Rule 64-4.307 Standard Operating Procedures

(1) Certified Marijuana Testing Laboratories must develop, maintain, and implement test methods and corresponding written quality documentation in conformity with this rule, any required accreditation pursuant to Rule 64-4.301, and Florida statutes. A Certified Medical Marijuana Testing Laboratory must create and maintain Standard Operating Procedures for the analytes and materials within Rule 64-4.310 F.S., 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 instructions provided with Proficiency Testing samples;
(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 Secure Storage;
(s) schedule and process for internal audits and corrective actions; and
(t) disposal of marijuana and laboratory waste.

(2) Standard Operating Procedures for analytical methods must conform to the following:

(a) Standard Operating Procedures must include:
1. The name of the testing method;
2. A list of all analytes tested for using said method;
3. The applicable Matrix or matrices;
4. Method sensitivity;
5. Common potential interferences;
6. The analytical instruments used;
7. Consumable supplies, Reagents, and standards;
8. Sample preservation and hold time;
9. Type, frequency, and acceptable criteria for Quality Control samples;
10. Type, frequency, and acceptable criteria for Calibration Standards;
11. Procedures for analyzing Analytical Batch samples;
12. Data quality assessment and acceptance criteria;
13. Calibration of results; and

14. Reagent and Certified Reference Material preparation.

(b) Laboratory Directors must review, approve, sign, and date each Standard Operating Procedure and each revision to a Standard Operating Procedure. All Standard Operating Procedures must include the dates of issue and dates of revision.

(c) The latest revised Standard Operating Procedures must be kept on Testing Facility premises and be accessible to all Employees during all hours of operation.

Rule 64-4.308 Testing Methods

(1) Testing methods must conform to the following:

(a) Methods applicable for Microbiological Testing:

1. United States Food and Drug Administration (FDA), 2016. Bacterial Analytical Manual (BAM), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

2. Association of Analytical Communities (AOAC), 2016. *Salmonella* in Foods with a Low Microbial Load, 2000.06, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

3. International Standards Organization (ISO), 2002. ISO 6579:2017 Microbiology of the Food Chain – Horizontal Method for the Detection, Enumeration, and serotyping of Salmonella, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

4. International Standards Organization (ISO), 2012. ISO 13136:2012 Microbiology of Food and Animal Feed, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

5. Salfinger, Yvonne, and Tortorello, Mary Lou, 2015. *Compendium of Methods for the Microbiological Examination of Foods*, *5th edition.* American Public Health Association, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

6. United States Department of Agriculture: Food Safety and Inspection Services (USDA FSIS), 2016. Microbiology Laboratory Guidebook, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

7. Association of Analytical Communities (AOAC), 2016. Yeast and Mold Counts in Foods, 997.02, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

8. AOAC International, Official Methods of Analysis of AOAC International (21th edition, 2019). 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.

9. Methods of analysis for contamination testing within United States Pharmacopeia and the National Formulary (USP-NF) (2018). 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.

(b) Methods applicable to Residual Solvent testing.

1. Environmental Protection Agency (EPA). 624.1 Purgeable by GC/MS, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

2. Environmental Protection Agency (EPA). 8260D Volatile Organic Compounds by GC/MS, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

3. Methods of analysis for contamination testing within United States Pharmacopeia and the National Formulary (USP-NF) (2018). 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.

(c) Methods applicable to Heavy Metals testing.

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

2. United States Department of Agriculture: Food Safety and Inspection Services (USDA FSIS), 2016. Chemistry Laboratory Guidebook, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

3. Environmental Protection Agency (EPA). 6010D Inductively Coupled Plasma-Atomic Emission Spectrometry, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

4. Environmental Protection Agency (EPA). 6020B Inductively Coupled Plasma-Mass Spectrometry, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

5. AOAC International, Official Methods of Analysis of AOAC International (21th edition, 2019). 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.

6. Methods of analysis for contamination testing within United States Pharmacopeia and the National Formulary (USP-NF) (2018). 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.

(d) Methods applicable to Agricultural Agent testing.

1. Association of Analytical Communities (AOAC), 2016. Pesticide Residues in Foods by Acetonitrile Extraction and Partitioning the Magnesium Sulfate, 2007.01, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

2. Food and Drug Administration (FDA), 2016. Pesticide Analytical Manual (PAM), incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

3. United States Department of Agriculture: Food Safety and Inspection Services (USDA FSIS), 2016. Chemistry Laboratory Guidebook, incorporated by reference

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

4. The U.S. Environmental Protection Agency Testing Methods for Evaluating Solid Waste: Physical/Chemical Methods Compendium (SW-846) 8000 Series, incorporated by reference herein and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

5. AOAC International, Official Methods of Analysis of AOAC International (21th edition, 2019). 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.

6. Methods of analysis for contamination testing within United States Pharmacopeia and the National Formulary (USP-NF) (2018). 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.

(e) Methods applicable to Water Activity and Moisture testing.

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

2. United States Department of Agriculture: Food Safety and Inspection Services (USDA FSIS), 2016. Chemistry Laboratory Guidebook, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

(f) Methods Applicable to Cannabinoid Profile testing.

1. Backer, Benjamin De., et al., 2009. Innovative development and validation of an HPLC/DAD method for the qualitative and quantitative determination of major cannabinoids in cannabis plant material. *Journal of Chromatography B*, 887 4115-4124, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

2. Recommended Method for the Identification and Analysis of Cannabis and Cannabis Products: Manual for Use by National Drug Analysis Laboratories. United Nations, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

3. Gambaro, Veniero., et al., 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, 245-254, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

4. Stolker, A.A.M., et al., 2004. Determination of cannabinoids in cannabis products using liquid chromatography-ion trap mass spectrometry. *Journal of Chromatography A*, 1058, 143-151, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.

5. Upton, Roy et al., 2014. Cannabis Inflorescence Cannabis Spp.: Standards of Identity, Analysis, and Quality Control. American Herbal Pharmacopoeia, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

(g) A Certified 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.

