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 PUBLIC HEARING ON PROPOSED ADOPTION AND REPEAL

TO: All Concerned Persons

1. On September 26, 2019, at 1:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed adoption and repeal of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on September 20, 2019, to advise us of the nature of the accommodation that you need. Please contact Gwen Knight, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be adopted provide as follows:

NEW RULE I MARIJUANA TESTING LABORATORY LICENSURE AND ACCREDITATION (1) A marijuana testing laboratory must meet all applicable requirements under the Montana Medical Marijuana Act (Title 50, chapter 46, part 3, MCA) and this subchapter in order to qualify for licensure or licensure renewal.

(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) certificates of insurance and bonding;
(b) business license;
(c) laboratory licensure fee payment;
(d) landlord permission form for laboratories, if applicable;
(e) laboratory employee fingerprint/background check clearance;
(f) laboratory security/storage plan;
(g) quality assurance plan;
(h) standard operating procedures;
(i) validation studies/data and results;
(j) proficiency data/results;

(k) director professional resume, college transcripts/degrees from an accredited college or university;

(l) director references; and

(m) Certificate of ISO/IEC 17025:2017 accreditation and associated audit reports by an approved accreditation or credentialing body.

(3) An application for a laboratory license will not be considered complete, and an on-site audit will not be scheduled, until all of the required documentation is provided.

(4) A laboratory audit will be scheduled with the applicant following receipt of all required documentation.

(5) A laboratory licensee applicant must implement processes that are ISO/IEC 17025:2017 compliant.

(6) An applicant, that meets all of the requirements of this subchapter and 50-46-311, MCA, but is not ISO/IEC 17025:2017 accredited, may be qualified for a provisional license pending ISO/IEC 17025:2017 accreditation approval, if written evidence of pending ISO accreditation and the results of an audit by the state laboratory indicate that accreditation will be achieved within 12 months from the date of licensure.

(7) A provisional laboratory license may not be extended or reissued beyond the date of the initial 12-month term.

(8) A licensed laboratory must maintain ISO accreditation for all methods/analytes in [NEW RULE VIII], at all times.

(9) If a laboratory's method/analyte ISO accreditation lapses or is revoked, the laboratory must not perform those methods until it is reinstated.

(10) For the purpose of this subchapter, the department adopts and incorporates by reference ISO/IEC 17025:2017, which sets forth general requirements for the competence of testing and calibration laboratories. A copy of the publication may be obtained from the American National Standards Institute (ANSI), 1899 L St. NW, 11th Floor, Washington, DC 20036; https://webstore.ansi.org/SDO/ISO.

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 MARIJUANA TESTING LABORATORY GENERAL REQUIREMENTS (1) A licensed marijuana testing laboratory must employ a full-time scientific director that meets the minimum requirements described in 50-46-311, MCA.

(2) The scientific director must ensure that:

(a) the laboratory achieves and maintains ISO/IEC 17025:2017 accreditation for all testing methods/analytes required in [NEW RULE VIII];

(b) the laboratory's processes and practices are compliant with ISO/IEC 17025:2017 standards;

(c) the laboratory maintains quality practices in the pre-analytic, analytic, and post-analytic phases of testing;

(d) testing personnel have been appropriately trained and demonstrate competency prior to providing testing services;

(e) policies and procedures are in place for monitoring personnel competence;

(f) approved standard operating procedures are in place, have been reviewed, and are followed by all testing personnel;

(g) appropriate test methods are in place;

(h) test method validations have been performed to determine the accuracy, precision, and limitations of methods;

(i) acceptable analytical test performance is established and maintained for each test system;

(j) quality assurance and quality control programs are established and maintained;

(k) remedial actions are taken and documented when significant deviations from the laboratory's established performance characteristics are identified and test results are reported only when test systems are functioning properly;

(l) the laboratory successfully participates in an approved proficiency testing (PT) program(s), as described in this subchapter, for all methods/analytes required in [NEW RULE VIII];

(m) the physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed; and

(n) the environment for employees is safe from physical, chemical, and biological hazards, and safety and biohazard requirements are followed.

(3) A scientific director must be physically present at the laboratory for the majority of time that testing is performed in order to adequately carry out their responsibilities.

