BEFORE THE DEPARTMENT OF REVENUE
OF THE STATE OF MONTANA

In the matter of the amendment of ARM 42.39.601, 42.39.603, 42.39.610, and 42.39.614 pertaining to revised marijuana sampling protocols and quality assurance testing requirements	))))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT

TO: All Concerned Persons

1. On June 17, 2024 at 10:00 a.m., the Department of Revenue 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 amendment of the above-stated rules. The auditorium is most readily accessed by entering through the north (basement) or the west (main) doors of the building.

2. The Department of Revenue will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, please advise the department of the nature of the accommodation needed, no later than 5 p.m. on May 31, 2024. Please contact Todd Olson, Department of Revenue, Director's Office, PO Box 7701, Helena, Montana 59604-7701; telephone (406) 444-7905; fax (406) 444-3696; or todd.olson@mt.gov.

3. GENERAL STATEMENT OF REASONABLE NECESSITY The department proposes to amend ARM 42.39.601, 42.39.603, 42.39.610, and 42.39.614 which is necessary to expand, improve, or clarify marijuana and marijuana product quality assurance sampling protocols and laboratory testing rules for the health and wellbeing of the Montana marijuana consumer based on the continually changing array of available marijuana products in Montana. Other amendments continue implementation of House Bill 128 (2023)(HB 128) (transfer of the cannabis laboratory program to the department) and initial implementation of House Bill 229 (2023)(HB 229) (statutory testing laboratory licensing criteria).

Proposed amendments include additions to definitions or terminology and updates to the Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, Marijuana-Infused Products, and Marijuana Pre-Rolls (SOP-001) to provide more comprehensive language for required quality assurance testing. The department also proposes to implement a Quality Assurance Testing Requirements Appendix (Appendix) which will be adopted and incorporated by reference in ARM 42.39.614, as permitted under 2-5-307, MCA. The purpose of the Appendix is to remove testing requirements found in the administrative rules tables and restate them in a publication which the department believes is clearer and more concise than the current tables and rule.

The proposed SOP-001 and Appendix are available for review at www.mtrevenue.gov\cannabis and are subject to the rulemaking process under the Montana Administrative Procedure Act.

The proposed rule amendments also seek to improve clarity for testing marijuana items that fall into gaps or cover more than one product type. Ultimately, as the marijuana industry in Montana evolves so must the rules concerning marijuana product safety testing.

The department proposes numerous amendments to the above-described rules, as a part of Governor Gianforte's Red Tape Relief Initiative, to improve rule text, employ beneficial cross-references, and simplify the rules.

While this general statement of reasonable necessity covers the basis for the proposed rule amendments, it is supplemented below to explain rule-specific proposals.

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

42.39.601 DEFINITIONS As used in this subchapter; the following definitions apply:

(1) remains the same.

(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~~ Secretary of Education.

(3) and (4) remain the same.

(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~~ an LCS, MB, REP, and MS.

(6) "Appendix" means the department's Quality Assurance Testing Requirements Appendix adopted and incorporated by reference in ARM 42.39.614.

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

(8) "As received" means the mass of the marijuana item as determined by the testing laboratory with no dry weight calculation applied.

~~(7)~~ (9) "Batch" has the same meaning provided ~~for~~ in ARM 42.39.102.

~~(8)~~ (10) "CBD" has the same meaning provided ~~for~~ in ARM 42.39.102.

~~(9)~~ (11) "CBDA" has the same meaning provided ~~for~~ in ARM 42.39.102.

~~(10)~~ (12) "Certificate of analysis (COA)" has the same meaning provided ~~for~~ in ARM 42.39.102.

(11) remains the same but is renumbered (13).

(14) "Composite laboratory test sample" and "composite sample" mean a series of sample increments taken from different laboratory test samples, strains of usable marijuana, marijuana concentrates or extracts, marijuana-infused products, marijuana items, harvest lots, process lots, or test batches thereof, that are combined, mixed, batched, or composited together for testing purposes.

(15) "Container" means the vessel or receptacle that comes into physical contact with the marijuana item.

(16) "Contaminant" means any physical, chemical, or biological substance that may be harmful if consumed at concentrations above the action level. Potency is not a contaminant.

