BEFORE THE DEPARTMENT OF PUBLIC HEALTH
AND HUMAN SERVICES
OF THE STATE OF MONTANA

In the matter of the adoption of New Rules I through VIII and the repeal of ARM 37.107.305 and 37.107.306 pertaining to medical marijuana testing laboratories	)))))	NOTICE OF ADOPTION AND REPEAL

TO: All Concerned Persons

1. On September 6, 2019, the Department of Public Health and Human Services published MAR Notice No. 37-889 pertaining to the public hearing on the proposed adoption and repeal of the above-stated rules at page 1480 of the 2019 Montana Administrative Register, Issue Number 17.

2. The department has adopted the following rules as proposed: New Rules III (37.107.307), IV (37.107.309), V (37.107.311), and VI (37.107.313).

3. The department has repealed the following rules as proposed: ARM 37.107.305 and 37.107.306.

4. The department has adopted the following rules as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

NEW RULE I (37.107.301) MARIJUANA TESTING LABORATORY LICENSURE AND ACCREDITATION (1) remains as proposed.

(2) An applicant for a testing laboratory license must provide, to the department's state laboratory, documentation to support fulfillment of these requirements, which includes but is not limited to the following:

(a) through (c) remain as proposed.

(d) ~~landlord~~ property owner permission form for laboratories, if applicable;

(e) through (10) remain as proposed.

AUTH: 50-46-344, MCA
IMP: 50-46-311, 50-46-326, 50-46-329, 50-46-344, Chap. 292, section 7, L. of 2019, MCA

NEW RULE II (37.107.302) MARIJUANA TESTING LABORATORY GENERAL REQUIREMENTS (1) through (6) remain as proposed.

(7) A licensed marijuana testing laboratory may:

(a) obtain samples of marijuana items from providers, registered cardholders, or other licensees for testing as provided in this subchapter;

(b) through (22) remain as proposed.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-311, 50-46-312, 50-46-326, 50-46-329, 50-46-344, Chap. 292, section 7, L. of 2019, MCA

NEW RULE VII (37.107.315) MARIJUANA TESTING LABORATORY FAILED TEST SAMPLES (1) through (10) remain as proposed.

(11) Failed harvest~~s,~~ lots~~,~~ or test batches may be remediated as long as the remediation method does not impart any substance or effect to the usable marijuana, marijuana concentrates, or marijuana-infused products that may have a toxic or deleterious effect on the health of the consumer.

(12) remains as proposed.

(13) No remediated harvest~~s,~~ lots~~,~~ or test batches may be sold or transferred ~~to a provider for sale~~ until the completion and successful passage of all quality assurance testing, and the results certified in a certificate of analysis, as required in these rules and Montana statute.

(14) With the exception of moisture analysis or residual solvent screening, ~~If~~ a remediated sample from a failed harvest~~,~~ lot~~,~~ or test batch that fails quality assurance testing ~~it~~ cannot be remediated again and the harvest lot or test batch must be destroyed. Harvest lots or test batches that fail initial quality assurance testing for moisture analysis or residual solvent screening may be remediated and retested a maximum of two times.

(15) remains as proposed.

AUTH: 50-46-344, MCA
IMP: 50-46-311, 50-46-326, 50-46-329, 50-46-344, Chap. 292, section 7, L. of 2019, MCA

NEW RULE VIII (37.107.316) MARIJUANA TESTING LABORATORY QUALITY ASSURANCE TESTING REQUIREMENTS (1) through (3) remain as proposed.

(4) Marijuana-infused products must be tested for the following:

(a) cannabinoid profile~~.~~; and

(b) microbiological screening.

(5) remains as proposed.

(6) The sample and related lot or test batch fail quality assurance testing for moisture analysis if the results exceed moisture content of ~~more~~ greater than ~~twelve~~ 12.0 percent.

(7) remains as proposed.

(8) The sample and related lot or test batch fail quality assurance testing for microbiological screening if the results exceed the following limits:

(a) and (b) remain as proposed.

(c) Culturable Mold: more than 10,000 colony forming units (CFU) per gram of ~~culturable mold~~ material;

(d) and (e) remain as proposed.

(9) A sample and related lot or test batch fail quality assurance testing for residual solvents if the results exceed the limits provided in the table below.

