DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

MARIHUANA SAMPLING AND TESTING

(By authority conferred on the executive director of the marijuana regulatory agency by section 206 of the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27206, sections 7 and 8 of the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27957 and 333.27958, and Executive Reorganization Order No. 2019-2, MCL 333.27001)

R 420.301 Definitions.

Rule 1. (1) As used in these rules:

(a) "Action limit" means the maximum permissible level of a contaminant in marihuana product allowable by the agency.

(b) "Acts" refers to the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801, and the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967, when applicable.

(c) "Agency" means the marijuana regulatory agency.

(d) "Batch" means all marihuana product of the same variety that has been processed together and exposed to substantially similar conditions throughout processing.

(e) "Cultivator" refers to a grower under the medical marihuana facilities licensing act or a marihuana grower under the Michigan Regulation and Taxation of Marihuana Act, or both.

(f) "Employee" means, except as otherwise provided in these rules, a person performing work or service for compensation. "Employee" does not include an individual providing trade or professional services who is not normally engaged in the operation of a marihuana establishment.

(g) "Final form" means the form a marihuana product is in when it is available for sale by a marihuana sales location not including consumer packaging. For marihuana products intended for inhalation, "final form" means the marihuana concentrate in an e-cigarette or a vaping device.

(h) "Good agricultural collection practices" or "GACP-GMP" means the World Health Organization's or the American Herbal Products Association's guidelines regarding the safety, efficacy**,** and sustainability of medicinal plant material being used in herbal medicines.

(i) "Good manufacturing practices" or "GMP" means the Food and Drug Administration's formal regulations regarding the design, monitoring, control, and maintenance of manufacturing processes and facilities. They are designed to ensure that products manufactured are to specific requirements including identity, strength, quality, and purity.

(j) "Harvest batch" means a designated quantity of harvested marihuana, all of which is identical in strain and has been grown and harvested together and exposed to substantially similar conditions throughout cultivation.

(k) "Immature plant" means a nonflowering marihuana plant that is no taller than 8 inches from the growing or cultivating medium and no wider than 8 inches produced from a cutting, clipping, tissue culture, or seedling that is in a growing or cultivating medium or in a growing or cultivating container.

(l) “Inactive ingredients” means binding materials, dyes, preservatives, flavoring agents, and any other ingredient that is not derived from the plant *Cannabis sativa L.*

(m) “Laboratory” refers to both a safety compliance facility under the medical marihuana facilities licensing act and a marihuana safety compliance facility under the Michigan Regulation and Taxation of Marihuana Act.

(n) “Limit of quantitation” or “LOQ” means the minimum concentration or mass of an analyte in a given matrix that can be reported as a quantitative result.

(o) “Marihuana business” refers to a marihuana facility under the medical marihuana facilities licensing act or a marihuana establishment under the Michigan Regulation and Taxation of Marihuana Act, or both.

(p) “Marihuana establishment” means a ~~e~~ a marihuana grower, marihuana safety compliance facility, marihuana processor, marihuana microbusiness, marihuana retailer, marihuana secure transporter, marihuana designated consumption establishment, or any other type of marihuana-related business licensed by the agency under the Michigan Regulation and Taxation of Marihuana Act.

(q) “Marihuana facility” means a location at which a licensee is licensed to operate under the medical marihuana facilities licensing act.

(r) “Marihuana product” means marihuana or a marihuana-infused product, or both, as those terms are defined in the act unless otherwise provided for in these rules.

(s) “Marihuana sales location” refers to a provisioning center under the medical marihuana facilities licensing act or a marihuana retailer under the Michigan Regulation and Taxation of Marihuana Act, or both.

(t) “Marihuana tracking act” means the marihuana tracking act, 2016 PA 282, MCL 333.27901 to 333.27904.

(u) “Medical marihuana facilities licensing act” or “MMFLA” means the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801.

(v) “Michigan Regulation and Taxation of Marihuana Act” or “MRTMA” means the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967.

(w) “Package tag” means an RFID tag supplied through the statewide monitoring system for the purpose of identifying a package containing a marihuana product.

(x) “Plant tag” means an RFID tag supplied through the statewide monitoring system for the purpose of identifying an individual marihuana plant.