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

d. Association of Analytical Communities (AOAC), 2002. Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

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

f. International Conference on Harmonization (ICH), 1996. Harmonized Tripartite Guideline Validations of Analytical Procedures: Text and Methodology, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

g. United States Department of Agriculture Food Safety and Inspection Services (USDA FSIS), 2010. Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods, incorporated by reference herein and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX;

2. The Certified Marijuana Testing Laboratory must submit alternative, scientifically valid testing methodologies to an independent third party that is qualified in the qualitative validation of testing methodologies. Such validation must include Proficiency Testing in which the Certified Marijuana Testing Laboratory must successfully achieve two consecutive passes.

3. A Certified Marijuana Testing Laboratory may only utilize an alternative, scientifically valid testing methodology upon the successful completion of subparagraphs (g)1. and (g)2., and the submission to the Department of documentary evidence that the requirements of this paragraph have been met. Proof and supporting documentation must be transmitted to the Office of Medical Marijuana Use at OMMULicenseOperation@flhealth.gov.

(2) Competency. An Analyst must demonstrate an Initial Display of Competency (IDOC) for a testing method prior to analyzing any Testing Sample using that method. An IDOC is comprised of one Method Blank and four Laboratory Fortified Blanks amended with the Analyte or Analytes for a specific test to a known concentration, and prepared and analyzed according to the same SOPs as testing samples. To pass, the calculated Residual Percent Deviation must be less than 20%, the recovery of each analyte in each Laboratory Fortified Blank must be between 80% and 120% of the amended concentration, and the Method Blank must not have any Analytes test above the LOD for that analysis. If an Analyst has not run a specific analysis within one calendar year, he or she must successfully complete an IDOC for this analysis prior to analyzing any Testing Samples using that testing method.

(3) Equipment. Certified Marijuana Testing Laboratories must use testing equipment that satisfies the requirements of all required accreditation pursuant to Rule 64-4.301. If any piece of equipment is not suitable for a specific method, it must not be engaged for that purpose. Testing equipment must be used and maintained according to the manufacturer's instructions and must be calibrated pursuant to the requirements of all accreditation under which it is operated. Certified Marijuana Testing Laboratories must retain records of all equipment repairs, maintenance, and Calibrations.

(4) Certified Marijuana Testing Laboratories must authorize any contracted ISO/IEC 17043 accredited Proficiency Test provider to submit all Proficiency Testing results to the Department and Certified 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 must be made unless it is necessary due to a documented error made by the accredited Proficiency Testing provider.

(5) Certified Marijuana Testing Laboratories must manage, analyze, and report all Proficiency Testing samples in the same manner as customer samples, including adherence to the same sample tracking, sample preparation, analysis methods, Standard Operating Procedures, Calibrations, Quality Control, and Acceptance criteria used in testing customer samples.

(6) The sample Matrix of the Proficiency Testing sample must match, as closely as possible, the Matrix type designated in the SOPs being used to prepare and analyze the Proficiency Testing sample.

Rule 64-4.309 Submission of Product for Testing

(1) An Medical Marijuana Treatment Center must submit to the Certified Marijuana Testing Laboratory finished products in their final, sealed retail packaging. For sampling purposes, a number of individual Final Products that sum to the amount enumerated in 64-4.310 for each Testing Field.

(a) A Testing Sample from a Retail Batch that is intended for use by qualified patients must be chosen at random from within the entirety of the Retail Batch. For sampling purposes, the Medical Marijuana Treatment Center must use the Department approved seed to sale system to generate the random selection of individual Final Products from the entire Retail Batch to create a Testing Sample for submission to the Certified Marijuana Testing Laboratory for testing.

(b) The Certified Marijuana Testing Laboratory must remove product from any packaging and homogenize all Increments into one Testing Sample. For Environmental Testing, three equal aliquots will be taken, one for primary analysis, one for analysis duplicate or backup for confirmation reanalysis, and one to remain untested and stored for 45 days. For Microbiological Testing, one 10g or 10ml aliquot will be analyzed for Total Combined Yeast and Mold. For the remainder of Microbiological Testing, two equal aliquots will be taken, one from primary analysis and one for reanalysis or storage for 45 days. Any portion of an aliquot not used must be stored for a minimum of 45 days. Untested sample may be used for and analysis necessary. The Certified Testing Laboratory may request additional product if necessary for the completion of any analysis.

(c) Final product for testing must be transported from the Medical Marijuana Treatment Center's Testing Facility and received by the Certified Marijuana Testing Laboratory within the same day. Transport of samples from a Medical Marijuana Treatment Center to a Certified Marijuana Testing laboratory, or from one Certified Marijuana Testing Laboratory to another, must comply with 381.986 (8)(g)1.-6., F.S. Standard Operating Procedures for the transportation of marijuana must be agreed upon by the Medical Marijuana Treatment Center and Certified Marijuana Testing Laboratory and followed at all times during the transportation of all product.

(d) A Certified Marijuana Testing Laboratory may also test Useable Whole Flower Marijuana, Derivative Product, or Edibles from any point in cultivation or processing. The satisfactory analysis of these samples that meet the enumerated Acceptable Limits in Rule 64-4.310 does not constitute a pass of any future Retail Batch created.

(e) A Certified Marijuana Testing Laboratory must begin preparation of samples for analysis within seven days from the sample departure date on the marijuana transportation manifest for Heavy Metals, Residual Solvents, Agricultural Agents, and Cannabinoid Profile analysis, and within 48 hours for Microbiological, Moisture, and Water Activity analysis.

(2) Rejection of Product for Testing. Certified Marijuana Testing Laboratories must reject marijuana for testing pursuant to this rule.

(a) A Certified Marijuana Testing Laboratory may reject, retain, and not analyze any sample that does not conform with the requirements of any agreement between Certified Marijuana Testing Laboratory and the providing Medical Marijuana Treatment Center, any Standard Operating Procedure or analytical method, or this rule.

