



10/22 Public Meeting Additional Materials - Cannabis Control Commission Public Meeting

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Cannabis Control Commission to Review Draft Testing Regulations



The Cannabis Control Commission (Commission) at its public meeting on Thursday, Oct. 22, began reviewing [draft regulations](#) related to Independent Testing Labs (ITLs) and the testing of cannabis and cannabis products. The Commission has produced this draft for review and intends to look at additional testing regulation updates in spring 2027. The draft regulations will be discussed at an upcoming meeting and be open for public comment in early 2027.

Some of the updates include:

- A new section under 935 CMR dedicated entirely to cannabis testing to promote public health and safety;
- Specifying the authorized activities, and operational and laboratory quality assurance requirements of ITLs;
- Detailing requirements for cannabis sample collection, storage, and retention;
- Expanding testing standards and action limits for contaminants of concern; and
- Setting rules for the repurposing, reanalysis, and remediation of cannabis products that failed regulatory compliance testing.

Commissioners will discuss the proposed regulations and associated policy questions at the [next public meeting on Nov. 12](#).

The Commission is undertaking a holistic review of its testing regulations and protocols as part of the implementation process for [Ch. 65 of the Acts of 2026 \(Ch.65\)](#). The draft testing regulations released today incorporated feedback from constituents gathered during an informal public comment period and public hearing [held in August](#), feedback from a previous [ITL listening session](#), as well as the [Commission's existing protocols](#).

The Commission will accept feedback on the draft testing regulations beginning in January during a larger public comment process for regulatory updates related to Ch. 65.

Button: [Read the Draft Regulations](#)

Memorandum

To: Commissioners
From: Testing Regulatory Working Group
Date: October 22, 2026
Subject: Testing Regulatory Working Group Recommendations

I. Purpose

This memorandum presents the Testing Regulatory Working Group's proposed draft of 935 CMR 503.000 (attached), together with corresponding recommendations relating to the Testing Protocol, certain Administrative Orders, as well as amendments to 935 CMR 500.000: *Adult Use of Marijuana* and 935 CMR 501.000: *Medical Use of Marijuana*. The memorandum also identifies an issue recommended for referral to the Ch. 65 Working Group.

II. Proposed Draft Redlines of 935 CMR 503.000: Independent Testing Laboratories and Testing Requirements

The proposed draft of 935 CMR 503.000, with redlined changes, is attached to this memorandum for review and consideration by Commissioners.

III. Corresponding Recommendations

In conjunction with the proposed draft of 935 CMR 503.000, the Testing Regulatory Working Group identified the following corresponding recommendations.

a. Recommended Referrals To Ch. 65 Working Group

Labeling: to add Metals and trace elements testing labeling requirements

If the quantification of metals in finished Marijuana does not exceed the action limits specified for “Ingestion Use Only”, as listed in 935 CMR 503.160(9)(e)5. and *Table G: Action Limits for Metals and Trace Elements*, the Production Batch of finished Marijuana must bear the additional label: "THIS PRODUCT HAS BEEN EVALUATED FOR IMPURITIES BASED ON ORAL CONSUMPTION ONLY. DO NOT INHALE THIS PRODUCT."



b. Recommended Amendments To The Testing Protocol

Retire and archive Protocol for Sampling and Analysis of Finished Marijuana and Marijuana Products for Marijuana Establishments, Medical Marijuana Treatment Centers and Colocated Marijuana Operations and all related Exhibits upon promulgation and implementation of 935 CMR 503.000 (incorporated into 935 CMR 503.000)

Issue new Guidance for newly established 935 CMR 503.000 requirements

c. Recommended Action For Administrative Orders

Rescind Administrative Order #4 upon promulgation and implementation of 935 CMR 503.000 (incorporated into 935 CMR 503.000)

Rescind Administrative Order #5 upon promulgation and implementation of 935 CMR 503.000 (incorporated into 935 CMR 503.000)

d. Recommended Amendments To 935 CMR 500.000

500.002: Definitions*

**Same recommended amendments proposed to 935 CMR 501.002*

Amend the following defined terms:

Beverage means a non-alcoholic Final Form Cannabis Product formulated and packaged for direct consumption as a drink, rather than as a concentrated liquid intended to be administered in measured doses or incorporated into another beverage. A Cannabis-containing liquid shall not be classified as a Beverage solely on the basis of its product name, labeling, or declared serving size..

Cannabinoid Profile means the amounts of tetrahydrocannabinol (THC) as total THC, total cannabidiol (CBD) as total CBD, delta-9-tetrahydrocannabinol (Δ 9-THC), cannabidiol (CBD), cannabidiolic acid (CBDA), cannabinol (CBN), and Delta-8-tetrahydrocannabinol (Δ 8-THC) in a Cannabis Product. Amounts of other Cannabinoids may be required by the Commission.

Edibles means a Cannabis Product intended to be consumed by humans by eating, chewing, or swallowing, including but not limited to gummies, chocolates, baked goods, and candies. These products, when created or sold by a Marijuana Establishment or a Medical Marijuana Establishment, shall not be considered a food or a drug as defined in M.G.L. c. 94, § 1. Edibles does not include Beverages or products separately classified as Tinctures or other route-specific dosage forms.

Independent Testing Laboratory means a laboratory that is licensed or registered by the Commission and is:

- (a) Currently and validly licensed under 935 CMR 500.101, or formerly and validly registered by the Commission;
- (b) Accredited to ISO 17025: 2017 or the International Organization for Standardization 17025 by a third-party accrediting body that is a signatory to the Global Accreditation Cooperation Incorporated Multilateral Recognition Arrangement (Global ACI MRA) or that is otherwise approved by the Commission;
- (c) Independent financially from any Medical Marijuana Establishment, Marijuana Establishment or Licensee; and
- (d) Qualified to test Marijuana and Marijuana Products, including MIPs, in compliance with M.G.L. c. 94C, § 34; M.G.L. c. 94G, § 15; 935 CMR 500.000; 935 CMR 501.000: *Medical Use of Marijuana*; and Commission protocol(s).

Laboratory Agent means an employee of an Independent Testing Laboratory registered in accordance with 935 CMR 503.029, who transports, possesses, or tests Cannabis or Marijuana in compliance with 935 CMR 500.000, 935 CMR 501.000: *Medical Use of Marijuana*, as applicable, and 935 CMR 503.000: *Independent Testing Laboratories and Testing Requirements*.

Mother Plant means a living Cannabis plant that is grown or maintained as a source of cuttings, Clones, or other vegetative propagation material, and will not be used to produce plant material for sale to another Marijuana Establishment or Medical Marijuana Establishment.

Strike the following defined terms (added to 935 CMR 503.002):

Strike Marijuana Vaporizer Device definition and **replace with** Vape Product definition*

**Same recommended amendments proposed to 935 CMR 501.002*

Vape Product means a Final Form Cannabis-containing product intended for vaporization and inhalation, including a filled cartridge, pod, disposable vaporizer, or equivalent consumer-ready vapor-delivery unit, excluding bulk vape oil and unfilled hardware.

500.029: Registration and Conduct of Laboratory Agents*

**Same recommended amendments proposed to 935 CMR 501.029*

Strike entire section (added to 935 CMR 503.029)

500.050: Marijuana Establishments

Strike 500.050(1)(b)2.: *Control Limitations (Independent Testing Laboratories)*
(incorporated into 935 CMR 503.050)*

**Same recommended amendments proposed to 935 CMR 501.0050(1)(a)2.*

500.050(1)(c)5. Standards Laboratory License Type

***Policy Question for discussion at Public Meeting**

(c) License Classes are as follows: ...

5. Independent Testing Laboratory and Standards Laboratory;

Strike 500.050(7): *Independent Testing Laboratory* (incorporated into 935 CMR 503.050)

500.101: Application Requirements

Strike 500.101(3)(f): *Additional Requirements for Independent Testing Laboratories*
(added to 935 CMR 503.050)

500.160: Testing of Marijuana and Marijuana Products*

**Same recommended amendments proposed to 935 CMR 501.160*

Strike entire section (incorporated into 935 CMR 503.000)

Amend internal citations to 500.160 to the new corresponding 935 CMR 503.000 citations*

**Same recommended amendments proposed to 935 CMR 501.000*

500.803: Suitability Standard for Registration as a Laboratory Agent*

**Same recommended amendments proposed to 935 CMR 501.803*

Strike entire section (added to 935 CMR 503.803)

e. Recommended Amendments To 935 CMR 501.000

501.025: *Responsibilities of Caregivers*

Add the following new language:

(1) Personal Caregivers.

(a) A Personal Caregiver may:

8. Transport Marijuana or Marijuana Products on behalf of a Registered Qualifying Patient to and from an Independent Testing Laboratory solely for testing, analyses, or laboratory services authorized under 935 CMR 503.000.

501.052: *Independent Testing Laboratories*

Strike entire section (incorporated to 935 CMR 503.050)

935 CMR 503.000 CANNABIS CONTROL COMMISSION
TESTING REGULATORY WORKING GROUP DRAFT 10-22-2026

935 CMR 503.000: INDEPENDENT TESTING LABORATORIES AND TESTING REQUIREMENTS

Section

- 503.001: Purpose
- 503.002: Definitions
- 503.029: Registration and Conduct of Laboratory Agents
- 503.050: Independent Testing Laboratories Licensing Requirements and Authorized Activities
- 503.105: General Operational Requirements for Independent Testing Laboratories
- 503.119: Sampling, Collection, Storage, and Retention of Samples
- 503.160: Required Testing
- 503.165: Reporting of Results
- 503.170: Testing Failures: Repurposing, Reanalysis, and Remediation
- 503.175: Waste Management and Destruction
- 503.803: Suitability Standard for Registration as a Laboratory Agent
- 503.824: Effective Date and Compliance
- 503.840: Non-conflict with Other Laws
- 503.900: Severability

503.001: Purpose

The purpose of 935 CMR 503.000 is to implement M.G.L. c. 6, § 223, M.G.L. c. 94G, M.G.L. c. 94I, St. 2012, c. 369, St. 2016, c. 334, St. 2017, c. 55, St. 2022, c. 180, and St. 2026, c. 65, and to carry out the authority granted to the Commission thereunder.

503.002: Definitions

Except as otherwise provided in 935 CMR 503.000, all terms defined in 935 CMR 500.002: *Definitions* and 935 CMR 501.002: *Definitions* shall apply to 935 CMR 503.000. For the purposes of 935 CMR 503.000, the following terms shall have the following meanings:

Accuracy means the degree of agreement between a measured result and an accepted reference value or true value. Accuracy shall be evaluated using an appropriate Reference Material, reference method, spike sample, or other scientifically justified means appropriate to the Analytical Method.

Analyte means a contaminant, chemical property, physical property, element, compound, organism, or group of any of the foregoing, the existence and amount of which a laboratory testing facility tests for, identifies, and quantifies, where applicable, in a Sample.

Analytical Batch means a defined quantity of prepared Samples that were analyzed together as a single group of analytical work under the same documented analytical procedure with applicable Calibration and Quality Control requirements.

Analytical Method means a documented laboratory procedure specifying the processes, equipment, materials, conditions, calculations, and data-processing requirements used to identify, measure, or otherwise evaluate an Analyte or characteristic in a Sample.

AOAC means the Association of Official Agricultural Chemists.

ASTM means the American Society for Testing Material.

Audit Trail means a chronological record generated by a computerized system that documents the creation, modification, or deletion of electronic data or associated Metadata and identifies, where applicable, the user, date and time, and reason for the change.

BAM means the U.S. Food and Drug Administration's Bacteriological Analytical Manual.

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Calibration means the process of establishing the relationship between the response of a measurement system and the corresponding values of standards or Reference Materials under specified conditions.

Cannabis Root or Shoot means a specified root or shoot portion of a living or harvested Cannabis plant collected for cultivation, environmental, or other regulatory testing.

Carryover means the persistence of an Analyte or other analytical response from a preceding sample, standard, or control into a subsequent analytical measurement at a level that can affect the validity or interpretation of the subsequent result.

Certificate of Analysis (COA) means an official document issued by an Independent Testing Laboratory that shows the results of Analytical Methods performed on a Sample of Cannabis or Cannabis Products.

Certified Reference Material (CRM) means a Reference Material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the assigned property value, associated Measurement Uncertainty, and Metrological Traceability.

Chain of Custody means the documented, chronological record of the collection, identification, transfer, receipt, handling, storage, and disposition of a Sample.

Concentrate (Ingredient) means a Cannabis concentrate, extract, or refined Cannabis-derived material intended for incorporation into another Cannabis Product or for further formulation or processing, including bulk vaporizer oil, distillate, cannabinoid isolates, and other concentrates used as manufacturing ingredients.

Concentrate (Final Product) means a Final Form Cannabis concentrate or extract intended for direct use or consumption rather than incorporation as an ingredient into another product. Examples include, but are not limited to, live resin, hash, shatter, wax, budder, crumble, rosin, and crystalline cannabinoid products.

Continuing Calibration Verification (CCV) means a reference standard or other Calibration Verification material analyzed at specified intervals during an analytical sequence to verify that the established Calibration remains valid and within specified acceptance criteria.

Control Charting means a statistical quality-control technique in which analytical results or other performance data are plotted over time against a central value and established control limits to monitor process stability and identify trends, shifts, or conditions requiring investigation.

Corrective and Preventive Action (CAPA) means a documented process for addressing the cause or potential cause of an identified nonconformity or other quality issue, including correction, corrective action, preventive action where applicable, and evaluation of effectiveness.

Detection Capability means the demonstrated ability of an Analytical Method to reliably detect an Analyte or target at a specified concentration or level under defined analytical conditions.

Demonstration of Capability (DOC) means a documented assessment used to demonstrate that an analyst or technician can properly perform an Analytical Method and generate results that meet specified performance and acceptance criteria.

Dilution Factor means the numerical factor used to account for the dilution, concentration, or other change in Sample amount or volume during Sample preparation or analysis when calculating the reported result.

Duplicate Sample means two Samples taken from and representative of the same material that are carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate Samples may be used to evaluate variance in the assessment method, including sampling and analysis.

Emulsion means a dispersion of one immiscible liquid phase within another liquid phase, in which the dispersed phase is distributed as droplets throughout the continuous phase. For purposes of Cannabis manufacturing, an Emulsion may contain Cannabis-derived constituents dispersed in an aqueous or other liquid phase, with or without emulsifying agents or other formulation ingredients.

Final Form means Cannabis and Cannabis Products, including all of its ingredients and any cartridge, device, or other component with which it is sold, that has been processed, packaged, and labeled in the form in which it will be dispensed or sold to a Patient, Caregiver, or Consumer, and that requires no further processing, subdivision, or repackaging before sale.

Flower (for Extraction) means a Cannabis inflorescence intended to undergo extraction or other processing to produce a Cannabis extract, concentrate, or other derivative rather than being sold or dispensed in its current form for direct use.

Flower (Product) means a dried or cured Cannabis inflorescence intended for direct use or as an ingredient in the manufacture of a Cannabis Product.

Foreign Organic Matter means organic material present in a Cannabis or Cannabis Product that is not part of the intended product and is not reasonably expected to be present as a component of the product.

Fresh-frozen Flower means harvested Cannabis inflorescence frozen before drying or curing to preserve its chemical and physical characteristics.

Growth Soil or Medium means soil, substrate, or other solid or liquid growth medium used to cultivate Cannabis plants, including soil-based, soilless, and hydroponic growth media.

Identification Capability means the demonstrated ability of an Analytical Method to correctly identify the target Analyte or constituent in the presence of other components that may be present in the test material.

IEC means the International Electrotechnical Commission.

Interference means the effect of a component or condition other than the Analyte that alters the analytical response or otherwise affects the ability of the method to correctly detect, identify, or quantify the Analyte.

Intermediate Precision means the Precision of analytical results obtained within the same laboratory under varied conditions, such as different days, analysts, equipment, or other controlled factors.

ISO means the International Organization for Standardization.

Kief means a collection of Cannabis trichomes or trichome-rich material separated from Cannabis plant material by mechanical means without chemical-solvent extraction.

Laboratory Information Management System (LIMS) means a computerized system used to manage laboratory operations and associated data, including Sample receipt and tracking, test assignments, analytical results, quality-control information, review and approval, reporting, and related laboratory records.

Laboratory Quality Management System (LQMS) means a documented system of policies, procedures, processes, and practices established and maintained by a laboratory to ensure the quality, validity, reliability, and integrity of its laboratory activities and results.

Linearity means the ability of an Analytical Method to produce analytical results that are directly proportional, or demonstrably related according to a defined mathematical relationship, to the concentration or amount of Analyte within a specified Range.

Limit of Detection (LOD) means the statistically calculated minimum concentration of an Analyte that can be measured with 99% confidence that the value is greater than zero. It is the lowest concentration or amount of an Analyte in a test material that can be reliably distinguished from the absence of the Analyte using the specified Analytical Method, but that is not necessarily quantified with acceptable Accuracy and Precision. It is also referred to as Method Detection Limit (MDL).

