

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 100—Division of Cannabis Regulation
Chapter 1—Marijuana

PROPOSED RULE

19 CSR 100-1.110 Testing

PURPOSE: Under Article XIV, Sections 1 and 2 of the Missouri Constitution, the Department of Health and Senior Services has the authority to regulate and control Marijuana Facilities and to ensure the safe use of marijuana product. This rule explains what regulations apply to the testing of marijuana product.

(1) Marijuana Testing, Generally.

(A) Testing licensees shall test all lots of marijuana product produced by marijuana facilities, including prerolls created at dispensary facilities, before it may be sold for use by a patient or consumer.

(2) Marijuana Testing Facility Certifications.

(A) Any licensee originally certified as a medical marijuana testing facility as of the effective date of this section shall be deemed certified to conduct those activities with respect to all marijuana product.

(B) A testing facility licensee's authority to engage in the process of testing marijuana product includes the acquisition, testing, certification, and transportation of marijuana product.

(3) Testing Facility Requirements. In addition to this chapter's other requirements for licensed facilities and licensees, testing licensees shall also comply with the following:

(A) Testing facility licensees shall be accredited under International Organization for Standardization (ISO) 17025 standards for cannabis testing and any other testing the testing facility performs for marijuana facilities;

1. A marijuana testing licensee must employ a laboratory director with a degree in a natural science, such as biology, chemistry, physics, engineering, or environmental sciences, and at least five years of experience in a regulated laboratory environment or a degree in another applicable field with at least 10 years of experience in a regulated laboratory environment.

2. Analysts processing marijuana samples, or overseeing the processing of marijuana samples, must have at least a bachelor's degree in a natural science, such as biology, chemistry, physics, engineering, or environmental sciences.

RECEIVED

By JCAR at 11:35 am, Jan 20, 2023

(B) Testing facility licensees shall become fully accredited to the standard set forth by ISO 17025 by an International Testing Licensee Accreditation Cooperation recognized accreditation body. Licensees shall achieve such accreditation within one (1) year of the date the licensee receives department approval to operate and shall maintain its accreditation as long the facility holds a certification;

1. The scope of the accreditation shall include all marijuana product testing performed at the facility.

2. Loss of accreditation shall be reported to the department by the testing facility within twenty-four (24) hours of the testing facility receiving notice of the loss.

3. Inspection and audit reports from the accrediting body shall be submitted to the department by the testing facility within twenty-four (24) hours of receipt.

A. During any periods of time when a licensee no longer complies with ISO 17025, the licensee shall not conduct testing of marijuana product, until approved by the department in writing, and may be subject to a fine of up to one thousand dollars (\$1000) for every day the facility is not in compliance. Upon return to compliance, the licensee shall not resume testing without department approval.

B. If a licensee loses ISO 17025 accreditation, the licensee shall not conduct testing of marijuana product and may be subject to a fine of up to one thousand dollars (\$1000) for every day the licensee is not in compliance.

4. If a licensee does not receive ISO 17025 accreditation within one (1) year of the date the licensee receives department approval to operate, the licensee shall not conduct testing of marijuana product and may be subject to a fine of up to one thousand dollars (\$1000) for every day the licensee is not in compliance.

(C) Testing facility licensees shall participate in a proficiency testing program provided by an organization that operates in conformance with the requirements of ISO/IEC 17043 once every six (6) months after the licensee has received approval to operate;

1. The scope of proficiency testing shall include all marijuana testing methods performed at the facility for all marijuana product types tested.

2. The licensee shall notify the department of the proficiency testing provider the facility chooses at least two (2) months prior to engaging with the provider in proficiency testing.

3. The licensee shall analyze proficiency test samples using the same procedures and equipment as used for testing marijuana product.

4. The licensee shall submit copies of proficiency test results to the department within twenty-four (24) hours of receipt.

5. The licensee shall take, and report to the department, corrective action on all failed proficiency tests, and failed tests must be repeated until the licensee obtains an acceptable result. If the licensee fails a proficiency test more than once, the licensee shall:

A. Suspend mandatory testing of the failed analyte(s) until an acceptable result is received; and

B. Investigate and report the cause of failure to the department.

(D) Testing licensees shall retain all remaining sample material that was not used in the testing process for a minimum of sixty (60) days after testing is complete;

1. Excess sample material shall be securely stored in a manner that prohibits sample degradation, contamination, and tampering, and the sample material must be made available to the department upon request.

