Health, 4052 Bald Cypress Way, Mail Bin A08, Tallahassee, FL 32399-1710, by email: Michael.Lawhorn@flhealth.gov or by telephone: (850)901-6515.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 3 days before the workshop/meeting by contacting: Michael Lawhorn at (850)901-6515. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

FISH AND WILDLIFE CONSERVATION COMMISSION

Marine Fisheries

The Florida Fish and Wildlife Conservation Commission announces a public meeting to which all persons are invited.

DATE AND TIME: Wednesday, May 7, 2025, 1:00 p.m. – 4:00 p.m. (ET)

PLACE: The virtual Nonnative Fish and Wildlife Technical Assistance Group meeting can be joined by either video or telephone conferencing. Please see below the corresponding information on how to join:

To join the meeting by video, use this link:

https://fsu.zoom.us/j/93690783396

To join the meeting by telephone, dial Dial-in (if needed)

+13052241968 and enter meeting ID 936 9078 3396#

GENERAL SUBJECT MATTER TO BE CONSIDERED: During the February 2021 Florida Fish and Wildlife Conservation Commission meeting, the Commissioners directed staff to develop a Technical Assistance Group (TAG) to help address nonnative fish and wildlife issues in Florida. The purpose of this TAG is to enhance and promote ongoing dialogue and mutual understanding among organizations and agencies, and their respective stakeholders, by working together to address and examine the regulatory structure for nonnative fish and wildlife in Florida. The objective of this May 2025 virtual meeting will be to provide the Nonnative Fish and Wildlife Technical Assistance Group members with updates on proposed rule changes for nonnative species. The TAG will not serve as an advisory committee, nor is it delegated any decision-making authority.

A copy of the agenda may be obtained by contacting: Sarah Funck, 620 S. Meridian St., Tallahassee, FL 32399, (850)617-9502, email: Sarah.Funck@MyFWC.com.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 3 days before the workshop/meeting by contacting: Sarah Funck, 620 S. Meridian St., Tallahassee, FL 32399, (850)617-9502, email: Sarah.Funck@myfwc.com. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

DEPARTMENT OF MILITARY AFFAIRS

RULE NO.: RULE TITLE:

70-1.001Florida Armed Forces Reserve Family Readiness Program Application Fund

The Department of Military Affairs announces a public meeting to which all persons are invited.

DATE AND TIME: CANCELLED May 02, 2025, 8:00 a.m.

PLACE: This meeting has been CANCELLED

GENERAL SUBJECT MATTER TO BE CONSIDERED: This is a notice of the cancellation of the meeting and FAR notice ID 29497135, Issue 4/23/2025 Vol. 51/79

A copy of the agenda may be obtained by contacting: This meeting has been CANCELLED

For more information, you may contact: Joseph Bagnall at (904)823-0201

AREA AGENCY ON AGING OF PALM BEACH/TREASURE COAST, INC.

The Area Agency on Aging of Palm Beach/Treasure Coast, Inc. announces a public meeting to which all persons are invited.

DATE AND TIME: May 20, 2025, 8:30 a.m.

PLACE: Area Agency on Aging, 4400 North Congress Avenue, West Palm Beach, FL 33407

GENERAL SUBJECT MATTER TO BE CONSIDERED: Agency governance

A copy of the agenda may be obtained by contacting: Dwight Chenette at (561)684-5885 or DChenette@aaapbtc.org

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 2 days before the workshop/meeting by contacting: Dwight Chenette at (561)684-5885 or DChenette@aaapbtc.org. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Dwight Chenette at (561)684-5885 or DChenette@aaapbtc.org

FLORIDA DEVELOPMENTAL DISABILITIES COUNCIL

The Florida Developmental Disabilities Council, Inc. announces a public meeting to which all persons are invited.

DATES AND TIMES: May 14, 2025, 6:30 p.m. - 7:30 p.m., Face to Face Pre-Meeting; May 15, 2025, 9:30 a.m. - 4:30 p.m., Face to Face Council Meeting; May 16, 2025, 8:30 a.m. - 1:30 p.m., Face to Face Council Meeting Continued. (Times are Tentative)

PLACE: The Florida Hotel and Conference Center, 1500 Sand Lake Road, Orlando, FL 32809

GENERAL SUBJECT MATTER TO BE CONSIDERED: To discuss general Council business.