Limit of Quantification (LOQ) means the lowest concentration of an Analyte that can be quantitatively reported by a specified Analytical Method with Accuracy and Precision meeting established acceptance criteria under defined conditions.

Liquid Ingredient means a Cannabis-containing liquid intended for use as an ingredient in manufacturing another product or for further formulation, rather than as a Final Form Beverage or other Final Form Cannabis product.

Matrix means the material or substance in which an Analyte is present and from which the Analyte is extracted, prepared, or otherwise analyzed.

Matrix Effect means a change in analytical response caused by components of the test material Matrix that are not the Analyte, resulting in enhancement or suppression of the measured response of the Analyte.

Measurement Capability means the demonstrated ability of an Analytical Method and its associated measurement system to produce results meeting established performance requirements over a specified measurement Range.

Measurement Uncertainty means a parameter that characterizes the dispersion of values that could reasonably be attributed to the quantity being measured, based on the information used in the measurement.

Metadata means information associated with data that provides context necessary to understand, interpret, Trace, or reconstruct the creation, processing, modification, or reporting of the data.

Metrological Traceability or Traceability means the property of a measurement result whereby the result can be related to a stated reference through a documented, unbroken chain of Calibrations, each contributing to the Measurement Uncertainty.

Mycotoxin means a secondary metabolite of a microfungus that is capable of causing death or illness in humans and other animals. For the purposes of this chapter, Mycotoxin shall include aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2 and ochratoxin A.

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Nonconforming Work means Independent Testing Laboratory work or an associated process that does not conform to applicable Commission requirements, approved methods, established Standard Operating Procedures, specified acceptance criteria, or other requirements governing the validity of laboratory activities or results.

Non-oral Mucosal Ointment or Lubricant means a Final Form Cannabis-containing ointment, gel, or lubricant intended for application to a mucosal surface other than the oral mucosa, excluding Suppositories.

Non-public Water means water obtained from a source other than a public water system and used in or associated with Cannabis cultivation or processing, including private wells and surface water.

Oral Dosage Ingredient means a Cannabis-containing ointment or similar semisolid preparation intended for application to the oral mucosa, including the gums and inner cheek.

Oromucosal or Sublingual Product means a Final Form Cannabis-containing product intended to be held, dissolved, sprayed, or absorbed in the mouth or under the tongue before swallowing.

Originating Independent Testing Laboratory means the Independent Testing Laboratory that receives a Test Sample Package from a Licensee for compliance panel testing.

Plant Growth Regulator means chemicals used to modify plant growth such as increasing branching, suppressing shoot growth, increasing return bloom, removing excess fruit, or altering fruit maturity.

Polymerase Chain Reaction (PCR) means a laboratory technique used to amplify a specific DNA sequence through repeated cycles of DNA denaturation, primer annealing, and enzymatic extension, producing sufficient copies of the target sequence for detection or analysis.

Pre-roll means a ready-to-use rolled Cannabis product containing Cannabis plant material.

Pre-roll with Added Distillate or Isolate means a ready-to-use rolled Cannabis product containing Cannabis plant material to which distillate, cannabinoid isolate, or another refined Cannabis-derived ingredient has been added.

Precision means the degree of agreement among individual analytical results obtained from repeated measurements of the same or equivalent test material under specified conditions.

Proficiency Testing (PT) means evaluation of the results from the analysis of samples, the true values of which are known to the supplier of the samples but unknown to the laboratory conducting the analyses.

Public Water means water supplied by a public water system and used in or associated with Cannabis cultivation or processing.

Qualification means the documented process of establishing equipment, instruments, systems, facilities, or other specified resources are properly installed, operate as intended, and are suitable for their intended use.

Quality Assurance (QA) means a planned and systematic set of activities used to provide confidence that laboratory operations, processes, and quality systems consistently meet specified requirements and produce valid and reliable results.

Quality Control (QC) means the operational techniques and activities used to monitor, evaluate, and control the quality of laboratory processes and analytical results to ensure that established requirements and acceptance criteria are met.

Range means the interval of Analyte concentration or amount between the lower and upper levels for which the Analytical Method has been demonstrated to meet established performance requirements.

Raw Data means original records and observations generated during the collection, measurement, analysis, or processing of a Sample that are necessary to reconstruct and evaluate the analytical activity.

Recovery means the proportion of an Analyte recovered from a test material following the complete analytical procedure, relative to the amount of Analyte known or established to be present in the test material before analysis.

Reference Material (RM) means material that is sufficiently homogeneous and stable with respect to one or more specified properties and is suitable for its intended use in measurement, Calibration, Quality Control, Method Validation or Verification, or other analytical activities.

Remediation means a process or treatment applied to Cannabis or a Cannabis Product to address a failed test result or other identified condition to produce a product that meets applicable requirements.

Repeatability means the Precision of analytical results obtained under the same operating conditions over a short period, including the same method, analyst, equipment, and laboratory environment.

Reproducibility means the Precision of analytical results obtained under changed conditions, including between different laboratories, when such evaluation is part of the intended use or performance assessment of the method.

Repurpose means to redirect Cannabis or a Cannabis-derived material that does not meet the acceptance criteria for its originally intended use to a different, legally authorized manufacturing or processing use.

Residual Solvent means a volatile organic chemical or solvent used in the manufacture of a Cannabis Product and that is not completely removed by practical manufacturing techniques.

Response Model means the mathematical model established to describe the relationship between analytical response and Analyte concentration or amount over the intended measurement Range. The Response Model shall be appropriate for the analytical technique and shall be demonstrated to adequately represent the observed data.

Retained Sample is a representative portion of an original Sample or sampled material that is collected, identified, preserved, stored, and maintained by a laboratory for a defined period following testing to support subsequent review, investigation, verification, or additional authorized analysis.

Robustness means the ability of an Analytical Method to maintain acceptable performance when subjected to deliberate, controlled variations in specified method parameters.

Rosin means a Cannabis-derived concentrate produced by mechanically applying heat and pressure to Cannabis plant material or a Cannabis-derived intermediate to separate resinous constituents, without the use of an added extraction solvent as the primary means of extraction.

Sanitization Treatment means the treatment of a Cultivation Batch or a Production Batch, conducted prior to compliance testing, that is intended to minimize microbiological contaminants in Cannabis and Cannabis Products.

Sample means a portion of material collected for the purpose of testing that is intended to represent the identity, composition, characteristics, and variability of the Cultivation or Production Batch from which it was obtained.

Sample Preparation Batch means a group of Samples prepared together during a defined period using the same documented sample preparation procedure and under substantially equivalent preparation conditions.

Second Confirmatory Test means a second full panel of tests performed for reanalysis of a Sample of Cannabis or Cannabis Products that failed an initial test for contaminants.

Selectivity means the ability of an Analytical Method to distinguish the Analyte from other components that may be present in the test material. For purposes of these regulations, Selectivity may be demonstrated through the method's ability to discriminate the Analyte from potential Interferences and shall support the method's intended qualitative or quantitative use.

Shake or Trim means loose Cannabis plant material consisting of small pieces of flower, leaves, sugar leaves, and other portions of harvested Cannabis separated during trimming, handling, or processing, excluding intact flower and separately classified Kief.

SI means the International System of Units.

Solventless-infused Pre-roll means a ready-to-use rolled Cannabis product containing Cannabis plant material to which a solventless Cannabis concentrate, such as hash or rosin, has been added.

SMPRs means the Association of Official Agricultural Chemists Standard Method Performance Requirements.

Specificity means the ability of an Analytical Method to unequivocally identify or quantify the Analyte in the presence of components that may be expected to be present in the test material, including Matrix components, impurities, degradation products, related substances, or other potential Interferences.

Stability means the ability of an Analyte, test material, standard, reagent, or prepared Sample to maintain its relevant chemical, physical, or microbiological characteristics under specified storage, handling, preparation, and analytical conditions for a defined period.

Standard Operating Procedure (SOP) means a written, approved, and controlled procedure describing how a specified laboratory activity is to be performed.

Subcontracted Independent Testing Laboratory means an Independent Testing Laboratory approved by the Commission pursuant to 935 CMR 503.XXX to perform certain required regulatory compliance testing on behalf of an Originating Independent Testing Laboratory.

Suppository means a Final Form Cannabis-containing dosage form intended for insertion into the rectum or vagina, where it dissolves, melts, or disperses to release its contents.

System Suitability means a set of predefined tests and acceptance criteria used to demonstrate that an analytical system, including applicable instrumentation, reagents, materials, and operating conditions, is functioning properly and is suitable for the intended analytical procedure at the time of use.

Terpene (or Terpenoid) means a class of naturally occurring or derived organic compounds composed of, or structurally related to, isoprene units, including hydrocarbons classified as Terpenes and their oxygenated, modified, or otherwise functionalized derivatives classified as Terpenoids. Terpenes and Terpenoids may occur naturally in Cannabis or be present in Cannabis Products because of processing or formulation. For purposes of this regulation, the term Terpenes shall be used as a collective term encompassing both Terpenes and Terpenoids, unless otherwise specified.

Test Sample Package means a Representative Sample of Cannabis or Cannabis Products collected by a Licensee to complete all required regulatory compliance testing in accordance with 935 CMR 503.000.

Topical Product means a Final Form Cannabis-containing product intended for external application to the skin, hair, nails, or localized body surfaces, including but not limited to creams, lotions, balms, salves, gels, and ointments intended for topical use.

USP means The United States Pharmacopeia.

Validation means the documented process of establishing, through objective evidence, that an Analytical Method developed by the laboratory or otherwise requiring establishment of performance characteristics is suitable for its intended use and consistently produces reliable results meeting predetermined performance requirements. Validation shall evaluate the performance characteristics applicable to the intended use of the method.

Vape Base Oil (Intermediate) means a Cannabis-derived or Cannabis-containing oil, whether formulated or unformulated, intended for use as an input in the manufacture of a vaporization product but not yet incorporated into the final vaporization product or cartridge. Vape Base Oil may contain Cannabis-derived constituents and permitted formulation ingredients, including diluents, carriers, or other excipients. Vape Base Oil does not include a finished vaporization product in its final container or cartridge.

Verification means the documented process of establishing, through objective evidence, that an established Analytical Method, including a compendial, consensus, regulatory, or transferred method, has been appropriately implemented by the laboratory and performs as required under the laboratory's actual conditions of use. Verification shall demonstrate, as applicable, that the laboratory can achieve the performance requirements established for the method and its intended use.

503.029: Registration and Conduct of Laboratory Agents

(1) The Commission shall issue a Laboratory Agent Registration Card to each applicant associated as an employee or volunteer with an Independent Testing Laboratory licensed pursuant to 935 CMR 500.103: *Licensure and Renewal*, and 935 CMR 503.050 who is determined to be suitable for registration. All such individuals shall:

- (a) Be 21 years of age or older;
- (b) Have not been convicted of any felony drug offense in the Commonwealth or a like violation of the laws of an Other Jurisdiction;
- (c) Have not been convicted of any offense involving the distribution of controlled substances to a minor or a like violation of the laws of an Other Jurisdiction; and
- (d) Be determined to be suitable for registration consistent with the provisions of 935 CMR 500.800: *Suitability Standard for Licensure and Registration*, 935 CMR 500.801: *Suitability Standard for Licensure*, or 935 CMR 503.803.

(2) An application for registration of a Laboratory Agent submitted to the Commission by an Independent Testing Laboratory shall include:

- (a) The full name, date of birth, and address of the individual;
- (b) All aliases used previously or currently in use by the individual, including maiden name, if any;
- (c) Written acknowledgment signed by the applicant of the limitations on his or her authorization to possess, test, Transfer, or Process Cannabis or Cannabis Products in the Commonwealth;
- (d) A copy of the applicant's driver's license, government-issued identification card, liquor purchase identification card issued pursuant to M.G.L. c. 138, § 34B, or other verifiable identity document acceptable to the Commission;
- (e) An attestation signed by the applicant that the applicant will not engage in the Diversion or Inversion of Cannabis and Cannabis Products;
- (f) Authorization to obtain a full set of fingerprints, in accordance with M.G.L. c. 94G, § 21, submitted in a form and manner as determined by the Commission; and
- (g) Background information including, as applicable:
 1. A description and the relevant dates of any criminal action under the laws of the Commonwealth, or an Other Jurisdiction, whether for a felony or misdemeanor and which resulted in conviction, or guilty plea, or plea of nolo contendere, or admission of sufficient facts;
 2. A description and the relevant dates of any civil or administrative action under the laws of the Commonwealth or an Other Jurisdiction, relating to any professional or occupational or fraudulent practices;
 3. A description and relevant dates of any past or pending denial, suspension, or revocation of a license or registration, or the denial of a renewal of a license or registration, for any type of business or profession, by Other Jurisdictions;

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4. A description and relevant dates of any past discipline by, or a pending disciplinary action or unresolved complaint by, the Commonwealth, or a like action or complaint by an Other Jurisdiction, with regard to any professional license or registration held by the applicant;
 - (h) A nonrefundable application fee paid by the Independent Testing Laboratory with which the Independent Testing Laboratory Agent will be associated; and
 - (i) Any other information required by the Commission.
- (3) An Independent Testing Laboratory Person Having Direct Control registered with the Massachusetts DCJIS pursuant to 803 CMR 2.04: *iCORI Registration* shall submit to the Commission a CORI report and any other background check information required by the Commission for each individual for whom the Independent Testing Laboratory seeks a Laboratory Agent registration, obtained within 30 calendar days prior to submission; provided however, that a CORI shall not be required when one was already completed within the previous calendar year for a Laboratory Agent working within and between Licensees who share the same Persons or Entities Having Direct and Indirect Control in accordance with 803 CMR 2.11(7): *Requirements for Requestors to Request CORI*.
- (4) The Commission shall conduct fingerprint-based checks of state and national criminal history databases, as authorized by M.G.L. c. 94G, §§ 15 and 21, and Public Law 92-544, to determine the suitability of Laboratory Agents. As part of these checks, fingerprints are used to check the national criminal history records of the Federal Bureau of Investigation (FBI). The Independent Testing Laboratory shall pay a nonrefundable fee in a form and manner determined by the Commission for the purpose of administering the fingerprint-based background check.
- (5) An Independent Testing Laboratory shall notify the Commission no more than one business day after a Laboratory Agent ceases to be associated with the Independent Testing Laboratory. The Laboratory Agent's registration shall be immediately void when the agent is no longer associated with the Independent Testing Laboratory.
- (6) A Registration Card shall be valid for one year from the date of issue, and may be renewed thereafter on a triennial basis on a determination by the Commission that the applicant for renewal continues to be suitable for registration.
- (7) After obtaining a Registration Card for a Laboratory Agent, an Independent Testing Laboratory is responsible for notifying the Commission, in a form and manner determined by the Commission, as soon as possible, but in any event, within five business days of any changes to the information that the Independent Testing Laboratory was previously required to submit to the Commission or after discovery that a Registration Card has been lost or stolen.
- (8) A Laboratory Agent shall always carry the Registration Card associated with the appropriate Independent Testing Laboratory while in possession of Cannabis Products, including at all times while at an Independent Testing Laboratory, or while transporting Cannabis or Cannabis Products.
- (9) A Laboratory Agent affiliated with multiple Independent Testing Laboratories shall be registered as a Laboratory Agent by each Independent Testing Laboratory and shall be issued a Registration Card for each lab.
- (10) Laboratory Agents are strictly prohibited from receiving direct or indirect financial compensation from any Marijuana Establishment for which the Laboratory Agent is conducting testing, other than reasonable contract fees paid for conducting the testing in the due course of work.
- (11) Laboratory Agents may not be employed by other types of Marijuana Establishments while employed as a Laboratory Agent at one or more Independent Testing Laboratories.
- (12) The Commission may deny an application for an Agent Registration Card for a Laboratory Agent in accordance with 935 CMR 500.031: *Denial of a Marijuana Establishment Agent Registration Card*.

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(13) The Commission may revoke an Agent Registration Card for a Laboratory Agent in accordance with 935 CMR 500.032: *Revocation of a Marijuana Establishment Agent Registration Card*.

503.050: Independent Testing Laboratory License Requirements and Authorized Activities

(1) Applicability of Other Commission Regulations. Independent Testing Laboratories and Laboratory Agents shall comply with all applicable requirements of 935 CMR 500.000: *Adult Use of Marijuana* and 935 CMR 501.000: *Medical Use of Marijuana*, except as otherwise expressly provided in 935 CMR 503.000. Independent Testing Laboratories and Laboratory Agents shall also comply with the applicable requirements of 935 CMR 503.000. Failure of an Independent Testing Laboratory or Laboratory Agent to comply with any such requirements may result in administrative or disciplinary action against the Independent Testing Laboratory or Laboratory Agent pursuant to applicable enforcement and disciplinary provisions of 935 CMR 500.000 or 935 CMR 501.000.