(12) and (13) remain the same but are renumbered (17) and (18).

~~(14)~~ (19) "Customer" has the same meaning provided ~~for~~ in ARM 42.39.102.

(20) "Dilution" means the act of combining the same or different test batches of a harvest lot of marijuana, the same or different test batches of a process lot or marijuana concentrate and extract, or the addition of any ingredient to a harvest lot or process lot with the intention of reducing the level of contaminants to below the action level in a laboratory test sample.

(21) "Direct marijuana-infused product" means a marijuana-infused product manufactured by infusing lipid-based products such as plant-based oils, animal fats, or petroleum-based products (e.g., coconut oil, vegetable oil, butter, salves, etc.) directly from tested and compliant usable marijuana. The term does not include marijuana-infused products manufactured using solvent-based or non-solvent-based concentrates and extracts.

(22) "Final form" means the form of a marijuana item when it is available for sale by a licensee to a customer.

(23) "Final packaging" means the packaging of the final form marijuana item.

~~(15)~~ (24) "Harvest lot" means ~~a~~ the specifically identified quantity of marijuana provided in SOP-001 that is cultivated utilizing the same growing practices, harvested within a 72-hour period at the same location, and cured under uniform conditions. A harvest lot may contain multiple strains until [one day less than six months from date of adoption]. Effective [six months from date of adoption], a harvest lot must not contain multiple strains and must be identical in strain.

(25) "Indirect marijuana-infused product" means a marijuana-infused product manufactured from only tested and compliant solvent based or non-solvent-based concentrates.

~~(16)~~ (26) "Ingredient" has the same meaning provided ~~for~~ in ARM 42.39.102.

(17) through (21) remain the same but are renumbered (27) through (31).

~~(22)~~ (32) "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, traceability, equipment preventative maintenance procedures, calibration procedures, and quality control testing.

(23) through (25) remain the same but are renumbered (33) through (35).

~~(26)~~ (36) "Marijuana" has the same meaning provided ~~for under~~ in 16-12-102, MCA, and ARM 42.39.102.

~~(27)~~ (37) "Marijuana concentrate and extract" or "concentrate and extract" has the same meaning provided ~~for under~~ in 16-12-102, MCA, and ARM 42.39.102.

~~(28)~~ (38) "Marijuana-infused products" has the same meaning provided ~~for under 16-12-102, MCA, and~~ in ARM 42.39.102.

~~(29)~~ (39) "Marijuana items" has the same meaning provided ~~for under~~ in ARM 42.39.102.

(40) "Marijuana Pre-roll" or "pre-roll" means any combination of the following typically constructed with rolling paper, a filter, tip, or cone: flower, shake, leaf, trim, kief, or marijuana concentrate and extract. Marijuana pre-rolls are divided into two subgroups: infused pre-rolls and non-infused pre-rolls. Infused pre-rolls contain

previously tested and compliant usable marijuana and previously tested and compliant marijuana concentrate and extract, kief, trim, or other marijuana items. Non-infused pre-rolls contain only previously tested and compliant usable marijuana.

~~(30)~~ (41) "Matrix" means the substances that are present in a sample except for the analytes of interest. The plural of the term – matrices – is also used, where appropriate.

(31) and (32) remain the same but are renumbered (42) and (43).

~~(33)~~ (44) "Method detection limit (MDL)" means a minimum concentration of a substance that can be measured and reported with 99~~%~~ percent confidence that the analyte concentration is greater than zero as determined from analysis of a sample containing the analyte in a given matrix.

(34) remains the same but is renumbered (45).

(46) "Non-solvent-based marijuana concentrate and extract" means a marijuana concentrate and extract manufactured from usable marijuana using water, ice, dry ice, a press, sieve, or filter and that does not use any solvent listed in the Appendix or solvent defined in (61). The term includes kief, hash, and rosin.

(35) remains the same but is renumbered (47).

~~(36)~~ (48) "Process lot" 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~~ SOPs, ingredients, reagents, and test batches from the same or different harvest lots~~; or~~

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

(c) any amount of marijuana pre-rolls constructed in the same 48-hour period, using the same equipment, SOP, ingredients, reagents, and test batches from the same or different harvest lots or process lots.

