Rule 64-4.016 Marijuana Testing Laboratories and Testing Standards.

(1) For the purposes of the department's marijuana testing laboratory rules, the following words and phrases shall have the meanings indicated.

(a) Analyst – An individual employed by a marijuana testing laboratory whose work-related tasks include preparing samples for analysis, preparing equipment and workspaces to perform analysis, conducting analyses, analyzing and recording results, maintaining testing-related workspaces and equipment, and maintaining marijuana samples in accordance with the requirements of this rule.

(b) Analytical batch – A group of samples that are prepared together for the same type of analysis, are sequentially analyzed using the same instrument calibration curve, and have common analytical quality control requirements.

(c) Applicant – An individual or entity that meets the requirements of section 381.988, F.S., and applies for certification as a marijuana testing laboratory pursuant to section 381.988(2), F.S., and this rule.

(d) Approval – Written notification from the department to an applicant that its application for certification as a marijuana testing laboratory has been found to be in compliance with the provisions of sections 381.986 and 381.988, F.S., and department rules, and that the department is awaiting notification that the marijuana testing laboratory is prepared to be inspected and authorized to begin testing marijuana and auditing medical marijuana treatment centers.

(e) Certificate of analysis – The report prepared by marijuana testing laboratory containing information about the analytical testing performed on marijuana obtained from a medical marijuana treatment center and the results of any testing. The report is provided to both the Office of Medical Marijuana Use and the marijuana treatment center that the sample originated from.

(f) Certification as a marijuana testing laboratory - Approval and authorization as a marijuana testing laboratory pursuant to subsections 381.988(1) and (3), F.S.

(g) Certified financials – Financial statements that have been audited in accordance with Generally Accepted Auditing Standards (GAAS) by a Certified Public Accountant, licensed pursuant to chapter 473, F.S.

(h) Contaminants unsafe for human consumption – Any microbial, fungus, yeast, mildew, herbicide, pesticide, fungicide, residual solvent, or metal found in an amount that exceeds any of the department's accepted limitations or other limitation pursuant to Florida law, whichever is lowest.

(i) Employee – Any person whose duties involve any aspect of testing low-THC cannabis, medical marijuana, derivative product, or edibles whether or not compensated for the performance of such duties.

(j) Environmental testing – Physical and biological laboratory analyses, to include chemistry, biochemistry, organic chemistry, pesticides, herbicides, fungicides, and metals.

(k) Filth and foreign materials – Hair, insects, feces, packaging contaminants, manufacturing waste, and other similar marijuana cultivation and processing by-products.

(l) Initial display of competency – An examination, provided by a marijuana testing laboratory, undertaken by an analyst to determine whether he or she is able to correctly, accurately, and repeatedly perform a specific analysis or analyze a specific measurement.

(m) Interests – Any form of ownership in or control of an applicant, a marijuana testing laboratory, or medical marijuana treatment center including, but not limited to, ownership of stock, membership interests, partnership interests, a sole proprietorship or otherwise which convey to the holder thereof an ownership right or an interest in or right to the profits, capital, or voting with respect to such applicant, marijuana testing laboratory, or medical marijuana treatment center.

(n) Laboratory batch – A set of not more than 20 samples for analysis. The set shall include testing samples as well as all applicable quality control samples, to include one method blank, duplicate laboratory fortified blanks, and duplicate matrix spikes, as required by the analytical method.

(o) Laboratory fortified blank – A sample initially without analytes of interest prepared along with testing samples that have been fortified with a known concentration of a target analyte or analytes for competency assessment purposes.

(p) Life science testing – Microbial laboratory analysis, to include microbiology and mycology, including yeast and mildew.

(q) Limit of detection – The lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

(r) Limit of quantitation – The minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

(s) Manager – Any person with the authority, directly or indirectly, to exercise or contribute to the operational control, direction or management of an applicant or a marijuana testing laboratory or who has direct or indirect authority to supervise any employee of an applicant or a marijuana testing laboratory. The term shall be interpreted broadly and shall include, but not be limited to, all officers, managers, and members of board of directors as well as

any other person engaged to undertake management or control of the applicant or a marijuana testing laboratory or any person or persons in control of an entity engaged to undertake management or control of the applicant or marijuana testing laboratory.

(t) Matrix – The component or substrate containing an analyte of interest.

(u) Matrix spike sample – A testing sample, created from a batch of marijuana provided by a medical marijuana treatment center, which has been fortified with a known concentration of an analyte or analytes to test for potential matrix interference.

(v) Method blank – A sample without analytes of interest prepared along with testing samples.

(w) Owner – Any person who, directly or indirectly, owns (actually or beneficially) or controls, a 5% or greater share of interests of the applicant or marijuana testing laboratory. In the event that one person owns a beneficial right to interests and another person holds the voting rights with respect to such interests, then in such case, both shall be considered the owner of such interests. In determining the owners of the applicant or a marijuana testing laboratory, the attribution of ownership rules set forth in the Treasury Regulations cited as 26 C.F.R. 1.414(c)-4(b) and (c) (4-1-17 edition), incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX, shall apply, but with the following exceptions and additions:

1. The use of the term "option" in 26 C.F.R. 1.414(c)-4(b) shall be interpreted broadly to include, but not be limited to, any and all 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.

2. The exception for attribution of a spouse's interest, as defined in paragraph (m) above and as set forth in 26 C.F.R. 1.414(c)-4(b)(5)(ii), shall not apply.

3. The age limitation contained in 26 C.F.R. 1.414(c)-4(b)(6) shall apply 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 subparagraph (m) above.

4. In the event that 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 shall be required to submit to a background screening only in the event that the interest or ownership was not imputed to another family member or guardian as outlined in paragraph (w)3. above.

5. To the extent that the above alterations to the provisions of 26 C.F.R. 1.414(c)-4 alter the outcome of any of the examples set forth therein, then, in such case, such example does not apply.

6. 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.

7. With regard to publicly traded companies with ownership interests in the applicant, any person who holds 10% or more interest in the publicly traded company shall be considered an owner.

(x) Potency testing – The analysis of the relative strength of cannabinoids.

(y) Processed batch – A homogenous portion of dried marijuana, derivative product, or edible intended for use by qualified patients that is collected from a medical marijuana treatment center by a marijuana testing laboratory for analysis.

(z) Proficiency testing –Testing of unknown samples provided to a marijuana testing laboratory by an ISO/IEC 17043 accredited, independent third-party auditor to determine the accuracy of the marijuana testing laboratory's analysis for specific analytes, matrices, or other measurements.

(aa) Quality assurance – A system developed either by the marijuana testing laboratory or an independent, third-party auditor to ensure that a specific level of products and services are delivered.

(ab) Quality assurance manual – A written collection of all quality assurance systems or protocols utilized by a marijuana testing laboratory that is available for review by any marijuana testing laboratory employee during working hours.

(ac) Quality control – A system developed either by the marijuana testing laboratory or an independent, third-party auditor to verify that the desired level of quality in existing products and services are maintained. Such verification shall include determining that appropriate equipment and instruments are used, continued inspection and overview of all facets of the testing process, and undertaking corrective action as necessary.

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

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

(af) Sampler – A marijuana testing laboratory employee who collects samples of marijuana from a medical marijuana treatment center for testing, and is specifically trained to fulfill this function.

(ag) Secure storage – The segregation of low-THC cannabis, medical marijuana, derivative product, or edibles in a manner that prevents access from unauthorized persons, compromise of the product's integrity, or premature spoilage.

(ah) Testing facility – Any area designated in the application for certification as a marijuana testing laboratory to be utilized in the preparation of low-THC cannabis, medical marijuana, derivative product, or edibles to be used in laboratory analysis, and any area where low-THC cannabis, medical marijuana, derivative product, or edible is tested in compliance with section 381.988, F.S., and this rule.

(ai) Testing sample – A sample for analysis created by a marijuana testing laboratory from a batch of marijuana provided by a medical marijuana treatment center, or another marijuana testing laboratory.

(2) Pursuant to sections 381.988(1)(e) and 381.988(3), F.S., certification as a marijuana testing laboratory shall only be awarded to applicants that demonstrate the capability of meeting the requirements of sections 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and 381.988, F.S., and this rule.

(3) All marijuana testing laboratories must be accredited or certified for environmental and life sciences testing pursuant to this subsection.

