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

In the matter of the adoption of New Rules I and II and the amendment of ARM 37.107.301, 37.107.302, 37.107.303., 37.107.307, 37.107.309, 37.107.311, 37.107.313, 37.107.315, and 37.107.316 pertaining to marijuana sampling protocols	))))))))	NOTICE OF PUBLIC HEARING ON PROPOSED ADOPTION AND AMENDMENT

TO: All Concerned Persons

1. On December 9, 2021, at 11:00 a.m., the Department of Public Health and Human Services will hold a public hearing via remote conferencing to consider the proposed adoption and amendment of the above-stated rules. Interested parties may access the remote conferencing platform in the following ways:

(a) Join Zoom Meeting at: https://mt-gov.zoom.us/j/81663908546; meeting ID: 816 6390 8546; or

(b) Dial by telephone +1 646 558 8656; meeting ID: 816 6390 8546. Find your local number: https://mt-gov.zoom.us/u/kbmAtL2uRQ.

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 November 24, 2021, to advise us of the nature of the accommodation that you need. Please contact Heidi Clark, 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 QUALITY ASSURANCE SAMPLING PROTOCOL (1) Testing laboratories shall collect samples of marijuana items from licensees for the required quality assurance testing.

(2) Testing laboratories shall develop and implement a sampling protocol standard operating procedure that details at minimum:

(a) the testing laboratory's method for obtaining a random and representative sample for all matrices;

(b) sterile sampling technique for all matrices;

(c) testing laboratory sampler training;

(d) appropriate sampling equipment;

(e) appropriate sample transportation and storage;

(f) maintenance of sample custody and integrity; and

(g) sampling documentation and records.

(3) Testing laboratories shall create a sampling plan prior to each sampling event that details at a minimum:

(a) the licensee's business/trade name and licensee ID number;

(b) the physical address from which the laboratory test samples are to be collected;

(c) the estimated route driven to the site(s) and any detours taken;

(d) the testing laboratory sampler's license ID number;

(e) the testing laboratory vehicle and license plate number; and

(f) the date and time the sampling route begins and ends.

(4) The testing laboratory shall ensure sample integrity is maintained during transport to and storage at the testing laboratory licensed facilities. If the marijuana item specifies on the label how the product shall be stored, the testing laboratory shall store the sample as indicated.

(5) An employee from the licensee requesting sample collection shall be present to observe sample collection but shall not assist the testing laboratory sampler while physically collecting the laboratory test samples.

(6) The testing laboratory sampler shall collect a laboratory test sample that is random and representative of the test batch, meets the standards of the state laboratory's "Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, and Marijuana Infused Products" SOP-001, and is sufficient to complete all required quality assurance testing including quality control samples and re-runs.

(7) All sample increments from the same test batch shall be placed into one sample container that is free of the analytes of interest and appropriate for the analysis required.

(8) At least 50% of the laboratory test sample must be homogenized prior to analysis.

(9) Sample increments and/or laboratory test samples from different test batches must not be combined, batched, or composited under any circumstance or at any time. Each test batch requires one laboratory test sample and one complete quality assurance compliance test.

(10) Testing laboratories must refuse sample collection if sample adulteration is suspected and shall report incidents of suspected adulteration to the state laboratory within three business days. Adulteration may include:

(a) the application of kief to usable marijuana test batches;

(b) the application of solvents to usable marijuana test batches;

(c) the use of any deleterious substance to evade undesirable test results;

(d) the addition of any substance to increase any cannabinoid test result; or

(e) the addition of any substance to alter the weight of a marijuana item.

(11) A licensee shall only order tests for marijuana items that the licensee has grown, produced, or processed.

(12) The licensee shall store and secure test batches in a manner that maintains sample integrity and security during laboratory testing.

(13) Failed or remediated marijuana items shall be re-tested at the same testing laboratory from which the original failed test results came unless explicit written permission from the state laboratory is granted prior to re-testing.

(14) The state laboratory may inspect marijuana sampling events to ensure sampling protocols are being followed.

(15) The state laboratory adopts and incorporates by reference the "Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, and Marijuana Infused Products" SOP-001 (Version 1.0), which describes the sampling protocol for marijuana, marijuana concentrates and extracts, and marijuana infused products. A copy of this publication is available electronically at https://dphhs.mt.gov/assets/MarijuanaLab/MarijuanaSamplingProtocolSOP.pdf and may also be obtained from the Department of Public Health and Human Services, Laboratory Services Bureau, 1400 E. Broadway, Helena MT, 59620.