2. When no longer subject to retention, sample material shall be disposed pursuant to waste disposal requirements of this chapter.

(E) Testing facility licensees shall participate in inter-lab comparison efforts as follows:

1. Licensees must provide marijuana product from remaining sample material up to twice a year, at the direction of the department, to other licensed facilities for testing;

2. Facilities must receive remaining sample material up to ten (10) times a year, at the direction of the department, from other licensed facilities for testing; and

3. The licensee receiving the marijuana product for testing will perform the sampling of the marijuana product, at the direction of the department.

(F) Testing licensees shall maintain all sampling and testing records for five (5) years.

(4) Testing Methods.

(A) Testing licensees must use published, peer-reviewed testing methods that have been validated for cannabis testing, except those for the cannabinoid profile, and—

1. Report to the department what method will be used prior to using that method;

2. Submit lab method verification to the department prior to offering the applicable testing to other licensed facilities;

A. Verifications must be submitted with an acceptable and graded external proficiency test by a third party, where all analytes are shown to have passed.

B. Verification protocols shall include all marijuana matrices tested, such as flower, infused products, and/or concentrates. If the initial verification was not performed on a marijuana matrix, a verification shall be performed for each matrix to be tested.

C. Verification protocols for microbiological methods shall include inoculation of marijuana matrices with live organisms where feasible to ensure that both extraction and detection for the assay are assessed. To further assess the accuracy of the assay, probability of detection analyses, inclusivity, exclusivity, lot-to-lot stability, and robustness studies must be included.

D. A verification of analytical chemistry methods must, at a minimum, verify accuracy, precision, analytical sensitivity, analytical selectivity, limit of detection, limit of quantitation, and reportable range.

E. A verification involving microbiological methods must, at a minimum, address accuracy, precision inclusivity/exclusivity, limit of detection, and reportable range.

3. All test methods should be based on compendia or published methods. In absence of reference to compendia or published methods, Association of Official Analytical Collaboration (AOAC) International Official Methods, AOAC Performance Tested Methods, AOAC Cannabis Standard Method Performance Requirements (SMPR), AOAC Appendix K, AOAC Appendix J, or other reputable sources may be referenced; and

4. All test methods must produce data in a format that meets scientific and regulatory standards.

(B) For cannabinoid profile, testing licensees must follow the AOAC International methods 2017.001, 2017.002, and 2017.019 and also submit lab method verification results to the department prior to offering cannabinoid profile testing to other licensed facilities.

(C) Testing licensees may acquire from cultivation, manufacturing, and dispensary facilities raw material, such as plant material, concentrates, extracts, and infused products, for testing method development.

(5) Sampling Requirements for Mandatory Testing.

(A) Sampling and testing of marijuana product for mandatory testing shall be done by the testing facility licensee at the harvest lot or process lot level. All samples must be collected, stored, and transported in a way that prevents contamination and degradation.

(B) Sampling and testing of each harvest lot or process lot shall be conducted with representative samples such that there is assurance that all harvest or process lots are adequately assessed for contaminants and that the cannabinoid profile is consistent throughout.

1. In the case of dry, unprocessed marijuana, the maximum amount of marijuana from which a sample may be selected is fifteen pounds (15 lbs.), and a minimum of five tenths of a percent (0.5%) of a harvest lot will be sampled for testing.

2. In the case of concentrates, extracts, vape cartridges, prerolls, and infused prerolls, the amount of material required for sampling is—

Process Lot Weight		Sample Required (1±0.2 g)
Pounds	Kilograms	
0-0.50	0-0.23	4
0.51-1.5	0.24-0.68	8
1.51-3.00	0.69-1.36	12
3.01-6.00	1.37-2.72	16
6.01-10.00	2.73-4.58	20
10+	4.58+	32

3. In the case of all other infused products, the amount of material required for sampling is—

Units for Sale	Representative Sample Units Required
2-15	2
16-50	3
51-150	5
151-500	8
501-3,200	13
3,201 – 35,000+	20

4. Where marijuana will be sold in a method of administration, the marijuana product must be sampled after it has been processed into its method of administration. All other marijuana products may be sampled in bulk after all processing of the harvest lot or process lot is complete.