(a) Marijuana testing laboratories must be accredited or certified by an independent third party as compliant with the requirements of the International Organization for Standardization, ISO/IEC 17025:2017 (revised March 2018), incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. Applicants with a current, valid ISO/IEC 17025:2005 (May 2005), incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX, accreditation or certification at the time of application shall satisfy the requirements of this paragraph, the department has determined that posting the incorporated materials on the internet would constitute a violation of the federal copyright law. The incorporated materials will be available for public inspection and examination at the Florida Department of Health, 4052 Bald Cyprus Way, Tallahassee, FL 32399. The independent third-party that awarded the ISO/IEC 17025:2017 or ISO/IEC 17205:2005 accreditation or certification must be qualified by the International Organization for Standardization, or its predecessor organization, to make such an evaluation. Marijuana testing laboratories must be qualified to analyze the following categories:

1. microbiology;
2. residual solvents;
3. metals;
4. pesticides;
5. water activity;
6. moisture;
7. filth and foreign material; and
8. cannabinoid potency.

(b) Marijuana testing laboratories must be accredited or certified as compliant with the requirements of the AOAC International, Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals – An Aid to the Interpretation of ISO/IEC 17025:2005 (2015), incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The incorporated material will be available for public inspection and examination at the Florida Department of Health, 4052 Bald Cyprus Way, Tallahassee, FL 32399. The independent third-party that awarded the accreditation or certification must be qualified by AOAC International, or its predecessor organization, to make such an evaluation.

(c) Certified marijuana testing laboratories must maintain any required accreditation or certification required by this subsection. If a marijuana testing laboratory loses or has suspended any accreditation or certification required by this subsection, it must report this loss within 24 hours of its occurrence, along with any supporting documentation, to the Office of Medical Marijuana Use, at OMMULicenseOperation@flhealth.gov, and to any medical marijuana treatment center it is contracted with.

(d) Any marijuana testing laboratory that loses or has suspended any accreditation or certification pursuant to subsection shall not test or provide results for any analyte, matrix, or other measurement in conformity with paragraph (e).

(e) The marijuana testing laboratory shall have 180 days from the date it lost or had suspended any accreditation or certification to correct any deficiencies and to reestablish same. Any marijuana testing laboratory that is unable to reestablish any lost accreditation or certification within this time shall have its certification revoked.

(4) All applicants must demonstrate that the person or entity seeking to be certified as a marijuana testing laboratory is not owned and/or controlled by a medical marijuana treatment center. Applicants must provide certified financials showing all transactions regarding ownership interests as defined in subsection (1)(i) of the calendar year prior to the date of application. If the applicant is an entity, each officer, manager, and member of the board of directors, as well as any other person engaged to undertake management or control of the applicant, or any person or persons in control of an entity engaged to undertake management or control of the applicant, shall provide certified financials showing all transactions regarding ownership interests as defined in subsection (1)(i) of the calendar year prior to the date of the application.

(5) Applicants and must demonstrate 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. Applicants must demonstrate compliance with the following security requirements to ensure the safety and security of all proposed testing facilities and secure storage areas:

(a) Maintain a fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detectors; pressure switches; and duress, panic, and hold-up alarms.

(b) Maintain a video surveillance system that records continuously 24 hours a day and meets the following criteria:

1. 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 area;

2. cameras are fixed at entrances and exits to the premises, which shall record from both indoor and outdoor, or ingress and egress, vantage points; and

3. recorded images must clearly and accurately display the time and date.

(c) The exterior of any testing facility, to include any secure storage area if separate from a testing facility, shall be equipped with dusk-to-dawn safety lighting that provides a minimum of five (5) footcandles of illumination to the areas directly around the premises, including all points of ingress and egress.

(d) No low-THC cannabis, medical marijuana, derivative product, or edible for testing purposes is received outside the hours of 7:00 a.m. through 9:00 p.m.

(e) All marijuana and marijuana samples are stored in an appropriate secured, locked room or a vault in a manner that does not accelerate spoilage or promotes other degradation.

(f) At least two employees must accept marijuana for testing.

(g) At least two employees, or two employees of a contracted security agency, are on the testing facility premises when marijuana is received and during any phase of testing.

(h) Each employee or contractor with access to testing facilities, secure storage, or otherwise has any access to marijuana is required to wear a photo identification badge at all times while on the premises.

(i) Implement an alcohol and drug-free workplace policy.

(j) Report to local law enforcement within 24 hours after the marijuana testing laboratory is notified or becomes aware of the theft, diversion, or loss of marijuana.

(6) Applicants must demonstrate the following minimum standards for personnel:

(a) All employees must be 21 years of age or older. No marijuana testing laboratory shall employ either directly or indirectly any person who is below 21 years of age.

(b) All employees must pass a background screening pursuant to section 435.04, F.S. A marijuana testing laboratory shall not employ any person who has been found guilty of, or has entered a plea of guilty or nolo contendere to, regardless of adjudication, any offense listed in chapters 837, 895, or 896, F.S., or similar law of another jurisdiction.

(c) Analysts processing marijuana samples, or overseeing the processing of marijuana samples, must at a minimum have a bachelor's degree in a natural science, to include, but not limited to, biology, chemistry, physics, engineering, or environmental sciences.

(d) A marijuana testing laboratory must employ a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain any required accreditation or certification pursuant to subsection (3).

(e) An analyst must demonstrate an initial display of competency prior to analyzing any sample. For the purposes of this rule an initial display of competency is the acceptable performance in precision, accuracy, specificity, reportable ranges, blanks, and unknown proficiency testing samples in accordance with the standards of any required accreditation or certification pursuant to subsection (3). If an analyst has not run a specific analysis within one calendar

year, he or she must successfully complete an initial display of competency for this analysis and shall not run such analysis until competency has been demonstrated.

(7) Marijuana testing laboratories shall develop, maintain, and implement test methods and corresponding written standard operating procedures in conformity with this rule, any required accreditation or certification pursuant to subsection (3), and Florida law. Standard operating procedures shall be created for the analytes and materials within subsections (27), (28), and (30), as well as 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) analytical methods;

(e) cleaning procedures for equipment, workspaces, and secure storage;

(f) contingency plans for data that is not within control limits, or is otherwise unacceptable for analysis;

(g) employee training;

(h) premises and sample security;

(i) proficiency testing

(j) quality assurance and quality control procedures;

(k) recordkeeping and record retention;

(l) sample preparation;

(m) sample identification;

(n) sample rejection;

(o) sample destruction;

(p) sample disposal;

(q) disposal of non-marijuana laboratory waste;

(r) sample storage;

(s) schedule and process for internal audits and corrective actions; and

(t) disposal of marijuana and laboratory waste.

(8) Marijuana testing laboratory standard operating procedures for analytical methods shall include:

(a) the name of the testing method;

(b) a list of all analytes used in the testing method;

(c) the applicable matrix or matrices;

(d) method sensitivity;

(e) potential interferences;

(f) the analytical instrument used;

(g) consumable supplies, reagents, and standards;

(h) sample preservation and hold time;

(i) type, frequency, and acceptable criteria for quality control samples;

(j) type, frequency, and acceptable criteria for calibration standards;

(k) procedures for analyzing batch samples;

(l) data quality assessment and acceptance criteria;

(m) calibration of results; and

(n) reagent solution and reference material preparation.

(9) Marijuana testing laboratory testing methods shall conform to, to the extent practicable, the following methods:

(a) The following U.S. Food and Drug Administration, Bacterial Analytical Manual chapters:

1. Chapter 4: Enumeration of *Escherichia coli* and the Coliform Bacteria (July 2017), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

2. Chapter 4A: Diarrheagenic *Escherichia coli* (October 2017), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

3. Chapter 5: *Salmonella* (March 2018), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX; and

4. Chapter 18: Yeasts, Molds and Mycotoxins (April 2001), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(b) Chapter 4.7 of the U.S. Food and Drug Administration, Elemental Analysis Manual for Food and Related Products, Version 1.1 (March 2015), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(c) The U.S. Food and Drug Administration, Pesticide Analytical Manual Volumes I. and II. (3rd edition, revised October 1999), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(d) The U.S. Food and Drug Administration, Water Activity (A_w) in Foods (April 1984), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(e) AOAC International, Official Methods of Analysis for Contaminant Testing of AOAC International (20th edition, 2016), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The incorporated material will be available for public inspection and examination at the Florida Department of Health, 4052 Bald Cyprus Way, Tallahassee, Florida 32399.

(f) Methods of analysis for contamination testing within United States Pharmacopeia and the National Formulary (USP-NF) (2018), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. The department has determined that posting the incorporated material on the internet would constitute a violation of the federal copyright law. The incorporated material will be available for public inspection and examination at the Florida Department of Health, 4052 Bald Cyprus Way, Tallahassee, Florida 32399.