(b) A Certified Marijuana Testing Laboratory must reject and not analyze any sample that:

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

2. upon inspection, the laboratory deems Testing Samples to have been tampered with, or otherwise in a condition unsuitable for testing, or to be or have been at an improper temperature, or to have improper Moisture content;

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

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

5. was not initially collected or acquired from a Medical Marijuana Treatment Center by a Sampler; or

6. Standard Operating Procedures for random sampling and transportation of Testing Samples were not observed.

(c) Certified Marijuana Testing Laboratories must not remediate any rejected sample. A sample rejected pursuant to this rule must not be returned to the Medical Marijuana Treatment Center from which it was collected. Rejected samples must be maintained for 30 days before being destroyed. Rejected samples must be destroyed by the Certified Marijuana Testing Laboratory. Samples must be removed from packaging prior to destruction. Useable Whole Flower Marijuana, solid Edibles, and other solid marijuana products rejected for testing must be ground and mixed with general waste maximum 50% marijuana by volume to render the waste unusable. Liquid marijuana products rejected for testing may be mixed with an appropriate solvent to a maximum 50% marijuana by volume to render the waste unusable and disposed of as hazardous waste. Certified Marijuana Testing Laboratories must log all instances of sample rejection and destruction along with the specific reason for the rejections.

(d) Samples rejected pursuant to this rule are not considered to have failed any accepted limitation, and the originating Medical Marijuana Treatment Center may have the Retail Batch resampled.

(e) Certified Marijuana Testing Laboratories must provide notice to the originating Medical Marijuana Treatment Center and the Department (at OMMUlicensingoperation@flhealth.org) within 24 hours of the rejection of a Testing Sample.

(3) Transfer of Product Between Laboratories. A Certified Marijuana Testing Laboratory may transfer Testing Samples to another Certified Marijuana Testing Laboratory for testing purposes if the originating Certified Marijuana Testing Laboratory cannot meet the obligations of all tests for the contracted Medical Marijuana Treatment Center. All such transfers must be performed in compliance with this rule.

(a) When transferring Testing Samples, a marijuana testing laboratory must 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 Certified Marijuana Testing Laboratory must determine whether to accept or reject any transferred Testing Sample in conformity with section (2) of this rule and any Standard Operation Procedure related to transfer Testing Sample acceptance or rejection.

(c) Rejected Testing Samples must be not be analyzed and must be destroyed in accordance with section (2). The receiving Certified Marijuana Testing Laboratory must provide notice to the transferring Certified Marijuana Testing Laboratory, the originating Medical Marijuana Treatment Center, and the Department at OMMULicenseOperation@flhealth.gov, within 24 hours of the rejection of any transferred Testing Sample.

(d) Samples rejected pursuant to this rule are not considered to have failed any accepted limitation, and the originating Medical Marijuana Treatment Center may have the Retail Batch resampled.

(e) A sample rejected pursuant to this rule must not be returned to the Medical Marijuana Treatment Center from which it was collected. Rejected Testing Samples must be maintained for at least 30 days before being destroyed pursuant to section (2). Certified Marijuana Testing Laboratories must log all instances of sample rejection and destruction along with the specific reason for the rejection.

(f) Samples generated from a Processed Batch rejected pursuant to this rule are not considered to have failed any accepted limitation, and the originating Medical Marijuana Treatment Center may have the Processed Batch resampled and analyzed.

Rule 64-4.310 Sample Testing

(1) All testing must occur within Florida. Certified Marijuana Testing Laboratories must test for the following: tetrahydrocannabinol potency, concentration of cannabidiol, and Contaminants Unsafe for Human Consumption. Contaminants Unsafe for Human Consumption include, but are not limited to, Microbiology, Mycotoxins, Residual Solvents, Heavy Metals, Agricultural Agents, Moisture, Water Activity, and Filth and Foreign Material. Notwithstanding the accepted limitations associated with paragraphs (2)(c)-(i), results must be reported accurately to three (3) significant figures as the concentration in milligrams per kilogram dry-weight for any test reported in parts per million (ppm) and to three (3) significant figures as the concentration in micrograms per kilogram dry-weight for any test reported in parts per billion (ppb). Any determined test result that exceeds an enumerated Acceptable Limits in this rule or Florida law, whichever is more restrictive, must constitute a failure. All failures must be confirmed using a portion of stored sample. Reanalysis of a failed analyte must occur after the first analysis which registered the initial failure. If reanalysis passes, the Certified Marijuana Testing Laboratory must be reported to the Department the data for both analyses and the reason for the initial failure. The Department shall decide if the Retail Batch may be sold. If a Retail Batch of Useable Whole Flower Marijuana or Derivative Product meant for inhalation fails any reanalysis, the Retail Batch may be used to create Derivative Product not meant for inhalation. Any final Retail Product created from a failed Retail Batch of Useable Whole Flower Marijuana or Derivative Product meant for inhalation must be tested again as a new Retail Batch. Any determined test result that meets the requirements of an enumerated accepted limitation in this rule or Florida law, whichever is more restrictive, must 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 verified when the Laboratory Director, or other authorized Employee, signs or authenticates the Certificate of Analysis containing those results.

(2) The following are minimum Acceptable Limits:

(a) Microbiology (bacteria, fungus,) accepted limitations, minimum Testing Sample size of 0.075% of the total Retail Batch weight or volume or a minimum of 9g or 9ml, whichever is larger:

1. Shiga toxin producing *Escherichia coli*, no detection within 1 gram.
2. Any *Salmonella* species, no detection within 1 gram.
3. *Aspergillus niger*, *Aspergillus fumigatus*, *Aspergillus flavus*, *Aspergillus terreus*, no detection within 1 gram.
4. Total Aerobic microbial count, less than 100 CFU within 1 gram in Non-Oral Transmucosal Products.
5. *Staphylococcus aureus*, no detection within 1 gram in Non-Oral Transmucosal Products.
6. *Pseudomonas aeruginosa*, within 1 gram in Non-Oral Transmucosal Products.
7. Bile tolerant gram-negative bacteria, within 1 gram in Non-Oral Transmucosal Products.

(b) Total Combined Yeast and Mold count, Acceptable Limits, minimum Testing Sample size of 0.075% of the total Retail Batch weight or volume, or a minimum of 10g or 10ml, whichever is larger:

1. Less than 10,000 CFU per gram in Useable Whole Flower, Derivative Products, and Edibles.
2. Less than 10 CFU per gram in Non-Oral Transmucosal Products.

(c) The aggregate of aflatoxins, as enumerated in this subparagraph, 20 parts per billion or less, minimum Testing Sample size of 0.05% of the total Retail Batch weight or volume or a minimum of 3g or 3ml, whichever is larger.