AUTH: 16-12-202, 16-12-209, MCA
IMP: 16-12-202, 16-12-209, MCA

NEW RULE II SUSPENSION OF TESTING LABORATORIES (1) The state laboratory may, after written notice to the testing laboratory, suspend the testing laboratory's license for a period of up to three months upon determining that a testing laboratory is providing inconsistent results in accordance with 16-12-202, MCA.

(2) The state laboratory will determine whether a testing laboratory is providing inconsistent results through evaluation of the testing laboratory's raw data.

(3) A suspension of licensure under this rule is subject to a contested case hearing before the Department of Public Health and Human Services' Office of Administrative Hearings and shall be conducted pursuant to the following administrative procedures: ARM 37.5.101, 37.5.117, 37.5.131, 37.5.301, 37.5.304, 37.5.307, 37.5.313, 37.5.322, 37.5.325, 37.5.328, 37.5.331, 37.5.334, and 37.5.337.

(4) A testing laboratory may not conduct any testing or transporting of marijuana or marijuana products during a period of suspension. Operating during a period of suspension shall be considered a violation of the marijuana laws as defined in ARM 42.39.102 and could result in the Department of Revenue taking further disciplinary action.

AUTH: 16-12-202, MCA
IMP: 16-12-202, MCA

4. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.107.301 ~~MARIJUANA~~ TESTING LABORATORY ~~LICENSURE AND ACCREDITATION~~ ENDORSEMENT REQUIREMENTS (1) A ~~marijuana~~ testing laboratory applicant must meet all applicable requirements under the Montana ~~Medical~~ Marijuana Regulation and Taxation Act (Title ~~50~~ 16, chapter ~~46~~ 12, ~~part 3,~~ MCA) and this subchapter in order to qualify for endorsement of either 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 in accordance with [MAR Notice No. 42-1033];

(b) remains the same.

~~(c) laboratory licensure fee payment;~~

(d) remains the same but is renumbered (c).

~~(e) laboratory employee fingerprint/background check clearance;~~

(d) department-issued employee badge;

(f) through (j) remain the same but are renumbered (e) through (i).

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

~~(l)~~ (k) scientific director references; and

(m) remains the same but is renumbered (l).

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

(4) An inspection of the testing laboratory ~~audit~~ will be scheduled with the applicant following receipt of all required documentation.

(5) ~~A laboratory licensee~~ An 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)~~ (6) A ~~licensed~~ testing laboratory must maintain ISO accreditation for all methods/analytes in ARM 37.107.316, at all times.

~~(9)~~ (7) If a testing laboratory's method/analyte ISO accreditation lapses or is revoked, the testing laboratory must not perform those methods until it is reinstated.

~~(10)~~ (8) For the purpose of this subchapter, the ~~department~~ state laboratory 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~~ 16-12-202, 16-12-209, MCA
IMP: ~~50-46-304, 50-46-311, 50-46-326, 50-46-329, 50-46-344~~ 16-12-202, 16-12-209, MCA

37.107.302 ~~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~~ 16-12-206, MCA.

(2) The scientific director must ensure that:

(a) the testing laboratory achieves and maintains ISO/IEC 17025:2017 accreditation for all testing methods/analytes required in ARM 37.107.316;

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

(c) the testing laboratory maintains quality practices in ~~the pre-analytic, analytic, and post-analytic phases of testing~~ accordance with their quality assurance plan;

(d) through (g) remain the same.

(h) test method validations have been performed initially and upon test method changes to determine the ~~accuracy, precision, and limitations of methods~~ minimum following requirements;

(i) accuracy;

(ii) precision;

(iii) linearity and working range;

(iv) coefficient of determination (r^2) for calibration curves;

(v) LOD;

(vi) LOQ;

(vii) MDL; and

(viii) reproducibility.

(i) and (j) remain the same.

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

(l) the testing laboratory successfully participates in an approved proficiency testing (PT) program(s), as described in this subchapter, for all methods/analytes required in ARM 37.107.316;

(m) the physical and environmental conditions of the testing 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~~ met.

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

(4) A ~~licensed marijuana~~ testing laboratory must be able to perform at least 75% of the quality assurance testing requirements defined in ARM 37.107.316.

(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~~ the seed-to-sale tracking system.

(6) A ~~licensed marijuana~~ testing laboratory must obtain written permission from the ~~test batch sample's provider~~ licensee prior to sending the ~~provider's test batch~~ laboratory test sample to another ~~licensed marijuana~~ testing 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, registered cardholders, 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)~~ (7) A ~~licensed~~ testing 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)~~ (8) A testing 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~~ including quality control ~~(QC)~~ data, standard curves, raw instrument data, calculations, spreadsheets, certificates of analysis, ~~provider~~ licensee reports, etc.~~; and~~

~~(c) all laboratory licensee employee training and payroll records.~~

~~(19)~~ (9) Records/data may be kept in either paper or electronic form on the premises and must be readily available for quality assurance and ~~audit~~ inspection purposes.