(y) “Pre-test” means to perform full compliance testing on samples, without reporting the results to the agency, and reporting results of subsequent testing to the agency.

(z) “Proficiency test” means a test that determines the performance of individual laboratories for specific tests or measurements and is used to monitor laboratories’ performance.

(aa) “Producer” refers to both a processor under the medical marihuana facilities licensing act and a marihuana processor under the Michigan Regulation and Taxation of Marihuana Act.

(bb) “Production batch” means a designated quantity of marihuana product, all of which was processed together, is homogeneous, identical in color, flavor, and other characteristics, and was processed under similar conditions throughout processing.

(cc) “These rules” means the administrative rules promulgated by the agency under the authority of the medical marihuana facilities licensing act, the marihuana tracking act, the Michigan Regulation and Taxation of Marihuana Act, and Executive Reorganization Order No. 2019-2, MCL 333.27001.

(dd) "Tag" or "RFID tag" means the unique identification number or Radio Frequency Identification (RFID) issued to a licensee by the statewide monitoring system for tracking, identifying, and verifying marihuana plants, marihuana products, and packages of marihuana product in the statewide monitoring system.

(ee) "Target analyte" means a non-marihuana inactive ingredient designated for analysis.

(2) Terms defined in the acts have the same meanings when used in these rules unless otherwise indicated.

History: 2020 AACS; 2022 MR 5, Eff. Mar. 7, 2022.

R 420.302 Adoption by reference.

Rule 2. (1) The following codes, standards, or regulations of nationally recognized organizations or associations are adopted by reference in these rules:

(a) AOAC International Official Methods of Analysis, 21st edition. Copies of the adopted provisions are available for inspection and distribution from the Association of Official Analytical Collaboration (AOAC) International, 2275 Research Boulevard, Suite 300, Rockville, Maryland, 20850, telephone number 1-800-379-2622, for the price of $870.00.

(b) National fire protection association (NFPA) standard 1, 2021 edition, entitled "Fire Code," is adopted by reference as part of these rules. Copies of the adopted provisions are available for inspection and distribution from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, Massachusetts, 02169, telephone number 1-800-344-3555, for the price of $114.50.

(c) The International Organization for Standardization (ISO), ISO 22000 / ISO/TS 22002-1:2009, Food Safety Bundle, available for purchase at: https://webstore.ansi.org/Standards/ISO/ISO22000TS22002FoodSafety, for the price of $275.00.

(d) International Organization for Standardization (ISO), ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories, available at: https://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+17025%3a2017, for the price of $162.00.

(e) International Organization for Standards (IS0), ISO/IEC 17065:2012, Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services, available at: https://webstore.ansi.org/Standards/ISO/ISOIEC170652012, for the price of $175.00.

(f) International Organization for Standards (IS0), ISO/IEC 17043:2010, Conformity Assessment – General Requirements for Proficiency Testing, available at: https://webstore.ansi.org/Standards/ISO/ISOIEC170432010, for the price of $200.00.

(2) The standards adopted in subrule (1)(a) to (d) of this rule are available for inspection and distribution at the agency, located at 2407 North Grand River Avenue, Lansing, Michigan, 48906. Copies of these standards may be obtained from the agency at the cost indicated in subrule (1)(a) to (d) of this rule, plus shipping and handling.

History: 2020 AACS; 2022 MR 5, Eff. Mar. 7, 2022.

R 420.303 Batch; identification and testing.

Rule 3. (1) A cultivator shall uniquely identify each immature plant batch with a single batch name and record the information in the statewide monitoring system. Each immature plant batch must consist of no more than 100 immature plants.

(2) A cultivator shall tag each individual plant that is greater than 8 inches in height from the growing or cultivating medium or more than 8 inches in width with an individual plant tag and record the identification information in the statewide monitoring system.

(3) A cultivator shall separate the plants as the plants go through different growth stages and ensure that the plant tag is always identified with the plant throughout the growing cycle so that all plants can be easily identified and inspected. A cultivator shall ensure that identification information is recorded in the statewide monitoring system in accordance with the acts, the marihuana tracking act, and these rules.

