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

In the matter of the amendment of ARM 37.107.303, 37.107.310, and 37.107.316 pertaining to Marijuana Sampling Protocols	))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT

TO: All Concerned Persons

1. On December 29, 2022, at 1:00 p.m., the Department of Public Health and Human Services will hold a public hearing via remote conferencing to consider the proposed 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/89833126215?pwd=K0FYYjNycVZCaUtISWVWNnkrZmozZz09, meeting ID: 898 3312 6215, and password: 194878; or

(b) Dial by telephone: +1 646 558 8656, meeting ID: 898 3312 6215, and password: 194878. Find your local number: https://mt-gov.zoom.us/u/kcDJos4JZY.

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 December 15, 2022, to advise us of the nature of the accommodation that you need. Please contact Kassie Thompson, 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 hhsadminrules@mt.gov.

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

37.107.303 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 U.S. Secretary of ~~the U.S. Department 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 a laboratory control sample, method blank, replicate, and matrix spike ~~the required quality control samples~~.

(6) remains the same.

(7) "As received" means the mass of the marijuana item as determined by

the testing laboratory with no dry weight calculation applied.

(7) through (11) remain the same, but are renumbered (8) through (12).

(13) "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.

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

(15) "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) through (14) remain the same, but are renumbered (16) through (18).

(19) "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.

(20) "Final form" means the form of a marijuana item at the time it is made available for sale by a licensee to a customer.

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

~~(15)~~(22) "Harvest lot" 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, and cured under uniform conditions. ~~A harvest lot may contain multiple strains.~~ Effective September 1, 2023, a harvest lot may not contain multiple strains and must be identical in strain.

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

(16) through (21) remain the same, but are renumbered (24) through (29).

~~(22)~~(30) "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 (33) remain the same, but are renumbered (31) through (41).

~~(34)~~(42) "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.

(43) "Non-solvent based marijuana concentrate and extract" means a marijuana concentrate and extract manufactured from only tested and compliant usable marijuana using water, ice, dry ice, a press, sieve, or filter and that does not use any solvent listed in the Quality Assurance Testing Requirements Appendix or solvent as defined in ARM 37.107.303. The term includes kief, hash, and rosin.

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

(a) non-infused pre-rolls contain only previously tested and compliant usable marijuana; and

(b) 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.

(35) remains the same, but is renumbered (45).

~~(36)~~(46) "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, 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, 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, standard operating procedure, ingredients, reagents, and test batches from the same or different harvest lots or process lots.

(37) and (38) remain the same, but are renumbered (47) and (48).

(49) "Quality Assurance Testing Requirements Appendix" means the State Laboratory's Quality Assurance Testing Requirements Appendix (Version 1.0), which sets forth testing requirements and action levels for marijuana and marijuana products. The state laboratory adopts and incorporates by reference the Appendix. A copy of the Appendix is available electronically at https://dphhs.mt.gov/assets/dnd/StateLaboratoryQualityAssuranceTestingRequirementsAppendix.pdf and may also be obtained from the Department of Public Health and Human Services, Laboratory Services Bureau, 1400 E. Broadway, Helena MT, 59620.

~~(39)~~(50) "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) remains the same, but is renumbered (51).

(52) "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.

(53) "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) through (45) remain the same, but are renumbered (54) through (58).

(59) "Solvent" means a class of chemical compounds described by their 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.

(60) "Solvent based marijuana concentrate and extract" means a marijuana concentrate and extract manufactured from only tested and compliant usable marijuana using solvents, or subcritical or supercritical CO2 and that does not use water in any state phase. The term includes tinctures, shatter, budder, wax, resin, and hash oils.

(46) through (51) remain the same, but are renumbered (61) through (66).

(67) "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 (68).

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

37.107.310 QUALITY ASSURANCE SAMPLING PROTOCOL (1) through (5) remain the same.

(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, and Marijuana Pre-Rolls" SOP-001, and is sufficient to complete all required quality assurance testing including quality control samples and re-runs.

(7) through (13) remain the same.

(14) The state laboratory 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~~ 2.0), 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

37.107.316 ~~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~~ Every harvest lot, process lot, and test batch thereof must be submitted for testing by the licensee and pass the testing requirements set forth under the Quality Assurance Testing Requirements Appendix and this subchapter prior to final sale to a customer and prior to use in the production of marijuana concentrates and extracts, marijuana infused products, marijuana pre-rolls, or other marijuana items therein.