(g) A marijuana testing laboratory may provide an alternative, scientifically valid testing methodology, subject to the following requirements:

1. Any alternative, scientifically valid testing methodologies must be validated in accordance with either:

a. the U.S. Food and Drug Administration, Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds (2nd edition, 2015), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX; or

b. the U.S. Food and Drug Administration, Guidelines for the Validation of Chemical Methods for FDA FVM Program (2nd edition, 2015), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

2. The marijuana testing laboratory must submit alternative, scientifically valid testing methodologies to an independent third-party qualified in the qualitative validation of testing methodologies. Such validation shall include proficiency testing in which the marijuana testing laboratory must successfully achieve two consecutive passes.

3. A marijuana testing laboratory may only utilize an alternative, scientifically valid testing methodology upon the successful completion of subparagraphs (g)1. and 2., and providing proof, to include supporting documentation, to the department that the requirements of this paragraph have been met. Proof and supporting documentation shall be transmitted to the Office of Medical Marijuana Use at OMMULicenseOperation@flhealth.gov.

(10) Laboratory directors shall review, approve, sign, and date each standard operating procedure and each revision to a standard operating procedure. All standard operating procedures shall include the dates of issue and dates of revision.

(11) Marijuana testing laboratories shall keep all standard operating procedures on testing facility premises, and shall ensure that each standard operating procedure is accessible to all employees during all hours of operation.

(12) Marijuana testing laboratories shall use testing equipment that satisfies the requirements of any required accreditation or certification pursuant to subsection (3). If any piece of equipment is not suitable for a specific method it shall not be engaged for that purpose. Testing equipment shall be used and maintained according to the manufacturer's instructions, and shall be calibrated pursuant to the requirements of any accreditation or certification it is operated under. Marijuana testing laboratories shall retain records of all equipment repairs, maintenance, and calibrations.

(13) Marijuana testing laboratories must participate in and pass proficiency testing for tetrahydrocannabinol potency, concentration of cannabidiol, and contaminants unsafe for human consumption as contained in subsections (27), (28), and (30) in accordance with this subsection. For purposes of the subsection, participation means that the marijuana testing laboratory will analyze and report to an ISO/IEC 17043 accredited, independent third-party auditor the results of all proficiency test samples, as required by the ISO/IEC 17043 accredited, independent third-party auditor and any required accreditation or certification pursuant to subsection (3).

(a) Marijuana testing laboratories shall contract with an ISO/IEC 17043 accredited, independent third-party auditor to conduct proficiency testing and/or audits in accordance with any required accreditation or certification pursuant to subsection (3). Proficiency testing must be undertaken for each analyte, matrix, or other measurement that a marijuana testing laboratory analyzes.

(b) The marijuana testing laboratory shall bear the cost of any proficiency testing program required by the department.

(c) Marijuana treatment laboratories shall authorize any contracted ISO/IEC 17043 accredited, independent third-party auditor to submit all proficiency testing results to the department and marijuana testing laboratory concurrently. After the closing date, 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 program provider.

(d) All fields of accreditation within each matrix category group for which a marijuana testing laboratory is accreditation or certification pursuant to subsection (3), or is pending accreditation or certification, must be satisfactorily analyzed, if available, on two of the most recent three proficiency testing rounds attempted. Proficiency test sample results shall be considered satisfactory when they are within the acceptance limits established by the contracted ISO/IEC 17043 accredited, independent third-party auditor. If a marijuana testing laboratory reports more than one result for a field of proficiency testing on a proficiency testing round, any unsatisfactory result constitutes a failed testing attempt for the corresponding certified or pending field of accreditation.

(e) A marijuana testing laboratory that meets the requirements of paragraph (c) for a particular field of proficiency testing is authorized to analyze that corresponding field of accreditation or certification. Otherwise, authorization for that field of accreditation shall be suspended until such time the marijuana testing laboratory can meet the requirements of paragraph (f) in accordance with paragraph (g).

(f) Marijuana testing laboratories shall participate in at least two proficiency testing rounds from an ISO/IEC 17043 accredited, independent third-party auditor per calendar year beginning on the calendar day the marijuana testing laboratory was certified, or had its certification renewed, by the department. Proficiency testing must occur not more than once every seven months between consecutive testing rounds in terms of closing dates for each proficiency testing attempt. All marijuana testing laboratories must pass proficiency testing within the first six months of certification or renewal. Proficiency testing is satisfactory when a marijuana testing laboratory is able to successfully analyze two of the three most recent testing rounds attempted. All proficiency testing results shall be provided to the Office of Medical Marijuana Use, at OMMULicenseOperation@flhealth.gov, within two (2) days of receipt.

(g) A marijuana testing laboratory that fails any proficiency testing shall not test or provide results for any analyte, matrix, or other measurement in which it failed in accordance with paragraph (h).

(h) The marijuana testing laboratory shall have 180 days from the date of the notice failure to cure any deficiencies and to pass proficiency testing for any failed analyte, matrix, or other measurement. Any marijuana testing laboratory that is unable pass proficiency testing for failed analytes, matrices, or other measurements within this time shall have its certification revoked.

(14) All marijuana testing laboratories must implement quality assurance and quality controls. Quality assurance and quality controls must be contained within written standard operating procedures and be in accordance with any required accreditation or certification pursuant to subsection (3). Each marijuana testing laboratory shall develop and maintain a written quality-assurance program manual which addresses every aspect of its quality assurance program, to include, but not limited to:

(a) quality control procedures;
(b) laboratory organization;
(c) personnel training;
(d) personnel responsibilities;
(e) objectives for measurement data;
(f) data and result traceability;
(g) preventative maintenance of equipment;
(h) calibration procedures;
(i) performance audits, to include internal and independent, third-party laboratory auditing;
(j) corrective action;
(k) recordation and maintenance of quality assurance records;
(l) standardization of testing procedures; and
(m) testing method validation.

(15) Once a year the laboratory director, or other authorized employee, shall review, amend as necessary, and approve of the marijuana testing laboratory's quality assurance program. The laboratory director, or other authorized employee, shall review and amend the quality assurance program and related written materials whenever a change of method, equipment, or laboratory director occurs.

(16) A marijuana testing laboratory shall contract with an independent, third-party auditor certified to conduct quality assurance and quality control audits in accordance with any required accreditation or certification pursuant to subsection (3). Quality assurance and quality control audits must occur at least once every year. Audit results shall be provided to the Office of Medical Marijuana Use, at OMMULicenseOperation@flhealth.gov, by the independent,

third-party auditor that conducted the quality assurance or quality control audit within five (5) days of the completion of the audit.

(17) A marijuana testing laboratory shall contract with an independent, third-party auditor to conduct audits of all laboratory equipment, facilities, personnel, and security. Such audits must occur once every six months. Audit results shall be provided to the Office of Medical Marijuana Use, at OMMULicenseOperation@flhealth.gov, by the independent, third-party auditor that conducted the quality assurance or quality control audit within five (5) days of the completion of the audit.

(18) A marijuana testing laboratory must establish a tracking system to document the complete chain of custody of marijuana samples from receipt through disposal. Chain of custody entries must show the date, time, name of employee or employees handling the sample, the condition of the sample, the condition of any container or packaging the sample was transported or stored in, the location of the sample, the sample's unique identifier, and the seed-to-sale information from the medical marijuana treatment center.

(19) Marijuana testing laboratories must maintain a laboratory inventory management system that is able to integrate with the department's seed-to-sale tracking system, once implemented.

(20) Marijuana testing laboratories must be able to conduct audits and onsite inspections of medical marijuana treatment centers to review standard operating procedures, testing records, and samples as required in section 381.986(8)(e)10.d., F.S. Marijuana testing laboratories must create specific standard operating procedures for each medical marijuana treatment center it has contracted with to provide audits and inspections. Such audits and inspections shall conform with the requirements of any required accreditation or certification pursuant to subsection (3). Audits and onsite inspection reports shall state whether the medical marijuana treatment center's marijuana or low-THC cannabis meets the requirements of section 381.986, F.S., and department rule, and that the marijuana or low-THC cannabis is safe for human consumption. Marijuana testing laboratories shall transmit reports of audit results and onsite inspections, formatted as an Optical Character Recognition Portable Document Format (OCR PDF), to the department within seven (7) days of the completion of the audit or inspection to OMMULicenseOperation@flhealth.gov.

(21) All low-THC cannabis, medical marijuana, derivative product, and edibles must be tested within the state of Florida.