(4) A cultivator shall destroy the individual plant tag prior to packaging. Once a tagged plant is harvested, it is part of a harvest batch so that a sample of the harvest batch can be tested by a licensed laboratory as provided in R 420.30**4** and R 420.305. A cultivator shall separate the harvest batch by product type and quarantine the harvested batch from all other marihuana and marihuana products when the marihuana batch has test results pending. A harvest batch must be easily distinguishable from other harvest batches until the batch is broken down into packages. A cultivator may not combine harvest batches.

(5) Before the cultivator transfers or sells the marihuana product to a marihuana sales location, a sample of the harvest batch must be tested for all required safety tests by a licensed laboratory as provided in R 420.30**4** and R 420.305. All test results must indicate passed in the statewide monitoring system before the marihuana is packaged for sale. A marihuana product from harvest batches may not be transferred or sold until tested, packaged, and tagged as required under subrule (4) of this rule. A cultivator may not transfer or sell marihuana under this rule to a marihuana sales location if the package contains more than 1 harvest batch.

(6) A cultivator may transfer or sell marihuana to a producer without first being tested by a laboratory if the marihuana product will be processed. After the producer has processed the material, the producer shall have the sample tested for all required safety tests pursuant to R 420.30**4** and R 420.305. A producer that received a package under this rule that has not been processed may transfer that package to another producer without having the package first tested by a laboratory for extraction.

(7) After test results indicate ~~a~~ passed test for all required safety tests and the harvest batch is packaged, each package must have a package tag attached. A cultivator shall ensure this information is placed in the statewide monitoring system in accordance with the acts, the marihuana tracking act, and these rules.

(8) A cultivator shall not transfer or sell any marihuana product that does not have a package tag attached and is not recorded in the statewide monitoring system in accordance with the acts, the marihuana tracking act, and these rules.

History: 2020 AACS; 2022 MR 5, Eff. Mar. 7, 2022.

R 420.303a Producer and sales location packaging and testing requirements.

Rule 3a. (1) A producer shall give a marihuana product a new package tag anytime the marihuana product changes form or is incorporated into a different product.

(2) A producer of a marihuana product in its final form shall have the sample tested pursuant to R 420.304 and R 420.305. The producer shall quarantine products from all other products when

the product has test results pending. The producer shall not transfer or sell a marihuana product to a marihuana sales location until after test results entered into the statewide monitoring system indicate a passed result for all required safety tests. Nothing in this subsection prohibits a producer from transferring or selling a package in accordance with the remediation protocol provided by the agency and these rules.

(3) A marihuana sales location may sell or transfer a marihuana product only to a marihuana customer under both of the following conditions:

(a) The marihuana product has received passing results for all required safety tests in the statewide monitoring system.

(b) The marihuana product bears the label required under the acts and these rules for retail sale.

History: 2022 MR 5, Eff. Mar. 7, 2022.

R. 420.304 Sampling; testing.

Rule 4. (1) A laboratory shall test samples as provided in the acts and these rules.

(2) A laboratory shall collect samples of a marihuana product from another marihuana business, and that marihuana business shall not interfere or prevent the laboratory from complying with all of the following requirements:

(a) The laboratory shall physically collect the sample of the marihuana product from another marihuana business to be tested at the laboratory. A laboratory shall comply with all the following:

(i) The laboratory shall ensure that samples of the marihuana product are identified in the statewide monitoring system and placed in secured, sealed containers that bear the labeling required under these rules.

(ii) The route plan and manifest must be entered into the statewide monitoring system, and a copy must be carried in the transporting vehicle and presented to a law enforcement officer upon request.

(iii) The marihuana must be transported in 1 or more sealed containers and not be accessible while in transit.

(iv) The vehicle a laboratory is using to transport samples of marihuana product must not bear markings or other indication that it is carrying marihuana or a marihuana-infused product.

(b) Except otherwise required by the agency, the laboratory shall collect a sample size that is sufficient to complete all required analyses, and not less than 0.5% of the weight of the harvest batch.

(c) The maximum harvest batch is 50 pounds. At least 50% of the sample taken must be homogenized for testing. The agency may publish sample sizes for marihuana products being tested.