(37) remains the same but is renumbered (49).

~~(38)~~ (50) "Property owner permission form" has the same meaning provided ~~for under~~ in ARM 42.39.102.

~~(39)~~ (51) "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.

~~(40)~~ (52) "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.

(53) "Reagent" means a compound, mixture, substance, or chemical ingredient added to a system to cause a chemical reaction or test if a reaction occurs. A reagent may be used to tell whether a specific chemical substance is present by causing a reaction to occur with a chemical substance.

(54) "Remediation" means the process or technique applied to marijuana items to remove contaminants from such marijuana items that have failed the required quality assurance compliance testing. Dilution is not a permissible form of remediation.

~~(41)~~ (55) "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.

(56) "Sampling event" means any instance of sample collection conducted by a testing laboratory sampler at a single licensed location for purposes of quality assurance compliance testing.

(42) through (44) remain the same but are renumbered (57) through (59).

~~(45)~~ (60) "Seed-to-sale tracking system" has the same meaning provided ~~for under~~ in ARM 42.39.102.

(61) "Solvent" means a chemical compound described by its function in chemistry to dissolve, suspend, or extract analytes of interest from materials. Solvents are divided into the following classes:

(a) Hydrocarbon solvents including aliphatic, aromatic, and paraffinic solvents;

(b) Oxygenated solvents including alcohols, ketones, esters, ethers, glycol ethers, and glycol ether esters; and

(c) Halogenated solvents that include halogens such as chlorine, bromine, or iodine.

(62) "Solvent based marijuana concentrate and extract" means a marijuana concentrate and extract manufactured from usable marijuana using solvents, or subcritical or supercritical carbon dioxide and that does not use water in any state phase. The term includes tinctures, shatter, budder, wax, resin, and hash oils.

(63) "SOP-001" means the department's Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, Marijuana-Infused Products, and Marijuana Pre-Rolls document, adopted and incorporated by reference in ARM 42.39.610.

(46) remains the same but is renumbered (64).

~~(47)~~ (65) "Test batch" has the same meaning provided ~~for under~~ in ARM 42.39.102.

(66) "Testing Laboratory Sampler" means an employee of a licensed testing laboratory who has been trained and authorized to collect random and representative laboratory test samples in accordance with ARM 42.39.610. A testing laboratory sampler shall not collect laboratory test samples from any licensee where an employment relationship exists or where the performance of any aspect of work for a marijuana business creates a conflict of interest.

~~(48)~~ (67) "THC" has the same meaning provided ~~for under~~ in ARM 42.39.102.

~~(49)~~ (68) "THCA" has the same meaning provided ~~for under~~ in ARM 42.39.102.

~~(50)~~ (69) "Total potential psychoactive THC" has the same meaning provided ~~for under~~ in ARM 42.39.102.

(51) remains the same but is renumbered (70).

(71) "Traceability" means the principle of maintaining an unbroken chain of documentation tracking all laboratory samples, standards, reagents, and equipment utilized at every step of the laboratory process. This includes sample collection, preparation, analysis, data acquisition, and reporting.

(52) remains the same but is renumbered (72).

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to amend ARM 42.39.601 to define new terms and amend existing definitions that apply to new or evolving marijuana product types that are subject to quality assurance testing requirements, such as marijuana pre-roll. The new definitions support the Appendix and SOP-001 and many amendments seek to improve overall clarity or language usage consistent with other department rules.

Notable among the proposed definitions is subcategorizing marijuana-infused products into direct marijuana-infused products and indirect marijuana-infused products. Marijuana concentrates and extracts are proposed for subcategorizing into solvent based marijuana concentrates and extracts and non-solvent based marijuana concentrates and extracts which is necessary to ensure terms for all product types are sufficiently captured in the testing rules, are based on the manufacturing processes used to create them, and are clear for industry in the interest of consumer safety.

Harvest lot and process lot definitions are proposed for amendment to clarify composition of laboratory test samples from these lots and how they must be analyzed at the testing laboratory because the current definition of harvest lot allows for egregious sample compositing by diluting contaminants to below the sensitivity of the analytical instrumentation which drastically increases the probability of contaminated product entering the market. A positive impact would also be achieved because the amendment, as adopted, would bring Montana's marijuana testing requirements into alignment with other states that have authorized marijuana for production and sale to the public.