(22) Marijuana testing laboratories shall create and maintain written standard operating procedures for the collection of samples in conformity with this subsection.

(a) Marijuana testing laboratories shall develop separate sampling procedures for each matrix and method analyzed. Sampling procedures must conform with the requirements of any required accreditation or certification pursuant to subsection (3), and the department's Marijuana Testing Laboratory Sampler Manual, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX, if applicable. All relevant procedures shall be provided to all samplers in the field.

(b) Only a trained sampler from a marijuana testing laboratory may collect samples for marijuana laboratory testing. The marijuana testing laboratory shall develop a comprehensive training program for samplers so that field sampling is undertaken in conformity with any standard operating procedure contemplated by the subsection, and the department's Marijuana Testing Laboratory Sampler Manual, if appicable.

(c) Marijuana testing laboratories must ensure that all sampling procedures include randomization techniques. Such techniques shall not be divulged to any medical marijuana treatment center. All randomization techniques must conform with any accreditation or certification required pursuant to subsection (3). Failure to properly utilize a randomization technique shall result in the samples collected using the improper sampling technique to be reported as having failed all accepted limitations. A marijuana testing laboratory must provide immediate notice of any failure to properly utilize a randomization technique to the medical marijuana treatment center that the samples were collected from, any other marijuana testing laboratory handling such samples. and the department, an OMMUBusinessLicensing@flhealth.gov.

(23) Sample collection method, process standards, and sample rejection.

(a) The collection of marijuana samples shall be done accordance with the requirements of this rule and the Marijuana Testing Laboratory Sampler Manual.

(b) Samples for analysis must meet the following requirements:

1. Testing samples must be taken directly from a processed batch that is intended to be dispensed to qualified patients. A sample for analysis may not be from a batch of marijuana specifically intended for laboratory testing, but not for dispensation to qualified patients, even if the marijuana is the same type and kind used in the processed batch intended to be dispensed to qualified patients.

2. The aggregate weight or volume of testing samples for analysis must meet the minimum size requirements of this subparagraph.

a. For any dried marijuana, a testing sample must be at least 0.1% of the total weight, but no less than 10 g of each processed batch.

b. For derivative product, a testing sample must be at least 1% of the total volume, but no less than 5 ml, of each processed batch.

c. For edibles, a testing sample must be at least 5% of the total weight for solids, but no less than 15 g, or at least 5% of the total volume for liquids or semisolids, but no less than 10 ml, of each processed batch.

3. A marijuana testing laboratory may obtain a greater amount of marijuana than indicated in paragraphs (b)2.a.-c. if any amount is insufficient for any required testing.

(24) Marijuana testing laboratories shall reject marijuana for testing in accordance with this subsection.

(a) A marijuana testing laboratory may reject, retain, and not analyze any sample which does not conform with the requirements of any agreement between it and the providing medical marijuana treatment center, any standard operating procedure or analytical method, or this rule.

(b) A marijuana testing laboratory shall reject, retain, and not analyze any sample which does not conform with the requirements of subparagraph (23)(b), or the Marijuana Testing Laboratory Sampler Manual.

(c) A marijuana testing laboratory shall reject and not analyze any sample that:

1. upon inspection has any outer packaging that appears to have been tampered with, contaminated, damaged, or is otherwise unfit for its intended use;

2. upon inspection the sample provided for testing appears that it may have been tampered with, or is otherwise in a condition unsuitable for testing, to include improper temperature and moisture content;

3. is not accompanied by a sample field log, chain of custody documentation, or a travel manifest;

4. appears to have a forged or altered sample field log, chain of custody documentation, or travel manifest; or

5. was not initially collected or acquired from a medical marijuana treatment center by a sampler.

(d) Marijuana testing laboratories shall not remediate any rejected sample.

(e) Samples rejected pursuant to this subsection shall not be returned to the medical marijuana treatment center from which it was collected. Rejected samples must be maintained for at least three (3) months before being destroyed. Marijuana testing laboratories shall log all instances of sample rejection and destruction along with the specific reason for the rejection.

(f) Samples rejected pursuant to this subsection are not considered to have failed any accepted limitation, and the originating medical marijuana treatment center may have the processed batch resampled and analyzed.

(25) A marijuana testing laboratory may transfer testing samples to another certified marijuana testing laboratory for testing purposes pursuant to this subsection.

(a) When transferring testing samples, a marijuana testing laboratory shall conform with the requirements of sections 381.986(8)(g)1.-6. F.S.

(b) Prior to any analysis of any transferred testing sample, the receiving marijuana testing laboratory shall determine whether to accept or reject any transferred testing sample in conformity with subsection (24) and any standard operation procedure related to transfer testing sample acceptance or rejection.

(c) Rejected testing samples shall be not be analyzed and will be destroyed in accordance with subsection (24)(e). The receiving marijuana testing laboratory shall provide notice to the transferring marijuana testing laboratory, the originating medical marijuana treatment center, and the department, at OMMUBussinessOperation@flhealth.gov, within 24 hours of any transfer testing sample rejection.

(d) Samples rejected pursuant to this subsection are not considered to have failed any accepted limitation, and the originating medical marijuana treatment center may have the processed batch resampled and analyzed.

(26) Marijuana testing laboratories must maintain at least two untested portions of each tested sample. These portions must be maintained in secured storage for a minimum of nine (9) months before being destroyed.

(27) Marijuana testing laboratories must test for the following: microbiology, residual solvents, metals, pesticides, herbicides, fungicides, and any other contaminants unsafe for human consumption. Notwithstanding the accepted limitations associated with subparagraphs (a)1.-3., results shall be reported accurately to three (3) significant figures as the concentration in milligrams per gram dry-weight. Any determined test result that exceeds an enumerated acceptable limitation in this rule or Florida law, whichever is more restrictive, shall constitute a failure. No processed batch which has been awarded a failure of any accepted limitation shall be dispensed. Any determined test result that meets the requirements of an enumerated accepted limitation in this rule or Florida law, whichever is more restrictive, shall constitute a pass. Accepted limitation failures and passes must be reported to both the medical marijuana treatment center which provided the sample and to the Office of Medical Marijuana, at OMMULicenseOperation@flhealth.gov, within 24 hours of the finding. For the purposes of this rule, a test result is considered determined when the laboratory director, or other authorized employee, signs or authenticates the report containing those results.

(a) Microbiology (bacteria, fungus, yeast, and mildew) accepted limitations for low-THC cannabis, medical marijuana, derivative product, or edibles:

1. Any *Escherichia coli*, no detection within 10 grams.

2. Any *Salmonella* species, no detection within 10 grams.

3. Total fungus, yeast, and mold, no detection within 1 gram.

4. The aggregate of aflatoxins, as enumerated in this subparagraph, 20 parts per billion or less.

a. B1 (CAS No. 1162-65-8);

b. B2 (CAS No. 7220-81-7);

c. G1 (CAS No. 1165-39-5); and

d. G2 (CAS No. 7241-98-7).

5. Ochratoxin A (CAS No. 303-47-9), 20 parts per billion or less.

(b) Residual solvents, accepted limitations for derivative product, to include as used in edibles:

1. Acetone (CAS No. 67-64-1), 750 parts per million or less.

2. Any butane (CAS No. 106-97-8), 800 parts per million or less.

3. Ethanol (CAS No. 64-17-5), 1,000 parts per million or less.

4. Ethyl acetate (CAS No. 141-78-6), 400 parts per million or less.

5. Ethyl ether (CAS No. 60-29-7), 500 parts per million or less.

6. Heptane (CAS No. 142-82-5), 500 parts per million or less.

5. Isopropyl alcohol (CAS No. 67-63-0), 500 parts per million or less.

6. Methanol (CAS No. 67-56-1), 250 parts per million or less.

7. Pentane (CAS No. 109-66-0), 750 parts per million or less.

8. Propane (CAS No. 74-98-6), 2,100 parts per million or less.

9. Any other solvent not allowed pursuant to department rule, none detected.

(c) Residual solvents not approved for use, but potentially present in testing due to the possible presence in department approved solvents, accepted limitations for derivative product, to include as used in edibles:

1. Acetonitrile (CAS No. 75-05-8), 60 parts per million or less.

2. Benzene (CAS No. 71-43-3), one (1) part per million or less.

3. Chloroform (CAS No. 67-66-3), two (2) parts per million or less.

4. 1, 2- dichloroethane (CAS No. 107-06-2), two (2) parts per million or less;

5. 1, 1- dichloroethene (CAS No. 75-35-4), eight (8) parts per million or less;