~~(20)~~ (10) A testing 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~~ 16-12-202, 16-12-209, MCA
IMP: ~~50-46-303, 50-46-304, 50-46-311, 50-46-312, 50-46-326, 50-46-329, 50-46-344~~ 16-12-202, 16-12-209, MCA

37.107.303 DEFINITIONS As used in this subchapter, the following definitions apply:

(1) "Acceptance criteria" means the specified limits placed on the characteristics of an item or method that are used to determine data quality.

(2) "Accredited college or university" means a college or university accredited by a regional or national accrediting agency that is an accreditor recognized by the Secretary of the U.S. Department of Education.

(3) "Action level" means the threshold value that provides the criteria for determining whether a sample passes or fails an analytical test.

(4) "Adulteration" means intentionally modifying or altering a marijuana item from its original form to increase its monetary value, evade undesirable test results, or conceal the true composition of a marijuana item.

(5) "Analytical batch" means a set of matrix-specific laboratory test samples that are prepared together over a 24-hour time period using the same set of reagents for the same analysis and includes the required quality control samples.

~~(1)~~ (6) "Applicant" means a person ~~applying for a testing laboratory license~~ seeking endorsement for testing laboratory licensure or renewal of licensure.

~~(2)~~ (7) "Batch" ~~means:~~ has the meaning provided for in ARM 42.39.102.

~~(a) a quantity of usable marijuana from a harvest lot; or~~

~~(b) a quantity of cannabinoid concentrate or extract or cannabinoid product~~

~~from a process lot.~~

~~(3)~~ (8) "CBD" ~~means cannabidiol~~ has the meaning provided for in ARM 42.39.102.

~~(4)~~ (9) "CBDA" ~~means cannabidiolic acid~~ has the meaning provided for in ARM 42.39.102.

(10) "Certificate of analysis (COA)" has the meaning provided for in ARM 42.39.102.

(11) "Coefficient of determination (r^2)" means a statistical measure that determines how well the regression approximates the actual data points in the calibration curve, with a regression of 1 being a perfect fit.

(12) "Continuing calibration verification (CCV)" means a quality control sample that includes each of the target analytes at the mid-range of the calibration to evaluate the validity of the instrument's calibration over the entire sample sequence.

(13) "Corrective action" means an action taken by a licensee to resolve, and prevent from recurrence, a problem with operations of the licensee.

(14) "Customer" has the meaning provided for in ARM 42.39.102.

~~(5) "Department" means the Department of Public Health and Human Services.~~

(15) "Good laboratory practice (GLP)" means a system of management controls for testing laboratories to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of analyses performed by the testing laboratory.

~~(6)~~ (16) "Harvest lot" ~~has the meaning provided for under ARM 42.39.102~~ means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 72-hour period at the same location, cured under uniform conditions, and uniform in strain.

(17) "Ingredient" has the meaning provided for in ARM 42.39.102.

(18) "Initial calibration verification (ICV)" means a quality control sample that includes each of the target analytes at the mid-range of the calibration using secondary source standards to evaluate the validity of the calibration standards and calibration standards preparation.

(7) remains the same but is renumbered (19).

~~(8) "Licensee" means any person licensed by the department to operate a testing laboratory.~~

(20) "ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.

(21) "ISO/IEC 17043" means the general requirements established by the ISO/IEC for proficiency testing.

(22) "Laboratory control sample (LCS)" means a quality control sample that includes each of the target analytes at the mid-range of the calibration spiked into an analyte free matching matrix or a matrix that is as closely representative of the matrix being analyzed as possible, in order to evaluate the efficiency of the preparatory/extraction process. The LCS is prepared in the same manner as the rest of the laboratory test samples in the analytical batch.

(23) "Laboratory quality assurance" means a set of operating principles that enable laboratories to produce defensible data of known accuracy and precision and includes employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing.

(24) "Laboratory test sample" means all sample increments collected from one test batch combined together into one sample container from which quality assurance compliance testing is conducted.

~~(9) "Limited access area" means a building, room, or other contiguous area upon the registered premises where marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under the control of the licensee.~~

(25) "Limit of detection (LOD)" means the lowest quantity of a substance or analyte that can be distinguished from the absence of the substance within a stated confidence limit.