(2) Control Limitations. In addition to the requirements set forth at 935 CMR 500.050: *Marijuana Establishments*, Independent Testing Laboratories and Standards Laboratories are subject to the following requirements:

- (a) An Independent Testing Laboratory or any associated Person or Entity Having Direct or Indirect Control, may not have a License in any other class.
- (b) No Laboratory Agent or employee of an Independent Testing Laboratory shall receive, directly or indirectly, financial compensation from an entity for which the Independent Testing Laboratory provides testing, analyses, or laboratory services pursuant to 935 CMR 500.000: *Adult Use of Marijuana*, 935 CMR 501.000: *Medical Use of Marijuana*, or 935 CMR 503.000, other than reasonable fees for such services.
- (c) No individual who possesses an interest in or is a Laboratory Agent employed by an Independent Testing Laboratory, and no immediate family member of that individual, shall possess an interest in or be employed by a Marijuana Establishment or a Medical Marijuana Establishment.

(3) Licensure Requirements. In addition to the requirements set forth at 935 CMR 500.005: *Fees*, 935 CMR 500.101: *Application Requirements*, 935 CMR 500.102: *Action on Applications*, and 935 CMR 500.103: *Licensure and Renewal*, Independent Testing Laboratories are subject to the following licensure requirements:

- (a) Prior to final licensure an Independent Testing Laboratory shall be:
 - 1. Accredited to the most current International Organization for Standardization (ISO) 17025 by a third-party accrediting body that is a signatory to the Global Accreditation Cooperation Incorporated Multilateral Recognition Arrangement (Global ACI MRA); or
 - 2. Certified, registered, or accredited by an organization approved by the Commission.
- (b) In addition to the requirements set forth in 935 CMR 500.101(1)(c): *Management and Operations Profile*, applicants for a license to operate an Independent Testing Laboratory may provide, as part of the Management and Operations Profile packet, documentation demonstrating accreditation that complies with 935 CMR 503.050(2)(a). If unable to demonstrate accreditation prior to provisional licensure, the applicant shall demonstrate accreditation prior to final licensure.

(4) Authorized Activities of Independent Testing Laboratories.

- (a) An Independent Testing Laboratory is authorized to:
 - 1. Test and analyze Cannabis and Cannabis Products for Licensees as required by and in accordance with 935 CMR 500.000: *Adult Use of Marijuana*, 935 CMR 501.000: *Medical Use of Marijuana*, and 935 CMR 503.000;
 - 2. Test and analyze Cannabis and Cannabis Products for a person who is 21 years of age or older in accordance with M.G.L. c. 94G, § 7, or for a Registered Qualifying Patient or a Personal Caregiver in accordance with M.G.L. c. 94I, § 2 and 935 CMR 501.000: *Medical Use of Marijuana*;
 - 3. In accordance with 935 CMR 503.105(5)(e), conduct research, method development, method evaluation, product characterization, or other activities unrelated to regulatory compliance testing as required by 935 CMR 503.160, provided, however, that such activities are conducted in compliance with 935 CMR 503.105(5) and all

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applicable requirements of 935 CMR 500.000, 935 CMR 501.000 and 935 CMR 503.000;

4. Perform testing or analyses of Cannabis or Cannabis Products that are not required by 935 CMR 500.000: *Adult Use of Marijuana*, 935 CMR 501.000: *Medical Use of Marijuana*, and 935 CMR 503.000 at the request of a Licensee, a person who is 21 years of age or older in accordance with M.G.L. c. 94G, § 7, or by a Registered Qualifying Patient or a Personal Caregiver in accordance with M.G.L. c. 94I, § 2 and 935 CMR 501.000: *Medical Use of Marijuana*, provided, however, that such testing or analyses is conducted in compliance with 935 CMR 503.105(5) and all applicable requirements of 935 CMR 500.000, 935 CMR 501.000 and 935 CMR 503.000.

(b) An Independent Testing Laboratory may possess, receive, process, transport, and securely store Cannabis and Cannabis Products, provided that such activities shall be conducted only as necessary for testing and analyses authorized or required by 935 CMR 500.000: *Adult Use of Marijuana*, 935 CMR 501.000: *Medical Use of Marijuana*, or 935 CMR 503.000.

(c) When the Cannabis or Cannabis Products submitted to an Independent Testing Laboratory for testing, analyses, or laboratory services by a person who is 21 years of age or older in accordance with M.G.L. c. 94G, § 7, or for a Registered Qualifying Patient or a Personal Caregiver in accordance with M.G.L. c. 94I, § 2 and 935 CMR 501.000: *Medical Use of Marijuana*:

1. The Independent Testing Laboratory shall receive and handle Cannabis or Cannabis Products in accordance with 935 CMR 503.000; and

2. The submission and receipt of Cannabis or Cannabis Products solely for testing, analyses, or laboratory services shall not constitute a Transfer, sale, or distribution of Cannabis or Cannabis Products; and no retail sale, dispensing, or other distribution of Cannabis or Cannabis Products shall occur in connection with such activities.

(d) An Independent Testing Laboratory may perform activities, including testing, analytical, or laboratory services, for non-Cannabis materials or products unrelated to its licensed activities, provided that such activities do not include the cultivating, manufacturing, or retail sale or distribution of Cannabis or Cannabis Products, and provided further that the Independent Testing Laboratory shall continue to comply with all requirements applicable to Independent Testing Laboratories under 935 CMR 500.000: *Adult Use of Marijuana*, 935 CMR 501.000: *Medical Use of Marijuana*, and 935 CMR 503.000.

503.105: General Operational Requirements for Independent Testing Laboratories

(1) General Laboratory Requirements.

(a) An Independent Testing Laboratory shall establish and maintain a documented quality management system appropriate to the scope, type, range, and volume of laboratory activities performed by the Independent Testing Laboratory.

(b) Laboratory activities shall be conducted by an Independent Testing Laboratory in a manner that ensures the validity, reliability, integrity, and Traceability of analytical results.

(c) An Independent Testing Laboratory shall comply with all applicable Commission requirements and shall perform Commission-required compliance testing only within the Independent Testing Laboratory's licensed and accredited scope of activities.

1. All regulatory compliance tests and Analytes shall be included within an Independent Testing Laboratory's scope of ISO-17025 accreditation and shall remain within the Independent Testing Laboratory's accreditation scope so long as the Independent Testing Laboratory offers such tests or Analytes for regulatory compliance testing.

2. Notwithstanding 935 CMR 503.050(1)(c)1., the Commission may defer the ISO-17025 accreditation requirement for a new regulatory compliance test or Analyte and permit an Independent Testing Laboratory to offer such test or Analyte upon completion of method Validation or Verification, as applicable, and review and approval by the Commission. The Commission may authorize the Independent Testing Laboratory to defer adding the new regulatory compliance test or Analyte to the scope of its accreditation until its next annual accreditation review.

(d) An Independent Testing Laboratory shall maintain the procedures, facilities, equipment, systems, personnel, and support services necessary to perform its laboratory activities and ensure the validity of analytical results.

(e) An Independent Testing Laboratory shall have Standard Operating Procedures for all regulatory compliance tests and procedures, quality management systems and laboratory activities performed by the Independent Testing Laboratory.

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(f) An Independent Testing Laboratory shall keep current all information required by 935 CMR 500.000: *Adult Use of Marijuana*, 935 CMR 501.000: *Medical Use of Marijuana*, 935 CMR 503.000, or otherwise required by the Commission. An Independent Testing Laboratory shall report any changes in or additions to the content of the information contained in any document to the Commission within five business days after such change or addition.

(2) Personnel and Competency. An Independent Testing Laboratory shall establish and maintain a documented competency program for all Laboratory Agents performing laboratory activities that may affect the validity or reliability of analytical results. An Independent Testing Laboratory shall document and maintain records of all initial and ongoing competency assessments and personnel authorizations.

(a). Initial Competency. Prior to independently performing any laboratory activity, a Laboratory Agent shall demonstrate competency through a documented, staged process appropriate to the activity. The initial competency process shall include, at minimum:

1. Procedure Review. A Laboratory Agent shall receive and undergo a documented review of the applicable Standard Operating Procedure, method, and associated requirements;
2. Training. A Laboratory Agent shall undergo documented instruction in the applicable procedure, including relevant theory, data integrity requirements, safety requirements, equipment, calculations, Quality Controls, and acceptance criteria;
3. Shadowing and Supervised Performance. A Laboratory Agent shall perform the activity under the direct supervision of qualified and authorized personnel;
4. Demonstration of Competency. A Laboratory Agent shall independently perform the activity demonstrating that the individual can perform the procedure competently and meet established accepted criteria.

(b). Ongoing Competency.

1. An Independent Testing Laboratory shall maintain an ongoing program for monitoring and reassessing Laboratory Agent competency. The frequency and manner of reassessment shall be appropriate to the complexity, frequency, and risk of the activity, but shall occur at least annually, and shall be established in the Independent Testing Laboratory's quality management system.
2. An ongoing competency assessment shall include direct observation or practical evaluation of a Laboratory Agent's demonstration of critical technical skills, where appropriate. Such assessments may include, but are not limited to, pipetting Accuracy and Precision, microbial enumeration and plate counting, Sample preparation, instrument operation, data processing, and other activities identified by the Independent Testing Laboratory as critical to the validity of analytical results.
3. Demonstration of Competency shall be reassessed by an Independent Testing Laboratory when warranted by changes to methods, equipment, procedures, personnel performance, quality-control trends, proficiency-testing performance, or other circumstances that may affect the reliability of analytical results.
4. Proficiency Testing and interlaboratory comparison results may be considered, by the Independent Testing Laboratory in evaluating ongoing Laboratory Agent competency and the effectiveness of laboratory activities.

(3) Facilities and Environmental Conditions.

(a) Suitability. An Independent Testing Laboratory's facilities shall be suitable for the laboratory activities performed and shall not adversely affect the validity of analytical results.

(b) Environmental Conditions. Environmental Conditions that may affect analytical results shall be controlled, monitored, and documented by an Independent Testing Laboratory as appropriate to the laboratory activity.

(c) Contamination and Interference. An Independent Testing Laboratory shall establish controls to prevent contamination, cross-contamination, Interference, or other environmental conditions from adversely affecting analytical results.

(d) Access and Security. Areas containing Samples, standards, records, or analytical equipment shall be appropriately controlled by an Independent Testing Laboratory in accordance with 935 CMR 500.110: *Security Requirements for Marijuana Establishments* to prevent unauthorized access or activities that may compromise laboratory operations or the integrity of analytical results.

(e) Separation of Activities. Laboratory activities shall be arranged and controlled by an Independent Testing Laboratory to prevent incompatible activities from adversely affecting the validity of analytical results.

(4) Equipment, Instrumentation, Reagents, and Reference Materials.

(a) General Equipment Requirements.

1. An Independent Testing Laboratory shall, on its Premises, possess or have access to equipment, instrumentation, software, measurement standards, Reference Materials, reagents, consumables, and auxiliary apparatus necessary to perform authorized laboratory activities and that may affect the validity of analytical results.
2. Equipment and instrumentation utilized by an Independent Testing Laboratory shall be suitable for their intended use, maintained in appropriate working condition, and capable of achieving the performance necessary to produce valid analytical results.
3. Equipment and instrumentation utilized by an Independent Testing Laboratory that may affect the validity of analytical results shall be identified and subject to documented controls appropriate to their intended use.

(b) Equipment and Instrumentation Qualification, Calibration, and Verification.

1. Equipment and instrumentation that may affect the validity of analytical results shall be qualified or otherwise demonstrate System Suitability.
2. Equipment and instrumentation used for measurement shall be Calibrated at intervals established in accordance with the manufacturer's specifications, applicable Analytical Method requirements, and the Independent Testing Laboratory's Standard Operating Procedures, and whenever Calibration is necessary to ensure the validity of analytical results or establish Metrological Traceability.
3. Equipment and instrumentation shall be verified at intervals established in accordance with the manufacturer's specifications, applicable Analytical Method requirements, and the Independent Testing Laboratory's Standard Operating Procedures, as appropriate to its intended use and risk, and whenever necessary to maintain confidence in its performance.
4. Calibration and Verification activities shall be performed in accordance with the manufacturer's specification, applicable Analytical Method requirements, and the Independent Testing Laboratory's applicable Standard Operating Procedures, and shall satisfy the established acceptance criteria.
5. Equipment or instrumentation that does not meet established performance criteria shall not be used by an Independent Testing Laboratory for analytical activities until its suitability for use has been established by the Independent Testing Laboratory.

(c) Equipment and Instrumentation Maintenance and Control.

1. Equipment and instrumentation that may affect the validity of analytical results shall be maintained in proper working condition by an Independent Testing Laboratory in accordance with the manufacturer's specifications, applicable Analytical Method requirements, and the Independent Testing Laboratory's Standard Operating Procedure and established maintenance schedules.
2. Equipment and instrumentation shall be cleaned, maintained, and operated by an Independent Testing Laboratory in a manner that prevents contamination, deterioration, or other conditions that could adversely affect analytical results.
3. Equipment and Instrumentation requiring Calibration, Verification, maintenance, or other defined performance checks shall have its status documented and readily identifiable, and its use controlled based on that status.
4. An Independent Testing Laboratory shall maintain records of maintenance, Calibration, Verification, and other activities as necessary to demonstrate the continued suitability of equipment for its intended use.

(d) Equipment and Instrumentation Failure and Out-of-Service Controls.

1. Equipment or instrumentation that is defective, damaged, malfunctioning, outside established acceptance criteria, or otherwise suspected of producing invalid or unreliable results shall be removed from service or otherwise controlled by an Independent Testing Laboratory to prevent its use for analytical activities.
2. An Independent Testing Laboratory shall evaluate the potential effect of equipment or instrumentation failure, malfunction, or deviation on analytical results generated since the last demonstrated acceptable performance of the equipment or instrumentation.
3. Where equipment or instrumentation failure, malfunction, or deviation may have affected the validity of reported results, the Independent Testing Laboratory shall take appropriate action in accordance with its Standard Operating Procedures for Nonconforming Work and corrective action.
4. Equipment or instrumentation that is defective, damages, malfunctioning, outside established acceptance criteria, or otherwise suspected of producing invalid or unreliable results shall not be returned to service by an Independent Testing Laboratory

until proper functioning and suitability for intended use for such equipment or instrumentation have been demonstrated, documented and internally approved by the Independent Testing Laboratory.

(e) Metrological Traceability.

1. An Independent Testing Laboratory shall establish and maintain Metrological Traceability for measurement results that affect the validity of analytical results.
2. Metrological Traceability shall be established through a documented chain of Calibrations or other appropriate references, as applicable to the measurement and its intended use.
3. Where Metrological Traceability to the International System of Units (SI) is technically possible, an Independent Testing Laboratory's measurement results shall be traceable to the SI through competent Calibration services, Certified Reference Materials, or other appropriate means consistent with ISO/IEC 17025.
4. Where Metrological Traceability to the SI is not technically possible, an Independent Testing Laboratory shall establish Traceability to an appropriate reference, such as a Certified Reference Material, reference measurement procedure, specified method, or consensus standard, where such reference is fit for the intended use.
5. Reference Materials used by an Independent Testing Laboratory to establish or verify the Accuracy of quantitative analytical results shall have documented identity, assigned value or concentration, and appropriate Traceability for their intended use.
6. Reference Materials prepared by an Independent Testing Laboratory shall be appropriately characterized and their assigned values established or verified using scientifically valid procedures and appropriate Reference Materials or methods.

(f) Reagents, Solutions, and Consumables.

1. Reagents, solutions, and consumables that may affect the validity of analytical results shall be suitable for their intended use by an Independent Testing Laboratory and maintained by the Independent Testing Laboratory under conditions that preserve their integrity and performance.
2. Reagents and solutions shall be appropriately identified and labeled by an Independent Testing Laboratory, including, as applicable, identity, concentration or purity, preparation or receipt date, expiration or re-Qualification date, and storage requirements.
3. Reagents, solutions, and consumables shall be stored and handled by an Independent Testing Laboratory in accordance with established requirements to prevent contamination, deterioration, or other conditions that could adversely affect analytical results.
4. An Independent Testing Laboratory shall ensure that reagents and solutions are within their established period of validity or otherwise demonstrated to remain suitable for use at the time of use.
5. Reagents, solutions, and consumables that are expired, deteriorated, contaminated, or otherwise unsuitable for use shall be removed from use and appropriately controlled by an Independent Testing Laboratory.
6. An Independent Testing Laboratory shall maintain records sufficient to demonstrate the identity, preparation or receipt, validity, and suitability for use of reagents and solutions that may affect the validity of analytical results.

(g) Reference Materials and Standards.