1. B1 (CAS No. 1162-65-8);
2. B2 (CAS No. 7220-81-7);
3. G1 (CAS No. 1165-39-5);
4. G2 (CAS No. 7241-98-7); and
5. Ochratoxin A (CAS No. 303-47-9), 20 parts per billion or less.

(d) Residual Solvents, Acceptable Limits for all Derivative Products and Edibles, minimum Testing Sample size of 0.05% of the total Retail Batch weight or volume or a minimum of 3g or 3ml, whichever is larger:

1. Acetone (CAS No. 67-64-1), 750 parts per million or less.
2. Acetonitrile (CAS No. 75-05-8), 60 parts per million or less.
3. Benzene (CAS No. 71-43-3), one (1) part per million or less.
4. Butane (CAS No. 106-97-8), 2,000 parts per million or less.
5. Chloroform (CAS No. 67-66-3), two (2) parts per million or less.
6. 1, 2- dichloroethane (CAS No. 107-06-2), two (2) parts per million or less;
7. 1, 1- dichloroethene (CAS No. 75-35-4), eight (8) parts per million or less;
8. Ethanol (CAS No. 64-17-5), 5,000 parts per million or less.
    a. Ethanol based products are exempt from accepted limitations for ethanol.
9. Ethyl acetate (CAS No. 141-78-6), 400 parts per million or less.
10. Ethyl ether (CAS No. 60-29-7), 500 parts per million or less.
11. Ethylene oxide (CAS No. 75-21-8), five (5) parts per million or less;
12. Heptane (CAS No. 142-82-5), 500 parts per million or less.
13. Hexane (CAS No. 110-54-3), 250 parts per million or less.
14. Isopropyl alcohol (CAS No. 67-63-0), 500 parts per million or less.
15. Methanol (CAS No. 67-56-1), 250 parts per million or less.
16. Methylene chloride (CAS No. 75-09-2), 125 parts per million or less.
17. Pentane (CAS No. 109-66-0), 750 parts per million or less.
18. Propane (CAS No. 74-98-6), 2,100 parts per million or less.
19. Trichloroethylene (CAS No. 79-01-6), 25 parts per million or less.
20. Toluene (CAS No. 108-88-3), 150 parts per million or less.
21. Total xylenes (m, p, o-xylenes) (CAS No. 1330-20-7), 150 parts per million or less.
22. Any other solvent not allowed pursuant to Department rule, none detected.

(f) Heavy Metals, Acceptable Limits for Useable Whole Flower Marijuana or Derivative Product meant for inhalation, minimum Testing Sample size of 0.05% of the total Retail Batch weight or volume or a minimum of 3g or 3ml, whichever is larger;

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.

(g) Heavy Metals, Acceptable Limits for Useable Whole Flower Marijuana, Derivative Product, or Edible not meant for inhalation, minimum Testing Sample size of 0.05% of the total Retail Batch weight or volume or a minimum of 3g or 3ml, whichever is larger;

1. Lead (CAS No. 7439-92-1), less than 500 parts per billion.
2. Arsenic (CAS No. 7440-38-2), less than 1500 parts per billion.
3. Cadmium (CAS No. 7440-43-9), less than 500 parts per billion.
4. Mercury (CAS No. 7439-97-6), less than 3000 parts per billion.

(h) Agricultural Agents, Acceptable Limits for Useable Whole Flower Marijuana, Derivative Product, or Edible meant for inhalation, minimum Testing Sample size of 0.05% of the total Retail Batch weight or volume or a minimum of 3g or 3ml, whichever is larger;

1. Abamectin (CAS No.71751-41-2), 100 parts per billion or less.
2. Acephate (CAS No.30560-19-1), 100 parts per billion or less.
3. Acequinocyl (CAS No.57960-19-7), 100 parts per billion or less.
4. Acetamiprid (CAS No.135410-20-7), 100 parts per billion or less.
5. Aldicarb (CAS No.116-06-3), 100 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. Bifenthrin (CAS No. 82657-04-3), 100 parts per billion or less.
9. Boscalid (CAS No. 188425-85-6), 100 parts per billion or less.
10. Captan (CAS No. 133-06-2), 700 parts per billion or less.
11. Carbaryl (CAS No. 63-25-2), 500 parts per billion or less.
12. Carbofuran (CAS No. 1563-66-2), 100 parts per billion or less.
13. Chlorantraniliprole (CAS No. 500008-45-7), 1000 parts per billion or less.
14. Chlordane (CAS No. 57-74-9), 100 parts per billion or less.
15. Chlorfenapyr (CAS No.122453-73-0), 100 parts per billion or less.
16. Chlormequat chloride (CAS No. 000-81-5), 1000 parts per billion or less.
17. Chlorpyrifos (CAS No.2921-88-2), 100 parts per billion or less.
18. Clofentezine (CAS No.74115-24-5), 200 parts per billion or less.
19. Coumaphos (CAS No.56-72-4), 100 parts per billion or less.
20. Cyfluthrin (CAS No.68359-37-5), 100 parts per billion or less.
21. Cypermethrin (CAS No.52315-07-8), 500 parts per billion or less.
22. Daminozide (CAS No.1596-84-5), 100 parts per billion or less.
23. Diazinon (CAS No.333-41-5), 100 parts per billion or less.
24. Dichlorvos (CAS No.62-73-7), 100 parts per billion or less.
25. Dimethoate (CAS No.60-51-5), 100 parts per billion or less.
26. Dimethomorph (CAS No.110488-70-5), 200 parts per billion or less.
27. Ethoprophos (CAS No.13194-48-4), 100 parts per billion or less.