(2) All marijuana items intended for ~~direct~~ final sale or transfer to customers 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 set forth in the Quality Assurance Testing Requirements Appendix and this subchapter.

(3) Prior to sale or transfer to another licensee, all marijuana items shall be submitted for testing by the licensee who cultivated or manufactured the product for the quality assurance testing requirements set forth in the Quality Assurance Testing Requirements Appendix and this subchapter. The test results shall be disclosed to the purchasing licensee.

(4) 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.

(5) Except as provided for under (6):

(a) composite laboratory test samples from the same or different process lots and test batches therein are prohibited; and

(b) composite laboratory test samples from the same or different harvest lots and test batches therein are strictly prohibited. Effective September 1, 2023, multi-strain harvest lots and, by extension, multi-strain composite laboratory samples are prohibited.

(6) Any request from a licensee to a testing laboratory to composite marijuana items from different harvest lots, process lots, or test batches thereof for quality assurance compliance testing in any fashion, combination, ratio, or configuration is prohibited unless written permission has been granted by the state laboratory.

(7) Useable marijuana: A licensee shall submit for testing all harvest lots and test batches therein of usable marijuana for the analyses set forth under Table 1.0 of the Quality Assurance Testing Requirements Appendix prior to final sale to customers and/or prior to use in the production of marijuana concentrates and extracts, marijuana infused products, or marijuana pre-rolls.

(8) Non-solvent based marijuana concentrate and extract: A licensee shall submit for testing all process lots and test batches therein of non-solvent based marijuana concentrate and extract for the analyses set forth under Table 1.0 of the Quality Assurance Testing Requirements Appendix prior to final sale to customers and prior to use in the production of marijuana infused products or marijuana pre-rolls.

(9) Solvent based marijuana concentrate and extract: A licensee shall submit for testing all process lots and test batches therein of solvent based marijuana concentrate and extract for the analyses set forth under Table 1.0 of the Quality Assurance Testing Requirements Appendix prior to final sale to customers

and/or prior to use in the production of marijuana infused products or marijuana pre-rolls.

(10) 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 1.0 of the Quality Assurance Testing Requirements Appendix prior to final sale to customers.

(11) Marijuana pre-rolls: A licensee shall submit for testing all process lots and test batches therein of marijuana pre-rolls for the analyses set forth under Table 1.0 of the Quality Assurance Testing Requirements Appendix prior to final sale to customers.

(12) 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 the following analyses prior to final sale to customers:

(a) potency; and

(b) microbiologicals.

(13) 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)~~(14) The ~~cannabinoid profile/~~potency test for each sample must include:

(a) through (e) remain the same.

~~(4)~~(15) 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%.

(5) through (8) remain the same, but are renumbered (16) through (19).

~~(9)~~(20) 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 Quality Assurance Testing Requirements 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)(21) Heavy metals will shall be tested at random until December 31, 2023. Effective January 1, 2024, heavy metals testing is mandatory. 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 Quality Assurance Testing Requirements 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)(22) 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 Quality Assurance Testing Requirements Appendix.

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

4. STATEMENT OF REASONABLE NECESSITY

The department proposes to amend ARM 37.107.303, 37.107.310, and 37.107.316 to improve and clarify laboratory testing rules for the analysis of marijuana products. These proposed rules are intended to clarify what contaminate testing is necessary for the wide array of currently available marijuana products and to account for new types of products continuously being introduced as the industry expands within Montana. The proposed rules include additions to terminology, updates to the Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, Marijuana Infused Products, and Marijuana Pre-Rolls (SOP-001), and provide more encompassing and comprehensive language on the required quality assurance testing. The department is also proposing creation of a Quality Assurance Testing Requirements Appendix to be adopted and incorporated by reference under these rules. The purpose of the appendix is to set forth testing requirements in a table format that is more clear, concise, and easier to read as compared to the current rules. The proposed rules are necessary to stay up to date with regulating the continually changing array of available marijuana products. Additionally, the proposed amendments will eliminate confusion concerning how and when to test marijuana items that are not currently addressed adequately in rule. As the marijuana industry in Montana continues to evolve and mature, so must the rules and regulations concerning marijuana product safety testing to adequately ensure the health and wellbeing of the Montana consumer.