(4) A licensed marijuana testing laboratory must be able to perform at least 75% of the quality assurance testing requirements defined in [NEW RULE VIII].

(5) A licensed marijuana testing laboratory can only refer quality assurance testing to another licensed marijuana testing laboratory in Montana which has met the requirements of this subchapter, and the referred testing laboratory must be identified in all testing reports, the certificates of analysis and in METRC.

(6) A licensed marijuana testing laboratory must obtain written permission from the test batch sample's provider prior to sending the provider's test batch sample to another licensed marijuana laboratory in Montana or return the product to the provider at their request.

(7) A licensed marijuana testing laboratory may:

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

(b) transport and dispose of samples as provided in this subchapter; and

(c) perform testing on marijuana items in a manner consistent with the laboratory's accreditation.

(8) A licensed laboratory may return a marijuana item obtained for purposes of testing to the provider. The return of such marijuana items must be documented in METRC.

(9) A licensed laboratory must document the following:

(a) receipt of samples for testing;

(b) size, weight, or quantity of the sample;
(c) provider from whom the sample was obtained;
(d) date the sample was collected, and who collected it;
(e) tests performed on samples;
(f) date(s) testing was performed;
(g) results of all testing performed;
(h) certification of all testing performed and corresponding results in a certificate of analysis; and
(i) disposition of any remaining test sample material.

(10) A laboratory licensee must clearly identify all limited access areas at the premises.

(11) All laboratory licensee employees must wear a department-issued identification badge.

(12) A laboratory licensee must maintain a daily log of all visitor activity at a registered premise. The log must contain:
(a) visitor first and last name;
(b) the date;
(c) arrival and departure times;
(d) visitor affiliation; and
(e) purpose of visit.

(13) Visitors must be accompanied by a laboratory licensee employee at all times.

(14) A laboratory licensee is responsible for the security of all marijuana items on the premises, in transit, and under the supervision of the licensee or licensee employee.

(15) A laboratory licensee must have a written security plan maintained on the premises that safeguards against theft, diversion, corruption, or tampering of quality assurance samples, and corresponding data/reports both on the premises, during transit, and storage.

(16) Commercial grade locks must be installed on every external door or gate of the laboratory, if applicable, as well as storage or transfer stations.

(17) A laboratory licensee must ensure general sanitary requirements are met on the premises to include:
(a) hand-washing facilities;
(b) proper and timely removal of all litter and waste; and
(c) toilet facilities that are maintained in a sanitary condition and good repair.

(18) A laboratory licensee must maintain the following records/data for at least three years:
(a) financial records that clearly reflect all financial transactions;
(b) testing data and reports to include quality control (QC) data, standard curves, raw instrument data, calculations, spreadsheets, certificates of analysis, provider reports, etc.; and
(c) all laboratory licensee employee training and payroll records.

(19) Records/data may be kept in either paper or electronic form on the premises and must be readily available for quality assurance and audit purposes.

(20) A laboratory licensee must establish written emergency procedures to be followed in case of a fire, chemical spill, or other emergency at all premises.

(21) A laboratory licensee must provide and maintain, at its own expense, analytical testing laboratory professional liability insurance with an aggregate limit of one million dollars prior to the issuance of a license.

(22) A laboratory licensee must obtain and maintain a $25,000 surety bond which names the department as loss payee in the event the laboratory licensee fails to adhere to the security plan approved by the department, or it otherwise operates the facility in a manner that allows for, or results in theft, loss, or diversion of marijuana items. A copy of the bond must be submitted to the department prior to a license being issued.

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 III MARIJUANA TESTING LABORATORY QUALITY ASSURANCE PROGRAM (1) The laboratory shall develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the laboratory. The quality assurance program shall, at a minimum, include a written quality assurance plan that addresses the following:

(a) quality control procedures;

(b) laboratory organization and employee training and responsibilities, including good laboratory practice (GLP);

(c) quality assurance objectives for measurement data;

(d) traceability of data and analytical results;

(e) instrument maintenance, calibration procedures, and frequency;

(f) performance and system audits;

(g) corrective and preventative action procedures;

(h) steps to change processes when necessary;

(i) record retention and document control;

(j) quality assurance sample retention and disposal;

(k) test procedure standardization; and

(l) method validation.