28. Etofenprox (CAS No.80844-07-1), 100 parts per billion or less.
29. Etoxazole (CAS No.153233-91-1), 100 parts per billion or less.
30. Fenhexamid (CAS No.126833-17-8), 100 parts per billion or less.
31. Fenoxycarb (CAS No.72440-01-8), 100 parts per billion or less.
32. Fenpyroximate (CAS No.134098-61-6), 100 parts per billion or less.
33. Fipronil (CAS No.120068-37-3), 100 parts per billion or less.
34. Flonicamid (CAS No.158062-67-0), 100 parts per billion or less.
35. Fludioxonil (CAS No.131341-86-1), 100 parts per billion or less.
36. Hexythiazox (CAS No.78587-05-0), 100 parts per billion or less.
37. Imazalil (CAS No.35554-44-0), 100 parts per billion or less.
38. Imidacloprid (CAS No.138261-41-3), 400 parts per billion or less.
39. Kresoxim-methyl (CAS No.143390-89-0), 100 parts per billion or less.
40. Malathion (CAS No.121-75-5), 200 parts per billion or less.
41. Metalaxyl (CAS No.57837-19-1), 20 parts per billion or less.
42. Methiocarb (CAS No.2032-65-7), 50 parts per billion or less.
43. Methomyl (CAS No.16752-77-5), 100 parts per billion or less.
44. Methyl parathion (CAS No.289-00-0), 100 parts per billion or less.
45. Mevinphos (CAS No.7786-34-7), 100 parts per billion or less.
46. Myclobutanil (CAS No.88671-89-0), 100 parts per billion or less.
47. Naled (CAS No.300-76-5), 250 parts per billion or less.
48. Oxamyl (CAS No.23135-22-0), 500 parts per billion or less.
49. Paclobutrazol (CAS No.76738-62-0), 100 parts per billion or less.
50. Pentachloronitrobenzene (CAS No.82-68-8), 150 parts per billion or less.
51. Permethrin (CAS No.52645-53-1), 100 parts per billion or less.
52. Phosmet (CAS No.732-11-6), 100 parts per billion or less.
53. Piperonyl butoxide (CAS No.51-03-6), 3000 parts per billion or less.
54. Prallethrin (CAS No.23031-36-9), 100 parts per billion or less.
55. Propiconazole (CAS No.60207-90-1), 100 parts per billion or less.
56. Propoxur (CAS No.144-26-1), 100 parts per billion or less.
57. Pyrethrins (CAS No.8003-34-7), 500 parts per billion or less.
58. Pyridaben (CAS No.96489-71-3), 200 parts per billion or less.
59. Spinetoram (CAS No.187166-15-0), 200 parts per billion or less.
60. Spinosad A and D (CAS No.168316-95-8, 131929-60-7), 100 parts per billion or less.
61. Spiromesifen (CAS No.283594-90-1), 100 parts per billion or less.
62. Spirotetramat (CAS No.203313-25-1), 100 parts per billion or less.
63. Spiroxamine (CAS No.118134-30-8), 100 parts per billion or less.
64. Tebuconazole (CAS No.107534-96-3), 100 parts per billion or less.
65. Thiacloprid (CAS No.111988-49-9), 100 parts per billion or less.
66. Thiamethoxam (CAS No.153719-23-4), 500 parts per billion or less.
67. Trifloxystrobin (CAS No.141517-21-7), 100 parts per billion or less.

(i) Agricultural Agents, Acceptable Limits for Useable Whole Flower Marijuana, Derivative Product, or Edible not meant for inhalation, minimum Testing Sample size of 0.05% of the total Retail Batch weight or volume or a minimum of 3g or 3ml, whichever is larger;

1. Abamectin (CAS No.71751-41-2), 300 parts per billion or less.
2. Acephate (CAS No.30560-19-1), 3000 parts per billion or less.
3. Acequinocyl (CAS No.57960-19-7), 2000 parts per billion or less.
4. Acetamiprid (CAS No.135410-20-7), 3000 parts per billion or less.
5. Aldicarb (CAS No.116-06-3), 100 parts per billion or less.
6. Azoxystrobin (CAS No.131860-33-8), 3000 parts per billion or less.
7. Bifenazate (CAS No.149877-41-8), 3000 parts per billion or less.
8. Bifenthrin (CAS No. 82657-04-3), 500 parts per billion or less.
9. Boscalid (CAS No. 188425-85-6), 3000 parts per billion or less.
10. Captan (CAS No. 133-06-2), 3000 parts per billion or less.
11. Carbaryl (CAS No. 63-25-2), 500 parts per billion or less.
12. Carbofuran (CAS No. 1563-66-2), 100 parts per billion or less.
13. Chlorantraniliprole (CAS No. 500008-45-7), 3000 parts per billion or less.
14. Chlordane (CAS No. 57-74-9), 100 parts per billion or less.
15. Chlorfenapyr (CAS No.122453-73-0), 100 parts per billion or less.
16.Chlormequat chloride (CAS No. 000-81-5), 3000 parts per billion or less.
17. Chlorpyrifos (CAS No.2921-88-2), 100 parts per billion or less.
18. Clofentezine (CAS No.74115-24-5), 500 parts per billion or less.
19. Coumaphos (CAS No.56-72-4), 100 parts per billion or less.
20. Cyfluthrin (CAS No.68359-37-5), 1000 parts per billion or less.
21. Cypermethrin (CAS No.52315-07-8), 1000 parts per billion or less.
22. Daminozide (CAS No.1596-84-5), 100 parts per billion or less.
23. Diazinon (CAS No.333-41-5), 200 parts per billion or less.
24. Dichlorvos (CAS No.62-73-7), 100 parts per billion or less.
25. Dimethoate (CAS No.60-51-5), 100 parts per billion or less.
26. Dimethomorph (CAS No.110488-70-5), 3000 parts per billion or less.
27. Ethoprophos (CAS No.13194-48-4), 100 parts per billion or less.
28. Etofenprox (CAS No.80844-07-1), 100 parts per billion or less.
29. Etoxazole (CAS No.153233-91-1), 1500 parts per billion or less.
30. Fenhexamid (CAS No.126833-17-8), 3000 parts per billion or less.
31. Fenoxycarb (CAS No.72440-01-8), 100 parts per billion or less.
32. Fenpyroximate (CAS No.134098-61-6), 2000 parts per billion or less.
33. Fipronil (CAS No.120068-37-3), 100 parts per billion or less.
34. Flonicamid (CAS No.158062-67-0), 2000 parts per billion or less.
35. Fludioxonil (CAS No.131341-86-1), 3000 parts per billion or less.
36. Hexythiazox (CAS No.78587-05-0), 2000 parts per billion or less.
37. Imazalil (CAS No.35554-44-0), 100 parts per billion or less.
38. Imidacloprid (CAS No.138261-41-3), 3000 parts per billion or less.
39. Kresoxim-methyl (CAS No.143390-89-0), 1000 parts per billion or less.
40. Malathion (CAS No.121-75-5), 2000 parts per billion or less.
51. Metalaxyl (CAS No.57837-19-1), 3000 parts per billion or less.
42. Methiocarb (CAS No.2032-65-7), 100 parts per billion or less.
43. Methomyl (CAS No.16752-77-5), 100 parts per billion or less.
44. Methyl parathion (CAS No.289-00-0), 100 parts per billion or less.
45. Mevinphos (CAS No.7786-34-7), 100 parts per billion or less.
46. Myclobutanil (CAS No.88671-89-0), 3000 parts per billion or less.