Based on previously-expressed stakeholder concerns about implementation schedules for single strain harvest lots, the department proposes a six-month transition period upon adoption of the rulemaking before the revised definition and requirement become enforceable.

Overall definition renumbering will be required based on the department's proposals.

42.39.603 TESTING LABORATORY ENDORSEMENT APPLICATION REQUIREMENTS (1) A testing laboratory applicant must meet all applicable requirements under the ~~Montana Marijuana Regulation and Taxation Act (Title 16, chapter 12, MCA) and this subchapter~~ marijuana laws in order to qualify for endorsement of either licensure or renewal.

(2) An applicant must provide~~, to~~ the department~~'s state laboratory,~~ with documentation to support fulfillment of these requirements, which includes the following:

(a) through (5) remain the same.

(6) An applicant that meets all of the ISO accreditation requirements under the ~~Montana Marijuana Regulation and Taxation Act (Title 16, chapter 12, MCA) and this subchapter and that is actively seeking ISO/IEC 17025:2017 accreditation~~ marijuana laws may be approved for endorsement ~~if written evidence of pending ISO accreditation and an inspection from the state laboratory indicate that accreditation will be achieved within 12 months from the date of endorsement~~.

(7) A testing laboratory must maintain ISO accreditation for all methods/analytes in ARM ~~37.107.316~~ 42.39.614, at all times.

(8) remains the same.

(9) ~~For the purpose of this subchapter, the state laboratory~~ 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: 16-12-202, 16-12-209, MCA
IMP: 16-12-202, 16-12-209, MCA

REASONABLE NECESSITY: Based on the justification described in the department's general statement of reasonable necessity (above), it is necessary for the department to amend ARM 42.39.603 to implement HB 128 and HB 229.

42.39.610 QUALITY ASSURANCE SAMPLING PROTOCOL (1) A ~~T~~testing ~~laboratories~~ laboratory ~~shall~~ must collect samples of marijuana items from licensees for the required quality assurance testing.

(2) A ~~T~~testing ~~laboratories~~ laboratory ~~shall~~ must develop and implement a sampling ~~protocol standard operating procedure~~ SOP that details at minimum:

(a) through (g) remain the same.

(3) Testing laboratories ~~shall~~ must create a sampling ~~plan~~ report form for each sampling event ~~that details at a minimum:~~, as required by SOP-001.

~~(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 testing laboratory sampler's badge ID number;~~

~~(d) the testing laboratory vehicle and license plate number; and~~

~~(e) the date and time the sampling route begins and ends.~~

(4) remains the same.

(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 they are 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) remains the same.

(8) At least 50~~%~~ percent of the laboratory test sample must be homogenized prior to its use for the appropriate analysis.

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

(a) through (11) remain the same.

(12) 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~~ department is granted prior to re-testing.

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

(14) The ~~state laboratory~~ department adopts and incorporates by reference the "Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, ~~and~~ Marijuana-Infused Products, and Marijuana Pre-Rolls" SOP-001 (Version ~~1~~ 3.0) ([date of adoption]), which describes the sampling protocol for marijuana, marijuana concentrates and extracts, marijuana-infused products, and marijuana pre-rolls. A copy of ~~this publication~~ SOP-001 is available from the department electronically at ~~https://dphhs.mt.gov/assets/MarijuanaLab/MarijuanaSamplingProtocolSOP.pdf~~ www.mtrevenue.gov/cannabis and may also be obtained ~~from the Department of Public Health and Human Services, Laboratory Services Bureau, 1400 E. Broadway, Helena MT, 59620~~ at 125 N. Roberts St., Helena, MT 59601.

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to amend ARM 42.39.610(1), (2), (5), (8), and (9) through (12) through changing non-substantive verbiage for overall consistency with the department's rule styling. Section (3) is proposed for amendment because sampling event protocols are provided in SOP-001 and the redundancy in the rule is unnecessary.

Proposed amendments to SOP-001

The department proposes to amend SOP-001, which is adopted and incorporated by reference in ARM 42.39.610(14), and amend the reference in (14) to reflect the transfer of the cannabis laboratory program to the department. An electronic draft of the proposed revisions to SOP-001 (new matter underlined, deleted matter interlined) is available for viewing and public comment at www.mtrevenue.com\cannabis.