(2) The scientific director shall annually review, amend if necessary, and approve the quality assurance program and plan both when they are created and when there is a change in methods, laboratory equipment, or the scientific director.

(3) All laboratory personnel involved in pre-analytic, analytic, and/or post-analytic testing processes for marijuana, marijuana concentrates, marijuana extracts, or marijuana-infused products shall review the quality assurance plan upon revision or at least annually.

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

NEW RULE IV MARIJUANA TESTING LABORATORY QUALITY CONTROL

(1) The marijuana testing laboratory shall use laboratory quality control (LQC) samples and adhere to good laboratory practices (GLP) in the performance of all quality assurance testing according to the following specifications:

(a) the laboratory shall analyze quality control samples in the same manner as the laboratory analyzes marijuana, marijuana concentrates, marijuana extracts, or marijuana-infused product quality assurance testing samples;

(b) the laboratory shall use at least one negative control and one positive control in each analytical batch for each target organism during microbial testing;

(c) if either of the controls produces unexpected results or fails, then the results for each sample in the analytical batch are invalid and the samples shall be re-prepped and reanalyzed with a new set of controls; and

(d) if the positive and negative controls produce the expected results then the results for each sample in the analytical batch are valid and must be reported.

(2) If the result of the quality control analysis is outside the laboratory's specified acceptance criteria, listed in the laboratory's quality assurance plan, specific method standard operating procedure (SOP), or the product instructions for use, the laboratory shall determine the cause and take corrective action steps to remedy the problem until the result is within the specified acceptance criteria.

(3) The laboratory shall prepare and analyze at least one each of the following quality control samples for each analytical chemistry batch:

(a) method blank;

(b) laboratory control sample (LCS):

(c) laboratory replicate sample; and

(d) laboratory matrix spike sample.

(4) The laboratory shall analyze, at minimum, a continuing calibration verification (CCV) sample at the beginning of each analytical sequence and at least every 10 samples thereafter.

(5) If the result of the quality control analysis is outside the laboratory's specified acceptance criteria, listed in the laboratory's quality assurance plan or specific method SOP, the laboratory shall determine the cause and take corrective action steps to remedy the problem until the result is within the specified acceptance criteria.

(6) If any quality control sample produces a result outside the specified acceptance criteria, the laboratory cannot report the result and the entire batch cannot be released for retail sale. The laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

(7) The laboratory must calculate the method detection limit and method reporting limit for each chemical method analysis according to the United States Food and Drug Administration (USFDA) "Elemental Analysis Manual for Food and Related Products," the United States Environmental Protection Agency (USEPA) "Definition and Procedure for the Determination of the Method Detection Limit, Revision 2," or a substantially equivalent standard.

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

NEW RULE V MARIJUANA TESTING LABORATORY REQUIRED PROFICIENCY TESTING (1) For a laboratory to become approved to conduct

quality assurance testing, the laboratory must, at its own expense, meet the proficiency testing requirements of this subchapter.

(2) A laboratory shall successfully participate in a proficiency testing program(s):

(a) at least every six months for each analyte/method in [NEW RULE VIII] that the laboratory performs on marijuana or marijuana-infused products;

(b) that are matrix specific or controlled when available; and

(c) that are provided by an organization operating in conformance with the requirements of ISO/IEC 17043:2010.

(3) The laboratory shall report all analytes available by the proficiency testing program provider and for which the laboratory licensee is required to test as required under this subchapter.

(4) The laboratory shall participate in the proficiency testing program by following the laboratory's existing standard operating procedures for testing marijuana or marijuana-infused products.

(5) The laboratory shall rotate the proficiency testing among all of the laboratory testing personnel who perform a specific test method(s) or have multiple analysts perform the same proficiency test, when sample quantity/volume permits.

(6) Laboratory testing personnel who participate in a proficiency testing program shall sign the corresponding analytical reports and proficiency providers attestation forms, if provided, to certify that the proficiency testing program was conducted in the same manner as the laboratory tests marijuana or marijuana-infused products.

(7) The scientific director shall review and verify the accuracy of results reported for all proficiency testing program samples analyzed.