47. Naled (CAS No.300-76-5), 500 parts per billion or less.
48. Oxamyl (CAS No.23135-22-0), 500 parts per billion or less.
49. Paclobutrazol (CAS No.76738-62-0), 100 parts per billion or less.
50. Pentachloronitrobenzene (CAS No.82-68-8), 200 parts per billion or less.
51. Permethrin (CAS No.52645-53-1), 1000 parts per billion or less.
52. Phosmet (CAS No.732-11-6), 200 parts per billion or less.
53. Piperonyl butoxide (CAS No.51-03-6), 3000 parts per billion or less.
54. Prallethrin (CAS No.23031-36-9), 400 parts per billion or less.
55. Propiconazole (CAS No.60207-90-1), 1000 parts per billion or less.
56. Propoxur (CAS No.144-26-1), 100 parts per billion or less.
57. Pyrethrins (CAS No.8003-34-7), 1000 parts per billion or less.
58. Pyridaben (CAS No.96489-71-3), 3000 parts per billion or less.
59. Spinetoram (CAS No.187166-15-0), 3000 parts per billion or less.
60. Spinosad A and D (CAS No.168316-95-8, 131929-60-7), 3000 parts per billion or less.
61. Spiromesifen (CAS No.283594-90-1), 3000 parts per billion or less.
62. Spirotetramat (CAS No.203313-25-1), 3000 parts per billion or less.
63. Spiroxamine (CAS No.118134-30-8), 100 parts per billion or less.
64. Tebuconazole (CAS No.107534-96-3), 1000 parts per billion or less.
65. Thiacloprid (CAS No.111988-49-9), 100 parts per billion or less.
66. Thiamethoxam (CAS No.153719-23-4), 1000 parts per billion or less.
67. Trifloxystrobin (CAS No.141517-21-7), 3000 parts per billion or less.

(j) Total Contaminant Load, Acceptable Limits for:
1. Useable Whole Flower and Derivative Product meant for inhalation, five (5) parts per million or less.
2. Useable Whole Flower, Derivative Product, and Edible not meant for inhalation, 30 parts per million or less.

(k) A Testing Sample that contains levels of any Microbiological, Residual Solvent, Heavy Metal, or Agricultural Agent, not otherwise enumerated in this rule or by Florida law, that could be toxic if consumed or applied, fails Acceptable Limits testing.

(l) Certified Marijuana Testing Laboratories must analyze a minimum Testing Sample size of 0.05% of the total Retail Batch weight or volume or a minimum of 3g or 3ml, whichever is larger of Useable Whole Flower Marijuana for water-activity levels according to the limitations listed below. Any Useable Whole Flower Marijuana, Derivative Product, or Edible which meets its respective criteria shall pass water-activity testing. Results must be reported accurately to two (2) significant figures.
1. Useable Whole Flower Marijuana, Water Activity 0.65 Aw or less.
2. Solid and semi-solid Derivative Product or Edible, Water Activity of 0.85 Aw or less, with the exception of water-based products which must be not be held to Water Activity standards.

(m) Certified Marijuana Testing Laboratories must analyze a minimum Testing Sample size of 0.05% of the total Retail Batch weight or volume or a minimum of 3g or 3ml,

whichever is larger of Useable Whole Flower Marijuana for Moisture content analysis. Useable Whole Flower Marijuana which has a Moisture content below 15.0% must pass Moisture-content testing. Results must be reported to the nearest tenth of a percent.

(n) Filth and Foreign Materials. Each individual product, upon being removed from final packaging, must be inspected for Filth and Foreign Materials before being used to create a Testing Sample. Accepted limitations for Useable Whole Flower Marijuana, Derivative Product, or Edibles:

1. Foreign material (to include mold, mildew, fungus, 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 1% by weight, or cover more than 10% of the total sample area.
2. Any feces, not more than 0.5 mg per kilogram.

(3) Potency Testing. Potency Testing for Useable Whole Flower Marijuana, Derivative Product, and Edibles must include the amount, in milligrams, of total active THC and total active CBD in the Final Product. The total amount of active THC and active CBD in in non-inhalation Derivative Products and Edibles must be reported in milligrams, accurately to three (3) significant figures, as the concentration of THC and CBD in milligrams per gram x the total weight of the product. For inhalation Derivative Products and Useable Whole Flower Marijuana, total active THC in milligrams must be calculated as the concentration of THC + (concentration of THCA x 0.877) in milligrams per gram x the total weight of the product. For inhalation Derivative Products and Useable Whole Flower, total active CBD in milligrams must be calculated as the concentration of CBD + (concentration of CBDA x 0.877) in milligrams per gram x the total weight of the product. Prior to Potency Testing, Useable Whole Flower must be dried to 12% (±0.5%) Moisture content. 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.

(4) Cannabidiol Profile. The Cannabinoid Profile results must be reported in percentage, accurate to 3 significant figures, as the concentration in milligrams per gram of each individual cannabinoid / the total concentration of all cannabinoids in milligrams per gram x 100. Testing Sample size of 0.05% of the total Retail Batch weight or volume or a minimum of 3g or 3ml, whichever is larger. The following cannabinoids must be tested for:

(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) The concentration of total active THC and total active CBD printed on the final retail packaging must be within 15% of the tested concentration. The percentage of the individual cannabinoids printed on the final retail packaging must ±0.5% of the tested value. If the concentration of total active THC or total active CBD printed on the final retail packaging varies by more than 15% from the tested concentration, the packaging must be corrected to display the accurate concentration prior to being sold to qualified patients. If the percentage of an individual cannabinoid printed on the final retail packaging varies by more than 0.1% from the tested value, the packaging must be corrected to displace the accurate concentration prior to being sold to qualified patients.