(C) A testing facility licensee shall not do any of the following:

1. Desiccate samples;
2. Pre-test samples;
3. Select the best or most desirable material from a lot or sample for testing;

or

4. Manipulate samples in any way that would alter the sample integrity or homogeneity of the sample. All sample increments must have the same chances of being selected; sampling must be random.

(6) Mandatory Sample Ordering and Chain of Custody.

(A) Testing licensees shall collect samples of a marijuana product from other licensees for mandatory testing, and no licensee may interfere with, assist with, or otherwise participate in the physical collection of a representative sample by a testing licensee.

(B) At the time of sampling for mandatory testing, the cultivation, manufacturing, or dispensary licensee must make the entire harvest or process lot available to the testing licensee for sample collection.

(C) An employee of the cultivation, manufacturing, or dispensary licensee shall be physically present to observe the sampling process and to ensure representative samples are taken from throughout the lot.

(D) Sampling of the lot shall take place in a designated sample area within the cultivation, manufacturing, or dispensary licensee's facility.

(E) Cultivation, manufacturing, and dispensary licensees will collaborate with testing licensees to record at least the following chain of custody information:

1. The sending facility's license number;
2. The legal name, address, and contact information of the licensee sending the marijuana product for testing;
3. The testing facility's license number;
4. The legal name, address, and contact information of the testing licensee;
5. For each lot to be sampled:
 - A. The marijuana product category;
 - B. The marijuana product tag number;
 - C. Total mass or volume of the harvest or process lot;
 - D. For infused products, the number of units for sale in the marijuana process lot;
 - E. The marijuana product sample tag number;
 - F. Total mass or volume of the marijuana harvest or process lot sample;
 - G. For infused products, the number of units sampled of the marijuana process lot;
 - H. Identification of the test or tests requested;
 - I. Whether the test or tests requested are for mandatory testing or for voluntary testing;
 - J. Whether a lot is being re-sampled because of a failed mandatory test;
 - K. Whether the marijuana product was remediated; and
 - L. The date, name, and signature of both the requesting facility's representative who was present for sampling and the testing facility's representative who conducted the sampling.

(F) Chain of custody records must be retained by both the requesting licensee and the testing licensee for five (5) years.

(G) For mandatory testing, it is the responsibility of the cultivation, manufacturing, or dispensary licensee to—

1. Order the tests necessary to comply with all applicable rules;
2. Ensure processing of the lot is complete prior to sampling;

3. Ensure the lot size from which a sample is taken meets the requirements of this chapter;

4. Only order a mandatory test for marijuana product produced by the licensee;

5. Not order more than one mandatory test for the same marijuana product lot without written approval from the department;

6. Ensure the marijuana product is not on administrative hold and not awaiting approval for retesting; and

7. Ensure remediation of the marijuana product was approved by the department.

(H) Violation of sampling requirements or manipulation of samples may result in fines up to one hundred thousand dollars (\$100,000) and suspension or revocation of license.

(I) If a licensee is permitted under this rule to transfer a lot that has failed testing, the licensee must notify the licensee to whom the lot is sold or transferred of the failed test.

(J) Once a marijuana product has passed mandatory testing, the marijuana product shall not be repackaged into a new lot in the statewide track and trace system.

(K) Once marijuana product has passed mandatory testing, a copy of the certificate of analysis for mandatory testing shall be provided to all licensees receiving the lot. Copies of the certificate of analysis may be provided electronically.

(7) Mandatory Testing Requirements.

(A) Testing licensees must perform mandatory testing using sampling, testing methods, and equipment that are appropriate for the tests performed and also permitted within the scope of the licensee's accreditation under ISO 17025.

(B) Within seven (7) days of collecting a sample, the testing facility shall file a report in the statewide track and trace system detailing, at a minimum:

1. All test results showing whether the lot passed or failed each required test;

2. The certificate of analysis provided to the licensee or third party; and

3. A photo of the sample received at the facility.

(C) Reporting of test results in the statewide track and trace system must coincide with or precede any notice of test results to the originating facility.