6. Ethylene oxide (CAS No. 75-21-8), five (5) parts per million or less;

7. Hexane (CAS No. 110-54-3), 60 parts per million or less.

8. Methylene chloride (CAS No. 75-09-2), 125 parts per million or less.

9. Naphtha (CAS No. 8030-30-6), 400 parts per million or less.

10. Petroleum ether (CAS No. 8032-32-4), 400 parts per million or less.

11. Trichloroethylene (CAS No. 79-01-6), 25 parts per million or less.

12. Toluene (CAS No. 108-88-3), 150 parts per million or less.

13. Total xylenes (m, p, o-xylenes) (CAS No. 1330-20-7), 150 parts per million or less.

(d) Metals, accepted limitations for low-THC cannabis, medical marijuana, derivative product or edibles;

1. Lead (CAS No. 7439-92-1), less than 500 parts per billion.

2. Arsenic (CAS No. 7440-38-2), less than 200 parts per billion.

3. Cadmium (CAS No. 7440-43-9), less than 200 parts per billion.

4. Mercury (CAS No. 7439-97-6), less than 100 parts per billion.

(e) Pesticides, herbicides, and fungicides, accepted limitations for low-THC cannabis, medical marijuana, derivative product, or edibles;

1. Abamectin (CAS No.71751-41-2), 20 parts per billion or less.

2. Acephate (CAS No.30560-19-1), 20 parts per billion or less.

3. Acequinocyl (CAS No.57960-19-7), 20 parts per billion or less.

4. Acetamiprid (CAS No.135410-20-7), 10 parts per billion or less.

5. Aldicarb (CAS No.116-06-3), 10 parts per billion or less.

6. Azoxystrobin (CAS No.131860-33-8), 10 parts per billion or less.

7. Bifenazate (CAS No.149877-41-8), 100 parts per billion or less.

8. Chlorfenapyr (CAS No.122453-73-0), 10 parts per billion or less.

9. Chlorpyrifos (CAS No.2921-88-2), 20 parts per billion or less.

10. Clofentezine (CAS No.74115-24-5), 40 parts per billion or less.

11. Coumaphos (CAS No.56-72-4), 10 parts per billion or less.

12. Cyfluthrin (CAS No.68359-37-5), 10 parts per billion or less.
13. Cypermethrin (CAS No.52315-07-8), 500 parts per billion or less.
14. Daminozide (CAS No.1596-84-5), 10 parts per billion or less.
15. DDVP (Dichlorvos) (CAS No.62-73-7), 20 parts per billion or less.
16. Diazinon (CAS No.333-41-5), 10 parts per billion or less.
17. Dimethoate (CAS No.60-51-5), 10 parts per billion or less.
18. Dimethomorph (CAS No.110488-70-5), 10 parts per billion or less.
19. Ethoprop(hos) (CAS No.13194-48-4), 10 parts per billion or less.
20. Etofenprox (CAS No.80844-07-1), 10 parts per billion or less.
21. Etoxazole (CAS No.153233-91-1), 10 parts per billion or less.
22. Fenhexamid (CAS No.126833-17-8), 80 parts per billion or less.
23. Fenoxycarb (CAS No.72440-01-8), 10 parts per billion or less.
24. Fenpyroximate (CAS No.134098-61-6), 100 parts per billion or less.
25. Fipronil (CAS No.120068-37-3), 10 parts per billion or less.
26. Flonicamid (CAS No.158062-67-0), 100 parts per billion or less.
27. Fludioxonil (CAS No.131351-86-1), 20 parts per billion or less.
28. Hexythiazox (CAS No.78587-05-0), 100 parts per billion or less.
29. Imazalil (CAS No.35554-44-0), 10 parts per billion or less.
30. Imidacloprid (CAS No.138261-41-3), 20 parts per billion or less.
31. Kresoxim-methyl (CAS No.143390-89-0), 20 parts per billion or less.
32. Malathion (CAS No.121-75-5), 10 parts per billion or less.
33. Metalaxyl (CAS No.57837-19-1), 10 parts per billion or less.
34. Methiocarb (CAS No.2032-65-7), 10 parts per billion or less.
35. Methomyl (CAS No.16752-77-5), 10 parts per billion or less.
36. Methyl parathion (CAS No.289-00-0), 10 parts per billion or less.
37. Mevinphos (CAS No.7786-34-7), 10 parts per billion or less.
38. Myclobutanil (CAS No.88671-89-0), 20 parts per billion or less.
39. Naled (CAS No.300-76-5), 10 parts per billion or less.
40. Oxamyl (CAS No.23135-22-0), 26 parts per billion or less.
41. Paclobutrazol (CAS No.67638-62-0), 10 parts per billion or less.
42. Pentachloronitrobenzene (CAS No.82-68-8), 30 parts per billion or less.
43. Permethrin (CAS No.52645-53-1), 20 parts per billion or less.
44. Phosmet (CAS No.732-11-6), 20 parts per billion or less.
45. Piperonyl butoxide (CAS No.51-03-6), 3,000 parts per billion or less.
46. Prallethrin (CAS No.23031-36-9), 20 parts per billion or less.
47. Propiconazole (CAS No.60207-90-1), 20 parts per billion or less.
48. Propoxur (CAS No.144-26-1), 20 parts per billion or less.
49. Pyrethrins (CAS No.8003-34-7), 500 parts per billion or less.
50. Pyridaben (CAS No.96489-71-3), 20 parts per billion or less.
51. Spinetoram (CAS No.187166-15-0), 40 parts per billion or less.
52. Spinosad A (CAS No.168316-95-8), 20 parts per billion or less.
53. Spinosad D (CAS No.131929-60-7), 20 parts per billion or less.
54. Spiromesifen (CAS No.283594-90-1), 30 parts per billion or less.
55. Spirotetramat (CAS No.203313-25-1), 20 parts per billion or less.
56. Spiroxamine (CAS No.118134-30-8), 10 parts per billion or less.
57. Tebuconazole (CAS No.107534-96-3), 10 parts per billion or less.
58. Thiacloprid (CAS No.111988-49-9), 10 parts per billion or less.
59. Thiamethoxam (CAS No.153719-23-4), 10 parts per billion or less.
60. Trifloxystrobin (CAS No.141517-21-7), 20 parts per billion or less.

(f) If a testing sample is found to contain levels of any microbiology, residual solvent, metal, pesticide, herbicide, or fungicide that could be toxic if consumed or applied that is not otherwise enumerated in this rule or by Florida law the testing sample shall be considered to have failed acceptable limitation testing.

(g) Marijuana testing laboratories shall analyze water-activity levels according to the following limitations. Any low-THC marijuana, medical marijuana, derivative product, or edible which meets its respective criteria shall pass water-activity testing. Results shall be reported accurately to two (2) significant figures.

1. Dry marijuana, water activity 0.65 A_w or less.

2. Solid and semi-solid derivative product or edible, water activity of 0.85 A_w or less.

(h) Marijuana testing laboratories shall analyze moisture content levels of dry marijuana. Dry marijuana which has a moisture content of 5.0% to 13.0% shall pass moisture-content testing. Results shall be reported to the nearest tenth of a percent.

(i) Filth and foreign materials, accepted limitations for low-THC cannabis, medical marijuana, derivative product, or edibles:

1. Foreign material (to include hair, insects, packaging contaminants, manufacturing waste, and other similar marijuana cultivation and processing by-products), not otherwise contemplated by this subsection, not more than an average of 5% by weight.

2. Any feces, not more than 0.5 mg per kilogram.

(28) Marijuana testing laboratories shall report any testing sample that is found to contain a level of any contaminant not listed in this rule that could be injurious to human health if consumed or otherwise introduced to the human body. Any such finding shall constitute a failure of an acceptable limitation. The marijuana testing laboratory shall report such findings to the originating medical marijuana treatment center and the department at OMMUBusinessLicensing@flhealth.gov within 24 hours of the finding.

(29) If a measured accepted limitation is below the enumerated point of failure, but is found at level equating to at least 75% of the accepted limitation, the marijuana testing laboratory shall report this to the medical marijuana treatment center and to the department, at OMMULicenseOperation@flhealth.gov, within 24 hours of the finding. The marijuana testing laboratory upon any such finding may perform an audit of the medical marijuana treatment center. An audit performed under this subsection may include any marijuana, as well as any soil, water, medical marijuana treatment center premises or vehicle, or equipment used in the cultivation and processing of marijuana.