1. Reference Materials and standards used by an Independent Testing Laboratory in laboratory activities shall be suitable for their intended use and appropriately characterized for the properties relevant to that use.
2. Reference Materials and standards shall have documented identity, source, assigned value or concentration, where applicable, and appropriate Traceability for their intended use.
3. Reference Materials and standards shall be stored and handled by an Independent Testing Laboratory under conditions appropriate to maintain their integrity and validity.
4. An Independent Testing Laboratory shall establish controls that Reference Materials and standards are within their established period of validity and suitable for use at the time of use.
5. Each lot of Reference Material or standard used by an Independent Testing Laboratory in quantitative analytical activities shall be uniquely identified and Traceable to the analytical records in which it was used.
6. Reference Materials or standards prepared by an Independent Testing Laboratory shall be appropriately characterized, and their assigned values or concentrations shall be established or verified using scientifically valid procedures and appropriate Reference Materials or methods.

7. Documentation supporting the identity, characterization, assigned value or concentration, Traceability, validity, and suitability for use of Reference Materials and standards shall be maintained by an Independent Testing Laboratory.
- (h) Equipment, Instrumentation, and Material Records.
 1. An Independent Testing Laboratory shall maintain records sufficient to demonstrate the identification, status, suitability, and history of equipment and instrumentation that may affect the validity of analytical results.
 2. An Independent Testing Laboratory shall maintain equipment and instrumentation records, which shall include, as applicable, Qualification, Calibration, Verification, Validation, maintenance, repair, malfunction, and out-of-service information.
 3. An Independent Testing Laboratory shall maintain records for Reference Materials and standards, which shall be maintained in accordance with Section 4.7, and shall support their identification, Traceability, validity, and use.
 4. Records required by 935 CMR 503.105(4) shall be readily retrievable and maintained by an Independent Testing Laboratory for the period specified in 935 CMR 503.105(11) or the Independent Testing Laboratory's Laboratory Quality Management System, whichever is longer.
- (5) Analytical Methods.
 - (a) General Method Requirements.
 1. Analytical Methods utilized by an Independent Testing Laboratory shall be appropriate for the intended use, Analyte, Matrix, concentration Range, and applicable reporting requirements.
 2. An Independent Testing Laboratory shall maintain Standard Operating Procedures for each Analytical Method used for regulatory compliance testing as required by 935 CMR 503.160.
 - (b) Standards and Published Methods.
 1. Where the Commission specifies an Analytical Method or reference standard, an Independent Testing Laboratory shall use the specified Analytical Method or reference standard unless otherwise authorized by the Commission in accordance with 935 CMR 500.850: *Waivers*.
 2. Each Analytical Method shall meet minimal analytical performance requirements as described in 935 CMR 503.160.
 3. Standard or published methods shall be appropriately selected, verified, and implemented by an Independent Testing Laboratory for their intended use.
 4. Each Analytical Method used to perform regulatory compliance testing as required by 935 CMR 503.160 shall be included and maintained within an Independent Testing Laboratory's accredited scope of activities.
 - (c) Laboratory-Developed, Modified, or Non-Standard Methods. An Independent Testing Laboratory may utilize an Analytical Method that is laboratory-developed, modified, non-standard, or utilized outside of its established scope for regulatory compliance testing required by 935 CMR 503.160 only upon prior written approval by the Commission and demonstration that the Analytical Method is fit for its intended purpose in accordance with 935 CMR 503.105(6) and complies with all applicable Commission requirements
 - (d) Method Changes.
 1. Changes to an Analytical Method by an Independent Testing Laboratory shall be evaluated, documented, and internally authorized by the Independent Testing Laboratory prior to implementation of such Analytical Method.
 2. Where a method change may affect the validity of analytical results, an Independent Testing Laboratory shall determine the need for additional Verification or Validation prior to implementation.
 - (e) Research and Development Activities.
 1. Analytical activities performed by an Independent Testing Laboratory for research and development, method development, method evaluation, product characterization, or other purposes unrelated to regulatory compliance testing as required by 935 CMR 503.160 may be performed outside an Independent Testing Laboratory's accredited scope of activities, provided that such activities comply with the requirements of 935 CMR 503.105(5).
 2. Certificates of Analysis and other analytical reports produced by an Independent Testing Laboratory shall clearly identify any Analytical Method or activity that is outside the scope of the Independent Testing Laboratory's accreditation scope.
 3. An Independent Testing Laboratory shall clearly distinguish research and development activities authorized by 935 CMR 503.105(5)(e) and any such results from regulatory compliance testing as required by 935 CMR 503.160.

4. Results or data generated by an Independent Testing Laboratory from activities described within 935 CMR 503.105(5)(e) shall not be used to demonstrate compliance with regulatory compliance testing as required by 935 CMR 503.160, support a Certificate of Analysis, or substantiate any marketing or regulatory compliance claims.
 5. Results or data generated by an Independent Testing Laboratory from activities described within 935 CMR 503.105(5)(e) shall be uploaded to the Seed-to-sale SOR and shall be made available to the Commission upon request.
 6. An Analytical Method used by an Independent Testing Laboratory for research and development activities authorized by 935 CMR 503.105(5)(e) shall be validated or verified, as applicable, with documented Validation reports and Standard Operation Procedures.
- (6) Method Validation and Verification.
- (a) General Requirements.
1. An Independent Testing Laboratory shall Validate or Verify each Analytical Method, as applicable, before such method is used for regulatory compliance testing as required by 935 CMR 503.160.
 - a. The extent of Validation or Verification shall be appropriate to the Analytical Method, its intended use, the Analytes and Matrices tested, the applicable reporting Range, and the potential consequences of an incorrect result.
 - b. Validation shall demonstrate, through documented laboratory studies, that an Analytical Method that is laboratory-developed, modified, non-standard, or utilized outside of its established scope is capable of consistently producing results that meet the requirements for its intended use.
 - c. Verification shall demonstrate that an established Analytical Method is suitable for its intended use under an Independent Testing Laboratory's actual conditions of use.
 - d. Software Validation shall be done on software used to generate, process, calculate, store, transfer, or report analytical results, including instrument software, Laboratory Information Management Systems, Laboratory Quality Management Systems, and interfaces with other systems, shall be validated to demonstrate that it performs as intended and produces accurate, complete, and reliable results. Validation shall include Verification of applicable calculations, data processing, system interfaces, and reporting of results to the Seed-to-sale SOR, as applicable.
 - e. Software shall maintain data integrity in accordance with 935 CMR 503.105(9). Audit Trails shall be enabled, protected from unauthorized alteration or deletion, and maintained to permit reconstruction of data creation, modification, processing, transfer, and reporting, including changes to analytical results and associated Metadata.
 - f. Software changes that may affect calculations, data integrity, system interfaces, or reporting shall be evaluated and validated, as appropriate, before implementation. Laboratories shall maintain documentation of software Validation and make Validation records, Audit Trails, calculation methods, and supporting calculation data available to the Commission upon request.
 2. An Independent Testing Laboratory shall maintain records supporting the determination and any resulting Validation, Verification, or re-Validation activities in accordance with 935 CMR 503.105(11).
- (b) Validation Protocol. Validation shall be conducted in accordance with a documented Validation protocol internally authorized by the Independent Testing Laboratory prior to commencement of the Validation Study.
1. The Validation protocol shall identify the following, as applicable:
 - a. The Analytical Method and method version;
 - b. The intended use of the Analytical Method;
 - c. Analytes and Matrices to which the Validation applies;
 - d. The applicable analytical and reporting Range;
 - e. The performance characteristics to be evaluated;
 - f. The study design, including Sample types, concentrations, replicates, and applicable sources of variability;
 - g. Predefined acceptance criteria for each applicable performance characteristic;
 - h. The statistical or other evaluation procedure to be used; and
 - i. Any other information required by the Commission.
 2. Validation and acceptance criteria shall be scientifically justified and appropriate for the intended use of the method.
- (c) Validation Characteristics.

1. Validation shall evaluate performance characteristics applicable to the intended use and type of Analytical Method.
 2. In accordance with 935 CMR 503.105(6)(g) and *Table A: Required Validation and Verification Characteristics*, applicable Validation characteristics may include Accuracy, Precision, Specificity or Selectivity, Limit of Detection, Limit of Quantification, Linearity or suitability of the Calibration model, Range, Robustness, prevention of Carryover, Intermediate Precision, and other performance characteristics necessary to demonstrate fitness for purpose.
 3. Validation shall include each Commission-approved Matrix for which the Analytical Method is intended to be used, or the Independent Testing Laboratory shall document a scientifically justified basis for demonstrating that Validation performed using one or more Matrices is representative of the other Matrices within the intended scope of the Analytical Method.
 4. Validation shall evaluate the applicable concentration and reporting Range and other conditions representative of the intended application.
- (d) Validation Report.
1. An Independent Testing Laboratory shall maintain a Validation report documenting the completed Validation study.
 2. The Validation report shall include the following, at a minimum:
 - a. Identification of the Analytical Method and version;
 - b. Reference to the approved Validation protocol;
 - c. The intended use and scope of the Validation;
 - d. The performance characteristics evaluated;
 - e. The predefined acceptance criteria;
 - f. A summary of the experimental data and applicable calculations;
 - g. Evaluation of the results against the predefined acceptance criteria;
 - h. Identification and evaluation of deviations, nonconforming results, or other limitations affecting the Validation;
 - i. Identification of any restrictions or limitations on the use of the Analytical Method;
 - j. A documented conclusion as to whether the Analytical Method has been demonstrated to be fit for its intended use; and
 - k. Any other information required by the Commission.
 3. The Validation report shall be reviewed and approved by an authorized Laboratory Agent of the Independent Testing Laboratory before the Analytical Method is used for regulatory compliance testing as required by 935 CMR 503.160.
- (e) Verification of Established Methods.
1. An established Analytical Method shall be verified when required to demonstrate suitability under an Independent Testing Laboratory's actual conditions of use.
 2. Verification shall evaluate the performance characteristics necessary to demonstrate that an Independent Testing Laboratory can properly perform the Analytical Method and obtain results meeting the established requirements.
 3. Verification shall be documented and shall include predefined acceptance criteria and a documented conclusion regarding suitability for the intended use.
 4. Verification shall not be used by an Independent Testing Laboratory as a substitute for Validation when the Analytical Method is laboratory-developed, modified, non-standard, or used outside of its established scope in a manner requiring Validation.
- (f) Method Changes and Validation.
1. Changes to a validated or verified Analytical Method, equipment, software, materials, critical reagents, Sample Matrix, analytical Range, Matrix Interference, or other conditions that may affect method performance shall be evaluated prior to implementation.
 2. An Independent Testing Laboratory shall determine and document whether the change requires Verification or Validation, with the scope of Validation based on the nature and potential impact of the change.
 3. The addition of a new Analyte to an existing validated Analytical Method does not require full re-Validation of such method, provided that the specific characteristics stated in 935 CMR 503.105(6)(g) and *Table A: Required Validation and Verification Characteristics*, as applicable, are validated for the newly added Analyte(s).
 4. The addition of a new Analyte to an existing verified Analytical Method does not require full re-Verification of such method, provided that the specific characteristics stated in 935 CMR 503.105(6)(g) and *Table A: Required Validation and Verification Characteristics* are verified for the new Analyte(s).

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(g). *Table A: Required Validation and Verification Characteristics* contains the Validation and Verification performance characteristics required for each assay type:

Table A: Required Validation and Verification Characteristics.

Method category	Required Validation and Verification Characteristics
Chromatographic quantitative methods — HPLC, UHPLC, GC	Specificity/Selectivity; Accuracy; Precision; Linearity/Response Model; Range; LOD; LOQ; Recovery; Carryover; Robustness; System Suitability
Chromatographic qualitative methods	Specificity/Selectivity; Detection Capability; Precision; Robustness; System Suitability
Mass spectrometric quantitative methods — LC-MS/MS, GC-MS, HRMS	Specificity/Selectivity; Accuracy; Precision; Linearity/Response Model; Range; LOD; LOQ; Recovery; Matrix Effects; Carryover; Stability; Robustness; System Suitability
Mass spectrometric qualitative identification methods	Specificity/Selectivity; Detection Capability; identification criteria; Precision; Matrix Effects; Carryover; Robustness; System Suitability
Elemental analysis — ICP-MS, ICP-OES, AAS	Specificity/Selectivity; Accuracy; Precision; Linearity/Response Model; Range; LOD; LOQ; Interference assessment; Recovery; Robustness; System Suitability
UV-Vis / spectrophotometric quantitative methods	Specificity/Selectivity; Accuracy; Precision; Linearity/Response Model; Range; LOD; LOQ; Robustness; System Suitability
FTIR / NIR identification methods	Specificity/Selectivity; Identification Capability; Precision; Robustness; System Suitability
Microbiological enumeration methods	Specificity; Accuracy; Precision; Detection Capability; quantitation capability; Range; Recovery; Repeatability; Reproducibility; media suitability; method suitability; Robustness
Microbiological detection methods	Specificity; Detection Capability; false-positive/false-negative assessment; Recovery; Precision; method suitability; Robustness
Titrimetric methods	Accuracy; Precision; Specificity; Range; Robustness; System Suitability
Physical/chemical measurement methods — pH, water activity, moisture, density, viscosity, etc.	Accuracy; Precision; Range; Measurement Capability; Robustness; equipment suitability

(7) Quality Control.

(a) Each quantitative Analytical Method used for regulatory compliance testing as required by 935 CMR 503.160 shall include Quality Control measures appropriate to the method, Matrix, Analytes, and intended use, and as set forth in *Table B: Minimum Quality Control Element*.

Table B: Minimum Quality Control Element.

Minimum QC element	Mass Spectrometry	Chromatography without Mass Spectrometry	Microbial Contaminant Testing	Water Activity	Moisture Content
Calibration / instrument Verification	Required	Required	As applicable to quantitative instruments	Certified standards or verified calibration salts	Method-appropriate calibration or verification
Continuing Calibration Verification (CCV)	Required for quantitative runs	Required for quantitative runs	N/A	Daily verification before Analysis Batches	Daily verification before Analysis Batches

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Control Charting	Required for designated quantitative QC results	Required for designated quantitative QC results	Required for appropriate quantitative controls	Required for designated quantitative QC results	Required for designated quantitative QC results
Positive control	Analyte-containing control or equivalent	Analyte-containing control or equivalent	Required for applicable detection and identification procedures	N/A	N/A
Negative control	Method/reagent blank, as appropriate	Method/reagent blank, as appropriate	Required where applicable to detect contamination or false-positive results	N/A	N/A
Blanks	Method and/or solvent blanks as appropriate	Method and/or solvent blanks as appropriate	Sterility and process blanks as applicable	N/A	N/A
Matrix spike / recovery	Required where applicable to validate recovery and matrix effects	Required where applicable to validate recovery and matrix effects	Matrix suitability, inhibition, or recovery control as applicable	N/A	N/A
Duplicate testing	At least 5% of compliance-based Samples	At least 5% of compliance-based Samples	At least 5% of compliance-based samples, with method-appropriate agreement criteria	At least 5% of compliance-based Samples	At least 5% of compliance-based Samples
Documented acceptance criteria	Required	Required	Required	Required	Required
Failed QC disposition	Investigate; reject affected results when validity is not established	Investigate; reject affected results when validity is not established	Investigate; reject affected results when validity is not established	Investigate; reject affected results when validity is not established	Investigate; reject affected results when validity is not established

(b) Quality Control Acceptance Criteria.

1. An Independent Testing Laboratory shall establish and document acceptance criteria for applicable Quality Control measures.
2. Quality Control measures shall be evaluated by an Independent Testing Laboratory against established acceptance criteria as part of the analytical process. Trending control charts shall be maintained to monitor ongoing consistency, including but not limited to the Accuracy and Precision of the method. Control charting may include trending Continuing Calibration Verification (CCV) standards.
3. An Independent Testing Laboratory shall not report regulatory compliance test results as required by 935 CMR 503.160 from an analytical sequence unless all Calibration, Calibration Verification, and applicable System Suitability requirements mandated by the validated Analytical Method have been successfully completed and documented by the Independent Testing Laboratory, provided, however, that data generated prior to successful completion of such requirements may be reported as Commission-required analytical results if the approved Analytical Method expressly permits the use of such data and establishes criteria for demonstrating their validity.
4. Quantitative results shall be determined only within the validated Calibration Range of the Analytical Method. Analytical results obtained outside the validated Calibration Range shall not be reported as quantitative results unless the Sample is appropriately prepared and reanalyzed within the validated Calibration Range.