(D) Harvest and process lots that have passed mandatory testing may not be retested for purposes of replacing mandatory testing results without written approval from the Department.

(E) Testing of the cannabinoid profile of the final marijuana product shall include those analytes listed below and shall be reported on a dry weight basis. The acceptable limits for each analyte will be a percentage deviation from the mean, using at least three (3) samples, in concentration throughout the lot of fifteen percent (15%) or less:

1. Delta-9 tetrahydrocannabinol (THC), CAS number 1972-08-3;

2. Tetrahydrocannabinol acid (THCA), CAS number 23978-85-0;
3. Cannabidiol (CBD), CAS number 13956-29-1;
4. Cannabidiolic acid (CBDA), CAS number 1244-58-2; and
5. Cannabinol (CBN), CAS number 521-35-7.

(F) The testing licensee shall ensure that any samples for mandatory testing of marijuana flower or marijuana trim, prerolls and infused prerolls, are homogenized in accordance with the following requirements:

1. The marijuana testing facility shall first remove any sample increments required to conduct testing for microbials and water activity; and

2. The marijuana testing facility shall then homogenize, by grinding or other suitable method, enough of the remaining sample material to run all remaining analyses required plus any extra that may be needed for retesting. If the finished product lot includes such things as stems, seeds, wrap, or leaves, those items must also be included in sample homogenization. Samples must be homogenized to attain an average particle size of less than 1 millimeter.

A. A crutch or filter, if present, shall be removed for cannabinoid profile screening.

B. In the preparation of samples intended for potency analysis, the laboratory may not adulterate or attempt to manipulate the potency of the sample.

(G) Testing for contaminants in the final marijuana product shall include, but shall not be limited to:

1. Microbial screening. A test will fail if it shows—

A. A total mycotoxin concentration, including aflatoxins and ochratoxin A, of greater than twenty (20) micrograms per kilogram;

B. Pathogenic *E. coli* or salmonella concentrations detectable in one (1) gram; and

C. Pathogenic *Aspergillus* species *A. fumigatus*, *A. flavus*, *A. niger*, or *A. terreus* detectable in one (1) gram;

2. Chemical residue screening. A test will fail if it shows—

Banned Analytes	Chemical Abstract Services (CAS) Registry number	Action Limit (ppm)
Abamectin	71751-41-2	> 0.5
Acephate	30560-19-1	> 0.4
Acequinocyl	57960-19-7	> 2
Acetamiprid	135410-20-7	> 0.2
Aldicarb	116-06-3	> 0.4
Azoxystrobin	131860-33-8	> 0.2
Bifenazate	149877-41-8	> 0.2

Bifenthrin	82657-04-3	> 0.2
Boscalid	188425-85-6	> 0.4
Carbaryl	63-25-2	> 0.2
Carbofuran	1563-66-2	> 0.2
Chlorantraniliprole	500008-45-7	> 0.2
Chlorfenapyr	122453-73-0	> 1
Chlormequat Chloride	7003-89-6	> 0.2
Chlorpyrifos	2921-88-2	> 0.2
Clofentezine	74115-24-5	> 0.2
Cyfluthrin	68359-37-5	> 1
Cypermethrin	52315-07-8	> 1
Daminozide	1596-84-5	> 1
DDVP (Dichlorvos)	62-73-7	> 1
Diazinon	333-41-5	> 0.2
Dimethoate	60-51-5	> 0.2
Ethoprophos	13194-48-4	> 0.2
Etofenprox	80844-07-1	> 0.4
Etoxazole	153233-91-1	> 0.2
Fenoxycarb	72490-01-8	> 0.2
Fenpyroximate	134098-61-6	> 0.4
Fipronil	120068-37-3	> 0.4
Flonicamid	158062-67-0	> 1
Fludioxonil	131341-86-1	> 0.4
Hexythiazox	78587-05-0	> 1
Imazalil	35554-44-0	> 0.2
Imidacloprid	138261-41-3	> 0.4
Kresoxim-methyl	143390-89-0	> 0.4
Malathion	121-75-5	> 0.2
Metalaxyl	57837-19-1	> 0.2
Methiocarb	2032-65-7	> 0.2
Methomyl	16752-77-5	> 0.4
Methyl parathion	298-00-0	> 0.2
MGK-264	113-48-4	> 0.2
Myclobutanil	88671-89-0	> 0.2
Naled	300-76-5	> 0.5
Oxamyl	23135-22-0	> 1
Paclobutrazol	76738-62-0	> 0.4
Permethrins*	52645-53-1	> 0.2
Prallethrin	23031-36-9	> 0.2