The proposed amendments to SOP-001 are necessary to update guidance

for the correct collection of a random and representative laboratory test sample and provide notice that sample results produced by the testing laboratory are required to be representative of the marijuana product ultimately sold to a consumer. Rule changes regarding SOP-001 are necessary to align the document and the rule with the proposed amendments to ARM 42.39.601 and 42.39.614.

Proposed changes also address liability concerns identified by laboratories regarding the handling of product for test batch weight confirmation as SOP-001 and rule allow for the licensee to physically weigh the test batch under the observation of the testing laboratory sampler.

Sampling information for "marijuana pre-roll" was added to section 7.6 of SOP-001 to ensure consistency across all sample collection and testing rules. Amendments have been proposed to clarify the testing laboratory sampler's responsibility to confirm the mass of harvest and production test batches during each sampling event and provide a procedure if a harvest test batch should exceed the 5-pound weight limit. Video surveillance language was added to ensure testing laboratory samplers conduct compliant sampling methodology. Section 10.1 of SOP-001 has been amended to identify the required elements in the creation of a sampling report form.

42.39.614 ~~TESTING LABORATORY~~ QUALITY ASSURANCE TESTING REQUIREMENTS ~~(1) Except as provided in (10), a 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 customer prior to selling or transferring the marijuana item to a customer.~~

~~(2)~~ (1) All marijuana items intended for ~~direct~~ final sale or transfer to a customer~~s~~ shall be tested in its final form. The addition of any ingredient or reagent after final quality assurance ~~compliance~~ testing will require retesting with respect to the mandatory quality assurance testing requirements provided in the Appendix and the marijuana laws.

(2) All laboratory test sample results shall be reported into the seed-to-sale tracking system on an 'as received' basis. Dry weight reporting or corrections are not permitted.

(3) Composite laboratory test samples from the same or different process lots and test batches therein are prohibited.

(4) Composite laboratory test samples from the same or different harvest lots and test batches therein are strictly prohibited. Effective [six months from the date of adoption], multi-strain harvest lots and multi-strain composite laboratory test samples are prohibited.

(5) Useable marijuana: a licensee shall submit for testing all harvest lots and test batches therein of usable marijuana for the analyses required in Table 1.0a of the Appendix prior to final sale to a customer. Usable marijuana, including trim or manicure, shall also be tested for the analyses provided in Table 1.0a of the Appendix prior to use in the production of marijuana pre-rolls and direct marijuana-infused products. A licensee may forgo testing of usable marijuana, including trim and manicure, only if that usable marijuana is subjected to solvent or non-solvent-based extraction for the production of marijuana concentrates and extracts.

(6) Solvent-based and non-solvent-based marijuana concentrate and extract: a licensee shall submit for testing all process lots and test batches therein of solvent-based and non-solvent-based marijuana concentrate and extract for the analyses provided in Table 1.0b of the Appendix prior to final sale to a customer and prior to use in the production of marijuana-infused products or marijuana pre-rolls.

(7) Marijuana-infused products: a licensee shall submit for testing all process lots and test batches therein of marijuana-infused products for the analyses set forth under Table 1.0c of the Appendix prior to final sale to a customer.

(8) Marijuana pre-rolls: If the potency of the marijuana pre-roll process lot in question is expected to change from that of the previously tested and compliant usable marijuana, a licensee shall submit for testing all the process lots and test batches therein of marijuana pre-rolls for the analyses provided in Table 1.0d of the Appendix prior to final sale to a customer. Examples include mixing multiple strains of usable marijuana into a process lot of pre-rolls and all process lots of infused pre-rolls.

(9) A licensee shall submit for testing all process lots and test batches therein of marijuana items that consist of two or more previously tested and compliant marijuana items into a final form marijuana item (such as moon rocks or canna-cigars) for potency prior to final sale to customers.

(10) Use of any untested marijuana item as an ingredient in marijuana concentrates and extracts, marijuana-infused products, marijuana pre-rolls, or any marijuana item therein is prohibited.