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- (c) Quality Control Failures. An Independent Testing Laboratory shall establish and maintain Standard Operating Procedures for:
1. Identifying and documenting Quality Control failures;
 2. Assessing the potential impact of Quality Control failures on analytical results;
 3. Determining whether affected results remain valid and may be reported;
 4. Taking corrective action, including following Corrective and Preventive Action; and
 5. Documenting the assessment, disposition, and Corrective and Preventive Action.
- (d) Quality Assurance and Performance Monitoring.
1. An Independent Testing Laboratory shall monitor analytical performance and identify trends, recurring conditions, or other factors that could affect the validity of analytical results.
 2. An Independent Testing Laboratory shall evaluate identified trends or conditions and take appropriate action to maintain the validity and reliability of analytical results.
- (8) Proficiency Testing and Interlaboratory Comparisons.
- (a) An Independent Testing Laboratory shall participate in blind Proficiency Testing at least annually for regulatory compliance testing as required by 935 CMR 503.160 for which Proficiency Testing is available and applicable to the Matrix tested by the Independent Testing Laboratory.
- (b) Tests requiring yearly Proficiency Testing shall include at minimum, but are not limited to:
1. Cannabinoid Profile (to include Delta-9-tetrahydrocannabinol (Δ 9-THC), Tetrahydrocannabinolic acid (Δ 9-THCA), and Cannabidiol (CBD));
 2. Microbial characterization.
 3. Mycotoxins;
 4. Residual Solvents and processing materials;
 5. Pesticides residues and Plant Growth Regulators;
 6. Water activity; and
 7. Moisture.
- (c) Proficiency Testing shall consist of either test-specific proficiency samples or appropriate characterized materials evaluated using applicable analytical assays.
- (d) Cannabis or hemp Matrices shall be selected over simple solution-based proficiency Samples when an appropriate Matrix is available.
- (e) Failure to obtain an acceptable Proficiency Testing result for an Analyte subject to regulatory compliance testing as required by 935 CMR 503.160 shall require documented investigation and corrective action by the Independent Testing Laboratory.
- (f) Interlaboratory Comparison. The Commission may initiate blind interlaboratory comparisons, comparative testing, or retesting to evaluate consistency of analytical results among Independent Testing Laboratories.
1. Commission-directed comparisons may involve a single analytical test, Analyte, Matrix, or a full testing panel and may be conducted without advance notice.
 2. The Commission may engage qualified third-party laboratories, reference laboratories, standards laboratories, Proficiency Testing providers, or other qualified and appropriate external entities to generate comparative results.
- (9) Data Integrity and Review.
- (a) Data Integrity.
1. An Independent Testing Laboratory shall retain original analytical data and associated Metadata necessary to reconstruct the acquisition, processing, evaluation, and reporting of each analytical result required by 935 CMR 503.000.
 2. An Independent Testing Laboratory's original data shall not be overwritten, deleted, or replaced or obscured in a manner that prevents reconstruction of the original analytical result or the changes subsequently made to the data.
- (b) Data Review.
1. An Independent Testing Laboratory's analytical data and records shall be complete, accurate, attributable, Traceable, and protected from unauthorized alteration, deletion, or substitution.
 2. Technical and Quality Review. An Independent Testing Laboratory's documented review shall evaluate, as applicable to the analytical activity, whether:
 - a. The applicable Analytical Method requirements were followed;
 - b. Quality Control requirements and acceptance criteria were met;
 - c. Calculations and data processing are correct;
 - d. The analytical data and records are complete;

- e. Deviations or other nonconforming conditions were identified and appropriately evaluated; and
 - f. The reported analytical result corresponds to the underlying analytical data.
- (c) Manual Integration and Data Processing.
- 1. Manual integration or manual alteration of chromatographic or mass spectrometric data by an Independent Testing Laboratory used to generate a reported analytical result is prohibited, except when necessary to correct a previously documented software processing error or address a demonstrated instrument or software issue, and such documentation shall be made available to the Commission upon request.
 - 2. Any manual integration or manual alteration of chromatographic or mass spectrometric data by an Independent Testing Laboratory shall be scientifically justified, performed in accordance with a Standard Operating Procedure, retain the original unaltered data, and be subject to documented internal review and authorization by Laboratory Agents authorized to perform such review prior to reporting the result.
 - 3. Peaks that are below the established Limit of Quantification (LOQ), below the lowest Calibration level, or otherwise insufficient in size or quality for reliable integration shall not be manually integrated or reported as quantitative results unless the Analytical Method specifically provides for such reporting.
- (d) Dilutions. Any dilution or Dilution Factor used by an Independent Testing Laboratory in Sample preparation or analysis shall be specified in, or supported by, the approved Analytical Method or a documented and scientifically justified procedure. The dilution or concentration factor applied to each Sample shall be recorded and Traceable to the reported analytical result.
- (e) Calibration Models.
- 1. An Independent Testing Laboratory shall maintain records sufficient to identify the Calibration model, Calibration standards, instrument method, data-processing method, and other applicable analytical parameters used to generate each reported analytical result.
 - 2. An Independent Testing Laboratory shall ensure that Calibration models and analytical processing parameters used for regulatory compliance testing as required by 935 CMR 503.160 are controlled and consistent with the approved Analytical Method and validated application.
 - 3. An Independent Testing Laboratory shall utilize linear Calibration for chromatographic and mass spectrometric quantitative methods unless a nonlinear Calibration model is demonstrated during method Validation to be appropriate for the intended analytical Range and to provide equivalent or improved performance. Any nonlinear Calibration model shall be scientifically justified, supported by method Validation, and specified in the approved Analytical Method.
- (10) Nonconforming Work and Corrective Action.
- (a) Nonconforming Work.
- 1. An Independent Testing Laboratory shall establish and maintain Standard Operating Procedures for identifying, documenting, evaluating, and controlling Nonconforming Work.
 - 2. Nonconforming Work shall be evaluated by an Independent Testing Laboratory to determine its significance and potential effect on the validity of analytical results.
- (b) Evaluation and Control of Nonconforming Work. When Nonconforming Work is identified, the Independent Testing Laboratory shall:
- 1. Assess the significance of the nonconformity;
 - 2. Determine whether the nonconformity may have affected the validity of analytical results;
 - 3. Take appropriate action to prevent the use or reporting of affected analytical results until their validity has been evaluated; and
 - 4. Where necessary, correct, withdraw, or amend affected analytical results and notify affected parties, and notify the Commission no later than 48 hours after notifying affected parties.
- (c) Corrective and Preventive Action.
- 1. Where a nonconformity is determined to be significant or indicative of a recurring or systemic condition, the Independent Testing Laboratory shall implement a Corrective and Preventive Action appropriate to the nature and significance of the nonconformity.
 - 2. Corrective and Preventive Actions shall address, as appropriate:
 - a. The cause or contributing factors of the nonconformity;
 - b. Actions necessary to correct the nonconformity;
 - c. Actions necessary to prevent recurrence; and

- d. Evaluation of whether the corrective action was effective.
- (d) Effectiveness of Corrective and Preventive Action.
 - 1. An Independent Testing Laboratory shall evaluate the effectiveness of corrective action where corrective action has been implemented.
 - 2. The Independent Testing Laboratory's evaluation shall determine whether the corrective action addressed the identified cause or contributing factors and whether the nonconformity or its recurrence has been adequately controlled.
 - 3. Where corrective action is determined to be ineffective, the Independent Testing Laboratory shall take additional action appropriate to the significance of the nonconformity.
- (11) Records and Record Retention.
 - (a) General Requirements.
 - 1. An Independent Testing Laboratory shall establish and maintain records sufficient to demonstrate compliance with applicable Commission requirements set forth in 935 CMR 503.000, including but not limited to the validity, reliability, and Traceability of laboratory activities and analytical results.
 - 2. Records shall be complete, accurate, attributable, legible, contemporaneous, and readily retrievable during the required retention period, and shall be available for inspection by the Commission upon request.
 - (b) Technical Records.
 - 1. An Independent Testing Laboratory shall maintain technical records sufficient to support the reconstruction and evaluation of each analytical activity.
 - 2. Technical records shall include, as applicable:
 - a. Sample identification and receipt information;
 - b. The Analytical Method or procedure used;
 - c. The Laboratory Agent performing the analytical activity;
 - d. Equipment, instrumentation, and relevant software used;
 - e. Reference Materials, standards, reagents, and solutions used;
 - f. Raw Data and observations;
 - g. Calculations and data processing;
 - h. Quality Control results and acceptance determinations;
 - i. Deviations, Nonconforming Work, corrective actions, and associated evaluations;
 - j. Review and authorization of results; and
 - k. The reported analytical result.
 - (c) Original Records and Changes.
 - 1. Original records and Raw Data shall be retained by an Independent Testing Laboratory in a manner that preserves their integrity and Traceability.
 - 2. Corrections to records made by an Independent Testing Laboratory shall not overwrite, delete, or replace or obscure the original information or data. Corrections shall be attributable to the Laboratory Agent making the correction and shall include the date and the reason for the change.
 - 3. Electronic records shall be maintained by an Independent Testing Laboratory in a manner that preserves the original data, associated Metadata, and applicable Audit Trail information sufficient to identify and reconstruct any changes to the data. An Independent Testing Laboratory shall maintain the ability to access, retrieve, and interpret all electronic records, including Raw Data, throughout the retention period.
 - (d) Electronic Records.
 - 1. Electronic records and data systems used to generate, process, review, report, or retain analytical results shall be controlled by an Independent Testing Laboratory to protect against unauthorized access, alteration, loss, or deletion.
 - 2. An Independent Testing Laboratory shall maintain appropriate controls for user access, data security, backup, Recovery, and retention of electronic records.
 - 3. Electronic records shall remain accessible and readable through the retention period.
 - (e) Storage and Retrieval.
 - 1. Record shall be stored by an Independent Testing Laboratory under conditions that protect them from loss, damage, deterioration, unauthorized access, and unauthorized alteration.
 - 2. Records shall be indexed or otherwise organized by an Independent Testing Laboratory to permit timely retrieval.
 - 3. Access to records shall be limited to authorized Laboratory Agents and the Commission upon request.

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- iv. An Independent Testing Laboratory shall maintain Standard Operating Procedures for retrieval and disposition of records throughout the retention period.
- (f) Retention. Records required by 935 CMR 503.105(11) shall be retained for a minimum of five years.

503.119: Sampling, Collection, Storage, and Retention of Samples

- (1) General Requirements.
- (a) A Production Batch shall undergo Sampling in accordance with 935 CMR 503.119 and regulatory compliance testing in accordance with 935 CMR 503.160 prior to being offered for sale, dispensed, or otherwise marketed for adult use or medical use.
- (b) Required analyses shall be determined based on the Cannabis or Cannabis Product Sample type and corresponding regulatory compliance testing as required by 935 CMR 503.160 and as set forth in Exhibit A.
- (c) A Licensee shall identify a Cannabis or Cannabis Product Sample in the Seed-to-sale SOR as set forth in *Table C: Assigned Seed-to-sale SOR Product Name*:

Table C: Assigned Seed-to-sale SOR Product Name.

<u>Cannabis or Cannabis Product</u> <u>Sample Type</u>	<u>Product Name in</u> <u>Seed-to-sale SOR</u>
Flower (Product)	Buds
Concentrate (Final Product)	Concentrate
Concentrate (Ingredient), Vape Base Oil	Concentrate (Bulk)
Fresh-frozen Flower	Fresh Frozen Flower
Flower (for Extraction)	Immature Plants
Edibles	Infused (edible)
Topicals, Oromucosal or Sublinguals, powder, Oral Muscosal Ointments, pills or tablets, Rosin	Infused (non-edible)
Beverages	Infused Beverage
Liquid Ingredient, Tinctures, Emulsions	Infused Liquid (Bulk)
Pre-rolls with Added Distillate or Isolate	Infused Pre-Rolls
Kief	Kief
Pre-rolls, Solventless-infused Pre-rolls	Raw Pre-Rolls
Cannabis seeds	Seeds
Shake and Trim	Shake/Trim
Non-oral Muscosal Ointments and Lubricants, Suppositories	Suppository
Growth Soil/medium, Mother Plant, Public Water, Non-public Water, Root or Shoot of Plant	Tissue Culture
Vape Product	Vape Product
Solvent or water waste from Cannabis cultivation, processing, or manufacturing	Waste

- (d) Test Sample Packages shall be submitted to an Independent Testing Laboratory by the Licensee or retrieved by the Independent Testing Laboratory from the Licensee's Premises. All transfers of Test Sample Packages shall be documented and conducted in accordance with the requirements set forth in 935 CMR 503.119(2).
- (e) The Licensee shall collect and provide to an Independent Testing Laboratory a Representative Sample of the Product Batch requiring regulatory compliance testing in accordance with 935 CMR 503.160 in a quantity sufficient for all required analyses.
- For each Production Batch, a Licensee shall submit no less than 30 grams of flower and no less than 10 grams of any other material to an Independent Testing Laboratory.
 - An Independent Testing Laboratory shall handle and prepare Samples in a manner that preserves the integrity and required quantity of any Sample portion designated for microbiological or other specified testing.

- (2) Chain of Custody.
- (a) All Test Sample Packages submitted to an Independent Testing Laboratory shall be accompanied by the documentation required pursuant to 935 CMR 500.105(13):

*Transportation between Marijuana Establishment or 935 CMR 501.105(13):
Transportation Between Medical Marijuana Establishments, as applicable.*

(b) The Chain of Custody shall document, at a minimum, the identity of the Production Batch, Sample identification, Sample quantity, date and time of collection, identity of the collector, analyses required, transfer of custody, and receipt by an Independent Testing Laboratory.

(c) The Licensee and Independent Testing Laboratory shall maintain Chain of Custody records in accordance with applicable requirements set forth in 935 CMR 500.105(9): *Recordkeeping* and 935 CMR 503.105(11).

(3) Sampling.

(a) A Licensee shall collect all Samples required for regulatory compliance testing in accordance with the requirements of 935 CMR 503.000.

1. For cured and dried flower, a Licensee shall create a Test Sample Package which shall be made from each strain-specific post-harvest batch after trimming and drying. Post-harvest batches are limited to 15 pounds of dry weight flower, shake, or trim.

2. For Fresh-frozen Flower, a Licensee shall create a Test Sample Package which shall be made from up to 60 pounds of Fresh-frozen flower. A Seed-to-sale SOR tag may be assigned by the Licensee to Production Batches of up to 120 pounds.

(c) Samples collected by a Licensee shall be representative of the Production Batch from which they are collected.

(d) A Licensee's Sampling procedures shall account for the physical form, quantity, homogeneity, production process, packaging configuration, and distribution of the product within the Production Batch.

(e) Sampling by the Licensee shall include material from cultivation locations or manufacturing units sufficient to reasonably represent the Production Batch. Where appropriate, Samples shall be collected by the Licensee from multiple sublocations, containers, units, or portions of the Production Batch.

(f) Where Cannabis or a Cannabis Product can be homogenized without altering its composition or analytical characteristics, the Independent Testing Laboratory shall homogenize the Sample using an appropriate procedure prior to preparation of analytical proportions.

(g) Where homogenization is not practicable, the Licensee shall collect representative sub-Samples from divergent sublocations within the Production Batch and combine or otherwise prepare them as appropriate for the required analyses.

(h) A Licensee's Sampling procedures shall not alter the Cannabinoid Profile or concentration of contaminants in a manner that could affect the representativeness of the Sample.

(i) The minimum quantity of Sample collected by the Licensee shall be sufficient for all required analyses and applicable quality-control, confirmatory testing, and retention requirements.

(4) Sample Collection.

(a) Sample collection by the Licensee shall be conducted using procedures and equipment appropriate for the product type and required analyses.

(b) A Licensee shall ensure that sampling equipment and surfaces that contact Samples shall be clean and, where appropriate, decontaminated between Samples to prevent cross-contamination.

(c) Marijuana Establishment Agents collecting Samples shall use appropriate practices to prevent contamination, loss, degradation, or alteration of the Sample.

(d) Each Sample shall be assigned a unique sample identifier by the Licensee that can be Traced to the applicable Cultivation Batch or Production Batch.