(30) Potency testing for low-THC cannabis, medical marijuana, derivative product, or edibles must include the relative strengths of the following cannabinoids. Cannabinoid results shall be reported accurately to three (3) significant figures as the concentration in milligrams per gram dry-weight. The dry-weight percentage shall be calculated as the percent of the cannabinoid ÷ (1- percent moisture ÷ 100). Findings must be reported to both the medical marijuana treatment center which provided the sample and to the Office of Medical Marijuana Use, at OMMULicenseOperation@flhealth.gov, within 24 hours of the finding.

(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.

(31) When testing edibles marijuana testing laboratories shall perform a homogeneity analysis for the cannabinoids enumerated in subsection (30). Homogeneity tests require at least 10 increments pursuant to the marijuana testing laboratory's standard operating procedure for creating test samples. The marijuana testing laboratory shall determine the relative standard deviation of the cannabinoid content between the 10 or more increments. The relative standard deviation is the standard deviation expressed as a percentage of the mean recovery. It is the coefficient of variation multiplied by 100, calculated as (the standard deviation ÷ mean recovery) × 100. If any results are less than the limit of quantitation, the absolute value of the limit of quantitation shall be used to calculate the relative standard deviation. A batch shall be considered homogenous if the relative standard deviation, with no outliers per Grubb's outlier test with a significance level of 0.05, is less than 15% on average, and the potency variance is no greater than 15 %. Edibles that do not meet these criteria shall fail homogeneity testing.

(32) All testing samples, whether having passed or failed any accepted limitation analysis, shall be retained for at least nine (9) months before being destroyed. Every testing sample that is destroyed shall be logged by the marijuana testing laboratory.

(33) Marijuana testing laboratories shall use quality control samples for each assay for chemical and microbiological analysis. Quality control samples shall be analyzed in the same manner as test samples for validation purposes.

(34) Marijuana testing laboratories shall prepare at least one method blank sample per laboratory batch. All method blank samples shall be prepared and analyzed in the same manner as testing samples. Method blanks that

contain analytes of interest above the limit of detection must be reanalyzed. If upon reanalysis the method blank is again above the limit of detection the marijuana testing laboratory shall determine and correct the source of the contamination, repeat the preparation of the laboratory batch, and reanalyze the testing samples. If method blank results continue to read above the limit of detection, the marijuana testing laboratory shall discontinue conducting the analysis until such time it is able to test at or below the limit of detection.

(35) Marijuana testing laboratories shall prepare and analyze laboratory fortified blanks for each laboratory batch. The percent of recovery for any analyte within each fortified blank, calculated as the quantitative sample result ÷ expected result × 100, shall be recorded. The acceptable range of recovery for any fortified blank is 80% to 120%.

(36) Marijuana testing laboratories shall prepare and analyze matrix spike samples for each laboratory batch. The percent of recovery for any analyte within each matrix spike, calculated as the quantitative sample result ÷ expected result × 100, shall be recorded. The acceptable range of recovery for any matrix spike sample is 70% to 130%, unless the testing sample the matrix spike sample was derived from is positive for any analyte within the matrix spike sample.

(37) Marijuana testing laboratories shall run duplicate laboratory fortified blanks and matrix spikes, and shall calculate their relative percent differences pursuant to this subsection. Relative percent difference is calculated as (quantitative sample result A – quantitative sample result B) ÷ ((quantitative sample result A + quantitative sample result B) ÷ 2) × 100. The relative percent difference between duplicates must be less than 20%.

(38) Marijuana testing laboratories shall prepare calibration standards pursuant to this subsection. Calibration standards shall be prepared by serially diluting a standard solution to produce working standards to be used in the calibration of instruments, the quantitation of analysis samples, and for use in fortified blanks and matrix spikes. Standard solutions shall either be:

(a) obtained from an independent third-party that has been accredited or certified as ISO/IEC 17025:2017 compliant, or has a current, valid ISO/IEC 17025:2005 accreditation or certification; or

(b) created by the marijuana testing laboratory, and found to be ISO/IEC 17025:2017 compliant by an independent third-party that has been accredited or certified as ISO/IEC 17025:2017 compliant, or has a current, active ISO/IEC 17025:2005 accreditation or certification.

(39) Marijuana testing laboratories shall generate quality control sample reports that contain the date of the analysis, the parameters of the analysis, the matrix or matrixes used, the analytes or materials tested for, the instrument of analysis, and measurements.

(40) The limit of detection shall be calculated in one of the following ways:

(a) the signal to noise ratio, as calculated by comparing the measured signals of known analyte concentrations with those within the method blanks to establish the minimum concentration an analyte can be consistently detected. Acceptable ratios shall be within the range of 3:1 to 2:1;

(b) based on the standard deviation of the instrument's response and the slope of the calibration curve, calculated as 3.3 × the standard deviation of the response ÷ the slope of the calibration curve. The standard deviation of the response shall be determined by comparing seven (7) blank samples. The limit of detection for chemical methods must be less than 1/10 of the action level for each analyte; or

(c) any other method published by the U.S. Food and Drug Administration or the U.S. Environmental Protection Agency. A marijuana testing laboratory utilizing a method pursuant to this paragraph shall provide the method to the Office of Medical Marijuana Use at OMMULicenseOperation@flhealth.gov.

(41) The limit of quantification shall be calculated in one of the following ways:

(a) the signal to noise ratio, as calculated by comparing the measured signals of know analyte concentrations with those of method blanks to establish the minimum concentration an analyte can be consistently detected. The minimum acceptable ratio is 10:1;

(b) based on the standard deviation of the instrument's response and the slope of the calibration curve, calculated as 10 × the standard deviation of the response ÷ the slope of the calibration curve. Standard deviation of the response is determined by comparing seven (7) blank samples; or

(c) any other method published by the U.S. Food and Drug Administration or the U.S. Environmental Protection Agency. A marijuana testing laboratory utilizing a method pursuant to this paragraph shall provide the method to the Office of Medical Marijuana Use at OMMULicenseOperation@flhealth.gov.

(42) Marijuana testing laboratories shall create and maintain data packages for every laboratory batch it analyzes. Data packages shall contain:

(a) the name and address of the laboratory that performed the testing;

(b) the names, titles, and signatures of the employees that performed any sample preparation, the sample analysis, and reviewed and approved the collected data;

(c) sample and batch quality control results;

(d) raw data for each sample;

(e) instrument raw data, if any;
(f) instrument test method with parameters;
(g) instrument tune reports;
(h) all instrument calibration data;
(i) sample preparation worksheets;
(j) laboratory workbook sheets relevant to the analysis run;
(k) analytical batch sample sequence;
(l) chain of custody documentation; and
(m) a copy of any report required by subsection (43).

(43) Upon the completion of any analysis, a marijuana testing laboratory shall generate a report containing all the information required in paragraph (a) below, and all the information required in paragraphs (b) and/or (c) below depending on the nature of the analysis. Additional information, analysis, or graphics not expressly required by paragraphs (a) through (c) may be included on any report contemplated by this subsection.

(a) Marijuana testing laboratory reports for environmental, life sciences, and potency testing must contain:
1. the name of the medical marijuana treatment center that provided the sample;
2. the cultivation facility where the marijuana was cultivated;
3. the processing facility where the marijuana was processed;
4. the strain or strains making up the sample;
5. the batch number and date and time the processed batch was created;
6. the batch number and date and time any laboratory batch was created;
7. the copy of any travel manifest or chain of custody documentation accompanying the laboratory batch;
8. the date and time sample preparation occurred;
9. the weight or volume of the sample prepared for use in the analysis;
10. the name of any person who performed the sample preparation;
11. the title of the standard operation procedure used to prepare the sample;
12. the date and time sample analysis occurred; and
13 the name of any person who performed the sample analysis.

(b) Marijuana testing laboratory reports for environmental and potency testing must contain:
1. the title of the standard operation procedure used in the sample analysis;
2. the type of instrument used to analyze the sample;
3. the final volume of the sample used in the analysis;
4. the sample matrix;
5. the analytes measured in the test;
6. the numerical concentration for each analyte and its minimum detection limit, or limit of detection;
7. the dilution factor of each analyte;
8. the percentage of each cannabinoid enumerated in subsection (24), and the total percentage of these cannabinoids within the sample; and
9. whether the sample has passed or failed in relation to accepted limits set by department rule for individual analytes.

(c) Marijuana testing laboratory results for life science testing must contain:
1. the total microbial count;
2. The sample matrix;
3. the analytes measured in the test;
4. the limit for the analysis conducted; and
5. whether the sample has passed or failed in relation to the accepted limitations for bacteria, fungus, and yeast.