~~(3)~~ (11) The ~~cannabinoid profile/~~potency test for each sample must include:

(a) through (c) remain the same.

(d) CBDA; ~~and~~

(e) CBD~~.~~; and

(f) all other cannabinoids a testing laboratory reports to the client on the certificate of analysis, which shall be entered into the seed-to-sale tracking system.

~~(4)~~ (12) The laboratory test sample and related lot or test batch fail quality assurance testing for moisture analysis if the results are greater than ~~12.0%~~ 15.0 percent.

~~(5)~~ (13) The laboratory test sample and related lot or test batch fail quality assurance testing for filth and foreign matter screening if the results are greater than the following action levels:

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

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

(6) and (7) remain the same but are renumbered (14) and (15).

~~(8)~~ (16) The laboratory test sample and related lot fail quality assurance testing for mycotoxins if the results are greater than the following action levels:

(a) and (b) remain the same.

~~(9)~~ (17) A laboratory test sample and related lot or test batch fail quality assurance testing for residual solvents if the results are greater than the action levels provided in ~~table 1.0~~ Table 2.0 of the Appendix.

~~Table 1.0~~

~~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)~~ (18) Heavy metals ~~will~~ shall be tested at random. A laboratory test sample and related lot or test batch fail quality assurance testing for heavy metals if the results are greater than the action levels provided in ~~table 2.0~~ Table 3.0 of the Appendix.

~~Table 2.0~~

~~Heavy Metals~~	~~Action Level ppm; Inhalable Marijuana Items~~	~~Action Level ppm; Other Marijuana Items~~
~~Inorganic Arsenic~~	~~0.2~~	~~1.5~~
~~Cadmium~~	~~0.2~~	~~0.5~~
~~Lead~~	~~0.5~~	~~0.5~~

~~Mercury~~	~~0.1~~	~~3.0~~

~~(11)~~ (19) A laboratory test sample and related lot or test batch fail quality assurance testing for pesticides if the results are greater than the action levels provided in ~~table 3.0~~ Tables 4.0a and 4.0b of the Appendix, as of their respective effective dates.

~~Table 3.0~~

~~Pesticides~~	~~(CAS) Registry Number~~	~~Action Level ppm; 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 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) Licensees must adhere to testing requirements for all marijuana and marijuana products intended for sale or transfer to customers.~~

~~(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 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 customers.~~

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

~~(i) pesticides;~~

~~(ii) residual solvents;~~

~~(iii) mycotoxin; and~~

~~(iv) heavy metals (random testing).~~

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

~~(i) cannabinoid profile/potency; and~~

~~(ii) microbiological.~~

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

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to amend ARM 42.39.614 to update and clarify quality assurance testing requirements and relocate and revise testing requirements from the rule into the Quality Assurance Testing Requirements Appendix (Appendix), which will be adopted and incorporated by reference into the rule.

The proposed Appendix and quality assurance testing requirements amendments are necessary to address new marijuana item classifications and subcategories and detail specific contaminant testing requirements for these items. The Appendix proposes to address the current inadequacy of marijuana product quality assurance testing requirements under the rule, such as products that previously fell under both the concentrate and extract and infused-product categories, pre-rolls, and products that use multiple marijuana items in the same formulation such as moon rocks.

Lastly, concise language regarding composite laboratory test samples is proposed to further clarify harvest lots and that a laboratory test sample consisting of more than a single harvest or process lot is strictly prohibited. Composite test batches for the purpose of contaminant testing significantly increases the probability of false negative sample results, thereby endangering the health of the consumer. The proposed amendments seek to fulfill the department's statutory mandate to ensure the quality of marijuana products and protect the health and wellbeing of the Montana consumer.

Proposed Appendix

The department's proposed Appendix contains new, understandable tables that detail the required quality assurance testing according to marijuana product type. Table 1.0a provides the required testing for usable marijuana; Table 1.0b provides the required testing for marijuana concentrates and extracts, Table 1.0c provides the required testing for marijuana-infused products; and Table 1.0d provides the required testing for marijuana pre-rolls. Additionally, the Appendix proposes to contain the relocated contaminant action level tables from the rule for residual solvents (Table 2.0), heavy metals (Table 3.0), and pesticides (Tables 4.0a and 4.0b). One notable update to the action level tables includes Table 4.0b which contains an expanded pesticides list and actions levels that span all product types that replaces the variable action levels for different product types. The proposed expanded pesticide list in Table 4.0b of the Appendix provides a more comprehensive screen for harmful chemicals which, if applied on marijuana flower and consumed, pose serious health and safety risks to consumers. Based on previously-expressed stakeholder concerns, the department proposes a six-month transition period from the adoption of this rulemaking before Table 4.0b becomes enforceable.