Phosmet	732-11-6	> 0.2
Piperonyl_butoxide	51-03-6	> 2
Propiconazole	60207-90-1	> 0.4
Propoxur	114-26-1	> 0.2
Pyridaben	96489-71-3	> 0.2
Pyrethrins+	8003-34-7	> 1
Spinosad	168316-95-8	> 0.2
Spiromesifen	283594-90-1	> 0.2
Spirotetramat	203313-25-1	> 0.2
Spiroxamine	118134-30-8	> 0.4
Tebuconazole	80443-41-0	> 0.4
Thiacloprid	111988-49-9	> 0.2
Thiamethoxam	153719-23-4	> 0.2
Trifloxystrobin	141517-21-7	> 0.2
Vitamin E acetate	58-95-7	> 0.2

3. Heavy metal screening. A test will fail if it shows—

Metal	Failure Level for Marijuana (Meant for Inhalation) (ppm)	Failure Level for Marijuana-Infused Products (ppm)
Total Arsenic	> 0.2	> 1.5
Cadmium	> 0.2	> 0.5
Total Chromium	> 0.6	> 2.0
Lead	> 0.5	> 0.5
Mercury	> 0.1	> 3.0

4. Residual solvents. A test will fail if it shows—

Solvent	Chemical Abstract Services (CAS) Registry number	Failure Level for Marijuana (Inhalation) (ppm)	Failure Level for Marijuana-Infused Products (ppm)
1,2-Dichloroethane	107-06-2	> 2	> 5
Acetone	67-64-1	> 750	> 5000
Acetonitrile	75-05-8	> 60	> 410
Benzene	71-43-2	> 1	> 2
Butanes (all isomers)	106-97-8	> 800	> 5000

Chloroform	67-66-3	> 2	> 60
Ethanol	64-17-5	> 1000	> 5000
Ethyl acetate	141-78-6	> 400	> 5000
Ethyl ether	60-29-7	> 500	> 5000
Ethylene Oxide	75-21-8	> 5	> 50
Heptane	142-82-5	> 500	> 5000
Hexanes (all isomers)	11054-3	> 50	> 290
Isopropyl alcohol	67-63-0	> 500	> 5000
Methanol	67-56-1	> 250	> 3000
Methylene chloride	75-09-2	> 125	> 600
Pentanes (all isomers)	109-66-0	> 750	> 5000
Propane	74-98-6	> 2100	> 5000
Toluene	79-01-6	> 150	> 890
Trichloroethylene	108-88-3	> 25	> 80
Total Xylenes (ortho-, meta-, para-)	1330-20-7	> 150	> 2170

5. Water activity and moisture content screening. A test will fail if it shows—

A. For dry, unprocessed marijuana, prerolls, infused prerolls, and manually extracted concentrates that are not oil, such as hash and kief, water activity that exceeds 0.65 a w and moisture content below 5.0% or above 15.0%; and

B. For all solid infused products, water activity that exceeds 0.85 a w.

6. Foreign matter screening. Testing shall be performed on the total representative sample prior to sample homogenization. A test will fail if it shows—

A. More than 5.0% of stems 3 mm or more in diameter; or

B. More than 2.0% of other foreign matter (powdery mildew, mold, mites, hair, dirt, etc.).

(8) Voluntary Testing.

(A) Upon request from a licensed cultivation, manufacturing, or dispensary facility, testing licensees may also test material that was not collected by the testing facility according to the rules for mandatory test sampling, but results from such voluntary tests will not satisfy mandatory testing requirements.

(B) Voluntary testing may be completed on a schedule agreeable to the submitting facility, but all test results from voluntary testing must be reported in the statewide track and trace system.

(C) Reporting of test results in the statewide track and trace system must coincide with or precede any notice of test results to the originating facility.