(8) The laboratory shall request the proficiency testing program provider to send all proficiency data and results concurrently to the state laboratory, when the data and results become available. If the proficiency provider does not provide this service then it is the responsibility of the laboratory to provide the proficiency testing program data and results to the state laboratory within three business days after the laboratory receives notification of their test results from the proficiency testing program provider.

(9) The laboratory must maintain a paper and/or electronic copy of all proficiency testing records, including analytical data, quality control, standard curves, spreadsheets, calculations, and worksheets and a copy of the proficiency testing provider report forms for a period of three years. The records must be easily and readily available to state laboratory staff or state auditors upon request.

(10) When performing a proficiency test, a marijuana testing laboratory may not:

(a) perform multiple analyses (such as replicates or duplicates) that are not normally performed in the course of analysis of a routine sample;

(b) average the results of multiple analyses for reporting when not specifically required to do so by the analytic method in question;

(c) permit anyone other than bona fide testing personnel who perform the analyses on a day-to-day basis for the laboratory to participate in the generation of data or reporting of results;

(d) discuss the results of proficiency testing with any other laboratory until after the deadline set for receipt of results by the proficiency testing provider;

(e) discuss the results of a proficiency testing audit across sites or locations, if the laboratory has multiple testing sites, until after the deadline set for receipt of results by the proficiency testing provider;

(f) send proficiency testing samples or portions of samples to another laboratory to be tested; or

(g) knowingly receive a proficiency testing sample from another laboratory for analysis and fail to notify the state laboratory of the receipt of the other laboratory's sample within five business days of discovery.

(11) The state laboratory may also provide inter-laboratory proficiency testing samples to laboratory licensees in order to ensure that Montana marijuana testing laboratories are providing consistent and uniform results.

(12) For the purposes of this subchapter, the department adopts and incorporates by reference ISO/IEC 17043:2010, which specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes. A copy of the publication may be obtained from the American National Standards Institute (ANSI), 1899 L St. NW, 11th Floor, Washington, DC 20036; https://webstore.ansi.org/SDO/ISO.

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

NEW RULE VI MARIJUANA TESTING LABORATORY SATISFACTORY AND UNSATISFACTORY PROFICIENCY TEST PERFORMANCE (1) The marijuana testing laboratory shall be deemed to have "successfully" participated in a proficiency testing program for an analyte tested in a specific method if the test results demonstrate a "satisfactory," "passed," or otherwise proficient performance determination by the proficiency testing program provider.

(2) The marijuana testing laboratory shall be deemed to have "unsuccessfully" participated in a proficiency testing program for an analyte tested in a specific method if the test results demonstrate an "unsatisfactory," "unacceptable," "questionable," or "failed or otherwise deficient" performance determination by the proficiency testing program provider.

(3) If a marijuana testing laboratory is notified by a proficiency provider of an "unsuccessful" result for an analyte tested in a specific method, the laboratory may continue to report test results for the analyte(s) if all of the following conditions are met:

(a) the laboratory notifies the state laboratory of the "unsuccessful" proficiency result in writing within five business days of receiving the report from the proficiency provider;

(b) the laboratory has "successfully" participated in a proficiency program for the failed analyte(s) in the specific method in the previous six months;

(c) the laboratory submits to the state laboratory, for approval, a corrective/preventative action plan detailing how the laboratory will proceed to

determine the cause of the failure within 10 business days of receiving the "unsuccessful" performance determination by the proficiency testing provider; and

(d) within 30 days of plan approval by the state laboratory, submit a corrective/preventative action final report describing the cause of the failure, the corrective action, and processes that will ensure the effectiveness of the corrective action.

(4) The state laboratory will approve or reject corrective action plans and final corrective action reports as soon as reasonably practicable.

(5) If a marijuana testing laboratory is notified by a proficiency provider of an "unsuccessful" result for an analyte tested in a specific method and the laboratory has not "successfully" participated in a proficiency program for the failed analyte(s) in the previous six months, the laboratory may not continue to report test results for the analyte(s) until all of the following conditions are met:

(a) the laboratory notifies the state laboratory of the "unsuccessful" proficiency result in writing within five business days of receiving the report from the proficiency provider;

(b) the laboratory submits to the state laboratory, for its approval, a corrective/preventative action plan detailing how the laboratory will proceed to determine the cause of the failure within 10 business days of receiving the "unsuccessful" performance determination by the proficiency testing provider;

(c) within 30 days of plan approval by the state laboratory, submit a corrective/preventative action final report demonstrating the cause of the failure, the corrective action, and processes that will ensure the effectiveness of the corrective action; and

(d) "successfully" participate in a proficiency test for the failed analyte(s) by a proficiency testing provider that meets the requirements of this subchapter.