(d) For a marihuana concentrate a laboratory must take a sample increment of 0.25 grams. The laboratory must take the following number of increments based upon the production batch size:

(i) 12 increments for a production batch of 1 to 2 pounds.

(ii) 15 increments for a production batch of 2 to 3 pounds.

(iii) 18 increments for a production batch of 3 to 4 pounds.

(iv) 23 increments for a production batch of 4 to 10 pounds.

(v) 29 increments for a production batch greater than 10 pounds.

(e) For marihuana-infused products a laboratory must take the following number of units based upon the production batch size:

(i) 2 units for a production batch of up to 100 units.

(ii) 4 units for a production batch of 101 to 500 units.

(iii) 6 units for a production batch of 501 to 1000 units.

(iv) 8 units for a production batch of 1001 to 5000 units.

(v) 10 units for a production batch of 5001 to 10,000 units.

(vi) 12 units for a production batch greater than 10,001 units.

(f) The laboratory shall develop a statistically valid sampling method and have it approved by the agency to collect a representative sample from each batch of marihuana product. The laboratory shall have access to the entire batch for the purposes of sampling.

(g) An employee of the marihuana business from which marihuana product test samples are collected shall be physically present to observe the laboratory employee collect the sample of marihuana product for testing and ~~shall~~ ensure that the sample increments are taken from throughout the batch.

(h) An employee of a marihuana business shall neither assist the laboratory employee nor touch the marihuana product or the sampling equipment while the laboratory employee is obtaining the sample.

(i) After samples have been selected, both the employee of the marihuana business that had the samples collected and the employee from the laboratory shall sign and date the chain of custody form, attesting to the following sample information:

(i) Marihuana product name.

(ii) Weight of marihuana product.

(iii) All marihuana products and samples are correctly identified in the statewide monitoring system.

(iv) If the product test sample is obtained for a retest, the laboratory confirms that it is not accepting a product test sample that is prohibited from being retested.

(j) A marihuana business shall enter in the statewide monitoring system the marihuana product test sample that is collected by a licensed laboratory, including the date and time the marihuana product is collected and transferred. The laboratory shall enter into the statewide monitoring system the test results within 3 business days of test completion.

(k) If a testing sample is collected from a marihuana business for testing in the statewide monitoring system, that marihuana business shall quarantine the marihuana product that is undergoing the testing from any other marihuana product at the marihuana business. The quarantined marihuana product may not be packaged, transferred, or sold until passing test results are entered into the statewide monitoring system.

(l) Any marihuana product that a laboratory collects for testing from a licensee under this rule may not be transferred or sold to any other marihuana business other than the licensee from whom the sample was collected. This provision does not apply to a laboratory that engages another laboratory to perform certain safety tests on a subcontracted basis.

(m) A laboratory may collect additional sample material from the same licensee from which the original sample was collected for the purposes of completing the required safety tests as long as the requirements of this rule are met.

(n) The agency may publish guidance that must be followed by marihuana businesses for chain of custody documentation.

History: 2020 AACS; 2022 MR 5, Eff. Mar. 7, 2022.

R. 420.305 Testing; laboratory requirements.

Rule 5. (1) A laboratory shall become accredited for all required safety tests in at least 1 matrix to the International Organization for Standardization (ISO), ISO/IEC 17025:2017, by an International Laboratory Accreditation Cooperation (ILAC) recognized accreditation body or by an entity approved by the agency within 1 year after the date the laboratory license is issued and agree to have the inspections, reports, and all scope documents sent to the agency.

(2) A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are based upon published peer-reviewed methods, have been validated for cannabis testing by an independent third party, and have been internally verified by the licensed laboratory according to Appendix J or K of Official Methods of Analysis authored by the Association of Official Analytical Collaboration (AOAC) International, with guidance from published cannabis standard method performance requirements where available. In the absence of published, peer reviewed, validated cannabis methods, method validation requirements of Appendix J or K of Official Methods of Analysis authored by the Association of Official Analytical Collaboration (AOAC) International must be met in full with guidance from published cannabis standard method performance requirements where available. The agency may monitor a laboratories analytical testing methodologies on an ongoing basis.