(e) A Licensee shall document each sampling event, including, at a minimum:

1. The date and time of collection;
2. Identity of the collector;
3. Production Batch and applicable Cultivation Batch identification;
4. Product type;
5. Sample identification;
6. Sampling procedure used, the location within the licensed Premises where sampling occurred, and the sublocation within the batch from which the Sample or Sample increment was collected;
7. Quantity collected;
8. Required analyses;

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9. Any deviation, unusual condition, or circumstance that could affect Sample representativeness or analytical results; and
 10. Any other information required by the Commission.
- (f) Samples shall be transferred by the Licensee to an Independent Testing Laboratory in a manner that maintains Sample integrity and prevents contamination, degradation, loss, or unauthorized access.
- (5) Storage of Samples.
- (a) In addition to the requirements set forth in 935 CMR 500.119(11): *Storage Requirements*, and Independent Testing Laboratory shall comply with the storage requirements of 935 CMR 503.105(5).
 - (b) An Independent Testing Laboratory shall store Samples under conditions that maintain the identity, integrity, and representative composition of the Sample until analysis is completed.
 1. Samples shall be maintained by the Independent Testing Laboratory under conditions appropriate for the product Matrix and required analyses and in accordance with the applicable Independent Testing Laboratory's Sample receipt, storage, and analytical procedures.
 2. Samples shall be protected by an Independent Testing Laboratory from conditions that may cause degradation or alteration, including but not limited to excessive heat, light, moisture loss or gain, or contamination.
 - (c) Samples shall remain securely stored by an Independent Testing Laboratory and access shall be limited to authorized Laboratory Agents, agents of the Commission, Commission Delegees, and state and local law enforcement, regulatory, or public health authorities acting within their lawful jurisdictions and in the course of their official capacity.
 - (d) An Independent Testing Laboratory shall document Sample receipt and storage conditions in accordance with its Laboratory Quality Management System.
- (6) Retention of Samples.
- (a) An Independent Testing Laboratory shall retain a portion of each Sample following completion of initial regulatory compliance testing as required by 935 CMR 503.160 in an amount sufficient, where practicable, to permit additional required reanalysis, confirmatory testing, investigation, or other follow-up testing. Where retention of sufficient Sample material is not practicable, the basis shall be documented by the Independent Testing Laboratory.
 - (b) Retained Samples shall remain identifiable to the original Sample and Production Batch and shall be stored under conditions appropriate to maintain Sample integrity in accordance with 935 CMR 503.119(5).
 - (c) Retained Samples shall be maintained by an Independent Testing Laboratory for a minimum of thirty days.
 - (d) A Retained Sample shall not be disposed, destroyed, transferred, or otherwise removed from an Independent Testing Laboratory's control before expiration of the retention period, except as authorized by the Commission.
 - (e) An Independent Testing Laboratory shall maintain records documenting the disposal of Retained Samples in accordance with 935 CMR 500.105(9): *Recordkeeping*.

503.160: Required Testing

- (1) Cannabis and Cannabis Products shall satisfy all applicable regulatory compliance testing requirements under 935 CMR 503.000 prior to being offered for sale, dispensed, or otherwise marketed for adult use or medical use. Testing of Cannabis or Cannabis Products shall be performed by an Independent Testing Laboratory in accordance with M.G.L. c. 94G, § 15 and 935 CMR 503.000. Testing of environmental media, including but not limited to soils, solid growing media, and water, shall also be performed in compliance with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries published by the Commission.
- (2) Regulatory Compliance Testing and Subcontracting.
 - (a) A Licensee shall submit all Cannabis and Cannabis Test Sample Packages for the regulatory compliance testing required by 935 CMR 503.160 to a single Independent Testing Laboratory.
 - (b) An Originating Independent Testing Laboratory may subcontract certain regulatory compliance testing as required by 935 CMR 503.160 to another Independent Testing

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Laboratory only upon prior approval by the Commission, and subject to the following conditions:

1. The Commission may approve subcontracting only when the Originating Independent Testing Laboratory is unable to perform certain required regulatory compliance tests due to:
 - a. A hardship involving its facilities, instrumentation, personnel, or required consumable materials; or
 - b. An actual or potential conflict of interest.
 2. Prior to transferring any Test Sample Packages to another Independent Testing Laboratory, the Originating Independent Testing Laboratory shall submit a subcontracting approval form provided by the Commission specifying:
 - a. The proposed term of the subcontracting agreement;
 - b. The reasons subcontracting is necessary; and
 - c. The regulatory compliance testing services to be performed by the Subcontracted Independent Testing Laboratory.
 3. The Originating Independent Testing Laboratory shall obtain written approval from the Commission before transferring any Test Sample Packages to the Subcontracted Independent Testing Laboratory. Such approval shall be limited to a determination that the requirements of 935 CMR 503.160(2) have been satisfied and shall not constitute a determination of compliance with any other applicable statutory or regulatory requirements.
 4. The Originating Independent Testing Laboratory shall not subcontract with more than one Independent Testing Laboratory at a time. Any Subcontracted Independent Testing Laboratory shall have the capacity to perform the full panel of regulatory compliance testing as required by 935 CMR 503.160;
 5. The Originating Independent Testing Laboratory shall update any Standard Operating Procedures, as applicable, to reflect the subcontracting arrangement and notify the Commission of such updates in accordance with 935 CMR 503.105(1)(f); and
- (c) A Licensee shall not direct or require the Originating Independent Testing Laboratory to subcontract any regulatory compliance testing required by 935 CMR 503.160. The determination to seek subcontracting approval shall be made solely by the Originating Independent Testing Laboratory, subject to Commission approval in accordance with 935 CMR 503.160(2)(b).
- (d) A Licensee shall not create multiple Test Sample Packages from the same Cannabis or Cannabis Product source package for the purpose of conducting regulatory compliance testing, except as authorized by 935 CMR 503.000 or as required by the Commission to protect public health or safety.
- (3) The Independent Testing Laboratory that obtained the Test Sample Package shall complete all required testing and analyses for each Sample for regulatory compliance testing in accordance with 935 CMR 503.160.
- (4) All Sample increments collected by an Independent Testing Laboratory shall be homogenized for chemistry testing prior to Sample analyses, notwithstanding Foreign Organic Matter and materials testing. Subsampling is only permitted for microbial contaminant testing and water activity and moisture content testing, prior to homogenization.
- (5) The Independent Testing Laboratory shall analyze each Sample for the following:
- (a) Cannabinoid Profile;
 - (b) Terpenes profile;
 - (c) Microbial contaminants;
 - (d) Mycotoxins;
 - (e) Metals and trace elements;
 - (f) Pesticides residues and Plant Growth Regulators;
 - (g) Residual Solvents and processing chemicals;
 - (h) Water activity and moisture content;
 - (i) Foreign Organic Matter and materials; and
 - (j) Vitamin E Acetate, if applicable.
- (6) Any Sanitization Treatment of a Cultivation Batch or Production Batch shall be declared by a Licensee to the Independent Testing Laboratory performing testing of batch in a form and manner specified by the Commission.

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(7) Clones are subject to the regulatory compliance testing requirements set forth in 935 CMR 503.160, but are exempt from testing required at 935 CMR 503.160(9)(e) for metals and trace elements.

(8) The Commission may, at its discretion, require additional testing or analyses where necessitated to safeguard public health or public safety and so identified by the Commission. A Licensee may be required by the Commission to submit Samples for additional testing, including testing on Analytes that are not listed in 935 CMR 503.160.

(9) Compliance Testing Standards and Action Limits.

(a) Cannabinoid Profile.

1. Testing for Cannabinoids is required for the following Cannabis and Cannabis Products and as set forth in Exhibit A:

*Policy Question to be considered at Public Meeting

2. Single-servings of Cannabis Products tested for potency in accordance with 935 CMR 500.150(4)(a) shall be subject to a potency variance of no greater than +/- 10%.

3. An Independent Testing Laboratory shall report the result of Cannabinoid Profile testing as set forth in 935 CMR 503.160(9)(a)5. and *Table D: Cannabinoid Profile* on the Certificate of Analysis as follows:

a. For ingestible Cannabis Products, an Independent Testing Laboratory shall report the results of Cannabinoid Profile testing at minimum as milligrams per serving weight.

b. For all other Cannabis, Cannabis Products, and ingredients, an Independent Testing Laboratory shall report the results of Cannabinoid Profile testing as wet weight-based percent.

4. Analytical Performance Requirement for Cannabinoid Profile Testing. An Independent Testing Laboratory shall comply with the following analytical performance requirements:

a. Analytes. The method shall be capable of independently identifying and quantifying Tetrahydrocannabinolic acid (Δ 9-THCA), Delta-9-tetrahydrocannabinol (Δ 9-THC), Cannabidiol (CBD), Cannabidiolic acid (CBDA), Cannabinol (CBN), and Delta-8-tetrahydrocannabinol (Δ 8-THC). Any cannabinoid for which a quantitative claim is made shall be included within the validated scope of the method and quantitatively determined.

b. Selectivity. The method shall demonstrate sufficient Selectivity to independently identify and quantify the Analytes specified in this Analytical Performance Requirement and to distinguish Delta-9-tetrahydrocannabinol (Δ 9-THC) from Delta-8-tetrahydrocannabinol (Δ 8-THC).

c. Accuracy. The method shall demonstrate a mean Recovery of 90 to 110% of the known concentration of the Analyte across the validated quantitative Range.

c. Precision. Relative standard deviation (RSD) shall not exceed 10% across the validated quantitative Range.

d. Matrix. The method shall be validated for each product Matrix for which the laboratory reports cannabinoid results.

5. An Independent Testing Laboratory shall test for the following Cannabinoids:

Table D: Cannabinoid Profile.

Cannabinoids
Tetrahydrocannabinol (THC) as Total THC
Total Cannabidiol (CBD) as Total CBD
Tetrahydrocannabinolic acid (Δ 9-THCA)
Delta-9-tetrahydrocannabinol (Δ 9-THC)
Cannabidiol (CBD)
Cannabidiolic acid (CBDA)
Cannabinol (CBN)
Delta-8-tetrahydrocannabinol (Δ 8-THC)

- vii. Total THC shall be calculated as the sum of Delta-9-tetrahydrocannabinol (Δ 9-THC) plus Tetrahydrocannabinolic acid (THCA) multiplied by 0.877 (Total THC = Δ 9-THC + (THCA x 0.877)).
- viii. Total CBD shall be calculated as the sum of Cannabidiol (CBD) plus Cannabidiolic acid (CBDA) multiplied by 0.877 (Total CBD = CBD + (CBDA x 0.877)).
- (b) Terpenes.
1. Testing for Terpene is required for the following Cannabis and Cannabis Products and as set forth in Exhibit A:

*Policy Question to be considered at Public Meeting

2. Testing for Terpenes is required for the following Cannabis Products and as set forth in Exhibit when Terpenes are added to the Cannabis Product or Terpenes claims are made by the Licensee:

*Policy Question to be considered at Public Meeting

3. An Independent Testing Laboratory shall report the result of Terpenes testing as set forth in 935 CMR 503.160(9)(b)5. and *Table E: Terpenes Profile* in wet weight-based percent on the Certificate of Analysis.

4. Analytical Performance Requirement for Terpenes. An Independent Testing Laboratory shall comply with the following analytical performance requirements:

- a. Analytes. Any terpene or terpenoid for which a quantitative claim is made shall be included within the validated scope of the method and independently identified and quantitatively determined.
- b. Selectivity. The method shall demonstrate sufficient Selectivity to independently identify and quantify the terpenes and terpenoids included within the validated scope of the method and to distinguish those Analytes from other components that may interfere with measurement.
- c. Accuracy. The method shall demonstrate a mean Recovery of 80 to 120% of the known concentration of the Analyte.
- d. Precision. The method shall demonstrate a relative standard deviation (%RSD) of not more than 10%.

5. An Independent Testing Laboratory shall test for the following Terpenes at minimum:

Table E: Terpenes Profile.

Terpenes
α -Pinene
β -Myrcene
D-Limonene
Terpinolene
β -Caryophyllene

- (c) Microbial Contaminants.
1. Testing for microbial contaminants is required for the following Cannabis and Cannabis Products and Cannabis Products:

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- (d) Mycotoxins.
1. Testing for Mycotoxins is required for the following Cannabis and Cannabis Products and as set forth in Exhibit A:

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2. An Independent Testing Laboratory shall report the result of Mycotoxin testing in unit micrograms per kilograms (μ g/kg) on the Certificate of Analysis and indicate "pass" or "fail" on the Certificate of Analysis.
3. The Sample shall be deemed to have passed Mycotoxin testing if the total combined result of the five required Mycotoxins listed in 935 CMR 503.160(9)(d)5. and *Table F: Action Limits for Mycotoxins* is less than 20 μ g/kg.

4. Analytical Performance Requirement for Mycotoxin Testing. An Independent Testing Laboratory shall comply with the following analytical performance requirements:
- a. Analytes. The method shall be capable of identifying and quantitatively determining aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, and ochratoxin A. Total aflatoxins shall be calculated as the sum of aflatoxin B1, aflatoxin B2, aflatoxin G1, and aflatoxin G2.
 - b. Limit of Quantification. The method shall demonstrate a Limit of Quantification below the applicable regulatory action limit for each required Analyte.
 - c. Accuracy. The method shall demonstrate a mean Recovery of 80–120% of the known concentration of the Analyte.
 - d. Precision. The method shall demonstrate a relative standard deviation (%RSD) of not more than 10%.
5. An Independent Testing Laboratory shall conduct Mycotoxins testing in accordance with the action limits set forth in the following table:

Table F: Action Limits for Mycotoxins.

Analyte	Chemical Abstract Services (CAS) Registry Number	Adult use and Medical use Cannabis and Cannabis Product Action Limit (<)
		(µg/kg)
Total Aflatoxins:		20
• Aflatoxin B1	1162-65-8	
• Aflatoxin B2	7220-81-7	
• Aflatoxin G1	1165-39-5	
• Aflatoxin G2	7241-98-7	
Ochratoxin A	303-47-9	

- (e) Metals and Trace Elements.
1. Testing for metals and trace elements is required for the following Cannabis and Cannabis Products and as set forth in Exhibit A:
- *Policy Question to be considered at Public Meeting
2. An Independent Testing Laboratory shall report the result of the metals and trace elements test in unit micrograms per gram (µg/g) on the Certificate of Analysis and indicate “pass” or “fail” on the Certificate of Analysis.
3. The Sample shall be deemed to have passed testing for metals and trace elements if the presence of metals and trace elements do not exceed the applicable action limits listed in 935 CMR 503.160(9)(e)5. and *Table G: Action Limits for Metals and Trace Elements.* based upon the intended use of the Cannabis or Cannabis Product.
- a. For Cannabis and Cannabis Products intended for ingestion, the action limits specified for "Ingestion Use Only" shall apply.
 - b. For Cannabis or Cannabis Products intended for any other use, the action limits specified for "Non-Ingestion Use" shall apply.
4. Analytical Performance Requirements for Metals and Trace Elements.
- a. Analytes. The method shall be capable of quantitatively determining arsenic, cadmium, lead, and mercury at concentrations applicable to the regulatory action limits set forth at 935 CMR 503.160(9)(e)5. and *Table G: Action Limits for Metals and Trace Elements.*
 - b. Accuracy. The method shall demonstrate a mean Recovery of 80 to 120% of the known concentration of each Analyte.
 - c. Precision. The method shall demonstrate a relative standard deviation (%RSD) of not more than 10%.
 - d. Limit of Quantification. The method shall demonstrate a Limit of Quantification below the applicable regulatory action limit for each required Analyte set forth at 935 CMR 503.160(9)(e)5. and *Table G: Action Limits for Metals and Trace Elements.*

5. An Independent Testing Laboratory shall conduct metals and trace elements testing in accordance with the action limits set forth in the following table:

Table G: Action Limits for Metals and Trace Elements.

Analyte	Adult use and Medical use Cannabis and Cannabis Product Action Limit (≤)	
	(µg/kg)	
	Non-Ingestion Use	Ingestion Use
Arsenic (As) (total)	200	1500
Cadmium (Cd)	200	500
Lead (Pb)	500	1000
Mercury (Hg) (total)	100	1500

- (f) Pesticide Residues and Plant Growth Regulators.
1. Testing for residual Pesticides and Plant Growth Regulators is required for the following Cannabis and Cannabis Products and as set forth in Exhibit A:

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2. The Independent Testing Laboratory shall report the result of Pesticides residues and Plant Growth Regulator testing in parts per billion (ppb) on the Certificate of Analysis and indicate “pass” or “fail” on the Certificate of Analysis.
3. The Sample shall be deemed to have passed the residual Pesticides and Plant Growth Regulator testing if the presence of any Pesticide residue or Plant Growth Regulator listed in 935 CMR 503.160(9)(f)5. and *Table H: Action Limits for Pesticide Residues and Plant Growth Regulators* are not detected.
4. Analytical Performance Requirement for Pesticide Residues and Plant Growth Regulators. An Independent Testing Laboratory shall comply with the following analytical performance requirements:
- a. Analytes. The method shall be capable of identifying each pesticide and Plant Growth Regulator specified in this section.
 - b. Limit of Detection. The method shall demonstrate a Limit of Detection of not more than 10 ppb for each required Analyte.
 - c. Identification. The method shall establish and apply predefined, objective identification criteria for each Analyte. Identification criteria shall demonstrate that a detected analytical response is attributable to the target Analyte and is distinguishable from Matrix components, Interferences, and other substances that may produce a similar analytical response. Identification criteria shall include, as appropriate to the analytical technique, retention time, spectral or mass-spectral characteristics, ion transitions and ion ratios, or other scientifically justified characteristics established during method Validation.
 - d. Confirmation. A result shall not be reported as a detection unless all applicable Analyte identification criteria established during method Validation are met.
 - e. Accuracy. The method shall demonstrate a mean Recovery of 80 to 120% of the known concentration of the Analyte.
 - f. Precision. The method shall demonstrate a relative standard deviation (%RSD) of not more than 20%.
5. An Independent Testing Laboratory shall conduct testing for Pesticide residues and Plant Growth Regulators in accordance with the action limits set forth in the following table:

Table H: Action Limits for Pesticide Residues and Plant Growth Regulators.

