Title 19 – DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30 – Division of Regulation and Licensure
Chapter 95 – Medical Marijuana

PROPOSED RULE

19 CSR 30-95.070 Testing Facility

PURPOSE: Under Article XIV of the Missouri Constitution, the Department of Health and Senior Services has the authority to regulate and control Medical Marijuana Facilities. This rule explains what regulations apply only to Testing Facilities.

(1) Access to Testing Facility Certifications. The number of testing facility certifications will be limited to ten (10) unless the department determines the limit must be increased in order to meet the demand for medical marijuana by qualifying patients.

(2) Testing Facility Requirements. In addition to the requirements of 19 CSR 30-95.040, testing facilities shall also comply with the following:

(A) Testing facilities must ensure all facility employees are trained in at least the following:

1. The use of security measures and controls that have been adopted by the facility for the prevention of diversion, inversion, theft, or loss of marijuana;
2. Proper use of the statewide track and trace system; and
3. Procedures for responding to an emergency, including severe weather, fire, natural disasters, and unauthorized intrusions;

(B) Testing facilities shall comply with International Organization for Standardization (ISO) 17025 standards for personnel at all times.

(C) During any periods of time when a facility no longer complies with ISO 17025 standards for personnel, the facility shall not conduct testing of medical marijuana. Upon return to compliance, the facility shall not resume testing until the department conducts an inspection of the facility.

(D) Testing facilities shall become fully accredited to the standard set forth by ISO 17025 by an International Laboratory Accreditation Cooperation recognized accreditation body. Testing facilities shall achieve such accreditation within one (1) year of the date the facility 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 medical marijuana 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 ten (10) days of receipt.

(E) Testing facilities shall participate in a proficiency testing program provided by an organization that operates in conformance with the requirements of ISO/IEC 17043 at least twice in a calendar year.

1. The facility shall notify the department of the proficiency testing provider the facility chooses, and the department will work with the proficiency testing provider to determine the schedule the provider will follow when sending proficiency testing samples to facilities for analysis.

2. The facility shall analyze proficiency test samples using the same procedures and equipment as used for testing medical marijuana.

3. Upon receipt of proficiency test results, the facility shall submit copies of those results to the department.

(F) Testing facilities shall install and maintain security equipment designed to prevent unauthorized entrance into limited access areas, which shall include any area where medical marijuana is tested, stored, or disposed, and to prevent diversion and inversion of medical marijuana including:

1. Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular or private radio signals, or other mechanical or electronic devices;

2. Electronic monitoring, including—

A. At least one (1) call-up monitor that is nineteen (19) inches or more;

B. A printer capable of immediately producing a clear still photo from any video camera image;

C. Video cameras with a recording resolution of at least 1920 x 1080, or the equivalent, at a rate of at least fifteen (15) frames per second, that operate in such a way as to allow identification of people and activities in the monitored space, and that provide coverage of—

(I) All entrances and exits from limited access areas, including windows; and

(II) All areas in which medical marijuana is tested, stored, or disposed, from at least two (2) angles;

D. A method for storing recordings from the video cameras for at least sixty (60) days in a secure on-site or off-site location or through a service or network that provides on-demand access to the recordings and that allows for providing copies of the recordings to the department upon request and at the expense of the facility;

E. A failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system; and

F. Sufficient battery backup for video cameras and recording equipment to support at least sixty (60) minutes of recording in the event of a power outage;

3. Controlled entry to limited access areas, which shall be controlled by electronic card access systems, biometric identification systems, or other equivalent means. Access information shall be recorded, and all records of entry to limited access areas shall be maintained for at least one (1) year.

(G) Testing facilities shall maintain all sampling and testing records for five (5) years.

(H) Testing facilities may only transport medical marijuana:

1. That the facility intends to test;

2. From cultivation, dispensary, manufacturing, and other testing facilities;

3. If the facility complies with the requirements of 19 CSR 30-95.100(2).

(3) Sampling requirements.

(A) Sampling and testing of medical marijuana shall be done at the lot level.

(B) Sampling and testing of each harvest lot or process lot shall be conducted with representative samples such that there is assurance that all 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 (15) pounds, and a minimum of zero point five (0.5) percent of a harvest lot will be sampled for testing.

2. In the case of concentrates and extracts, the amount of material required for sampling is:

Process Lot Weight		**Sample Increments 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	**Sample Increments**
2-15	2
16-50	3
51-150	5
151-500	8
501-3,200	13
3,201 – 35,000+	20

(4) Testing requirements.

(A) Testing facilities shall test all lots of medical marijuana produced by cultivation or infused products manufacturing facilities. Testing shall only be performed on the final medical marijuana product equivalent to what will be dispensed to the patient.

(B) Mandatory testing requirements may only be met through testing of samples collected by the testing facility according to section (3) of this rule.

(C) Upon request from a licensed cultivation, manufacturing, or dispensary facility, testing facilities may also test material received directly from the facility, including—

1. Medical marijuana plants at any stage of growth;
2. Infused products at any stage of production; and
3. Components used for the production of final medical marijuana product, such as water or growing materials.

(D) Within five (5) business days of collecting a sample, the testing facility shall file a report in the statewide track and trace system detailing all test results and stating whether the lot passed or failed each required test. Filing of this report must coincide with or precede any notice of test

results to the originating facility.

(E) Testing of the cannabinoid profile of the final medical marijuana product shall include those analytes listed below, and the acceptable limits for each analyte will be a percentage deviation from the mean in concentration throughout the lot of fifteen (15) percent 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) Testing for contaminants in the final medical marijuana product shall include, but shall not be limited to:

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

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

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

C. Pathogenic Aspergillus species *A. fumigatus, A. flavus, A. niger,* or *A. terreus* detectable in 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

* Permethrins cumulative residue of cis- and trans-permethrin isomers
+ Pyrethrins cumulative residues of pyrethrin 1, cinerin 1 and jasmolin 1

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

Metal	**Failure Level for Medical Marijuana (Meant for Inhalation) (ppm)**	**Failure Level for Medical Marijuana-Infused Products (ppm)**
Inorganic 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 Medical Marijuana (Inhalation) (ppm)**	**Failure Level for Medical 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, for dry, unprocessed marijuana, water activity that exceeds 0.65 A_w and moisture content that is not between 5.0% and 13.0%.

6. Foreign matter screening. A test will fail if it shows:

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

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

(5) Medical marijuana that fails mandatory testing shall not be retested and will be immediately placed on hold by the testing facility through the statewide track and trace system pending disposal or remediation.

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

(7) Testing facilities shall retain any portion of a sample that was not used in the testing process for, at a minimum, forty-five (45) business days after testing is complete.

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

(B) When no longer subject to retention, sample material shall be disposed pursuant to 19 CSR 30-90.070(4)(E).

AUTHORITY: Sections 1.3.(1)(b), 1.3.(2), 1.3.(3), and 1.3.(4) of Article XIV, Mo. Const. Original rule filed May 24, 2019. Emergency rule filed May 24, 2019, effective June 3, 2019, expires February 27, 2020.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions less than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule has an estimated cost to private entities of at least $500,000 in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*