(3) A laboratory shall conduct the required safety tests specified in subdivisions (a) to (i) of this subrule on marihuana product that is part of the harvest batch or production batch as specified in R 420.303, except as provided in subrule (4) of this rule. The minimum testing portions to be used in compliance testing shall be consistent with the testing portions used during method validation. The agency may publish a guide indicating which of the following safety tests are required based on product type when the marihuana product has changed form:

(a) Potency analysis. All of the following apply to a potency analysis under this subdivision:

(i) In the preparation of samples intended for potency analysis, the laboratory may not adulterate or attempt to manipulate the total potency of the sample by any means, including by the addition of trichomes that were removed during the grinding and homogenization process.

(ii) All flower material used for potency testing must be representative of the product used by the end consumer and homogenized in such a way that it is representative of the way a consumer would be using the product. Kief must not be reintroduced to the flower sample during the homogenization process, unless fully validated to Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Collaboration (AOAC) International.

(iii) Potency analysis performed just as the marihuana product is without any corrective factor taken for moisture content that includes concentrations of the following:

(A) Total tetrahydrocannabinol (THC), including reporting all cannabinoids that can be tested for using a method that meets the requirements of subrule 2 of this rule.

(B) Tetrahydrocannabinoic acid (THC-A).

(C) Total cannabidiol (CBD) including reporting all cannabinoids that can be tested for using a method that meets the requirements of subrule 2 of this rule.

(D) Cannabidiolic acid (CBD-A).

(E) Additional cannabinoids, which may be tested with approval from the agency.

(b) Inspection for foreign matter including powdery mildew, organic, and inorganic material.

(c) Microbial screening including an optimized incubation period for all non-molecular automated systems methods and all plating-based methods used to report quantitative total yeast and mold results.

(d) Chemical residue testing performed for the list of banned chemical residues and the required LOQs published by the agency.

(e) Heavy metals testing as required in this rule.

(f) Residual solvents for production batches of marihuana infused products and edible marihuana products. The agency shall publish a list of required residual solvents to be tested for and their action limits.

(g) Water activity.

(h) Mycotoxin screening if requested by the agency.

(i) Target analytes if requested by the agency. The agency shall publish a list of required target analytes to be tested for and their LOQs.

(4) All marihuana producers may become certified to GMP by a body accredited under ISO 17065. This accreditation may enable the licensee certain allowances with testing. The agency will publish those allowances and information on how to obtain approval for allowances. The standard used for certification for GMP must be American National Standards Institute (ANSI) accredited or equivalent.

(5) All marihuana cultivators may become certified to GACP-GMP by a body accredited under ISO 17065. This accreditation may enable the licensee certain allowances with testing. The agency will publish these allowances and information on how to obtain approval for allowances. The standard used for certification for GACP-GMP must be World Health Organization and American Herbal Products Association or equivalent.

(6) Except as otherwise provided in R 420.306, if a sample collected pursuant to R 420.304 or provided to a laboratory pursuant to these rules does not pass the required safety tests, the marihuana business that provided the sample shall destroy the entire batch from which the sample was taken and document the destruction of the sample using the statewide monitoring system pursuant to the acts and these rules within 90 calendar days.

(7) A laboratory shall conduct residual solvent testing on batches of marihuana concentrates and marihuana-infused products. The agency shall publish a list of required residual solvents to be tested for and their action limits.

(8) A laboratory shall maintain any marihuana samples for at least 30 calendar days after test completion and destroy the resulting waste in accordance with R 420.209.

(9) Potency shall include the following cannabinoid concentrations listed in subdivisions (a) to (f) of this subrule, subject to subdivisions (g) and (h) of this subrule:

(a) Total THC concentration.

(b) THC-A concentration.

(c) The following calculation must be used for calculating Total THC, where Σ is the sum and M is the mass or mass fraction of each THC isomer being reported or THC-A:

M Σ THC + (0.877 x M Σ THC-A) =Total THC

(d) Total CBD concentration.

(e) CBD-A concentration.

(f) Total CBD. The following calculation must be used for calculating Total CBD, where M is the mass or mass fraction of CBD and CBD-A:

M total CBD = M CBD + 0.877 x M CBD-A.

(g) For marihuana and marihuana concentrates**,** total THC and total CBD must be reported in percentages.