(9) Testing Failures.

(A) The Department will place a hold on marijuana product that fails mandatory testing through the statewide track and trace system.

(B) All product that fails mandatory testing must be reanalyzed, remediated, or destroyed within three (3) months of initial test failure. Product that fails mandatory testing may be reanalyzed, remediated, or destroyed as follows:

1. Before taking action with any product that fails mandatory testing, licensees must, within fifteen (15) days of test failure, notify the department of their intent to proceed in one of the following ways:

A. Reanalysis of previously tested sample;

B. Remediation of the harvest or process lot through remediation actions specifically allowed by rule;

C. Destruction of the harvest or process lot; or

D. Submission of a request to perform remediation not specifically allowed by rule.

2. After notifying the department, licensees may:

A. Reanalyze the original sample collected for testing;

(I) Reanalysis must be performed by a testing facility that did not perform the initial analysis.

(II) If the sample passes reanalysis, a testing facility that did not perform the initial analysis or reanalysis may sample the lot and perform testing on that new sample in compliance with all rules for mandatory testing.

B. Complete marijuana product remediation through a remediation process specifically allowed by this rule. After a product has been remediated, a testing facility that did not perform the initial analysis shall resample the lot and perform testing on that new sample in compliance with all rules for mandatory testing;

C. Destroy the product; or

D. Submit a request to remediate the product through a method not specifically approved by this rule. Such requests must be approved by the department, in writing, prior to the licensee taking any remediation actions.

(C) Heavy Metal Failures. Marijuana product that fails mandatory or voluntary testing for heavy metals shall be placed on hold through the statewide track and trace system pending disposal or, if approved by the Department, reanalysis. Product that fails testing for heavy metals may not be remediated.

(10) Approved Remediation Processes. Marijuana product that fails testing, except for heavy metal failure, may be remediated. After notifying the department of intent to remediate, licensees may conduct the following remediation processes without additional approval:

(A) Failed microbial screening may be remediated through solvent-based extraction or processing, such as hydrocarbon, ethanol, or carbon dioxide.

(B) Failed residual solvent testing may be remediated by returning the product to a purging process within the facility.

(C) Failed water activity testing may be remediated by:

1. Solvent-based extraction or processing; or
2. Additional drying or curing.

(D) Failed chemical residue screening may be remediated through solvent-based extraction or processing, such as hydrocarbon, ethanol or CO₂.

(E) A lot that fails reanalysis may not be reanalyzed again but may be remediated one time.

(F) A lot that fails remediation may not be remediated again but may be reanalyzed one time.

(11) A medical or marijuana facility may be required by the department to submit samples of marijuana product for testing at any time and without notice.

(A) The department may have the marijuana product tested at a marijuana testing facility, the Missouri State Public Health Laboratory, or any other lab authorized to conduct the required tests.

1. If the department requests that a marijuana testing facility test the marijuana product, the facility may not charge the department any more than it would ordinarily charge any other entity for whom it performs the same or similar tests.

(B) Samples collected will be tested by the department to determine whether the marijuana product is safe for human consumption and is accurately labeled or to verify the result of marijuana testing conducted by a marijuana testing laboratory.

(C) Samples may be collected either through random process to determine accuracy of testing results or when the department has reasonable grounds to believe—

1. Marijuana product is contaminated or mislabeled;
2. A licensee is in violation of any rule, statute, or Article XIV; or
3. The results of a test would further an investigation by the department.

(12) Testing licensees may test marijuana product and hemp product received from third parties.

(A) Samples from third parties must be delivered by the third parties to the testing facility.

(B) Prior to engaging in these services, testing licensees must submit standard operating procedures related to these services to the department for review, which must include:

1. Tagging and tracking;
2. Chain of custody; and
3. Testing methods if different from the testing methods established for testing of marijuana product for medical and marijuana facilities.

AUTHORITY: Sections 1.3.(1)(b), 1.3.(2), 2.4(1)(b), and 2.4(4) of Article XIV, Mo. Const. Emergency rule filed January 20, 2023, effective February 3, 2023, expires August 1, 2023. Original rule filed January 20, 2023.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Department of Health and Senior Services, MMPublicComment@health.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*