(26) "Limit of quantitation (LOQ)" means the lowest concentration of an analyte in the specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

(27) "Marijuana" has the meaning provided for under 16-12-102, MCA, and ARM 42.39.102.

(28) "Marijuana concentrate and extract" or "concentrate and extract" has the meaning provided for under 16-12-102, MCA, and ARM 42.39.102.

(29) "Marijuana infused products" has the meaning provided for under 16-12-102, MCA, and ARM 42.39.102.

~~(10)~~ (30) "Marijuana items" ~~means:~~ has the meaning provided for under ARM 42.39.102.

~~(a) marijuana;~~

~~(b) usable marijuana;~~

~~(c) dried leaves and flowers of the marijuana plant;~~

~~(d) marijuana derivatives, concentrates, extracts, resins, infused products, edible products, ointments, tinctures, suppositories, topicals; and~~

~~(e) other marijuana-related products.~~

(31) "Matrix" means the substances that are present in a sample except for the analytes of interest.

(32) "Matrix spike (MS)" means a quality control sample that is prepared by adding a known concentration of target analytes to a laboratory test sample spiked at a mid-range concentration of the calibration to evaluate matrix interference effects. The MS is prepared in the same manner as the rest of the laboratory test samples in the analytical batch.

(33) "Method blank (MB)" means a quality control sample that is prepared using an analyte free matching matrix or a matrix that is as closely representative of the matrix being analyzed as possible to verify the absence of contamination in the preparatory/extraction process. The MB is prepared in the same manner as the rest of the laboratory test samples in the analytical batch.

(34) "Method detection limit (MDL)" means a minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero as determined from analysis of a sample containing the analyte in a given matrix.

(35) "Method reporting limit (MRL)" means the lowest amount of an analyte in a sample that can be quantitatively determined with stated, acceptable precision and accuracy under stated analytical conditions.

(36) "Preventative action" means a proactive action implemented to eliminate the cause of a potential nonconformance or other quality problem before it occurs.

~~(11)~~ (37) "Process lot" ~~has the meaning provided for under ARM 42.39.102~~ means:

(a) any amount of marijuana concentrate or extract of the same type and processed in the same 48-hour period, using the same extraction methods, standard operating procedures, and test batches from the same or different harvest lots; or

(b) any amount of marijuana products of the same type and processed in the same 48-hour period, using the same ingredients, standard operating procedures, and test batches from the same or different harvest lots or process lots of marijuana concentrate or extract.

(38) "Proficiency test" means an evaluation of a testing laboratory's performance against pre-established criteria by means of interlaboratory comparisons of test measurements.

~~(12)~~ (39) "Property owner permission form" ~~means a completed, signed, and notarized form which gives an applicant, or licensee renting or leasing the property, permission from the property owner to operate the testing laboratory on the property~~ has the meaning provided for under ARM 42.39.102.

(40) "Quality control sample" means a sample that is produced and used by a testing laboratory for the purpose of ensuring the quality of the data and results. Quality control samples include initial calibration verifications, continuing calibration verifications, laboratory control samples, method blanks, replicates, and matrix spikes. When quality control samples fail it is assumed the preparatory/extraction process, instrumentation, procedures, equipment, etc., are out of statistical control.

(41) "Raw data" means any testing laboratory worksheet, records, memorandum, notes, or exact copies thereof, that are the result of original observations and activities of testing laboratory study and are necessary for the reconstruction and evaluation of the report of that study.

(42) "Replicate (REP)" means a quality control sample that is a sub-sample of a laboratory test sample used to evaluate the reproducibility of the preparatory/extraction process. The REP is prepared in the same manner as the rest of the laboratory test samples in the analytical batch.

(43) "Sample increment" means an individual portion of material collected from a test batch.

(44) "Sample integrity" means maintaining marijuana items in a manner that prevents the degradation of testing laboratory results over time between the harvest/process lot, test batch, laboratory test sample, and customer product. Sample integrity factors include consistent storage, temperatures, humidity, and light exposure along with proper handling, transport, and tampering prevention.

(45) "Secondary source standard" means chemical standards sourced from a different supplier or from a different lot number of the same supplier.

(46) "Seed-to-sale tracking system" has the meaning provided for under ARM 42.39.102.

(47) "Standard operating procedure (SOP)" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

~~(13)~~ (48) "Test batch" ~~means a portion of a harvest or process lot that has been submitted for quality assurance testing~~ has the meaning provided for under ARM 42.39.102.

~~(14)~~ (49) "THC" ~~means tetrahydrocannabinol~~ has the meaning provided for under ARM 42.39.102.

~~(15)~~ (50) "THCA" ~~means tetrahydrocannabinolic acid~~ has the meaning provided for under ARM 42.39.102.