5. 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: Todd Olson, Department of Revenue, Director's Office, PO Box 7701, Helena, Montana 59604-7701; telephone (406) 444-7905; fax (406) 444-3696; or e-mail todd.olson@mt.gov and must be received no later than 5:00 p.m., June 30, 2024.

6. Todd Olson, Department of Revenue, Director's Office, has been designated to preside over and conduct the hearing.

7. The Department of Revenue 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, which includes the name and e-mail or mailing address of the person to receive notices and specifies that the person wishes to receive notice regarding particular subject matter or matters. Notices will be sent by e-mail unless a mailing preference is noted in the request. A written request may be mailed or delivered to the person in number 5 above or faxed to the office at (406) 444-3696, or may be made by completing a request form at any rules hearing held by the Department of Revenue.

8. An electronic copy of this notice is available on the department's web site at www.mtrevenue.gov, or through the Secretary of State's web site at sosmt.gov/ARM/register.

9. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor of HB 229, Representative Hopkins, was contacted by email on August 11, 2023 and May 13, 2024.

10. With regard to the requirements of 2-4-111, MCA, the department has determined that this rulemaking may significantly and directly impact small businesses, as described below.

SMALL BUSINESS IMPACT STATEMENT. The department has analyzed the proposed rule amendments, SOP-001, and the Appendix and concludes they may significantly and directly impact small businesses licensed assuming that testing laboratories, cultivators, dispensaries, or manufacturers of marijuana and marijuana products meet the definition of a small business under 2-4-102(13), MCA. As of April 30, 2024, there are 229 cultivator, 142 manufacturer, and three testing laboratory licensees active within Montana.

The department's proposal to amend the definition of harvest lot in ARM 42.39.601 requires these lots be composed of a single marijuana strain and will increase testing costs for those cultivators who composite multiple marijuana strains into one laboratory test sample for quality assurance compliance testing.

The department's proposal in ARM 42.39.614 prohibits all sample types from being compositing for purposes of contaminant testing. The department presents estimated fiscal impact through an evaluation of four different license groups (based on 2023 annual dispensary sales volume): (1) the small group with sales of approximately $200,000; (2) the medium group with sales of approximately $500,000; (3) the large group with sales of approximately $2M; and (4) the extra-large group with sales of $6M and above.

The cost analyses provided below were calculated by reviewing market test pricing (i.e. tests conducted by licensed marijuana testing laboratories at their designated cost, outside of the department), establishing a low and high price range, and accounting for testing in an environment without composited test batches. The estimated average annual testing cost ranges are:

- for the small group - from $5,663 - $8,900 with an average testing cost as a percentage of annual sales ranging from 2.29% - 3.60%.
- for the medium group - from $8,143 - $12,796 with an average testing cost as a percentage of annual sales ranging from 1.60% - 2.51%.
- for the large group - from $28,577 - $44,907 with an average testing cost as a percentage of annual sales ranging from 1.19% - 1.53%.
- for the extra-large group - from $99,172 - $155,841 with an average testing cost as a percentage of annual sales ranging from 1.15% - 1.81%.

The department reiterates that any of the above-described costs would be paid by a licensee to the licensed testing laboratory of its choice and are only estimates. Testing costs may vary as licensees that composite larger numbers of strains or more concentrates and extracts into a single laboratory test sample will be more affected than those licensee that participate in sample compositing with less frequency. Licensees can mitigate increased costs through changes in its business practice.

In order to ease the transition for affected licensees, the department proposes

to delay implementation of the requirement for six months from adoption of this rulemaking.

/s/ Todd Olson	/s/ Brendan Beatty
Todd Olson	Brendan Beatty
Rule Reviewer	Director of Revenue

Certified to the Secretary of State May 14, 2024.