DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

MARIHUANA SAMPLING AND TESTING

Filed with the secretary of state on June 22, 2020

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the executive director of the marihuana 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, R 420.302, R 420.303, R 420.304, R 420.305, R 240.306, R 420.307, and R 420.308 are added to the Michigan Administrative Code as follows:

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) "Bureau of fire services" or "BFS" means the bureau of fire services in the department of licensing and regulatory affairs.

(f) "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.

(g) "Final form" means the form a marihuana product is in when it is available for sale by a marihuana sales location. For marihuana products intended for inhalation, the marihuana concentrate in the e-cigarette or vaping device.

(h) "Good agricultural collection practices" or "GACP-GMP" means the World Health Organizations or American Herbal Products Associations 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 location at which a licensee is licensed to operate 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 to operate 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-testing” means performing full compliance testing on samples, then not reporting the results to the agency, and reporting results of subsequent testing to the agency.

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

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

(dd) “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.

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 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, 2018 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 $106.00.

(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.

(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, MI, 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.

R. 420.303 Batch; identification and testing.

Rule 3. (1) A cultivator shall uniquely identify each immature plant batch with a single plant tag 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 growth span 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) After 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 420.304 and R 420.305. A cultivator shall quarantine a harvest batch from other plants or batches that have test results pending. A harvest batch must be easily distinguishable from other harvest batches until the batch is broken down into packages.

(5) Before the marihuana product leaves the cultivator, except as provided in subrule (6) of this rule, a sample of the harvest batch must be tested by a licensed laboratory as provided in R 420.304 and R 420.305. All test results must indicate passed in the statewide monitoring system before the marihuana is packaged. A marihuana product from harvest batches must not be transferred or sold until tested, packaged, and tagged as required under subrule (4) of this rule. A marihuana product from a harvest batch that fails safety testing may only be sold or transferred under the remediation protocol as provided in R 420.306.

(6) A cultivator may transfer or sell marihuana to a producer without first being tested by a laboratory in order to produce fresh frozen, or if the marihuana product will be refined to a concentrate, with agency approval. After the producer has processed the material, the producer shall have the sample tested pursuant to R 420.304 and R 420.305. The agency may publish guidance for fresh frozen and concentrate production, transfer, and sale.

(7) After test results show a passed test and the harvest batch is packaged, the cultivator shall destroy the individual plant tags. 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 has not been packaged with a package tag attached and recorded in the statewide monitoring system in accordance with the acts, the marihuana tracking act, and these rules.

(9) After a producer receives or purchases a package in the statewide monitoring system, and the producer proceeds to process the marihuana product in accordance with the scope of a producer license, the acts, and these rules, the producer shall give the marihuana product a new package tag anytime the marihuana product changes form or is incorporated into something else.

(10) After a package is created by a producer of the marihuana product in its final form, the producer shall have the sample tested pursuant to R 420.304 and R 420.305. 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 test. 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.

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

(a) The marihuana product has received passing test results in the statewide monitoring system.

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

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 allow the collection of samples for testing, according to the following requirements:

(a) The laboratory shall physically sample 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. Prior to September 1, 2020, the maximum harvest batch size is 15 pounds. From September 1, 2020, through December 31, 2020, the maximum harvest batch size is 20 pounds. From January 1, 2021 through March 31, 2021, the maximum harvest batch is 25 pounds. After March 31, 2021, 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 other marihuana products being tested. The laboratory must develop a statistically valid sampling method to collect a representative sample from each batch of marijuana product. The laboratory must have access to the entire batch for the purposes of sampling.

(c) An employee of the marihuana business from which marihuana product test samples are being taken 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.

(d) 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.

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

(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.

(f) The 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.

(g) 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 must not be packaged, transferred, or sold until passing test results are entered into the statewide monitoring system.

(h) Any marihuana product that a laboratory collects for testing from a licensee under this rule must 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 who engages another laboratory to perform certain safety tests on a subcontracted basis.

(i) 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.

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

R. 420.305 Testing; laboratory requirements.

Rule 5. (1) A laboratory shall do all of the following:

(a) Become fully accredited 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 and reports of the International Organization for Standardization made available to the agency.

(b) Maintain internal standard operating procedures for the required safety tests in subrule (3) of this rule and for sampling of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards and have been approved by the agency.

(c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.

(2) A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists must be published in full. 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.

(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 as specified in R 420.303, except as provided in subrule (4). After the testing on the harvest batch is completed, 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 performed just as the marihuana product is without any corrective factor taken for moisture content that includes concentrations of the following:

(i) Tetrahydrocannabinol (THC).

(ii) Tetrahydrocannabinol acid (THC-A).

(iii) Cannabidiol (CBD).

(iv) Cannabidiol acid (CBD-A).

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

(b) Foreign matter inspection.
(c) Microbial screening.
(d) Chemical residue testing that includes all of the following:
(i) Pesticides.
(ii) Fungicides.
(iii) Insecticides.
(e) Heavy metals testing as required in this rule.
(f) Residual solvents. The agency shall publish a list of required residual solvents to be tested for and their action limits.
(g) Water activity.
(h) Under the medical marihuana facilities licensing act, 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 an ISO 17065 accreditation body. 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 an accrediting body. 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 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 dispose of the entire batch from which the sample was taken and document the disposal of the sample using the statewide monitoring system pursuant to the acts and these rules.

(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 days after test completion and dispose of the resulting waste in accordance with R 420.209.

(9) Potency shall include the following cannabinoid concentrations listed in subdivisions (a) to (f), subject to subdivisions (g) and (h):
(a) THC concentration.
(b) THC-A concentration.
(c) Total THC. The following calculation must be used for calculating Total THC, where M is the mass or mass fraction of delta-9 THC or delta-9 THC-A:
M total delta-9 THC = M delta-9 THC + 0.877 x M delta-9 THC-A.
(d) 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 Delta-9-THC and CBD in milligrams (mg) per serving under MRTMA and in milligrams (mg) per dose under MMFLA.

(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 considered to be a failed sample. A marihuana sample that is at or below the action limit is considered to be a passing sample.

(11) For the purposes of chemical residue testing 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) The agency shall establish a proficiency testing program and designate laboratory participation. All laboratories must participate in the program. A laboratory shall analyze proficiency test samples using the same procedures with the same number of replicate analyses, standards, testing analysts, and equipment as used for marihuana product testing. A laboratory shall successfully analyze a set of proficiency testing samples not less than annually. A laboratory shall have annual proficiency testing submitted directly to the agency from the proficiency testing vendor for review. The agency will not accept copies. All failed proficiency tests must include corrective action documentation and an additional acceptable proficiency test. Proficiency test results must be conveyed as numerical accuracy percentages, not simply as PASS/FAIL results. Actual PASS/FAIL results must be calculated based on accuracy thresholds generated by reproducibility studies specific to each assay.

(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.

(17) A laboratory shall comply with random quality assurance compliance checks upon 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. There are no established safety standards for this analysis.

(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) Under the medical marihuana facilities licensing act, the agency may request mycotoxin testing. A marihuana sample with a value that exceeds the published acceptable level is

considered to be a failed sample. A marihuana sample that is below the acceptable value is considered to be a passing sample.

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, except as indicated under subrule (3) of this rule.
(2) A failed marihuana product must pass 2 separate tests with new samples consecutively to be eligible to proceed to sale or transfer.
(3) 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.
(4) The marihuana business that provided the sample is responsible for all costs involved in a retest.

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.
(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.

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.