(44) Prior to the dissemination of any report contemplated by sections (42) and (43) to the department or a medical marijuana treatment center, the marijuana testing laboratory's laboratory director, or other authorized employee, shall:
(a) review the quantitative analytical results for technical correctness 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) verifying approval of the results through signing and dating the data package.

(45) Marijuana testing laboratories must maintain data packages for seven (7) years from the date of their creation. Travel manifests, initial display of competency documentation, medical marijuana treatment center audit reports, and medical marijuana treatment center onsite inspection reports shall be retained for a minimum of three (3) years from the date of their creation. Quality control and proficiency testing reports shall be retained for a minimum of two (2)

years from the date the marijuana testing laboratory received them. Video surveillance recordings must be maintained for a minimum of 45 days or longer upon the request of a law enforcement agency.

(46) Upon request by the department, a marijuana testing laboratory shall provide the department copies of the following within two (2) days of the department's request:

(a) proof of accreditation or certification pursuant to subsection (3);

(b) standard operation procedures;

(c) analytical methods;

(d) equipment logs;

(e) raw analytical data;

(f) initial display of competency documentation;

(g) medical marijuana treatment center travel manifests;

(h) marijuana testing laboratory travel manifests;

(i) chain of custody documentation;

(j) sample rejection logs;

(k) quality assurance reports;

(l) proficiency testing reports;

(m) quality assurance manual;

(n) personnel qualification, training, and competency documentation;

(o) purchasing and supply records;

(p) method verification and validation records;

(q) quality assurance and quality control records;

(r) customer service records;

(s) nonconforming work and corrective action records;

(t) internal and external audit records;

(u) testing facility and secure storage area security records;

(v) data backup records;

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

(x) raw data:

(y) traceability records;

(z) standards records;

(aa) calibration records;

(ab) extraction logs, reference materials records;

(ac) analyst laboratory notebooks and logbooks;

(ad) sample analysis reports;

(ae) laboratory contamination records;

(af) laboratory cleaning records;

(ag) safety and chemical-hygiene records;

(ah) any other generated report related to the testing of marijuana; and

(ai) any other generated report related to the audit or onsite inspection of medical marijuana treatment centers, to include any materials used in the creation of such report.

(47) Marijuana testing laboratories must dispose of laboratory waste pursuant to section 381.0098, F.S. Any non-laboratory waste marijuana must be disposed of in accordance with department rule.

(48) Application for certification as a marijuana testing laboratory.

(a) Pursuant to section 381.988(1)(e), F.S., and subsection (2) of this rule, all applicants seeking certification as a marijuana testing laboratory shall comply with the below requirements.

(b) Each individual or entity that meets the requirements of section 381.988(1), F.S., and this rule desiring to be certified as a marijuana testing laboratory shall submit an application to the department using Form DH####-OMMU-##/####, "Application for Marijuana Testing Laboratory Certification," incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. Separate applications and certifications shall be required for all testing facilities and secure storage areas maintained on separate premises even though they are operated by the same applicant. Separate certifications are not required for separate buildings located on the same or adjoining grounds.

(c) Each applicant at the time of submission must provide the following along with the application:

1. A non-refundable application fee of $#####.

2. Proof of laboratory accreditation or certification pursuant to subsection (3), to include all related materials.

3. A list of all owners, officers, board members, and managers indicating the date of each individual's most

recent level 2 background screening pursuant to section 381.988(1)(d), F.S., within the calendar year prior to application. Each owner, officer, board member, and manager shall go to the Florida Department of Law Enforcement (FDLE) or one of its approved vendors for fingerprinting and, at such time, shall give to FDLE or the FDLE-approved vendor the entity ORI number FL924890Z (DOH – OFFICE OF MEDICAL MARIJUANA USE). The report will be sent directly to the Office of Medical Marijuana Use. The provision of this list is required as part of a complete application for certification. The list does not indicate passage of any background screening and to be eligible for certification as a marijuana testing laboratory, all of the applicant's owners, officers, board members, and managers must have successfully passed a Level-2 background screening.

4. Proof that the proposed testing facility, to include any area of secure storage, is located within the state of Florida. Proof under this subparagraph may be demonstrated by the provision of a certified copy of a lease or deed.

(d) If the applicant intends to claim any exemption from public records disclosure under section 119.07, F.S., or any other exemption from public records disclosure provided by law for any part of its application, it shall indicate on the application the specific sections for which it claims an exemption and the statutory basis for the exemption. The applicant shall submit a redacted copy of the application redacting those items identified as exempt concurrent with the submission of the application for approval under paragraph (g) below. Failure to provide a redacted copy of the application at the time of submission or failure to identify and redact information claimed as trade secret will result in the release of all application information in response to a public records request, unless the information falls under another public records exemption. All identified trade secrets are subject to the department review in accordance with section 381.83, F.S.

(e) The department will review each application and notify the applicant of any omissions related to the items in paragraphs (b) and (c) above within 15 days. An applicant will have five (5) business days to respond to complete its application. Applications considered complete will be provided to subject matter experts for review as to whether the application should be recommended for certification. An applicant may not add, remove, or change information in its application once it is complete and has been provided to subject matter experts for review.

(f) Failure to provide the following, after the notice and cure period set forth in paragraph (e) above, shall result in the application being denied prior to any scoring as contemplated in paragraph (h) below:

1. The $######## application fee;

2. Documentation of the accreditation or certification required pursuant to subsection (3);

3. Certified financials as required under subsection (4);

4. Proof that the proposed testing facility, to include any area of secure storage, is located within the state of Florida; or

5. A list of all owners, officers, board members, and managers.

(g) Applications and all required exhibits and supporting documents shall be delivered to the Department of Health, ATTN: Office of Medical Marijuana Use, at 4052 Bald Cypress Way, Bin M-01, Tallahassee, Florida.

(h) Third-party subject matter experts will substantively review, evaluate, and recommend applications using Form DH###-OMMU-##/2018, "Marijuana Testing Laboratory Certification Scoresheet," incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. Subject matter experts shall certify that they do not have a conflict of interest and will evaluate and provide a finding of adequacy for each assigned section of the application according to the rubric set forth in DH####-OMMU-##/2018.

(i) Subject matter experts shall have the following qualifications:

a. Subject matter experts reviewing Section 1of the application, the accreditation and/or certification components, shall have at least two (2) years of professional experience in either auditing for ISO/IEC 17025 certification or accreditation, auditing for AOAC ISO/IEC 17025 methods certification or accreditation, or U.S. Food and Drug Administration certifications, or a comparable standard.

b. Subject matter experts reviewing Sections 2 to 4 of the application, the analysis components, shall have at least two (2) years of professional experience or an advanced degree in one of the following areas: food sciences, agriculture sciences, or environmental sciences, or a comparable field.

c. Subject matter experts reviewing Sections 5 and 6 of the application, the onsite inspection and audit components, shall have at least two (2) years of professional experience in one of the following fields: inspecting or auditing ISO accredited/certified laboratories, inspecting or auditing AOAC ISO/IEC 17025 accredited/certified laboratories, or inspecting or auditing U.S. Food and Drug Administration certified laboratories, or a comparable accreditation or certification.

d. Subject matter experts reviewing Sections 7,8, 10, and 13 of the application, the accountability, security, and personnel components, shall have at least two (2) years of professional experience or an advanced degree related to operating a business in a highly regulated environment.

e. Subject matter experts reviewing Section 9, laboratory director, of the application shall have at least two (2) years of management experience within a business operating in the food, agriculture, or environmental testing laboratory.

f. Subject matter experts reviewing Sections 11 and 12 of the application, the legal and financial components, shall have an active CPA license or an active license to practice law and experience in business structuring.

(j) The department shall award certification to any applicant that the subject matter experts have evaluated as adequate for each section of DH####-OMMU-##/####. Any application which demonstrates a failure to pass a background screening or fails to comply with any requirement of sections 381.986 and 381.988, F.S., and this rule shall be denied certification.

(k) Upon notification that it has been certified as a marijuana testing laboratory, and prior to any receipt, handling, or testing of any low-THC cannabis, medical marijuana, derivative product, or edible, the marijuana testing laboratory must request, and undergo, an initial inspection by the department pursuant to department rule to determine that it is in compliance with sections 381.986 and 381.988, F.S., this rule, and the representations made in its application for certification. Failure to contact the department within 30 days of the receipt of the department's notification of certification to schedule an initial inspection shall be considered as the applicant's intent to withdraw its application for certification.