Copies of the proposed Quality Assurance Testing Requirements Appendix and SOP-001 are located at:

https://dphhs.mt.gov/assets/dnd/MarijuanaSamplingProtocolSOPVersion2.pdf

https://dphhs.mt.gov/assets/dnd/StateLaboratoryQualityAssuranceTestingRequirementsAppendix.pdf

ARM 37.107.303

The department proposes to amend ARM 37.107.303 by adopting new terms and definitions along with amending existing definitions. The proposed revisions are necessary to further improve clarity of the testing requirements applicable to marijuana products. The most notable proposed definitions include subcategorizing marijuana infused products into "direct marijuana infused products" and "indirect marijuana infused products." Additionally, marijuana concentrates and extracts are subcategorized into "solvent based marijuana concentrates and extracts" and "non-solvent base marijuana concentrates and extracts." Including definitions for these product types provides much needed clarity in the rules to ensure these products are adequately tested prior to sale. Additionally, harvest lot and process lot definitions have been amended to clarify what a laboratory test sample from these lots must consist of and how it shall be analyzed at the testing laboratory. The proposed amendments are necessary to clarify the terms used throughout the rules and to provide for a better understanding of the quality assurance testing regulations to ensure marijuana items are properly screened.

ARM 37.107.310

The department is proposing to amend SOP-001, adopted by reference in ARM 37.107.310(14). The proposed rule change is necessary to align with proposed amendments to ARM 37.107.303 and 37.107.316. The proposed rule change also addresses stakeholder feedback received as part of public comment during a prior rulemaking under MAR Notice No. 37-967 that were deemed outside the scope of the rulemaking at the time. Sampling information for the proposed term "marijuana pre-roll" was added to SOP-001 to ensure consistency across all testing rules. Language addressing potential liability concerns by laboratory samplers resulting from accidental damage of product was included to allow for the licensee to physically weigh the product so long as it is under the observation of the testing laboratory sampler. Language requiring licensees to submit to the laboratory the mass of each harvest lot test batch was included to ensure compliant sampling occurs in the field and to monitor lot weight discrepancies. Video surveillance language was added to ensure laboratory samplers conduct rule compliant sampling methodology. The department is also proposing to increase the harvest lot test batch size from 5.0 pounds to 10.0 pounds to accommodate growth of the industry within Montana. These proposed amendments to SOP-001 are necessary to ensure a random and representative laboratory test sample is collected correctly as well as ensuring the sample results produced by the testing laboratory are representative of the marijuana product ultimately sold to the consumer.

ARM 37.107.316

The department is proposing to amend ARM 37.107.316 to clarify and update the quality assurance testing language. The proposed amendments address new marijuana item classifications and subcategories and detail specific contaminant testing requirements for these items. These amendments also address stakeholder feedback received as part of public comment during a prior rulemaking under MAR Notice No. 37-967 that were deemed outside the scope of the rulemaking at the

time. Additionally, language has been added to avoid scenarios under which certain marijuana products were technically not required to undergo quality assurance testing under the rule. Clarity is provided on how to test marijuana items which previously were not adequately addressed in rule. The department is also proposing to expand and move testing requirements stated in the rule to a newly created "Quality Assurance Testing Requirements Appendix." The proposed expanded pesticide list provides a much more comprehensive screen for harmful chemicals, which could be applied on marijuana flower and later consumed. The percent moisture action level has been increased in response to stakeholder feedback received as part of public comment during a prior rulemaking under MAR Notice No. 37-967 and has been set to follow nationally recognized American Herbal Pharmacopeia standards. Mandatory heavy metal quality assurance testing is proposed for usable marijuana and marijuana concentrates and extracts, and the authorization of random heavy metal testing is removed. Concise language regarding composite laboratory test samples is added to clearly state that this type of laboratory test sample is prohibited unless the state laboratory grants written approval. The proposed amendments ensure the quality of marijuana products in Montana and protect the health and wellbeing of the Montana consumer.

Fiscal Impact

The proposed rules are not anticipated to have a significant fiscal impact on the department.

