



ADMINISTRATIVE RULES OF MONTANA

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 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

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