(6) Testing of Edibles. When testing Edibles, Certified Marijuana Testing Laboratories must perform a homogeneity analysis for the cannabinoids enumerated in section (4). Homogeneity tests require at least 10 Increments from one Final Product per 100 individual items per Retail Batch, rounding up to each next 100 (i.e. 101 items would require two individual Final Products to undergo homogeneity testing). The Relative Standard Deviation of the cannabinoid content between the 10 Increments in each Final Product tested must be less than or equal to 15% to constitute a pass. 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 value of the Limit of Quantitation must be used to calculate the relative standard deviation. A Processed Batch is homogenous if the Relative Standard Deviation, with no outliers per Grubb's outlier test with a significance level of 0.05, is less than or equal to 15%, and the potency variance is no greater than 15%. Edibles that do not meet these criteria fail homogeneity testing.

(7) Certified Marijuana Testing Laboratories must 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. The Certified Marijuana Testing Laboratory must report such findings to the originating Medical Marijuana Treatment Center and the Department at OMMULicenseOperation@flhealth.gov within 24 hours of the finding. Samples for research and development purposes only are not required to be reported to the Department.

(a) Any Certificate of Analysis generated by research and development samples must be clearly labeled "R&D ONLY NOT FOR RETAIL."

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

(8) Certified Marijuana Testing Laboratories must maintain at least one untested portion of each Testing Sample, whether having passed or failed any accepted limitation analysis. These Testing Samples must be securely stored for a minimum of 90 days before being destroyed. Every Testing Sample that is destroyed must be logged by the Certified Marijuana Testing Laboratory.

Rule 64-4.311 Quality Control Samples

(1) Certified Marijuana Testing Laboratories must use Quality Control samples in each analysis, where applicable. Quality Control samples must be analyzed in the same manner as test samples for validation purposes.

(a) Certified Marijuana Testing Laboratories must prepare at least one Method Blank sample per Laboratory Batch. All Method Blank samples must 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 Certified Marijuana Testing Laboratory must 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 Certified Marijuana Testing Laboratory must discontinue conducting the analysis until such time it is able to test at or below the Limit of Detection.

(b) Certified Marijuana Testing Laboratories must prepare and analyze Laboratory Fortified Blanks for each Laboratory Batch. The percent of recovery for any analyte within each Laboratory Fortified Blank, calculated as the quantitative sample result ÷ expected result × 100, must be recorded. The Certified Marijuana Testing Laboratory must determine acceptable ranges of recovery in Laboratory Fortified Blanks which must be approved within the scope of accreditation to ISO 17025.

(c) Certified Marijuana Testing Laboratories must prepare and analyze Matrix Spike Samples for each Laboratory Batch. The percent of recovery for any analyte within each Matrix Spike Sample, calculated as the quantitative sample result ÷ expected result × 100, must be recorded. The Certified Marijuana Testing Laboratory must determine acceptable ranges of recovery in Matrix Spike Samples which must be approved within the scope of accreditation to ISO 17025.

(d) Certified Marijuana Testing Laboratories must run duplicate Laboratory Fortified Blanks and Matrix Spike Sample and must 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 as follows;

1. Mycotoxins: 15% or less;
2. Residual Solvents: 20% or less;
3. Heavy Metals: 15% or less;
4. Agricultural Agents: 15% or less; and
5. Cannabinoids: 10% or less.

(e) Certified Marijuana Testing Laboratories shall run, where applicable, an Initial Calibration Verification (ICV) after the Calibration Curve, and Continuing Calibration Verification (CCV) after the ICV and once every 12 hours thereafter in the analysis run.

The Certified Marijuana Testing Laboratory shall calculate the RPD between the ICV and the corresponding Calibration Curve level, and the CCV and the corresponding Calibration Curve level. RPD is calculated as (quantitative sample result A – quantitative sample result B) ÷ ((quantitative sample result A + quantitative sample result B) ÷ 2) × 100. The RPD between the Calibration Curve level and corresponding CCV or ICV must be no more that 20%.

1. If the CCV results exceeds more than 20% above the corresponding Calibration Curve level concentration, any analyte result below the LOD may be reported. Otherwise the samples affected by the failed CCV shall be reanalyzed after a new Calibration Curve has been established and accepted.
2. If the CCV result exceeds more than 20% below the corresponding Calibration Curve level concentration, any analyte result above the Acceptable Limits may be reported. Otherwise the samples affected by the failed CCV shall be reanalyzed.

(f) Methods containing multiple Analytes may have the following number of Analytes in a Quality Control sample fall outside the accepted range to a maximum of 30%:

1. Methods containing fewer than 11 analytes are allowed no measurements outside the accepted range.
2. Methods containing 11 to 30 analytes are permitted one (1) Quality Control sample outside the accepted range.
3. Methods containing 31 to 50 analytes are permitted two (2) Quality Control samples outside the accepted range.
4. Methods containing 51 to 70 analytes are permitted three (3) Quality Control samples outside the accepted range.
5. Methods containing 71 or more analytes are permitted four (4) Quality Control samples outside the accepted range.

(g) 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 Laboratory Batch must be reanalyzed. If after reanalysis the same Quality Control sample falls outside the accepted criteria, the Certified Marijuana Testing Laboratory 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 Certified Marijuana Testing Laboratory must discontinue conducting the analysis until the Certified Marijuana Testing Laboratory is able to correct the cause of the unsatisfactory Quality Control sample measurement.

(h) Certified Marijuana Testing Laboratories must generate Quality Control sample reports that contain the date of the analysis, the parameters of the analysis, the Matrix or Matrixes used, the Analytes tested for, the instrument of analysis, and measurements.

Rule 64-4.312 Calibration Standards.