(51) "Total CBD" means the sum of CBD and CBDa calculated using the following equation:

(a) Total CBD mg/g=(CBDa mg/g x 0.877)+CBD mg/g

(52) "Total THC" means the sum of THC and THCa calculated using the following equation:

(a) Total THC mg/g=(THCa mg/g x 0.877)+THC mg/g

(53) "Validation" means the confirmation, by examination and objective evidence, that the requirements for an analytical method are fulfilled.

AUTH: ~~50-46-344~~ 16-12-202, 16-12-209, MCA
IMP: ~~50-46-303, 50-46-307, 50-46-308, 50-46-310, 50-46-318, 50-46-344~~ 16-12-202, 16-12-209, MCA

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

(a) remains the same.

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

(c) through (i) remain the same.

(j) ~~quality assurance~~ laboratory test sample retention and disposal;

(k) through (2) remain the same.

(3) All testing 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~~ 16-12-202, 16-12-209, MCA
IMP: ~~50-46-304, 50-46-311, 50-46-326, 50-46-344~~ 16-12-202, 16-12-209, MCA

37.107.309 ~~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 testing laboratory shall analyze quality control samples in the same manner as the testing laboratory analyzes marijuana, marijuana concentrates~~,~~ ~~marijuana~~ and extracts, or marijuana-infused product ~~quality assurance~~ laboratory test~~ing~~ samples;

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

(c) remains the same.

(d) if the positive and negative controls produce the expected results then the ~~results for each~~ laboratory test sample results 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)~~ (2) The testing laboratory shall prepare and analyze at least one each of the following quality control samples for each analytical ~~chemistry~~ batch:

(a) method blank (MB);

(b) laboratory control sample (LCS)~~:~~;

(c) ~~laboratory~~ replicate ~~sample~~ (REP); and

(d) ~~laboratory~~ matrix spike ~~sample~~ (MS).

(3) The testing laboratory shall analyze an initial calibration verification (ICV) sample immediately following an instrument calibration.

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

(5) If ~~the result of the~~ any quality control ~~analysis~~ sample result is outside the testing laboratory's specified acceptance criteria~~,~~ listed in the testing laboratory's quality assurance plan ~~or~~, specific method SOP, or product instructions for use, the testing 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 testing laboratory cannot report the result and the entire analytical batch cannot be released for ~~retail~~ sale. The testing laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

(7) The testing laboratory must calculate the method detection limit (MDL) and method reporting limit (MRL) 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~~ 16-12-202, 16-12-209, MCA
IMP: ~~50-46-304, 50-46-311, 50-46-326, 50-46-344~~ 16-12-202, 16-12-209, MCA

37.107.311 ~~MARIJUANA~~ TESTING LABORATORY REQUIRED PROFICIENCY TESTING (1) For a testing laboratory to become ~~approved~~ endorsed to conduct quality assurance testing, the testing laboratory must, at its own expense, meet the proficiency testing requirements of this subchapter.

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

(a) through (c) remain the same.

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

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

(5) The testing 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) Testing ~~L~~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) remains the same.

(8) The testing 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 testing laboratory to provide the proficiency testing program data and results to the state laboratory within three business days after the testing laboratory receives notification of their test results from the proficiency testing program provider.

(9) The testing 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 the 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 laboratory test sample;

(b) remains the same.

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

(d) discuss the results of proficiency testing with any other testing 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 testing 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 testing laboratory to be tested; or

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

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

(12) For the purposes of this subchapter, the ~~department~~ state laboratory 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~~ 16-12-202, 16-12-209, MCA
IMP: ~~50-46-304, 50-46-311, 50-46-326, 50-46-344~~ 16-12-202, 16-12-209, MCA

37.107.313 ~~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 testing laboratory may continue to report test results for the analyte(s) if all of the following conditions are met:

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

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

(c) the testing laboratory submits to the state laboratory, for approval, a corrective~~/~~ and preventative action plan detailing how the testing 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~~/~~ and 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 a corrective action plans and/or 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 testing laboratory has not "successfully" participated in a proficiency program for the failed analyte(s) in the previous six months, the testing laboratory may not continue to report test results for the analyte(s) until all of the following conditions are met:

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

(b) the testing laboratory submits to the state laboratory, for its approval, a corrective/ and preventative action plan detailing how the testing 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/ and 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) remains the same.

