



**MONTANA
ADMINISTRATIVE
REGISTER**



DEPARTMENT OF REVENUE

NOTICE OF PROPOSED RULEMAKING

MAR NOTICE NO. 2025-372.1

Summary

Amending the Quality Assurance Testing Protocol Document (SOP-001) to Increase Test Batch Size In Response to Testing Laboratory Constraints and Updating Web Page URLs

Hearing Date and Time

Wednesday, November 5, 2025, at 10:00 a.m.

Hearing Information

Third Floor Reception Area Conference Room of the Sam W. Mitchell Building, located at 125 North Roberts, Helena, Montana

Comments

Comments may be submitted using the contact information below. Comments must be received by Wednesday, November 12, 2025, at 5:00 p.m.

Accommodations

The agency 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. Requests must be made by Friday, October 17, 2025, at 5:00 p.m.

Contact

General Reasonable Necessity Statement

The department proposes to amend ARM 42.39.601, 42.39.610, 42.39.614, and the Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, Marijuana-Infused Products, and Marijuana Pre-Rolls (SOP-001) (v.3.0), adopted and incorporated by reference in ARM 42.39.610(14), which is necessary to increase the size of an acceptable “test batch” for marijuana and marijuana product quality assurance sampling protocols and laboratory testing. The department’s proposed increase in test batch size is in direct response to the needs of industry in that there is only one operational quality assurance testing laboratory in the state, where one year ago there were three, and the volume of marijuana and marijuana products tested by the laboratory is unsustainable without causing significant delays in tested product, which has an immediate and direct impact on sellable inventory statewide.

Incidental to the above-described amendments for test batch size, the department also proposes amendments to ARM 42.39.601(31), 42.39.610(1) and (6), and SOP-001, to clarify that random and representative samples are required for all types of testing. This includes licensee-initiated testing for general compliance, research and development (R&D), retesting, etc. These proposed amendments are necessary as the department is experiencing issues where a licensee, knowingly or unknowingly, uses R&D potency results on product labeling and those potency results are coming from a sample that is much smaller than it should be to be valid. This is not the intent of R&D testing and the department believes the proposed amendments are the least impactful approach to address issues of R&D potency shopping.

An electronic draft of the proposed revisions to SOP-001 (new matter underlined, deleted matter interlined) is available for viewing and public comment at <https://revenue.mt.gov/cannabis/testing-laboratory-endorsement>. For ease of reference, the proposed amendments can be found in sections 7.1.1 (pg. 4), 7.1.6 and 7.1.9 (Table 1.0; page 5), (new) 7.7.3 (page 14) and (renumbered) 7.7.8 (page 15), and 11.0 (pg. 18; version history).

Lastly, the department proposes to amend/update web address URLs in the rules for SOP-001 and the Quality Assurance Testing Requirements Appendix (Appendix) adopted and incorporated by reference in the rules.

Rulemaking Actions

AMEND

The rules proposed to be amended are as follows, stricken matter interlined, new matter underlined:

42.39.601 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 U.S. Secretary 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 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.
- (7) "Applicant" means a person seeking endorsement for testing laboratory licensure or renewal of licensure.
- (8) "Batch" has the same meaning provided in ARM 42.39.102.
- (9) "CBD" has the same meaning provided in ARM 42.39.102.
- (10) "CBDA" has the same meaning provided in ARM 42.39.102.
- (11) "Certificate of analysis (COA)" has the same meaning provided in ARM 42.39.102.
- (12) "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.
- (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) "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.
- (15) "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.
- (16) "Corrective action" means an action taken by a licensee to resolve, and prevent from recurrence, a problem with operations of the licensee.
- (17) "Customer" has the same meaning provided in ARM 42.39.102.
- (18) "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.
- (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 when it is available for sale by a licensee to a customer.
- (21) "Final packaging" means the packaging of the final form marijuana item.
- (22) "Harvest lot" means 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 February 23, 2025. Effective February 24, 2025, a harvest lot must 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.
- (24) "Ingredient" has the same meaning provided in ARM 42.39.102.
- (25) "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.
- (26) "ISO" means International Organization for Standardization.

- (27) "ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.
- (28) "ISO/IEC 17043" means the general requirements established by the ISO/IEC for proficiency testing.
- (29) "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. An LCS is required for contaminant testing only.
- (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.
- (31) "Laboratory test sample" means all sample increments collected from one test batch combined together into one sample container from which ~~quality assurance compliance~~any type of testing is conducted.
- (32) "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.
- (33) "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.
- (34) "Marijuana" has the same meaning provided in 16-12-102, MCA, and ARM 42.39.102.
- (35) "Marijuana concentrate and extract" or "concentrate and extract" has the same meaning provided in 16-12-102, MCA, and ARM 42.39.102.
- (36) "Marijuana-infused products" has the same meaning provided in ARM 42.39.102.
- (37) "Marijuana items" has the same meaning provided in ARM 42.39.102.
- (38) "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.