A copy of the agenda may be obtained by contacting: Kristen Conlin 1(800)580-7801 or 1(850)488-4180

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 72 hours before the workshop/meeting by contacting: Kristen Conlin 1(800)580-7801 or 1(850)488-4180. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Kristen Conlin 1(800)580-7801 or 1(850)488-4180

Section VII
Notice of Petitions and Dispositions Regarding Declaratory Statements

NONE

Section VIII
Notice of Petitions and Dispositions Regarding the Validity of Rules

Notice of Petition for Administrative Determination has been filed with the Division of Administrative Hearings on the following rules:

NONE

Notice of Disposition of Petition for Administrative Determination has been filed with the Division of Administrative Hearings on the following rules:

NONE

Section IX
Notice of Petitions and Dispositions Regarding Non-rule Policy Challenges

NONE

Section X
Announcements and Objection Reports of the Joint Administrative Procedures Committee

NONE

Section XI
Notices Regarding Bids, Proposals and Purchasing

DEPARTMENT OF ENVIRONMENTAL PROTECTION
Division of Recreation and Parks
Invitation to Bid BDC51-24/25 St. Goerge Island - Playground Equipment Replacement & Pavilion Renovations
NOTICE OF INVITATION TO BID: The Florida Department of Environmental Protection, Bureau of Design and Construction, is soliciting formal, competitive, sealed bids from contractors for bid number BDC51-24/25 St. Goerge Island - Playground Equipment Replacement & Pavilion Renovations. More info @ https://tinyurl.com/5484phv4.

Section XII
Miscellaneous

DEPARTMENT OF STATE
Index of Administrative Rules Filed with the Secretary of State Pursuant to subparagraph 120.55(1)(b)6. – 7., F.S., the below list of rules were filed in the Office of the Secretary of State between 3:00 p.m., Wednesday, April 23, 2025, and 3:00 p.m., Tuesday, April 29, 2025.

Rule No.	**File Date**	**Effective Date**
6A-1.09441	4/23/2025	5/13/2025
6A-5.066	4/23/2025	5/13/2025
6A-5.081	4/23/2025	5/13/2025
6A-6.053	4/23/2025	5/13/2025
6A-6.0571	4/23/2025	5/13/2025
6A-6.0576	4/23/2025	5/13/2025
6A-6.09021	4/23/2025	5/13/2025
6A-25.021	4/23/2025	5/13/2025
6M-4.400	4/23/2025	5/13/2025
6M-4.500	4/23/2025	5/13/2025
6M-8.603	4/23/2025	5/13/2025
6M-8.605	4/23/2025	5/13/2025
6M-8.700	4/23/2025	5/13/2025
6M-8.701	4/23/2025	5/13/2025
19-3.016	4/28/2025	5/18/2025
59A-35.090	4/23/2025	5/13/2025
66B-1.005	4/25/2025	5/15/2025
66B-1.006	4/25/2025	5/15/2025
66B-1.014	4/25/2025	5/15/2025
66B-2.005	4/24/2025	5/14/2025
66B-2.006	4/24/2025	5/14/2025
66B-2.014	4/24/2025	5/14/2025
68B-8.001	4/29/2025	5/19/2025
68B-8.002	4/29/2025	5/19/2025
68B-8.003	4/29/2025	5/19/2025
68B-8.004	4/29/2025	5/19/2025
68B-8.005	4/29/2025	5/19/2025
68B-8.006	4/29/2025	5/19/2025
68B-8.007	4/29/2025	5/19/2025
68B-8.008	4/29/2025	5/19/2025
68B-8.009	4/29/2025	5/19/2025
68B-8.010	4/29/2025	5/19/2025
68B-8.011	4/29/2025	5/19/2025
68B-8.012	4/29/2025	5/19/2025
68B-8.013	4/29/2025	5/19/2025
68B-8.014	4/29/2025	5/19/2025
68B-8.015	4/29/2025	5/19/2025
LIST OF RULES AWAITING LEGISLATIVE APPROVAL SECTIONS 120.541(3), 373.139(7) AND/OR 373.1391(6), FLORIDA STATUTES		
Rule No.	**File Date**	**Effective Date**
14-10.0043	4/11/2025	**/**/****
60FF1-5.009	7/21/2016	**/**/****
64B8-10.003	12/9/2015	**/**/****
65C-9.004	3/31/2022	**/**/****

DEPARTMENT OF ENVIRONMENTAL PROTECTION
Office of the Secretary
Florida State Clearinghouse

The state is coordinating reviews of federal activities and federally funded projects as required by Section 403.061(42), F.S. This includes Outer Continental Shelf activities and other actions subject to federal consistency review under the Florida Coastal Management Program. A list of projects, comments and deadlines, and the address for providing comments, are available at: https://fldep.dep.state.fl.us/clearinghouse/. For information, call (850)717-9076. This public notice fulfills the requirements of 15 CFR 930.

Section XIII
Index to Rules Filed During Preceding Week

NOTE: The above section will be published on Tuesday beginning October 2, 2012, unless Monday is a holiday, then it will be published on Wednesday of that week.