~~Residual Solvents~~	
~~Solvent*~~	~~ppm~~
~~Acetone~~	~~5,000~~
~~Benzene~~	~~2~~
~~Butanes~~	~~5,000~~
~~Chloroform~~	~~2~~
~~Cyclohexane~~	~~3,880~~
~~Dichloromethane~~	~~600~~
~~Ethyl acetate~~	~~5,000~~
~~Heptanes~~	~~5,000~~
~~Hexanes~~	~~290~~
~~Isopropanol (2-propanol)~~	~~5,000~~
~~Methanol~~	~~3,000~~
~~Pentanes~~	~~5,000~~
~~Propane~~	~~5,000~~
~~Toluene~~	~~890~~
~~Xylene**~~	~~2,170~~

~~*And isomers thereof.~~
~~**Usually 60% m-xylene, 14% p-xylene, 9% o-xylene with 17% ethyl benzene.~~

	Chemical Abstract Services	
Residual Solvents	(CAS) Registry Number	ppm
Acetone	67-64-1	5,000
Benzene	71-43-2	2
Total Butanes	See[1]	5,000
* n-butane	106-97-8	
* iso-butane	75-28-5	
Chloroform	67-66-3	2
Cyclohexane	110-82-7	3,880
Dichloromethane	75-09-2	600
Ethyl acetate	141-78-6	5,000
Heptane	142-82-5	5,000
Total Hexanes	See[2]	290
* n-hexane	110-54-3	
* 2-methylpentane	107-83-5	
* 3-methylpentane	96-14-0	
* 2,2-dimethylbutane	75-83-2	
* 2,3-dimethylbutane	79-29-8	
Isopropanol (2-propanol)	67-63-0	5,000
Methanol	67-56-1	3,000
Total Pentanes	See[3]	5,000
* n-pentane	109-66-0	
* iso-pentane	78-78-4	
* neo-pentane	463-82-1	

Propane	74-98-6	5,000
Toluene	108-88-3	890
Total Xylenes	See[4]	2,170
* 1,2-dimethylbenzene	95-47-6	
* 1,3-dimethylbenzene	108-38-3	
* 1,4-dimethylbenzene	106-42-3	

1 Total butanes should be calculated as sum of n-butane and iso-butane.
2 Total hexanes should be calculated as sum of n-hexane, 2-methylpentane, 3-methylpentane, 2,2-dimethylbutane and 2,3-dimethylbutane.
3 Total pentanes should be calculated as sum of n-pentane, iso-pentane, and neo-pentane.
4 Total xylenes should be calculated as sum of 1,2-dimethylbenzene, 1,3-dimethylbenzene, and 1,4-dimethylbenzene.

(10) and (11) remain as proposed.

(12) Providers must adhere to testing requirements for all marijuana and marijuana products intended for sale or transfer to cardholders.

(a) through (e) remain as proposed.

(f) All cannabinoid products listed in (e) must use marijuana extract and concentrate that has passed quality assurance testing requirements ~~for direct sale or transfer to cardholders~~ as set forth in (d).

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-308, 50-46-311, 50-46-326, 50-46-344, Chap. 292, section 7, L. of 2019, MCA

5. The department has thoroughly considered the comments and testimony received. A summary of the comments received and the department's responses are as follows:

COMMENT #1: Several comments were received from laboratories and a provider regarding inconsistent language pertaining to quality assurance testing for marijuana/cannabis infused products in New Rule VIII(4), (12)(e), and (12)(f).

RESPONSE #1: The department agrees with the various commenters' observations and has revised the rule to remedy the inconsistency by adding microbiological screening to (4)(b) to be consistent with (12)(e) and modifying the language in (12)(f) to be consistent with (12)(d).

COMMENT #2: A commenter disagreed with New Rule IV(3), which states that the laboratory must incorporate a Laboratory Control Sample (LCS) in each analytical chemistry batch for quality control purposes. The commenter states that this control is unnecessary, burdensome, and is only required in EPA regulated environments.

RESPONSE #2: The department disagrees. The LCS is a sample with a known value, usually prepared and certified by an outside agency, which is carried through the preparation and analysis procedures as if it were a true sample. The LCS is important to establish that the testing system in use is under control or operating as expected in order to yield a valid result. The equivalent of an LCS is common in other regulated testing environments such as FDA, CLIA, EPA, and USDA to name a few. It can be referred to as a certified reference material, an external quality control sample, or an independent check solution or sample, but irrespective of the name, it serves as an important quality control requirement in high quality laboratory testing environments.