- (39) "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.
- (40) "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.
- (41) "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.
- (42) "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.
- (43) "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.
- (44) "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.
- (45) "Preventative action" means a proactive action implemented to eliminate the cause of a potential nonconformance or other quality problem before it occurs.
- (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, SOPs, ingredients, reagents, and test batches from the same or different harvest lots;
 - (b) any amount of marijuana-infused products of the same type and processed in the same 48-hour period, using the same ingredients, reagents, 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.

- (47) "Proficiency test" means an evaluation of a testing laboratory's performance against pre-established criteria by means of interlaboratory comparisons of test measurements.
- (48) "Property owner permission form" has the same meaning provided in ARM 42.39.102.
- (49) "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.
- (50) "Raw data" means any testing laboratory worksheet, records, memorandum, notes, or exact copies 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.
- (51) "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.
- (52) "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.
- (53) "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.
- (54) "Sample increment" means an individual portion of material collected from a test batch.
- (55) "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.
- (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.

- (57) "Secondary source standard" means chemical standards sourced from a different supplier or from a different lot number of the same supplier.
- (58) "Seed-to-sale tracking system" has the same meaning provided in ARM 42.39.102.
- (59) "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.
- (60) "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.
- (61) "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.
- (62) "Standard operating procedure (SOP)" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.
- (63) "Test batch" has the same meaning provided in ARM 42.39.102.
- (64) "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.
- (65) "THC" has the same meaning provided in ARM 42.39.102.
- (66) "THCA" has the same meaning provided in ARM 42.39.102.
- (67) "Total potential psychoactive THC" has the same meaning provided in ARM 42.39.102.
- (68) "Total THC" means the sum of THC and THCa calculated using the following equation:
- (a) $\text{Total THC} = (\text{THCa} \times 0.877) + \text{THC}$.

- (69) "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.
- (70) "Validation" means the confirmation, by examination and objective evidence, that the requirements for an analytical method are fulfilled.

Authorizing statute(s): 16-12-202, 16-12-209, MCA

Implementing statute(s): 16-12-202, 16-12-209, MCA

Reasonable Necessity Statement

The department proposes to amend ARM 42.39.601(31) to clarify that random and representative samples are required for all types of testing which is provided in the third paragraph of the department's general statement of reasonable necessity (above).

42.39.610 QUALITY ASSURANCE SAMPLING PROTOCOL

- (1) A testing laboratory must collect samples of marijuana items from licensees for the ~~required quality assurance~~ any type of testing.
- (2) A testing laboratory must develop and implement a sampling SOP 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 must create a sampling report form for each sampling event, as required by SOP-001.

- (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 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 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 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 department 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.
- (10) A licensee shall only order tests for marijuana items that the licensee has grown, produced, processed, or legally purchased from another licensee.
- (11) The licensee shall store and secure test batches in a manner that maintains sample integrity and security during laboratory testing.
- (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 department is granted prior to re-testing.
- (13) The department may inspect marijuana sampling events to ensure sampling protocols are being followed.
- (14) The department adopts and incorporates by reference the "Quality Assurance Sampling Protocol for Usable Marijuana, Marijuana Concentrates and Extracts, Marijuana-Infused Products, and Marijuana Pre-Rolls" SOP-001 (Version ~~3-04.0~~ 3-04.0)

(~~August 24, 2024~~)([date of adoption]), which describes the sampling protocol for marijuana, marijuana concentrates and extracts, marijuana-infused products, and marijuana pre-rolls. A copy of SOP-001 is available from the department electronically at ~~www.mtrevenue.gov/cannabis~~<https://revenue.mt.gov/cannabis/testing-laboratory-endorsement> and may also be obtained at 125 N. Roberts St., Helena MT 59601.

Authorizing statute(s): 16-12-202, 16-12-209, MCA

Implementing statute(s): 16-12-202, 16-12-209, MCA

Reasonable Necessity Statement

The department proposes to amend ARM 42.39.610 and SOP-001, which is adopted and incorporated by reference in ARM 42.39.610(14), as described in the department's general statement of reasonable necessity (above).

42.39.614 QUALITY ASSURANCE TESTING REQUIREMENTS

- (1) All marijuana items intended for final sale or transfer to a customer shall be tested in its final form. The addition of any ingredient or reagent after final quality assurance testing will require retesting with respect to the mandatory quality assurance testing requirements provided in the Quality Assurance Testing Requirements Appendix and the marijuana laws. The department adopts and incorporates by reference the Quality Assurance Testing Requirements Appendix (Version 1.0) (August 24, 2024), which provides quality assurance testing requirements from marijuana item classifications and subcategories and details specific contaminant testing requirements for these items. A copy of the Appendix is available from the department electronically at ~~www.mtrevenue.gov/cannabis~~<https://revenue.mt.gov/cannabis/testing-laboratory-endorsement> and may also be obtained at 125 N. Roberts St., Helena, MT 59601.
- (2) Composite laboratory test samples from the same or different process lots and test batches therein are prohibited.
- (3) Composite laboratory test samples from the same or different harvest lots and test batches therein are strictly prohibited. Effective February 24, 2025, multi-strain harvest lots and multi-strain composite laboratory test samples are prohibited.
- (4) Usable 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 forego 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.