Analyte	Adult use and Medical use Cannabis and Cannabis Product Action Limit	Limit of Detection (LOD)
		(ppb)

Bifenazate	Detected	≤10
Bifenthrin	Detected	
Cyfluthrin	Detected	
Etoxazole	Detected	
Imazalil	Detected	
Imidacloprid	Detected	
Myclobutanil	Detected	
Spiromesifen	Detected	
Trifloxystrobin	Detected	

(g) Residual Solvents and Processing Chemicals.

1. Testing for Residual Solvents and processing chemicals is required for the following Cannabis and Cannabis Products and as set forth in Exhibit A:

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2. Only chemicals listed in 935 CMR 503.160(9)(g)7. and *Table I: Action Limits for Residual Solvents and Processing Chemicals* and *Table J: Action Limits for Residual Levels of Propane, n-Butane, and Iso-Butane*. may be used as solvents in the production of Cannabis oil, provided, however, that Dichloromethane and trichloroethylene shall not be used in the production of Cannabis or Cannabis Products.

3. All solvents and processing chemicals used during the production of adult use or medical use Cannabis and Cannabis Products shall be declared by a Licensee to the Independent Testing Laboratory performing testing for the Licensee in a form and manner specified by the Commission.

4. An Independent Testing Laboratory shall report the results of the Residual Solvents and processing chemicals testing in unit parts per million (ppm) on the Certificate of Analysis and indicate "pass" or "fail" on the Certificate of Analysis.

5. The Sample shall be deemed to have passed the Residual Solvents and processing chemicals testing if the presence of any Residual Solvent or processing chemical is reported at or below the indicated action limits listed in 935 CMR 503.160(9)(g)7. and *Table I: Action Limits for Residual Solvents and Processing Chemicals* and *Table J: Action Limits for Residual Levels of Propane, n-Butane, and Iso-Butane*.

a. Notwithstanding subsection 935 CMR 503.160(9)(g)7., the limit for ethanol does not apply to ethanol majority based Tinctures or emulsions.

b. Notwithstanding 935 CMR 503.160(9)(g)7., the limit for ethanol or isopropyl alcohol does not apply to Cannabis Products that are topicals.

6. Analytical Performance Requirement for Residual Solvents and Processing Chemicals. An Independent Testing Laboratory shall comply with the following analytical performance requirements:

a. Analytes. The method shall be capable of identifying and quantitatively determining each Residual Solvent and processing chemical specified in 935 CMR 503.160(9)(g)7. and *Table I: Action Limits for Residual Solvents and Processing Chemicals* and *Table J: Action Limits for Residual Levels of Propane, n-Butane, and Iso-Butane*.

b. Limit of Quantification. The method shall demonstrate a Limit of Quantification sufficient to quantitatively determine each required Analyte at concentrations at or below the applicable regulatory action limits specified in 935 CMR 503.160(9)(g)7. and *Table I: Action Limits for Residual Solvents and Processing Chemicals* and *Table J: Action Limits for Residual Levels of Propane, n-Butane, and Iso-Butane*.

c. Identification. The method shall establish and apply predefined, objective identification criteria for each Analyte. Identification criteria shall demonstrate that a detected analytical response is attributable to the target Analyte and is distinguishable from Matrix components, other solvents, and other substances that may product a similar analytical response. Identification criteria shall include, as appropriate to the analytical technique, retention time, spectral or mass-spectral characteristics, or other scientifically justified characteristics established during method Validation.

d. Accuracy. The method shall demonstrate a mean recover of 80 to 120% of the known concentration of the Analyte.

e. Precision. The method shall demonstrate a relative standard deviation (%RSD) of not more than 10%.

f. System Suitability. The laboratory shall demonstrate that the analytical system meets the system suitability criteria established during method Validation before reporting results.

7. An Independent Testing Laboratory shall conduct Residual Solvents and processing chemicals testing in accordance with the action limits set forth in the following tables:

Table I: Action Limits for Residual Solvents and Processing Chemicals.

Analyte	Chemical Abstract Services (CAS) Registry Number	Adult use and Medical use Cannabis and Cannabis Product Action Limit (≤)
		(ppm)
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Butyl acetate	123-86-4	5000
Chloroform	67-66-3	60
Dichloromethane (methylene chloride)	75-09-2	600
Dimethyl sulfoxide	67-68-5	5000
Ethanol	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethyl ether	60-29-7	5000
Heptanes	142-82-5	5000
Hexanes	110-54-3	290
Isobutyl acetate	110-19-0	5000
Isopropyl acetate	108-21-4	5000
Methanol	67-56-1	3000
Methyl acetate	79-20-9	5000
Methylethyl ketone	78-93-3	5000
Methylisobutyl ketone	108-10-1	4500
Pentanes	109-66-0	5000
2-Propanol (isopropyl alcohol)	67-63-0	5000
Propyl acetate	109-60-4	5000
Toluene	108-88-3	890
Trichloroethylene (1,1,2-trichloroethene)	79-01-6	80
Xylenes	1330-20-7	2170

Table J: Action Limits for Residual Levels of Propane, n-Butane, and Iso-Butane.

Analyte	Chemical Abstract Services (CAS) Registry Number	Adult use and Medical use Cannabis and Cannabis Product Action Limit (≤)	
		(ppm)	
		Inhalation	Non-Inhalation
Propane	74-98-6	2100	5000
n-Butane	106-97-8	800	5000
Iso-Butane	75-28-5	800	5000

a. The ingredients in the solvents listed in 935 CMR 503.160(9)(g)7. and *Table J: Action Limits for Residual Levels of Propane, n-Butane, and Iso-Butane*. shall be of purity suitable for use in food intended for human consumption. At a minimum, the solvent must be high-purity (>99%) of propane, n-butane, or iso-butane, or a blend these three hydrocarbon gases.

(h) Water Activity and Moisture Content.

1. Testing for water activity and moisture content is required for the following Cannabis and Cannabis Products and as set forth in Exhibit A:

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2. The Independent Testing Laboratory shall analyze the Representative Sample of dried flower to determine the level of water activity and the percentage of moisture content for each test.

a. The dried flower Sample, including Pre-rolls, shall be deemed to have passed water activity testing if the water activity does not exceed 0.65 Aw and 15% moisture content.

b. A solid Edible Cannabis Product shall be deemed to have passed water activity testing if the water activity does not exceed 0.85 Aw.

3. The Independent Testing Laboratory shall report the result of the water activity and moisture content test on the Certificate of Analysis and indicate "pass" or "fail" on the Certificate of Analysis.

4. Analytical Performance Requirement for Moisture and Water Activity Testing. An Independent Testing Laboratory shall comply with the following analytical performance requirements:

a. Moisture. The method shall be capable of quantitatively determining moisture content at concentrations applicable to the regulatory action limit specified in 935 CMR 503.160(9)(h)5. and *Table K: Action Limits for Water Activity and Moisture Content.*

b. Moisture Analyzer. Laboratories using a gravimetric moisture analyzer shall use a drying temperature not exceeding 105 °C.

c. Moisture Analyzer Performance Verification. Laboratories using a gravimetric moisture analyzer shall verify instrument performance using a suitable moisture control material with an assigned value established for the specified drying temperature, such as sodium tartrate dihydrate. The measured moisture content shall be within ±10% of the assigned value.

d. Karl Fischer Titration. Independent Testing Laboratories using Karl Fischer titration shall verify instrument performance using an appropriate certified water standard with a concentration representative of the intended measurement Range, such as a 10% water standard. The measured value shall be within ±10% of the assigned value.

e. Water Activity. The method shall be capable of quantitatively determining water activity at concentrations applicable to the regulatory action limit specified in 935 CMR 503.160(9)(h)5. and *Table K: Action Limits for Water Activity and Moisture Content.*

f. Water Activity Performance Verification. Independent Testing Laboratories measuring water activity shall verify instrument performance using an appropriate certified water activity standard with an assigned value representative of the applicable measurement Range. The measured value shall be within ±10% of the assigned value.

g. Performance Verification. The applicable performance Verification shall be successfully completed before reporting analytical results.

5. An Independent Testing Laboratory shall conduct testing for water activity and moisture content in accordance with the action limits set forth in the following table:

Table K: Action Limits for Water Activity and Moisture Content.

Water Activity and Moisture Content	Adult use and Medical use Cannabis and Cannabis Product Action Limit (≤)
	(Aw)
Flower (Product) and Pre-rolls	0.65
Solid Edibles	0.85
Flower (Product) and Pre-rolls	15% Moisture

(i) Foreign Organic Matter and Materials.

1. Visual inspection for Foreign Organic Matter and materials is required for the following Cannabis and Cannabis Products and as set forth in Exhibit A:

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- 2. An Independent Testing Laboratory shall visually examine a minimum of 20 grams of the Representative Sample of Cannabis or Cannabis Products for the presence of Foreign Organic Matter and materials, including visible mold, mildew, or other fungal growth.
- 3. An Independent Testing Laboratory shall report the result of the Foreign Organic Matter and materials inspection by indicating “pass” or “fail” on the Certificate of Analysis.
- 4. An Independent Testing Laboratory shall perform Foreign Organic Matter and materials inspection on the total Representative Sample prior to Sample homogenization.
- 5. An Independent Testing Laboratory shall photograph the Sample at the time of visual inspection for Foreign Organic Matter and materials testing, and shall perform the a visual inspection of the exterior and interior of the dried flower Sample.
- 6. An Sample shall be deemed to have passed the Foreign Organic Matter and materials inspection if the presence of Foreign Organic Matter and material does not exceed the limits in 935 CMR 503.160(9)(i)7. and *Table L: Action Limits for Foreign Organic Matter and Materials.*
- 7. An Independent Testing Laboratory shall conduct testing for Foreign Organic Matter and materials in accordance with the action limits set forth in the following table:

Table L: Action Limits for Foreign Organic Matter and Materials.

Foreign Organic Matter and Materials	Adult use and Medical use Cannabis and Cannabis Product Action Limit
Foreign Organic Matter, material or visible mold, mildew, or other fungal growth	None detected in the 20 g examination sample

(j) Vitamin E Acetate.

1. Testing for Vitamin E Acetate is required for the following Cannabis and Cannabis Products and as set forth in Exhibit A:

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- 2. An Independent Testing Laboratory shall report the result of the Vitamin E Acetate test in parts per million (ppm) on the Certificate of Analysis and indicate “pass” or “fail” on the Certificate of Analysis.
- 3. If the presence of Vitamin E Acetate is detected, the Test Sample Package is deemed noncompliant and the Independent Testing Laboratory shall report such results to Commission with 72 hours of detection.
- 4. Analytical Performance Requirement for Vitamin E Acetate Screening. An Independent Testing Laboratory shall comply with the following analytical performance requirements:
 - a. Analyte. The method shall be capable of identifying and quantitatively determining vitamin E acetate in applicable Cannabis Products specified in 935 CMR 503.160(9)(j)i.
 - b. Limit of Quantification. The method shall demonstrate a Limit of Quantification of not more than 100 ppm for vitamin E acetate.
 - c. Identification. The method shall establish and apply predefined, objective identification criteria demonstrating that a detected analytical response is attributable to vitamin E acetate and is distinguishable from Matrix components, Interferences, and other substances that may produce a similar analytical response. Identification criteria shall include, as appropriate to the analytical technique, retention time, spectral or mass-spectral characteristics, or other scientifically justified characteristics established during method Validation.

5. No Action Limit. Vitamin E acetate testing under 935 CMR 503.160(9)(j) is a screening requirement and does not establish a regulatory action limit for Vitamin E acetate.

503.165: Reporting of Results

(1) Reporting of Results Generally.

(a) An Independent Testing Laboratory shall report all testing and analytical results required by 935 CMR 503.160, including but not limited to initial results, failed results, results that do not meet applicable acceptance criteria or regulatory compliance limits specified in 935 CMR 503.160, and results obtained prior to any corrective action, reanalysis, or other subsequent testing or analysis. Such result shall be reported regardless of whether subsequent testing or analysis produces a passing or otherwise compliant result.

(b) An Independent Testing Laboratory shall simultaneously report results specified in 935 CMR 503.165(1)(a) and upload the corresponding Certificates of Analysis to the Seed-to-sale System of Record no later than 72 hours after completing the regulatory compliance testing required by 935 CMR 503.160.

(c) Certificate of Analysis Requirements. The Independent Testing Laboratory shall report the results of each analysis required by 935 CMR 503.160 on a Certificate of Analysis. At minimum, the Certificate of Analysis shall include the following:

1. General Independent Testing Laboratory Information.

- a. The Independent Testing Laboratory's name, address, and License number;
- b. The Sample ID assigned to the Sample by the Independent Testing Laboratory;
- c. The date the Certificate of Analysis is issued;

2. Licensee Information.

- a. The Licensee's name, address, and License number(s);
- b. The Seed-to-sale SOR transportation manifest number;
- c. The date the Test Sample Package was received by the Independent Testing Laboratory;

3. Sample Identification.

- a. The Seed-to-sale SOR Sample ID assigned to the Test Sample Package created by the Licensee;
- b. The Seed-to-sale SOR Source ID assigned to the Licensee's Production Batch;
- c. The Production Batch ID used by the Licensee;
- d. The Seed-to-sale SOR Production Batch ID used by the Licensee;

4. Sample Properties.

- a. The Sample size;
- b. The Matrix, and the physical description of the Sample;
- c. For Marijuana-infused Products, the serving size;
- d. The Sample condition, including a photograph of the Test Sample Package upon receipt by the Independent Testing Laboratory;
- e. An express statement whether the source Cultivation Batch or Production Batch was subjected to a Sanitization Treatment;
- f. An express statement whether the source Production Batch was Remediated prior to reanalysis, including the Remediation method used;

5. Cannabis or Cannabis Product Characterization.

- a. The Cannabis or Cannabis Product classification as reported by the Licensee in accordance with Exhibit A;
- b. The production stage, if known;
- c. The source package batch of the Cannabis or Cannabis Product;
- d. The intended route of consumption for the Cannabis or Cannabis Product (e.g. inhalation, ingestion), if known;
- e. The extraction solvent or chemical used to concentrate cannabinoids from flower, if applicable;

6. Test Types Run.

- a. The complete list of test or analyses performed by the Independent Testing Laboratory, specifying for each:
 - i. The Analytical Method used, including a reference to the applicable laboratory Standard Operating Procedure by its identifying number and a description of the analytical technique employed;
 - ii. The Limit of Detection, Limit of Quantification, and Measurement of Uncertainty for each Analyte;
 - iii. The date each test or analysis was performed; and

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- iv. The registration number of each Laboratory Agent who performed the test or analysis and each Laboratory Agent who oversaw such test or analysis;
- b. The results of each test or analysis performed, including:
 - i. The measured concentration for each Analyte detected in accordance with 935 CMR 503.160; and
 - ii. An express statement whether the Sample tested or analyzed has passed or failed the regulatory compliance testing requirements, in accordance with 935 CMR 503.160;
- c. A case narrative of the laboratory process and information related to the Sample, including notes and other statements of the Independent Testing Laboratory;
- d. ISO Accreditation Number; and
- e. The signature of a Laboratory Agent certifying under the pains and penalties of perjury that the report is complete and accurate.

(2) Reporting of Subcontracted Regulatory Compliance Test Results. Where regulatory compliance testing required by 935 CMR 503.160 is performed by a Subcontracted Independent Testing Laboratory pursuant to 935 CMR 503.160(2), the following requirements shall apply:

- (a) Notwithstanding the reporting timeframe established in 935 CMR 503.165(1)(b), the Originating Independent Testing Laboratory shall remain responsible for reporting all regulatory compliance test results as required by 935 CMR 503.160, 935 CMR 503.165.000, and 935 CMR 503.170.000 and uploading the corresponding Certificate of Analysis to the Seed-to-sale System of Record no later than 72 hours after the later of:
 - 1. Completion of the required testing or analyses performed by the Originating Independent Testing Laboratory; or
 - 2. Receipt of the results of the required testing or analyses performed by the Subcontracted Independent Testing Laboratory.
- (b) The Originating Independent Testing Laboratory shall be responsible for preparing the final Certificate of Analysis uploaded to the Seed-to-sale SOR, which shall include all regulatory compliance testing results as required by 935 CMR 503.160, 935 CMR 503.165.000, and 935 CMR 503.170.000. The Certificate of Analysis shall clearly identify each test or analysis performed by the Subcontracted Independent Testing Laboratory.
- (c) The Originating Independent Testing Laboratory shall establish and maintain a Standard Operating Procedure for reviewing results received from a Subcontracted Independent Testing Laboratory to verify conformance with applicable regulatory requirements, testing methods, and data quality criteria prior to incorporating such results into the final Certificate of Analysis.
- (d) The Subcontracted Independent Testing Laboratory shall report all regulatory compliance test results to the Originating Independent Testing Laboratory in accordance with the applicable requirements of ISO/IEC 17025:2017.