COMMENT #3: A commenter expressed concerns over the proposed frequency (at least every six months for each analyte/method) of proficiency testing proposed in New Rule V(2)(a) and stated that it is financially burdensome. The commenter suggested once every four years would be acceptable. Another commenter stated that once every four years was too infrequent, but once a year might be okay.

RESPONSE #3: The department disagrees with both comments. Proficiency testing is mandated in legislation as a requirement to ensure that the laboratory is able to meet all testing requirements and serves as a means to ensure that laboratory staff are proficient and remain proficient in performing their laboratory testing responsibilities. The proposed frequency of proficiency testing for marijuana testing laboratories is in keeping with or even less stringent than other regulated laboratory testing environments.

COMMENT #4: A commenter recommended that New Rule VIII(6) be revised to clarify the action limit for moisture testing to be expressed as greater than 12.0 percent rather than "more than twelve percent."

RESPONSE #4: The department agrees and has revised the rule accordingly.

COMMENT #5: A commenter asked for a definition of the term "analytical batch" used in New Rule IV(3).

RESPONSE #5: The department will define the term "analytical batch" as part of a future rulemaking proposal by adding the term in the definitions rule in ARM 37.107.110.

COMMENT #6: A commenter expressed concerns about the use of "matrix spikes" as a required quality control sample in New Rule IV(3). The commenter was concerned that restrictions on shipping concentrated, controlled substances might interfere with their ability to obtain adequate reference materials for quality control use and that the cost of obtaining reference materials might be prohibitive.

RESPONSE #6: The department agrees that the availability of vendors for reference concentrates may be more limited for controlled cannabinoids than for other analytes. However, matrix spikes are used to evaluate the performance of an

analytical procedure when testing a specific type of matrix and should be part of an overall approach to ensure laboratory quality.

COMMENT #7: A commenter asked for clarification of New Rule VIII(9), regarding residual solvents. The commenter indicated that the footnote to the provided table of solvents which read "and isomers thereof" was too vague and requested that the department provide clarification by adding the specific isomers and/or their CAS numbers.

RESPONSE #7: The department agrees and has revised the table to include solvent isomers and their CAS numbers.

COMMENT #8: A commenter requested that adequate time be provided for laboratories to procure instrumentation, validate methods, and add heavy metals to their ISO certification prior to the quality assurance testing implementation date in a future rule amendment.

RESPONSE #8: The department agrees and will ensure that laboratories have adequate time to implement heavy metals testing prior to its mandated quality assurance testing date.

COMMENT #9: A commenter suggested that a "trip blank" be added to the required quality control samples in New Rule IV(3) due to their concerns regarding possible solvent contamination of provider test samples during transportation to and storage in the testing laboratory.

RESPONSE #9: As the commenter mentioned, a trip blank is generally used only when sampling for volatile organic compound studies and serves a useful purpose for this type of analytical procedure. While the commenter presents a genuine concern, it is difficult to perceive how an equally useful quality control sample would be implemented for marijuana testing procedures in a manner that would improve the quality and reliability of testing outcomes. Therefore, New Rule IV(3) will not be revised at this time.

COMMENT #10: A commenter suggested the department should provide marijuana testing laboratories with approved quality assurance test methods for laboratories to follow, similar to EPA methods for public drinking water testing.

RESPONSE #10: The department disagrees. There are currently no nationally recognized standardized testing methods for testing medical marijuana products. Although many testing laboratories use similar testing equipment and analytical methods, marijuana testing laboratories must develop and validate their testing methods. The new rules proposed by the department communicate additional requirements that testing laboratories are expected to fulfill in order to ensure quality and consistency of results.

COMMENT #11: A commenter indicated that New Rule VII (Marijuana Testing Laboratory Failed Test Samples) is in direct conflict with ARM 37.107.410.

RESPONSE #11: The department agrees and will repeal ARM 37.107.410 through a future rulemaking process.

COMMENT #12: A commenter suggested that New Rule VII should allow for more than one chance to remediate a sample from a failed test.