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

NEW RULE VII MARIJUANA TESTING LABORATORY FAILED TEST SAMPLES (1) If the results of quality assurance testing for any analyte/method exceed the action limits defined in [NEW RULE VIII], then the sample and related lot or test batch has "failed" quality assurance testing.

(2) When a marijuana testing laboratory performs quality assurance testing, the laboratory must verify that the following quality control criteria are within acceptable limits based upon the laboratory's method specific standard operating procedures, the laboratory quality assurance plan, and the manufacturer's instructions for use, if applicable:

(a) standard curves;
(b) method blank;
(c) laboratory control sample(s);
(d) positive and negative controls;
(e) laboratory replicate values;
(f) matrix spike sample(s);
(g) continuing calibration verification sample;
(h) sample preparation controls; and

(i) crossing thresholds.

(3) If the quality control criteria for initial quality assurance testing are within acceptable limits, then the results of all individual samples within the analytical batch are considered valid, including "failed" samples and must be reported.

(4) A provider may request that the laboratory resample the failed batch or lot for repeat testing within seven calendar days of receiving notice from the laboratory of any failed testing and resampled analyses must be completed by the laboratory within 30 days of receiving the request from the provider.

(5) Quality assurance testing on resampled batches or lots must include all of the analytes defined in [NEW RULE VIII].

(6) The results of resample quality assurance tests are considered valid and must be reported if the quality control criteria are within the acceptable limits.

(7) The provider is responsible for the costs of resampling and retesting.

(8) If the quality control criteria for initial quality assurance testing are not within acceptable limits, then the results of all individual samples within an analytical batch are considered invalid (failed run) and the entire run must be repeated with new controls and not reported.

(9) The laboratory should document and investigate failed runs, as part of the laboratory's quality assurance plan, to determine the root cause of the failure and whether corrective and preventative action measures are warranted.

(10) A provider is not permitted to sell or transfer to a registered cardholder, marijuana items that have a failed quality assurance test.

(11) Failed harvests, 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) Remediation methods used on specific lots or batches of marijuana or marijuana-infused products that have failed initial quality assurance testing must be disclosed to the state laboratory and to the Medical Marijuana Program prior to remediation.

(13) No remediated harvests, 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) If a remediated sample from a failed harvest, lot, or test batch fails quality assurance testing it cannot be remediated again and the test batch must be destroyed.

(15) A laboratory licensee must document all sampling, testing, retesting, remediation, and destruction that are a result of failing a test under this subchapter.

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 MARIJUANA TESTING LABORATORY QUALITY ASSURANCE TESTING REQUIREMENTS (1) Except as provided in (10), a provider must submit for testing a sample of every test batch from a harvest lot of

marijuana and process lots of marijuana-infused products, extracts, and concentrates intended for use by a registered cardholder prior to selling or transferring the marijuana item to a registered cardholder.

(2) Usable marijuana lots consisting of dried leaves and flowers must be tested for the following:

(a) cannabinoid profile;

(b) moisture analysis;

(c) foreign matter screening;

(d) microbiological screening; and

(e) pesticides screening.

(3) Marijuana concentrate and extract lots must be tested for the following:

(a) cannabinoid profile;

(b) microbiological screening;

(c) residual solvents screening; and

(d) pesticides screening.

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

(a) cannabinoid profile.

(5) The cannabinoid profile for each sample must include:

(a) THCA;

(b) THC;

(c) Total THC;

(d) CBDA;

(e) CBD; and

(f) Total CBD.

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

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

(a) five percent of stems 3mm or more in diameter; and

(b) two percent of seeds or other foreign matter.