5. SMALL BUSINESS IMPACT STATEMENT

Pursuant to 2-4-111, MCA, the department has analyzed whether the proposed rule amendments will significantly and directly impact small businesses. The department has concluded the rules will significantly and directly impact small businesses licensed as testing laboratories, cultivators, or manufacturers of marijuana. The department does not collect or have information to enable it to determine the number of licensees that meet the definition of a small business under 2-4-102(13), MCA. For the purpose of this analysis, the department presumes a significant portion of the licensed entities meet the definition of a small business.

Currently, there are 278 cultivator, 175 manufacturer, and four testing laboratory licensees active within Montana. The following rule amendments are anticipated to have a significant and direct impact on these licensees: (A) requiring heavy metals testing for marijuana flower and marijuana concentrates and extracts; (B) requiring harvest lots to be identical in strain; and (C) increasing harvest lot test batch sizes from 5.0 pounds to 10.0 pounds.

A. *Heavy Metals Testing*

The department is proposing to make testing for heavy metals mandatory for marijuana flower and marijuana concentrates and extracts. Under current rule, heavy metals testing for these products must only be conducted at random. Shifting

from random testing to mandatory testing will require some testing laboratories to purchase additional instrumentation. Based on consultations with an instrumentation manufacturer, the department estimates the price of purchasing appropriate instrumentation will range from approximately $150,000 to $300,000. These equipment costs are anticipated to be at least partially offset by additional revenue generated by testing laboratories from conducting heavy metals testing. The return on investment in the equipment depends heavily on the sample volume of the particular testing laboratory. As such, the department is unable to quantify how much of the initial testing equipment cost will be offset by additional revenue from testing. The testing requirement will also increase testing costs for licensees who grow marijuana flower or manufacture marijuana concentrates and extracts. The extra cost per sample cannot be quantified by the department because each testing laboratory is anticipated to charge differently for testing depending on their business model and return on investment.

In order to ease the transition for licensees to mandatory testing of heavy metals, the department is proposing to delay implementation of the requirement until January 1, 2024. The department believes this time period of approximately one year from the date of publication of this rulemaking notice will ensure a smooth transition to the new testing requirement by allowing testing laboratories time to purchase necessary instrumentation, validate methodology, and assess testing costs. In addition to the delayed implementation date, the department has previously made known its intent to propose implementation of mandatory heavy metals testing through communications with stakeholders and as part of a prior rulemaking under MAR Notice No. 37-967.

B. *Identical Strain Harvest Lots*

The department is proposing to amend the definition of harvest lot to require lots to be composed of a single strain. Under current rule, harvest lots are permitted to consist of multiple strains. The requirement for harvest lots to be composed of a single strain will increase testing costs for some cultivators by disallowing compositing of multiple marijuana strains into one sample for quality assurance compliance testing. The department is unable to quantify the resulting amount of increase in costs because these costs are anticipated to vary significantly from licensee to licensee. Licensees that currently composite larger numbers of strains into a harvest lot will incur higher testing costs than those that currently composite fewer strains. These costs can be mitigated by licensees changing their business practices to grow fewer strains during a single harvest. The department is proposing delaying implementation of this requirement to September 1, 2023, to afford licensees ample time to transition to the new requirement.

C. *Increase of harvest lot test batch size from 5.0 pounds to 10.0 pounds*

The department is proposing to increase the harvest lot test batch size from 5.0 pounds to 10.0 pounds. This will decrease the amount of testing required for cultivators, which will reduce testing costs for these licensees. The department is

unable to quantify the resulting decrease in costs because testing costs are not static, and growing regimens are based upon continually evolving growing practices and production of different strains. The department is proposing delaying implementation of this requirement to September 1, 2023, to afford licensees ample time to transition to the new test batch size requirement.

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: Kassie Thompson, 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 hhsadminrules@mt.gov, and must be received no later than 5:00 p.m., January 6, 2023.

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. An electronic copy of this notice is available on the department's web site at https://dphhs.mt.gov/LegalResources/administrativerules, or through the Secretary of State's web site at http://sosmt.gov/ARM/register.

10. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

/s/ ROBERT LISHMAN
Robert Lishman
Rule Reviewer

/s/ CHARLES T. BRERETON
Charles T. Brereton, Director
Department of Public Health and Human Services

Certified to the Secretary of State November 29, 2022.