RESPONSE #12: The department agrees that failed testing for moisture or solvents may be remediated up to two times before requiring destruction for the harvest lot or test batch. Remediation for all other failed quality assurance tests may only occur once. The department has revised the rule accordingly.

COMMENT #13: A commenter suggested that following a remediation of a failed harvest or test batch, providers should only have to retest for those analytes that the original harvest lot test batch failed.

RESPONSE #13: The department disagrees. Since remediation processes and methods are not standardized or validated like EPA methods, such practices or processes may unintentionally impart or impose changes to the physical, chemical, or biological composition of the failed harvest lot or test batch.

COMMENT #14: A commenter stated that New Rule VII(13) has the word "provider" which should probably be "cardholder."

RESPONSE #14: The department has revised the language to meet the intent of the rule.

COMMENT #15: A commenter stated New Rule VIII (Marijuana Testing Laboratory Quality Assurance Testing Requirement) is in direct conflict with ARM 37.107.407.

RESPONSE #15: The department agrees and will repeal ARM 37.107.407 through a future rulemaking process.

COMMENT #16: A commenter stated that New Rule VIII(12) is confusing and unnecessary and should be deleted.

RESPONSE #16: The department disagrees and believes that (12) provides clarification of testing requirements for marijuana products at difference stages of production.

COMMENT #17: A commenter suggested that New Rule II(9) should include the dates and times that testing began and ended as well as the test method used and the initials of the analyst running the test.

RESPONSE #17: The department disagrees. Most of the requested items are already included in New Rule II. However, the intent of the rule is not to provide an all-inclusive list for every item that a laboratory must document. Marijuana testing laboratories must maintain a quality management system that allows for traceability of sample related information or data in all phases of the testing process. The state laboratory will audit laboratories on an annual basis to ensure that licensed marijuana testing laboratories' practices can accomplish this.

COMMENT #18: "In the interest of providing a level playing field," a commenter wanted to know if the new rules provide a time extension for existing laboratories to achieve ISO accreditation.

RESPONSE #18: The proposed new rules do not provide an extension for existing laboratories with provisional licenses to achieve ISO accreditation. The proposed new rules clearly indicate that current licenses will not be reissued a laboratory license without having achieved and maintained ISO accreditation and meeting all of the additional requirements in New Rules I and II.

COMMENT #19: A commenter provided a list of items they believe should be addressed in rule, including: penalties for violations, rules for product labels, sampling protocols, sample storage and transportation protocols, a list of penalties for different levels of violations, penalties for sampling, provider rules for batching, and laboratory rules for batching.

RESPONSE #19: Many of the suggestions provided by the commenter are outside of the scope of this rulemaking process, which is limited to rules governing medical marijuana testing labs. Additionally, many of the suggestions are already currently addressed by statute in the Montana Medical Marijuana Act, existing rules, and/or Medical Marijuana Program guidance documents.

As to laboratory batching, the department is unsure how the commenter defines laboratory batching as the term can have different connotations in a laboratory setting. If the commenter's use of this term refers to the practice of combining multiple different test samples into a single test sample for the purpose of decreasing analytical cost, maximizing profit and/or increasing throughput, as opposed to enhancing testing quality, then this practice is inconsistent with the intent of the proposed new rules for marijuana testing laboratories and would not be supported by the department.

COMMENT #20: A commenter provided a written statement to the department expressing their displeasure with department programs and state personnel.

RESPONSE #20: The comments are outside the scope of this rulemaking process.

COMMENT #21: A commenter noted that New Rule I(2)(d) uses the term "landlord permission form" while Chapter 292, Laws of Montana 2019, replaced references to landlords in the Medical Marijuana Act with references to property owners. The

commenter asks whether the landlord permission form should be referred to as a property owner permission form.

RESPONSE #21: The department agrees the landlord permission form should be referred to as a property owner permission form and has revised the rule accordingly.

COMMENT #22: A commenter noted that New Rule II(7)(a) provides that a "licensed marijuana testing laboratory may obtain samples of marijuana items from providers or other licensees for testing," but does not address testing of samples submitted by registered cardholders as permitted under 50-46-311(8)(c), MCA.

RESPONSE #22: The department has revised the rule to take into account that registered cardholders may submit samples of marijuana items for testing as allowed under the statute.