(h) For marihuana infused products**,** potency must be reported as milligrams of Total THC and Total CBD per gram.

(10) The agency shall publish a list of action limits for the required safety tests in subrule (3) of this rule, except for potency. A marihuana sample with a value that exceeds the published action limit is a failed sample. A marihuana sample that is at or below the action limit is a passing sample.

(11) For chemical residue and target analyte testing, the agency shall publish a list of quantification levels. Any result that exceeds the action limit is a failed sample.

(12) If a sample provided to a laboratory pursuant to this rule and R 420.304 passes the safety tests required under subrule (3) of this rule, the laboratory shall enter the information in the statewide monitoring system of passed test results within 3 business days of test completion. Passed test results must be in the statewide monitoring system for a batch to be released for immediate processing, packaging, and labeling for transfer or sale in accordance with the acts and these rules.

(13) A laboratory shall enter the results into the statewide monitoring system and file with the agency within 3 business days of test completion.

(14) All laboratories shall participate in the proficiency testing program established by the agency. A laboratory shall analyze proficiency test samples from any ISO 17043 accredited vendor on an annual basis unless the agency requests additional testing. The proficiency testing provider shall be accredited for all relevant tests required by the agency and by an accreditation body recognized under the International Laboratory Accreditation Cooperation (ILAC). All testing must use the same procedures with the same number of replicates, standards, testing analysts, and equipment as used for marihuana product testing. A laboratory shall successfully analyze 1 set of proficiency testing samples for all required analytes not less than annually. A laboratory shall have all proficiency testing results submitted directly to the agency from the vendor for review. All failed proficiency tests must include corrective action documentation and must be repeated until the laboratory obtains an acceptable result for all analytes proficiency test. Proficiency tests must be externally graded and results must be reported numerically and not as pass or fail results for all quantitative methods.

(15) The agency shall take immediate disciplinary action against any laboratory that falsifies records or does not comply with the provisions of this rule, including sanctions or fines, or both.

(16) A laboratory shall not do any of the following:

(a) Desiccate samples.

(b) Pre-test samples.

(c) Select the best or most desirable material from a batch for testing. All sample increments must have the same chances of being selected.

(d) Manipulate samples in any way that would alter the sample integrity or homogeneity of the sample.

(17) A laboratory shall comply with random compliance checks at the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(18) A laboratory may perform terpene analysis on a marihuana product by a method approved by the agency, and the method must be accredited on the same frequency as all required safety tests.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation.

(20) The agency may request mycotoxin testing. A marihuana sample with a value that exceeds the published acceptable level is a failed sample. A marihuana sample that is below the acceptable value is a passing sample.

(21) Marihuana-infused products found to contain Salmonella spp. or Shiga toxin producing E. coli (STEC) must be reported to the agency, in a separate written communication, at the same time as the safety compliance test results are entered into the statewide monitoring system.

History: 2020 AACS; 2022 MR 5, Eff. Mar. 7, 2022.

R 420.305a Validations.

Rule 5a. (1) All validations must be submitted to the agency for approval with an acceptable proficiency test that meets the standards in R 420.305(14), where all required analytes are shown to have passed.

(2) Laboratories shall use microbial testing methodologies for the required safety tests in R 420.305 that are sourced from published peer reviewed methods, have been validated for cannabis testing by an independent third party, and have been internally verified by the licensed laboratory according to Appendix J of Official Methods of Analysis authored by the Association of Official Analytical Collaboration (AOAC) International, with guidance from published cannabis standard method performance requirements where available. In the absence of published, peer reviewed, validated cannabis methods, Appendix J of Official Methods of Analysis authored by the Association of Official Analytical Collaboration must be met in full with guidance from the cannabis standard method performance requirements where available. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts. The agency may monitor a laboratory's microbial methodologies on an ongoing basis. All of the following apply to validated methodologies under this rule:

(a) All validations must be submitted to the agency for approval with an acceptable and graded external proficiency test by a third party, where all required analytes are shown to have passed.

(b) Validation protocols should perform inoculation of marihuana matrices with live organisms where feasible to ensure that both extraction and detection for the assay are tested. To further test the accuracy of the assay, probability of detection (POD) analyses, inclusivity, exclusivity, lot-to-lot stability, and robustness studies must be included in the validation studies.