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

(a) Salmonella: non-detectable in a gram of material;

(b) E. Coli: non-detectable in a gram of material;

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

(d) Total of Aflatoxin B1, B2, G1, G2: 20 µg/kg; and

(e) Ochratoxin A: 20 µg/kg of substance.

(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.

(10) Heavy metals will be tested at random. A sample and related lot or test batch fail quality assurance testing for heavy metals if the results exceed the limits provided in the table below.

Heavy Metals

	Limits; Unprocessed/Dry Flower	Limits; Extract
Inorganic arsenic	2.0 µg/g	10 µg/g
Cadmium	0.82 µg/g	4.1 µg/g
Lead	1.2 µg/g	6.0 µg/g
Mercury	0.4 µg/g	2.0 µg/g

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

Pesticides

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppl; Unprocessed/Dry Flower	Action Level ppm; Extract
Abamectin	71751-41-2	0.5	2.5
Acequinocyl	57960-19-7	2	10
Bifenazate	149877-41-8	0.2	1
Bifenthrin	82657-04-3	0.2	1
Chlormequat Choloride	999-81-5	1	5
Cyfluthrin	68359-37-5	1	5
Daminozide	1596-84-5	1	5
Etoxazole	153233-91-1	0.2	1

Fenoxycarb	72490-01-8	0.2	1
Imazalil	35554-44-0	0.2	1
Imidacloprid	138261-41-3	0.4	2
Myclobutanil	88671-89-0	0.2	0.6
Paclobutrazol	76738-62-0	0.4	2
Pyrethrins†	8003-34-7	1	5
Spinosad	168316-95-8	0.2	1
Spirotetramat	203313-25-1	0.2	1
Trifloxystrobin	141517-21-7	0.2	1

† Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

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

(a) Usable marijuana, including trim and manicure must be tested for:

(i) pesticides;

(ii) moisture content;

(iii) cannabinoid profile/potency;

(iv) microbiological;

(v) mycotoxin;

(vi) filth and foreign matter; and

(vii) heavy metals (random testing).

(b) A provider has the option to forgo testing of usable marijuana, including trim and manicure, if that usable marijuana is subject to further processing before sale or transfer to cardholders.

(c) Marijuana extract and concentrate that is intended for direct sale or transfer to cardholders must be tested for:

(i) pesticides;

(ii) cannabinoid profile/potency;

(iii) microbiological;

(iv) mycotoxin;

(v) heavy metals (random testing); and

(vi) residual solvents.

(d) Marijuana extract and concentrate that is intended for further processing before direct sale or transfer to cardholders must be tested for:

(i) pesticides;

(ii) residual solvents;

(iii) mycotoxin; and

(iv) heavy metals (random testing).

(e) Cannabinoid products intended for human consumption, ingestion, and cannabinoid suppositories, topicals, and transdermal patches must be tested for:

(i) cannabinoid profile; and

(ii) microbiological.

(f) All cannabinoid products listed in (e) must use marijuana extract and concentrate that has passed 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

4. The department proposes to repeal the following rules:

37.107.305 MARIJUANA TESTING LABORATORY LICENSEE REQUIREMENTS, found on page 37-26731 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-311, 50-46-312, 50-46-326, 50-46-328, 50-46-329, MCA

37.107.306 MARIJUANA TESTING LABORATORIES ACCREDITATION, found on page 37-26732 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-311, 50-46-312, MCA

5. STATEMENT OF REASONABLE NECESSITY

In 2019, Montana's 66th Legislature passed Senate Bill (SB) 265 and House Bill (HB) 598, which revise the Montana Medical Marijuana Act. With respect to medical marijuana testing laboratories, the bills shift responsibility for licensing and inspection to the Department of Public Health and Human Services' State Laboratory. The bills also direct the department's state laboratory to promulgate administrative rules pertaining to requirements for the licensure, accreditation, and operation of medical marijuana testing laboratories.

In order to implement the statutory mandates of SB 265 and HB 598, the department is proposing to adopt New Rules I through VIII, pertaining to medical marijuana testing laboratories. The proposed rules have been developed by the department's state laboratory to address requirements for licensure, accreditation, and operation of medical marijuana testing laboratories.