AUTH: 50-46-344 16-12-202, 16-12-209, MCA
IMP: 50-46-304, 50-46-311, 50-46-329, 50-46-344 16-12-202, 16-12-209, MCA

37.107.315 MARIJUANA TESTING LABORATORY FAILED LABORATORY TEST SAMPLES (1) If the results of quality assurance testing for any analyte/method exceed the action limits levels defined in ARM 37.107.316, then the laboratory test sample and related lot or test batch has "failed" quality assurance testing.

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

(a) remains the same.

(b) method blank;

(c) laboratory control sample(s);

(b) coefficient of determination (r^2);

(c) quality control samples:

(i) ICV, CCV, LCS, MB, REP, and MS;

(d) positive and negative controls; and

(e) laboratory replicate values;

(f) matrix spike sample(s);

(g) continuing calibration verification sample;

(h) sample preparation controls; and

(i) (e) crossing cycle thresholds.

(3) If the quality control criteria for initial quality assurance testing are within acceptable limits, then the results of all individual laboratory test samples within the

analytical batch are considered valid, including "failed" laboratory test samples and must be reported

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

(5) and (6) remain the same.

(7) The ~~provider~~ licensee 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~~ laboratory test samples within an analytical batch are considered invalid (failed run) and the entire run must be repeated with new quality controls and not reported.

(9) The testing laboratory should document and investigate failed runs, as part of the testing 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~~ licensee is not permitted to sell or transfer to ~~a registered cardholder,~~ customers marijuana items that have a failed quality assurance test.

(11) Failed harvest lots, process 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 and extracts, or marijuana-infused products that may have a toxic or deleterious effect on the health of the ~~consumer~~ customer.

(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 harvest lots, process lots, or test batches may be sold or transferred 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, a remediated laboratory test sample from a failed harvest lot, process lot, or test batch that fails quality assurance testing cannot be remediated again and the harvest lot, process lot, or test batch must be destroyed. Harvest lots, process 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. Test batches that fail pesticide analysis cannot be remediated and shall be destroyed.

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

AUTH: ~~50-46-344~~ 16-12-202, 16-12-209, MCA
IMP: ~~50-46-304, 50-46-311, 50-46-326, 50-46-329, 50-46-344~~ 16-12-202, 16-12-209, MCA

37.107.316 ~~MARIJUANA~~ TESTING LABORATORY QUALITY ASSURANCE TESTING REQUIREMENTS (1) Except as provided in (10), a ~~provider~~ licensee 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~~ customer prior to selling or transferring the marijuana item to a ~~registered cardholder~~ customer.

~~(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.~~

(2) All marijuana items intended for direct sale or transfer to customers shall be tested in its final form. The addition of any ingredient after final quality assurance compliance testing will require retesting.

~~(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; and~~

~~(b) microbiological screening.~~

~~(5)~~ (3) The cannabinoid profile/potency for each sample must include:

(a) through (f) remain the same.

~~(6)~~ (4) The laboratory test sample and related lot or test batch fail quality assurance testing for moisture analysis if the results ~~exceed moisture content of~~ are greater than 12.0 ~~percent~~ %.

~~(7)~~ (5) The laboratory test sample and related lot or test batch fail quality assurance testing for filth and foreign matter screening if the results ~~exceed~~ are greater than the following ~~limits~~ action levels:

(a) ~~five percent~~ 5.0% of stems 3mm or more in diameter; and

(b) ~~two percent~~ 2.0% of seeds or other foreign matter.

~~(8)~~ (6) The laboratory test sample and related lot or test batch fail quality assurance testing for microbiological screening if the results ~~exceed~~ are greater than the following ~~limits~~ action levels:

(a) ~~Salmonella~~ *Salmonella*: non-detectable in ~~a~~ 1.0 gram of material;

(b) ~~E. Coli~~ Shiga-toxin producing *Escherichia Coli* (STEC): non-detectable in ~~a~~ 1.0 gram of material; and

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

(c) Pathogenic *Aspergillus* species *A. flavus, A. fumigatus, A. niger, and A. terreus*: Each non-detectable in 1.0 gram of material.

(7) Microbiological testing using molecular methods must include an enrichment step.

(8) The laboratory test sample and related lot fail quality assurance testing for mycotoxins if the results are greater than the following action level:

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

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

(9) A laboratory test sample and related lot or test batch fail quality assurance testing for residual solvents if the results ~~exceed~~ are greater than the ~~limits~~ action levels provided in ~~the~~ table ~~below~~ 1.0.

Table 1.0

	~~Chemical Abstract Services~~	
Residual Solvents	(CAS) Registry Number	Action Level 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) Heavy metals will be tested at random. A laboratory test sample and related lot or test batch fail quality assurance testing for heavy metals if the results ~~exceed~~ are greater than the ~~limits~~ action levels provided in ~~the~~ table ~~below~~ 2.0.