(c) Methods adopted from a matrix specific standard method, inclusivity and exclusivity do not require a comprehensive reassessment, provided that there were no modifications to the methods, including, but not limited to, all of the following:

(i) Referenced media.

(ii) Primers.

(iii) Probes.

(iv) Antibodies.

(v) Critical chemistries that were not modified.

(d) Microbial methods must include environmental monitoring and quality control of all buffers, media, primers, and incubators.

History: 2022 MR 5, Eff. Mar. 7, 2022.

R 420.305b Quality assurance and quality control.

Rule 5b. (1) A laboratory must have a procedure for monitoring the validity of results.

(2) This monitoring must occur on an ongoing basis and be reviewed by the laboratory manager. The monitoring must include all of the following:

(a) Use of reference materials or quality control materials.

(b) A functional check or checks of measuring and testing equipment.

(c) Use of working standards and verification with control charts, where applicable.

(d) Intermediate checks on measuring equipment.

(e) Review of reported results.

(f) Intra-laboratory comparisons, which involve proficiency testing.

(3) A laboratory shall adhere to all required quality control procedures specified in the reference method or methods to ensure that routinely generated analytical data is scientifically valid and defensible and is of known and acceptable precision and accuracy.

(4) A laboratory shall have a written quality assurance manual that includes, but is not limited to, all of the following items:

(a) Laboratory organization and responsibilities.

(c) Field sampling procedures.

(d) Instrument and equipment preventative maintenance and calibration procedures.

(e) Data reduction, validation, reporting, and verification.

(f) Identification of laboratory errors, customer complaints, and corrective actions.

(5) A laboratory shall prepare a written description of its quality control activities, included as part of a quality control manual. All of the following items must be addressed in the quality control manual:

(a) Daily, weekly, monthly, and annual requirements.

(b) An analytical testing batch.

(c) All analytical testing runs must be bracketed with quality controls.

(6) Method specific quality control acceptance criteria, which must be followed.

(7) A laboratory shall have standard operating procedures for all sampling and testing performed.

(8) All standard operating procedures for the required safety tests in R 420.305 and for sampling and testing of marihuana and marihuana products shall conform to ISO/IEC 17025:2017 standards, Good Laboratory Practice Standards 40 CFR 160, and shall be approved by the agency prior to the performance of any safety tests.

(9) A laboratory shall maintain a quality control and quality assurance program that conforms to Good Laboratory Practice Standards 40 CFR 160 and ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

History: 2022 MR 5, Eff. Mar. 7, 2022.

R 420.306 Testing marihuana product after failed initial safety testing and remediation.

Rule 6. (1) A laboratory may test marihuana product that has failed initial safety testing.

(2) A failed marihuana product must pass 2 separate tests with new samples consecutively to be eligible to proceed to sale or transfer.

(3) Products that failed testing for Aspergillus may be remediated after subsequent testing for mycotoxins in accordance with R 420.305(3)(h).

(4) The agency may publish a remediation protocol including, but not limited to, the sale or transfer of marihuana product after a failed safety test as provided in these rules.

(5) The marihuana business that provided the sample is responsible for all costs involved in a retest.

History: 2020 AACS; 2022 MR 5, Eff. Mar. 7, 2022.

R 420.307 Research and development testing.

Rule 7. (1) As used in this rule, "research and development testing" means optional testing performed before final compliance testing.

(2) Except for R 420.304(2)(b), when performing research and development testing, the laboratory must comply with these rules.

(3) Punitive action shall not be taken against a marihuana business for conducting research and development testing when permitted.

(4) The agency may publish guidance for research and development testing that must be followed by all marihuana businesses.

(5) All research and development testing must be entered into the statewide monitoring system.

(6) Research and development testing performed after compliance testing has been completed shall not replace safety compliance test results.

History: 2020 AACS; 2022 MR 5, Eff. Mar. 7, 2022.

R 420.308 Severability.

Rule 8. If any rule or subrule of these rules, in whole or in part, is found to be invalid by a court of competent jurisdiction, such decision will not affect the validity of the remaining portion of these rules.

History: 2020 AACS.