- (5) 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.
- (6) 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.
- (7) 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.
- (8) 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 cannabis cigars) for potency prior to final sale to customers.
- (9) Use of any untested marijuana item in the production of marijuana-infused products and marijuana pre-rolls is prohibited. Use of any untested marijuana item, except for usable marijuana – including trim and manicure – in the production of concentrates and extracts is prohibited.
- (10) The potency test for each sample must include:
 - (a) THCA;
 - (b) THC;
 - (c) Total potential psychoactive THC for marijuana items that require the application of heat for administration/consumption only;
 - (d) CBDA;
 - (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.
- (11) The laboratory test sample and related lot or test batch fail quality assurance testing for moisture analysis if the results are greater than 15.0 percent.
- (12) 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; or
 - (b) 2.0 percent of seeds or other foreign matter.
- (13) The laboratory test sample and related lot or test batch fail quality assurance testing for microbiological screening if the results are greater than the following action levels:
 - (a) *Salmonella* species: non-detectable in 1.0 gram of material;
 - (b) Shiga-toxin producing *Escherichia coli* (STEC): non-detectable in 1.0 gram of material; and
 - (c) Pathogenic *Aspergillus* species *A. flavus*, *A. fumigatus*, *A. niger*, and *A. terreus* : Each non-detectable in 1.0 gram of material.
- (14) Microbiological testing using molecular methods must include an enrichment step that follows the protocol provided by the manufacturer, molecular method used, or product instructions for use. Decreasing the enrichment time outside of the range provided above is strictly prohibited.
- (15) The laboratory test sample and related lot fail quality assurance testing for mycotoxins if the results are greater than the following action levels:
 - (a) Total of Aflatoxin B1, B2, G1, G2: 20 µg/kg; and
 - (b) Ochratoxin A: 20 µg/kg of substance.
- (16) 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 2.0 of the Appendix.
- (17) Heavy metals 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 3.0 of the Appendix.
- (18) 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 Tables 4.0a and 4.0b of the Appendix, as of their respective effective dates.

Authorizing statute(s): 16-12-202, 16-12-209, MCA

Implementing statute(s): 16-12-202, 16-12-209, MCA

Reasonable Necessity Statement

The department proposes to amend/update the web address URL for the Appendix in ARM 42.39.614(1) as described in the fourth paragraph of the department's general statement of reasonable necessity (above).

Small Business Impact

With regard to the small business impact analysis requirements of 2-4-111, MCA, as amended by HB 592 (2025), the department has analyzed the proposed rule amendments, amendments to SOP-001, and the group or class of businesses directly affected by this rulemaking, and concludes those impacted small businesses are the testing laboratories, cultivators, dispensaries, or manufacturers of marijuana and marijuana products if they meet the definition of a small business under 2-4-102(13), MCA. As of September 1, 2025, there are 214 cultivators, 144 manufacturers, and one testing laboratory licensee active within Montana.

The department's estimate of positive fiscal impact is through an evaluation of four different license groups (based on 2024 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 estimated decreased testing costs based on average annual testing cost ranges are:

Increase Flower test batch size to 15 Lbs:

- for the small group – from \$418- \$523 with an average testing cost as a percentage of annual sales ranging from 0.18% - 0.23%.
- for the medium group - from \$1,200 - \$1,500 with an average testing cost as a percentage of annual sales ranging from 0.22% - 0.28%.
- for the large group - from \$5,073 - \$6,341 with an average testing cost as a percentage of annual sales ranging from 0.23% - 0.29%.
- for the extra-large group - from \$45,000 - \$56,250 with an average testing cost as a percentage of annual sales ranging from 0.58% - 0.72%.

Stated differently, and based on the data presented above, the department also provides the following table to illustrate projected annual cost savings for testing marijuana flower:

Projected Annual Flower Testing Cost Savings	
	15 Lb Lot
Sample Count Reduction	6,390
% Reduction of Samples	22.1%
Low Range Cost Reduction	\$1,278,000
Mid Range Cost Reduction	\$1,437,750
High Range Cost Reduction	\$1,597,500

Documentation of the small business impact analysis is available upon request.

Bill Sponsor Notification

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

Interested Persons

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 contact person in this notice or may be made by completing a request form at any rules hearing held by the Department of Revenue.

Rule Reviewer

Todd Olson

Approval

Brendan Beatty, Director of Revenue