~~Heavy Metals~~

Table 2.0

Heavy Metals	~~Limits; Unprocessed/Dry Flower~~ Action Level ppm; Inhalable Marijuana Items	~~Limits; Extract~~ Action Level ppm; Other Marijuana Items
Inorganic ~~a~~Arsenic	~~2.0 µg/g~~ 0.2	~~10 µg/g~~ 1.5
Cadmium	~~0.82 µg/g~~ 0.2	~~4.1 µg/g~~ 0.5
Lead	~~1.2 µg/g~~ 0.5	~~6.0 µg/g~~ 0.5
Mercury	~~0.4 µg/g~~ 0.1	~~2.0 µg/g~~ 3.0

(11) A laboratory test sample and related lot or test batch fail quality assurance testing for pesticides if the results ~~exceed~~ are greater than the ~~limits~~ action levels provided in ~~the~~ table ~~below~~ 3.0.

~~Pesticides~~

Table 3.0

~~Analyte~~ Pesticides	~~Chemical Abstract Services~~ (CAS) Registry Number	Action Level ~~ppl~~ ppm; ~~Unprocessed~~/Dry Flower	Action Level ppm; Concentrates and Extracts
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~~ Chloride	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~~ Licensees must adhere to testing requirements for all marijuana and marijuana products intended for sale or transfer to ~~cardholders~~ customers.

(a) remains the same.

(b) A ~~provider~~ licensee 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~~ customers.

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

(i) through (vi) remain the same.

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

(i) through (iv) remain the same.

(e) ~~Cannabinoid~~ Marijuana infused products intended for human consumption, ingestion, ~~and cannabinoid~~ or used as suppositories, topicals, and transdermal patches must be tested for:

(i) cannabinoid profile/potency; and

(ii) microbiological.

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

AUTH: ~~50-46-344~~ 16-12-202, 16-12-209, MCA
IMP: ~~50-46-303, 50-46-304, 50-46-308, 50-46-311, 50-46-326, 50-46-344~~ 16-12-202, 16-12-209, MCA

5. STATEMENT OF REASONABLE NECESSITY

In 2021, Montana's 67th Legislature passed, and the Governor signed, House Bill (HB) 701, which amends the Montana Marijuana Regulation and Taxation Act, codified at 16-12-101, et seq., MCA. With respect to marijuana testing laboratories, the bill shifts responsibility for licensing of testing laboratories from the Department of Public Health and Human Services (department) to the Department of Revenue (DOR) and creates a new process under which the department is responsible for the endorsement of a testing laboratory to perform the required testing before a testing laboratory may apply for licensure and renewal of licensure. The bill also repeals the department's rulemaking authority under Title 50, chapter 46, part 3, MCA and in its place creates new rulemaking authority under 16-12-202 and 16-12-209, MCA.

These new rules and proposed amendments are designed to implement HB 701. The proposed rulemaking establishes testing laboratory endorsement requirements, sampling protocols, and parameters under which the department may suspend the licensure of a testing laboratory. The proposed rulemaking also updates quality control measures, contaminate testing requirements, terminology, and statutory

references to align the rules with the new law. The proposed rulemaking is necessary to comply with changes to the law effected by HB 701 and to ensure marijuana products are tested in a manner that protects the safety of Montana consumers.

NEW RULE I

The department is proposing New Rule I to establish quality sampling protocols for testing laboratories. The results of any laboratory analysis are only as good as the sample collected. If representative samples are inconsistently collected between testing laboratories it can result in public safety risks, low consumer confidence, and negative effects on the cannabis industry. The rule is designed to provide for standardization of sampling practices among testing laboratories and to ensure consistent results so that consumers receive reliable information about marijuana products.

The rule is necessary to implement the requirement under 16-12-209, MCA, for the department to establish a sampling protocol and to ensure testing laboratories follow uniform standards and protocols for sampling and testing.

NEW RULE II

Although under HB 701, DOR licenses testing laboratories, 16-12-202, MCA, authorizes suspension of testing laboratory licensure by the department if raw testing data indicates the testing laboratory is providing inconsistent results. The statute requires suspension to be based upon rules adopted by the department. New Rule II sets forth the standard upon which licensure of a testing laboratory may be suspended by the department. The rule is necessary to implement the requirements of the statute, inform testing laboratories of the suspension criteria, and the right to a fair hearing before the Office of Administrative Hearings.