(1) Certified Marijuana Testing Laboratories must prepare Calibration Standards pursuant to and in compliance with this rule. Calibration Standards must be prepared by 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 Laboratory Fortified Blanks and Matrix Spike Samples. Standard solutions must either be: obtained from an independent body accredited as ISO/IEC 17034:2017 compliant, or has a current, valid ISO/IEC 17034:2005 by an accreditation body that is a signatory for Certified Reference Material producer (RMP) to mutual recognition arrangement (MRA) recognized through ILAC; or created by the Certified Marijuana Testing Laboratory and found to be ISO/IEC 17034:2017 compliant by an independent accreditation body that is a signatory for RMP to MRA recognized through ILAC.

(a) The Limit of Detection (LOD) must be calculated, where applicable, in one of the following ways:

1. 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 must be within the range of 3:1 to 2:1;

2. 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 must be determined by comparing seven Method Blank samples. The Limit of Detection for chemical methods must be less than 1/10 of the action level for each analyte; or

3. any other method published by the U.S. Food and Drug Administration or the U.S. Environmental Protection Agency. A Certified Marijuana Testing Laboratory utilizing a method pursuant to this paragraph must provide the method to the Office of Medical Marijuana Use at OMMULicenseOperation@flhealth.gov.

(b) The Limit of Quantification (LOQ) must be calculated, where applicable, in one of the following ways:

1. 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;

2. 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 Method Blank samples. The LOQ for chemical methods must be, at a maximum, ½ of the analyte limit; or

3. any other method published by the U.S. Food and Drug Administration or the U.S. Environmental Protection Agency. A Certified Marijuana Testing Laboratory utilizing a method pursuant to this paragraph must provide the method to the Office of Medical Marijuana Use at OMMULicenseOperation@flhealth.gov.

Rule 64-4.313 Certificate of Analysis

(1) Upon the completion of any analysis, a Certified Marijuana Testing Laboratory must generate a Certificate of Analysis for the Medical Marijuana Treatment Center containing the results from each Final Product tested, 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 rule.

(a) Certificates of Analysis for Environmental, Microbiological, and Cannabinoid Profile testing must contain:

1. the name of the Medical Marijuana Treatment Center that provided the sample;
2. the cultivation facility or facilities where the marijuana was cultivated;
3. the processing facility or facilities where the marijuana was processed;
4. the strain or strains making up the sample;
    a. if the Retail Batch is comprised of more than two strains, the Testing Sample can be referred to as "mixed strain."
5. the batch number and date the Retail Batch was created;
6. the batch number and date any Laboratory Batch was created;
7. the date sample preparation occurred;
8. the total weight or volume of the Final Product received for testing;
9. the internal laboratory identification number of any person who performed the sample preparation;
10. the date and time of the sample's 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 internal laboratory identification number of any person who performed the sample analysis.

(b) Certificates of Analysis for Environmental and Cannabinoid Profile 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 measured in the Testing Sample and its Limit of Detection;
7. the dilution factor of each analyte;
8. the percentage of each cannabinoid enumerated in Rule 64-4.310, 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 rule 64-4.310 for individual analytes.

(c) Certificates of Analysis for Microbiological Testing must contain:

1. presence or absence of microbes in 1 gram;

2. concentration of aflatoxins;
3. concentration of ochratoxin;
4. the sample Matrix;
5. the analytes measured in the test;
6. the limit for the analysis conducted; and
7. whether the sample passed or failed in relation to the Acceptable Limits for bacteria, fungus, yeast, and Mycotoxins.

(d) Certificates of Analysis generated by the Certified Marijuana Testing Laboratory mush be delivered electronically within 30 days of the sample departure date noted on the marijuana transportation manifest.

(2) Data Packages. Certified Marijuana Testing Laboratories must create and maintain Data Packages for every analyzed Laboratory Batch. Data packages must contain:

(a) the name and address of the laboratory that performed the testing;
(b) the name and address of the facility where the marijuana was cultivated;
(c) the name and address of the facility where the marijuana was processed;
(d) internal laboratory identification numbers of all Employees that performed any sample preparation, the sample analysis, and reviewed and approved the collected data;
(e) Laboratory Batch Quality Control results;
(f) raw data for each sample;
(g) instrument raw data, if any;
(h) instrument test method with parameters;
(i) instrument tune reports, where applicable;
(j) all instrument Calibration and/or tune data;
(k) Internal Standard report;
(l) Initial Calibration Certification Report;
(m) Continuing Calibration Verification Report;
(n) sample preparation worksheets;
(o) laboratory workbook sheets relevant to the analysis run;
(p) Analytical Batch sample sequence;
(q) all travel manifest documents;
(r) chain of custody documentation; and
(s) a copy of any Certificate of Analysis required by section (1)

(3) Prior to the dissemination of any documentation contemplated by sections (1) and (2) to the Department or a Medical Marijuana Testing Laboratory, the Certified Marijuana Testing Laboratory's Laboratory Director, or his designee, must:

(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) verify approval of the results by signing and dating the Data Package.

(4) Certified Marijuana Testing Laboratories must maintain Data Packages for seven (7) years from the date created. Travel manifests, Initial Display of Competency documentation, Medical Marijuana Treatment Center audit reports, and Medical Marijuana Treatment Center onsite 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 marijuana testing laboratory. Video surveillance recordings must be maintained for a minimum of 90 days or longer upon the request of a law enforcement agency or as ordered by any court of competent jurisdiction.

(5) Records. Upon request by the Department, a Certified Marijuana Testing Laboratory must provide the Department copies of the following within three business days of the Department's request:

(a) proof of accreditation pursuant to Rule 64-4.301, Certified Marijuana Testing Laboratory Certification and Renewal;
(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 results;
(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) equipment service records;
(s) non-conforming work and corrective action records;
(t) internal and external audit records;
(u) Testing Facility and Secure Storage area security records;
(v) Data Packages;
(w) data backup records;
(x) laboratory data reports, data review, and data approval records;
(y) any report or Certificate of Analysis created for a Medical Marijuana Treatment Center;
(z) raw analytical testing data:
(aa) traceability records;
(bb) standards records;
(cc) Calibration records;
(dd) extraction logs, Certified Reference Materials records;
(ee) Analyst laboratory notebooks and logbooks;

(ff) sample analysis reports;
(gg) laboratory contamination records;
(hh) laboratory cleaning records;
(ii) safety and chemical-hygiene records;
(jj) any other generated report related to the testing of marijuana; and
(kk) 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.

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_____.