(49) The department shall not grant certification to any applicant that fails to correct any deficiency observed by the department during the initial inspection within 30 days of the department's notice to the applicant of the observed deficiency.

(50) Marijuana testing laboratories must adhere to the requirements of sections 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and 381.988, F.S., this rule, and the representations made within the application. A marijuana testing laboratory certified pursuant to this rule may request a variance or waiver from the representations made in its application pursuant to section 120.542, F.S.

(51) Any certified marijuana testing laboratory that meets the requirements of sections 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and 381.988, F.S., and this rule, desiring to renew its certification shall submit a renewal application to the department using DH###-OMMU-XX/2018, "Application for Marijuana Testing Laboratory Certification Renewal," incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

(a) The biennial period is defined as the two calendar years directly proceeding the date the department transmits its approval of either a marijuana testing laboratory's initial certification or renewal certification. A marijuana testing laboratory's provision of a DH###-OMMU-XX/2018 to the department does not toll the biennial period.

(b) An application for renewal must be consistent with and be in compliance with the renewal applicant's application for certification, as well as any subsequent variances approved by the department. No application amendment request shall be submitted as part of the renewal application.

(c) The completed renewal application must include:

1. A non-refundable renewal fee of $#####.

2. Proof of laboratory accreditation or certification pursuant to subsection (3), to include all related materials.

3. A list of all owners, officers, board members, and managers indicating the date of each individual's most recent level 2 background screening pursuant to section 381.988(1)(d), F.S., within the calendar year prior to application. Each owner, officer, board member, and manager shall go to the FDLE or one of its approved vendors for fingerprinting and, at such time, shall give to FDLE or the FDLE-approved vendor the entity ORI number FL924890Z (DOH – OFFICE OF MEDICAL MARIJUANA USE). The report will be sent directly to the Office of Medical Marijuana Use. The provision of this list is required as part of a complete renewal application for certification. The list does not indicate passage of any background screening and to be eligible for certification renewal, all of the applicant's owners, officers, board members, and managers must have successfully passed a level 2 background screening.

4. The employment of a laboratory director to supervise the activities of the marijuana testing laboratory and meets the requirements of subsection (6)(d).

5. Proof that any testing facility, to include any area of secure storage, is located within the state of Florida

6. A completed renewal inspection as detailed in subsection (52) below.

(d) If the renewal applicant intends to claim any exemption from public records disclosure under section 119.07, F.S., or any other exemption from public records disclosure provided by law for any part of its renewal, it shall indicate on the renewal materials the specific sections for which it claims an exemption and the statutory basis for the exemption. The renewal applicant shall submit a redacted copy of the renewal application and materials redacting those items identified as exempt.

(e) Failure to submit the $##### renewal fee or the documentation required by DH###-OMMU-XX/2018 and in subparagraphs (c) 2. and 3. is grounds for denial. Renewal applicants failing to submit the fee will be notified by the department and provided five (5) business days to cure the deficiency. Failure to submit the $###### fee shall result in the denial of the renewal application.

(f) An application for renewal must be consistent with and be in compliance with the renewal applicant's initial application for certification, as well as any subsequent variance approved by the department. A renewal applicant shall not submit any variance request as part of the renewal application.

(g) Within 15 days of the receipt of a DH###-OMMU-XX/2018, the department shall schedule a renewal inspection for each of the renewal applicant's testing facilities and secure storage areas in accordance with subsection (53). The renewal application shall not be deemed complete until the completion of all renewal inspections.

(h) All DH###-OMMU-XX/2018s shall be formatted as required in that form and shall be delivered along with all required fees and materials to the Office of Medical Marijuana Use, 4052 Bald Cypress Way, Bin M-01, Tallahassee, Florida 32399.

(52) Marijuana testing laboratory inspections, either initial, renewal, or upon the department's discretion, shall be undertaken pursuant to this subsection.

(a) A marijuana testing laboratory must receive written authorization from the department prior to operating any facility that tests or securely stores marijuana for the purposes of testing. To request authorization for any facility, a marijuana testing laboratory must electronically submit the following information to the department at OMMULicenseOperation@flhealth.gov:

1. the name of the marijuana testing laboratory;

2. the telephone number and email address of the marijuana testing laboratory's primary point of contact for the specific testing facility or secure storage area the certification was applied for; and

3. the address of the facility to be authorized.

(b) Within 15 days of receiving an DH###-OMMU-XX/2018, the department shall contact the marijuana testing laboratory's primary point of contact to schedule a certification inspection. Upon determination of a certification inspection date and time, the department shall send email confirmation to the marijuana testing laboratory's primary point of contact.

(c) The department may conduct an on-site inspection of any marijuana testing laboratory facility during normal working hours.

(d) During any inspection, the marijuana testing laboratory shall ensure that its quality manual, analytical methods, quality control data, proficiency test data, laboratory standard operating procedures, and all records needed to verify compliance with sections 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and 381.988, F.S., this rule, and the specific representations in its application for certification, to include any subsequent variances approved by the department, are available for review during the inspection. The marijuana testing laboratory shall allow department personnel to examine records; observe the marijuana testing laboratory's facilities, procedures, and equipment; and interview employees during the on-site inspection.

(e) During any inspection, a marijuana testing laboratory must demonstrate that its facility, equipment, operations, standard operating procedures, and personnel are in compliance with sections 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and 381.988, F.S., this rule, and the specific representations in its application for certification, to include any subsequent variances approved by the department.

(f) If the department identifies any violation of sections 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and 381.988, F.S., or this rule during an inspection of a marijuana testing laboratory facility, the department shall notify the marijuana testing laboratory within 15 days of the completion of the inspection. Within 21 calendar days of receipt of a written notice of a violation, the marijuana testing laboratory shall notify the department of the corrective action taken to resolve the violation and the date of the correction in writing. Within 30 days of receipt of any additional information submitted by the renewal applicant, the department shall determine whether the omissions, deficiencies, or violations have been addressed, and whether any additional action must be taken by the marijuana testing laboratory, or if disciplinary action is appropriate. The department shall conduct additional inspections to confirm that the violation has been resolved and corrective action has been taken, unless resolution of the violation can be confirmed absent a physical visit to the facility.

(g) In the case of an inspection for initial certification or certification renewal, the failure to resolve any omission, deficiency, or violation identified during an inspection shall be grounds for the denial of certification as a marijuana testing laboratory.

(53) The following disciplinary actions against shall be taken against certified marijuana treatment laboratories for violations of sections 381.986 and 381.988, F.S., and this rule chapter.

(a) The following shall result in revocation of the marijuana testing laboratory's certification:

1. Knowingly providing falsifying results, to include peak shaving.

2. Knowingly testing marijuana that did not originate from a medical marijuana treatment center.

3. Knowingly testing samples that were rejected pursuant to this rule.

4. Dispensing any marijuana.

5. Performing any analysis on marijuana while certification is suspended.

6. Falsifying any required accreditation or certification pursuant to subsection (3).

(b) The first instance of the following shall result in a 180-day suspension of certification. If an additional instance of the violation occurs within a calendar year of the first instance, the marijuana testing laboratory's certification shall be revoked.

1. Allowing an analyst without a current, valid initial display of competency to perform any analysis.

2. Allowing a non-analyst to perform any analysis.

3. Using expired standards, surrogates, internal standards, or spikes.

4. A sampler who fails to follow the sampling procedures or the Marijuana Testing Laboratory Sampler Manual.

5. The failure to follow and maintain proper security measures.

6. Using preparation or analytical methods that have not been certified by an independent, third-party auditor.

7. Any failure to transport marijuana in accordance section 381.988, F.S., and this rule.

8. Falsifying travel manifests, field reports, instrument maintenance logs, or chain of custody reports.

(c) If it is demonstrated that the marijuana testing laboratory took remedial action to correct the first instance of violation within paragraph (b), then such violation shall result in a 60-day suspension of certification. If an additional instance of the violation occurs within a calendar year of the first instance, the marijuana testing laboratory's certification shall be revoked.

(d) The first instance of the following shall result in a 60-day suspension of certification. If a second instance of the violation occurs within two calendar years of the first instance, the marijuana testing laboratory's certification shall be suspended for 180 days. If a third instance of the violation occurs within two calendar years of the first instance, the marijuana testing laboratory's certification shall be revoked.

1. following any outdated standard operating procedure, or manual.

2. knowingly hiring any employee who does not meet this rule's criteria of employment.

Rulemaking Authority Section 381.986(8)(K), 381.988(2), (3), (9) FS. Law Implemented Section 381.986(8)(e)10.d., 381.988 FS. History–New_____.