ARM 37.107.301

The department is proposing to amend ARM 37.107.301 to remove requirements for licensure and implement requirements for endorsement. These proposed amendments are necessary to align the rule with the requirements of HB 701 and the shifting of licensing authority to DOR. The department is also proposing to update terminology within the rule to be consistent with the new law and ensure consistency of terms used throughout the rules.

ARM 37.107.302

The department is proposing to amend ARM 37.107.302 to update requirements applicable to testing laboratories. The amendments remove requirements for testing laboratories that are unrelated to testing standards, practices, and procedures. The amendments also update method validation and standard testing laboratory practices. The proposed amendments are necessary to align the rule with the department's new rulemaking authority under HB 701. The department is also proposing to update terminology within the rule to be consistent with the new law and ensure consistency of terms used throughout the rules.

The department proposes to remove language in (7) and (9) because it is redundant and found elsewhere in rule.

The department proposes to remove language in (8) as the seed-to-sale tracking system cannot adequately track the return movement of marijuana products obtained for purposes of testing.

ARM 37.107.303

The department proposes to amend ARM 37.107.303 by adopting necessary definitions for new terminology, and amending existing terminology for clarity and to conform to HB 701. Certain definitions refer directly to the DOR's ARM 42.39.102 to ensure consistency in the use of terms between the department and DOR as part of the dual oversight for testing laboratories established under HB 701. The proposed revisions are necessary to clarify the meaning of terms used throughout the rules and to provide for a better understanding of the rules.

ARM 37.107.307

The department is proposing to amend ARM 37.107.307 for clarity and to update the terminology within the rule to be consistent with the new law and ensure consistency of terms used throughout the rules.

ARM 37.107.309

The department is proposing to amend ARM 37.107.309 for clarity and to update the terminology within the rule to be consistent with the new law and ensure consistency of terms used throughout the rules. The department is also proposing removal of language in (2) because it is duplicative of language in (5). Furthermore, the department proposes adopting (3) concerning an initial calibration verification (ICV) quality control sample to increase quality control measures and standardization between all testing laboratories.

ARM 37.107.311

The department is proposing to amend ARM 37.107.311 for clarity and to update the terminology within the rule to be consistent with the new law and ensure consistency of terms used throughout the rules. The proposed amendments do not substantively alter requirements of the existing rule.

ARM 37.107.313

The department is proposing to amend ARM 37.107.313 for clarity and to update the terminology within the rule to be consistent with the new law and ensure consistency of terms used throughout the rules. The proposed amendments do not substantively alter requirements of the existing rule.

ARM 37.107.315

The department is proposing to amend ARM 37.107.315 by clarifying quality control criteria for the determination of failed laboratory test sample results. The department proposes adopting language in (14) to specify that laboratory test samples which fail pesticide testing do not qualify for remediation. Pesticides pose dangerous health

risks to consumers and sufficient remediation procedures are not available. The department is also proposing to update the terminology within the rule to be consistent with the new law and ensure consistency of terms used throughout the rules.

ARM 37.107.316

The department is proposing to amend ARM 37.107.316 by removing language in (2) that is redundant with language under (12). The department is proposing new language to ensure all marijuana products are tested in their final form and not altered after quality assurance compliance testing is completed. This requirement is designed to ensure testing results are representative of the product sold to the consumer.

The department is also proposing amendments to microbiological testing to provide a more targeted and uniform approach to detecting human pathogenic contaminates in marijuana products. The reference to E. coli has been amended to Shiga-toxin producing *Escherichia Coli* (STEC). STEC is a known human pathogenic species of E. coli. Additionally, the reference to culturable mold has been altered to refer to pathogenic *Aspergillus* species *A. flavus, A. fumigatus, A. niger, and A. terreus*. These are the four known mold species that have been found to cause human health issues particularly in immunocompromised consumers. These amendments provide a more meaningful metric for determining specific harmful mold and E. coli in cannabis.

The department is proposing amendments to (10) to bring action levels for heavy metal testing in line with nationally recognized publications and other states' cannabis testing programs. Heavy metal exposure is harmful to human health. The cannabis plant is a known bio-accumulator and is capable of absorbing heavy metals from its surrounding environment. The proposed amendments to heavy metal action levels are designed to ensure consumer safety and are attainable using today's available instrumentation.

Fiscal Impact

There is no anticipated fiscal impact associated with this rulemaking.

6. 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: Heidi Clark, 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., December 17, 2021.

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

8. 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 6 above or may be made by completing a request form at any rules hearing held by the department.

9. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was notified by email on October 28, 2021.

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

/s/ Robert Lishman
Robert Lishman
Rule Reviewer

/s/ Adam Meier
Adam Meier, Director
Public Health and Human Services

Certified to the Secretary of State November 9, 2021.