New Rule I – Marijuana Testing Laboratory Licensure and Accreditation

The department is proposing New Rule I to address the requirements medical marijuana testing laboratories must meet to qualify for licensure and licensure renewal. The rule identifies requirements for issuance or renewal of a license and specifies the process under which the department will review license applications. The rule also implements new requirements for medical marijuana testing laboratories under SB 265 and HB 598 such as International Organization Standardization (ISO) certification. The rule is necessary to identify the

requirements for obtaining a license and the process under which the department will review license applications.

New Rule II – Marijuana Testing Laboratory General Requirements

The department is proposing New Rule II to address the general requirements for operation of medical marijuana testing laboratories, including the role and responsibilities of the scientific director referenced in SB 265 and HB 598. The rule also specifies general operational requirements for medical marijuana testing laboratories including recordkeeping requirements, security requirements, personnel requirements, and insurance and bonding requirements.

The rule is necessary to provide medical marijuana testing laboratories with notice of the rules they must follow and to implement the requirements of SB 265 and HB 598.

New Rule III – Marijuana Testing Laboratory Quality Assurance Program

The department is proposing New Rule III to address the requirements and content of the quality assurance program and plan that must be developed and maintained by each medical marijuana testing laboratory. The rule is necessary to ensure medical marijuana testing laboratories maintain and follow written procedures to conduct testing in a manner that assures the reliability and validity of analytical testing data produced by the laboratory.

New Rule IV – Marijuana Testing Laboratory Quality Control

The department is proposing New Rule IV to address requirements for marijuana testing and laboratory quality control samples and use thereof for quality assurance test interpretation. The rule is necessary to ensure the reliability and validity of analytical testing data produced by the laboratory.

New Rule V – Marijuana Testing Laboratory Required Proficiency Testing

The department is proposing New Rule V to address requirements for frequency, quality, and use of marijuana proficiency samples, as well as requirements to provide proficiency testing data and results to the state laboratory. The rule is necessary to monitor the performance of medical marijuana testing laboratories and to ensure medical marijuana laboratories maintain their own level of competence in performing specific tests.

New Rule VI – Marijuana Testing Laboratory Satisfactory and Unsatisfactory Proficiency Test Performance

The department is proposing New Rule VI to specify what constitutes a successful and unsuccessful performance. The rule is necessary to provide medical marijuana testing laboratories with notice of how proficiency testing will be evaluated by the

department and to ensure that laboratories who fail a proficiency test take corrective measures to ensure future testing is properly performed.

New Rule VII – Marijuana Testing Laboratory Failed Test Samples

The department proposes New Rule VII to specify the process for interpretation of testing results and retesting of quality assurance samples when a quality assurance analyte/method exceeds the action limits defined in New Rule VIII. This rule is necessary to provide notice of the ability to have a sample retested, the requirements for retesting, and the consequence of failure to pass the initial or subsequent test.

New Rule VIII – Marijuana Testing Laboratory Quality Assurance Testing Requirements

The department is proposing New Rule VIII to address required tests and corresponding action limits for quality assurance tests performed on marijuana, marijuana concentrates, marijuana extracts, and marijuana-infused products. This rule is necessary to implement the requirements of SB 265 regarding the substances for which marijuana and marijuana products must be tested, establish permissible contaminant levels, and to provide notice of these testing requirements.

ARM 37.107.305 and 37.107.306

The department is proposing to repeal these rules because licensing and operational requirements for medical marijuana testing laboratories are addressed in New Rules I and II, which have been proposed by the department's state laboratory in accordance with SB 265 and HB 598.

Fiscal Impact

The department anticipates no fiscal impact regarding the proposed rulemaking.

6. The department intends these proposed rule adoptions and repeals to be applied retroactively to October 1, 2019.

7. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Gwen Knight, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., October 4, 2019.

8. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

9. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 7 above or may be made by completing a request form at any rules hearing held by the department.

10. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsors were notified by letters sent via U.S. mail on July 23, 2019.

11. With regard to the requirements of 2-4-111, MCA, the department has determined that the adoption and repeal of the above-referenced rules will not significantly and directly impact small businesses.

/s/ Robert Lishman
Robert Lishman
Rule Reviewer

/s/ Marie Matthews, for
Sheila Hogan, Director
Public Health and Human Services

Certified to the Secretary of State August 27, 2019.