COMMENT #23: A commenter recommends that mandatory heavy metals testing be implemented immediately.

RESPONSE #23: Mandatory heavy metals testing will be addressed in a future rulemaking and in a manner that allows marijuana testing laboratories to have adequate time to implement heavy metals testing prior to its mandated quality assurance testing date.

COMMENT #24: A commenter recommends the department maintain current rules for marijuana infused product testing of pesticides when precursor materials for the marijuana infused product has been tested for pesticides and that the department adopt California pesticide standards for marijuana infused products when the precursors have not been tested for pesticides.

RESPONSE #24: The proposed New Rule VIII ensures that all marijuana extracts and concentrates (precursors) are tested for pesticides when intended for further processing and before direct sale or transfer to cardholders. The new rule does not allow for marijuana infused products to be produced when the precursors have not been tested for pesticides, and therefore no further modification of this rule is required for this purpose.

COMMENT #25: A commenter recommends that New Rule II(4) should be modified as follows: "A licensed marijuana testing laboratory may refer no more than 25% of the quality assurance testing requirements defined in [New Rule VIII] to another licensed marijuana testing laboratory in Montana, for a limited period approved by the state."

RESPONSE #25: The department disagrees with the recommended revisions as they do not meet the intent of the new rule. New Rule II allows medical marijuana testing laboratories to send limited amounts of testing to other licensed medical marijuana laboratories under certain circumstances including but not limited to

instances of instrument failure, personnel loss, natural disaster, compliance issues, or business considerations. It would not permit a licensed laboratory or license applicant to exist as a sample collection entity that purely refers samples to another licensed laboratory for testing.

COMMENT #26: A commenter would like the department to create a new rule that mandates the medical marijuana testing laboratory sample retention period.

RESPONSE #26: A licensed medical marijuana laboratory should define their sample retention policy or standard operating procedure in the laboratory's quality manual. Policies or procedures may differ between laboratories as long as they are in accordance with department requirements for sample conditions of storage, security, retesting, and disposal.

COMMENT #27: A commenter has recommended that KEIF, hash, and pressed rosins be excluded from residual solvent screening before transfer or direct sale to cardholders because they are mechanically produced.

RESPONSE #27: The department disagrees. Since production methods for these products are not standardized among manufacturers, the department cannot assume that solvents or other chemicals may not be introduced during the production process.

COMMENT #28: A commenter requests that New Rule VIII(8)(c) be revised for clarity and consistency to read: "Culturable Mold: more than 10,000 colony forming units (CFU) per gram of material."

RESPONSE #28: The department agrees with the proposed revision and has revised the rule accordingly.

COMMENT #29: A commenter mentioned several instances where there may be a potential conflict between requirements of the proposed new rules and METRC or the METRC Lab User Guide.

RESPONSE #29: The proposed new rules are intended to provide necessary quality standards and requirements for medical marijuana testing laboratories in the pre-analytical, analytical, and post analytical phases of laboratory testing. The METRC manual and Lab User Guide is intended to instruct medical marijuana laboratories on how to enter data into the seed to sale tracking system. The rules adopted in this notice set the controlling requirements with respect to laboratory practices in those testing phases. The department will review and consider revising the METRC Lab User Guide in order to avoid potential sources of confusion.

COMMENT #30: A commenter stated the department should look into whether retesting via METRC is sufficient or whether it needs to add a formal mechanism/form for retesting requests by providers.

RESPONSE #30: The department does not believe it is necessary to have a department form for the provider to request retesting by a medical marijuana laboratory or to seek permission from the state laboratory. However, in keeping with good laboratory practices, the laboratory should have a process in their quality manual for documenting testing requests or changes in testing requests from their clients. As long as failed tests and remediation/retesting are performed in adherence to the requirements of New Rule VII, the laboratory can continue to enter retesting in METRC as usual.

COMMENT #31: A commenter stated that "Mold" should read, "Total Yeast and Mold," in New Rule VIII(8)(c).

RESPONSE #31: The department disagrees as yeast is not referenced anywhere else in New Rule VIII.

/s/ Robert Lishman
Robert Lishman
Rule Reviewer

/s/ Sheila Hogan
Sheila Hogan, Director
Public Health and Human Services

Certified to the Secretary of State October 8, 2019.