(3) Reporting of Non-Detects and Results Below Quantitation.

- (a) An Independent Testing Laboratory shall report an analytical result as "Not Detected" (ND) only when the Analyte is not detected by the applicable Analytical Method at or above the method's validated Detection Capability.
- (b) "Not Detected" shall not be reported by an Independent Testing Laboratory as, or interpreted as, a concentration of zero.
- (c) An Independent Testing Laboratory shall not report a result as "Not Detected" when the analytical data demonstrates the presence of the Analyte, but the concentration is below the method's validated quantitation limit. Such results shall be reported in a manner that clearly distinguishes them from both non-detects and quantitatively determined results.
- (d) An Independent Testing Laboratory shall not use "Not Detected" as a substitute for a result that is below a regulatory limit specified in 935 CMR 503.160, below a quantitation limit, outside the validated reporting Range, or otherwise not quantitatively reportable.
- (e) An Independent Testing Laboratory shall establish and document, in its Analytical Methods and reporting Standard Operating Procedures, the criteria used to distinguish between "Not Detected", results below the Limit of Quantification, and reportable quantitative results.

(4) An Independent Testing Laboratory shall maintain the results of all regulatory compliance testing required by 935 CMR 503.160 for no less than three years.

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(5) Test results shall be valid for a period of one year. Cannabis or Cannabis Products with test dates in excess of one year shall be deemed expired and may not be dispensed, sold, transferred, or otherwise converted or conveyed until such Cannabis or Cannabis Products have been retested.

503.170: Testing Failures: Repurposing, Reanalysis, and Remediation

(1) If a Sample fails a regulatory compliance test as required by 935 CMR 503.160, the Production Batch from which the Sample was collected fails for such regulatory compliance test and shall not be sold, transferred, or otherwise dispensed to Consumers or Patients without first being Repurposed, reanalyzed or Remediated in accordance with 935 CMR 503.170.

(2) Any Cannabis or Cannabis Product that may not undergo Repurposing as set forth in 935 CMR 503.170(5), reanalysis as set forth in 935 CMR 503.170(6), or Remediation as set forth in 935 CMR 503.170(7) may be subject to an Order of Destruction issued by the Commission at its discretion.

(3) Independent Testing Laboratories and Licensee shall establish and maintain a Standard Operating Procedure for responding to failures of regulatory compliance testing required by 935 CMR 503.160. Such procedures shall include, at a minimum, the following requirements:

- (a) Independent Testing Laboratories and Licensees shall each independently notify the Commission within 72 hours of receiving regulatory compliance test results indicating contamination for which Remediation is not permitted under 935 CMR 503.170(7).
- (b) Independent Testing Laboratories and Licensees shall each provide the Commission with any additional information concerning contamination or immediately upon request by the Commission.
- (c) The Licensee's notification to the Commission shall include a proposed plan for the destruction of the contaminated Cannabis or Cannabis Products and an assessment of the source of contamination.

(4) Repurposing, reanalysis, or Remediation of Cannabis or Cannabis Products that have failed regulatory compliance testing for Pesticide residues or Plant Growth Regulators as set forth in 935 CMR 503.160(9)(f) is prohibited. Any such test results indicating noncompliance with 935 CMR 503.160(f) shall be immediately reported by the Licensee and Independent Testing Laboratory to the Commission in accordance with 935 CMR 503.170(3), and the Commission shall refer any such result to the Department of Agricultural Resources, which has exclusive jurisdiction over Pesticides in accordance with M.G.L. c. 132B.

(5) Repurposing.

(a) Notwithstanding 935 CMR 503.170(1), a Licensee may repurpose Cannabis and Cannabis Products that have failed regulatory compliance testing as required by 935 CMR 503.160 for the production of other Final Form Cannabis Products, including but not limited to resins or concentrates, provided that the Cannabis or Cannabis Products have failed only the following regulatory compliance tests:

- 1. Cannabinoid Profile;
- 2. Microbial contaminants;
- 3. Residual Solvents and processing chemicals;
- 4. Water activity and moisture content; and
- 5. Foreign Organic Matter and materials.

(b) Repurposing shall not be used by a Licensee to circumvent regulatory compliance testing as required by 935 CMR 503.160, render an unacceptable material compliant through dilution, or authorize use of material that is prohibited from further processing.

(c) Final Form Cannabis Products that have been produced from repurposed Cannabis or Cannabis Products shall be tested and demonstrate compliance with the regulatory testing requirements set for in 935 CMR 503.160 prior to being sold, transferred, or otherwise dispensed to Consumers or Patients.

(6) Reanalysis.

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(7) Remediation.

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- (a) Remediation may be performed for Cannabis or Cannabis Products that have failed the following regulatory compliance testing requirements as required by 935 CMR 503.160:
1. Microbial contaminants;
 2. Mycotoxins;
 3. Metals and trace elements;
 4. Residual Solvents and processing chemicals; and
 5. Water activity and moisture content, provided, however that Edibles may not be Remediated.
- (b) Any Cannabis or Cannabis Products that have failed regulatory compliance testing as required by 935 CMR 503.160 may be Remediated, where authorized pursuant to 935 CMR 503.170(7)(a), no more than two times, subject to the following requirements.
1. A Licensee may treat Final Form Cannabis or Final Form Cannabis Products to reduce the concentration of metals, bacteria, fungus, or mycotoxins, provided, however, that such treatment shall not bind, mask, or otherwise interfere with the detection or quantification of such contaminants during regulatory compliance testing as required by 935 CMR 503.160 without reducing the actual concentration of the contaminants.
 2. A Licensee may Remediate Cannabis or Cannabis Products that fail regulatory compliance testing as required by 935 CMR 503.160, provided that such Remediation does not introduce or result in the formation of any toxic or harmful substances in the Cannabis or Cannabis Products.
 3. A Licensee shall Remediate the entire Production Batch from which the Sample was collected.
 4. Remediation solvents or methods used on the Cannabis or Cannabis Product shall be disclosed to the Independent Testing Laboratory performing the regulatory compliance testing as required in 935 CMR 503.160. Such information shall also be provided to the Commission upon request.
 5. The Licensee shall track and record all Remediation in the Seed-to-sale SOR. Such information shall include the following:
 - a. The date of Remediation;
 - b. The location where Remediation was performed;
 - c. The Remediation technique;
 - d. The name of all Marijuana Establishment Agents and Medical Marijuana Establishment Agents that performed the Remediation;
 - e. Any other information required by the Commission.
- (c) Cannabis or Cannabis Products that have been Remediated after failing regulatory compliance testing shall undergo and pass all regulatory compliance tests required by 935 CMR 503.160, subject to the following requirements:
1. A Licensee shall hold a Remediated Production Batch for a minimum of 5 calendar days following completion of Remediation before submitting a new Sample of such Production Batch to an Independent Testing Laboratory for regulatory compliance test as required by 935 CMR 503.160.
 2. The Licensee shall submit the new Sample to an Independent Testing Laboratory for full-panel regulatory compliance testing in accordance with 935 CMR 503.160. The Licensee may submit the Sample to the Originating Independent Testing Laboratory that reported the initial failed result or to a different Independent Testing Laboratory. The Independent Testing Laboratory shall perform full-panel regulatory compliance testing using an appropriately validated or verified Analytical Method in compliance with 935 CMR 503.105(6) and 935 CMR 503.160.
- (d) Any Cannabis or Cannabis Product that fails any regulatory compliance test as required by 935 CMR 503.160 after the second Remediation attempt and second reanalysis shall not be sold, transferred, or otherwise dispensed to Consumers or Patients and the Licensee shall destroy the Cannabis or Cannabis Products in accordance with 935 CMR 503.175.

503.175: Waste Management and Destruction

- (1) Cannabis Waste. Except as otherwise provided in 935 CMR 503.175(2), excess Cannabis or Cannabis Products remaining in the possession of an Independent Testing Laboratory shall be stored, secured, managed, and rendered unusable and disposed of in accordance with 935 CMR 500.105(12): *Waste Disposal* and 935 CMR 500.110: *Security Requirements for Marijuana Establishments*, as applicable. An Independent Testing Laboratory may return excess Cannabis or Cannabis Products to the Licensee for disposal or dispose of such Cannabis or Cannabis Products directly in accordance with the applicable regulatory requirements.

(2) Hazardous Waste. Hazardous waste generated through laboratory activities shall be identified, accumulated, stored, transported, treated, and disposed of by the Independent Testing Laboratory in accordance with applicable federal and state hazardous waste requirements, including but not limited to 310 CMR 30.000: *Hazardous Waste*. Nothing in 935 CMR 500.000: *Adult Use of Marijuana*, 935 CMR 501.000: *Medical Use of Marijuana*, or 935 CMR 503.000 shall be construed to authorize the management or disposal of hazardous waste in a manner inconsistent with applicable federal and state hazardous waste requirements.

(3) Cannabis and Cannabis Products that Fail Regulatory Compliance Testing. Cannabis and Cannabis Products that fail regulatory compliance testing as required by 935 CMR 503.160 shall be segregated by an Independent Testing Laboratory or Licensee from compliant Cannabis and Cannabis Products and stored, secured, and managed to prevent unauthorized use, sale, transfer, or distribution. Notwithstanding 935 CMR 500.105(12): *Waste Disposal*, such Cannabis or Cannabis Products shall not be disposed of by an Independent Testing Laboratory or a Licensee by grinding, shredding, or otherwise mechanically process such Cannabis or Cannabis Products. Any subsequent destruction or disposal shall otherwise comply with the requirements of 935 CMR 503.175(1) or 935 CMR 503.175(2), as applicable, and shall not interfere with any Commission investigation, sampling, inspection, or other regulatory oversight.

503.803: Suitability Standard for Registration as a Laboratory Agent

(1) 935 CMR 503.803 shall apply to Laboratory Agents in their capacity as employees or volunteers for an Independent Testing Laboratory licensed pursuant to 935 CMR 503.029 and shall be used by the Independent Testing Laboratory Executive registered with the DCJIS pursuant to 803 CMR 2.04: *iCORI Registration* and the Commission for purposes of determining suitability for registration as a Laboratory Agent with the Licensee.

(2) For purposes of determining suitability based on background checks performed in accordance with 935 CMR 503.029:

- (a) All conditions, offenses, and violations are construed to include Massachusetts law or similar law(s) of Other Jurisdictions.
- (b) All criminal disqualifying conditions, offenses, and violations include the crimes of attempt, accessory, conspiracy, and solicitation.
- (c) Juvenile dispositions shall not be considered as a factor for determining suitability.
- (d) Where applicable, all look back periods for criminal conditions, offenses, and violations included in 935 CMR 503.803 and *Table M* commence on the date of disposition; provided however, that if disposition results in incarceration in any institution, the look back period shall commence on release from incarceration.
- (e) Unless otherwise specified in 935 CMR 503.803: *Table M*, a criminal condition, offense or violation shall include both convictions, which include guilty pleas and pleas of nolo contendere, and dispositions resulting in continuances without a finding or other disposition constituting an admission to sufficient facts, but shall exclude other non-conviction dispositions.
- (f) All suitability determinations will be made in accordance with the procedures set forth in 935 CMR 500.800: *Suitability Standard for Licensure and Registration*. In addition to the requirements established in 935 CMR 500.800: *Suitability Standard for Licensure and Registration* shall:
 1. Consider whether offense(s) or information that would result in a Presumptive Negative Suitability Determination under 935 CMR 503.803: *Table M* renders the subject unsuitable for registration, regardless of the determination of the Licensee; and
 2. Consider appeals of determinations of unsuitability based on claims of erroneous information received as part of the background check during the application process in accordance with 803 CMR 2.17: *Requirement to Maintain a Secondary Dissemination Log* and 803 CMR 2.18: *Adverse Employment Decision Based on CORI or Other Types of Criminal History Information Received from a Source Other than the DCJIS*.

(3) Laboratory Agents shall remain suitable at all times a License or registration remains in effect. An individual subject to this section shall notify the Commission in writing of any charge or conviction of an offense that would result in a presumptive negative suitability determination or mandatory disqualification under 935 CMR 503.803: *Table A* within ten days of such individual's arrest or summons, and within ten days of the disposition on the merits of

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the underlying charge. Failure to make proper notification to the Commission may be grounds for disciplinary action. If the Commission lawfully finds a disqualifying event and the individual asserts that the record was sealed, the Commission may require the individual to provide proof from a court evidencing the sealing of the case.

(4) In accordance with M.G.L. c. 94G, § 15(b)(5), the Commission is prohibited from issuing a registration to a Laboratory Agent who has been convicted of a felony drug offense in the Commonwealth or Other Jurisdictions that would be a felony drug offense in the Commonwealth.

Table M: Registration as a Laboratory Agent. Applies solely to applicants for registration as a Laboratory Agent in accordance with 935 CMR 503.803 at an Independent Testing Laboratory licensed pursuant to 935 CMR 500.050: *Marijuana Establishments*, 935 CMR 500.103: *Licensure and Renewal*, and 935 CMR 503.050.

Time Period	Precipitating Issue	Result
Present (during time from start of application process through action on application or renewal).	Open/Unresolved Criminal Proceedings: Any outstanding or unresolved criminal proceeding, the disposition of which may result in a felony conviction under the laws of the Commonwealth or a similar law in Other Jurisdictions.	Mandatory Disqualification
Present	Open/Unresolved Marijuana Business-Related License Violations (Massachusetts or Other Jurisdictions): An outstanding or unresolved violation of the regulations as included in 935 CMR 500.000: <i>Adult Use of Marijuana</i> , 935 CMR 501.000: <i>Medical Use of Marijuana</i> , 935 CMR 503.000, or a similar statute or regulations in Other Jurisdictions that has either (a) remained unresolved for a period of six months or more; or (b) the nature of which would result in a determination of unsuitability for registration.	Presumptive Negative Suitability Determination
Present	Submission of Untruthful Information to the Commission Including, but Not Limited to: Submission of information in connection with an agent application, waiver request or other Commission action that is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure; or making statements during or in connection with a Commission inspection or investigation that are deceptive, misleading, false or fraudulent, or that tend to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure; or	Presumptive Negative Suitability Determination
Present	Open Professional or Occupational License Cases	Mandatory Disqualification
Indefinite	Felony Convictions in Massachusetts or Other Jurisdictions: For drug offenses or trafficking crimes under M.G.L. c. 94C, § 32E, or like crimes in Other	Mandatory Disqualification

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	Jurisdictions.	
Preceding Five Years	Felony Convictions or CWOFF in Massachusetts or Other Jurisdictions: For crimes of violence against a person, "violent crime" to be defined the same way as under M.G.L. c. 140, § 121 and M.G.L. c. 127, § 133E.	Presumptive Negative Suitability Determination
Preceding Seven Years	Felony Convictions or CWOFF in Massachusetts or Other Jurisdictions: For crimes of dishonesty or fraud.	Presumptive Negative Suitability Determination
Preceding Five Years	The applicant's or Licensee's prior actions posed or would likely pose a risk to the public health, safety, or welfare; and the risk posed by the applicant's or Licensee's actions relates or would likely relate to the operation of a Marijuana Establishment.	May make a Negative Suitability Determination in accordance with 935 CMR 500.800(8)

503.824: Effective Date and Compliance

On and after [DATE], an Independent Testing Laboratory shall conduct all activities in accordance with the applicable requirements of 935 CMR 503.000.

503.840: Non-conflict with Other Laws

Nothing in 935 CMR 503.000 shall be construed to limit the applicability of any other law as it pertains to the rights of landlords, employers, Law Enforcement Authorities, or regulatory agencies, except as otherwise provided in 935 CMR 503.000.

503.900: Severability

The provisions of 935 CMR 503.000 are severable. If a court of competent jurisdiction declares any section, subsection, paragraph, or provision unconstitutional or invalid, the validity of the remaining provisions shall not be affected.

REGULATORY AUTHORITY

935 CMR 503.000: M.G.L. c. 6, § 223, M.G.L. c. 94G, M.G.L. c. 94I, St. 2012, c. 369, St. 2016, c. 334, St. 2017, c. 55, St. 2022, c. 180, and St. 2026, c. 65.

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Exhibit A

*Policy Question to be considered at Public Meeting

Required Regulatory Compliance Testing Per Sample Type											
Cannabis or Cannabis Product Sample Type	Cannabinoids	Terpenes	Microbials	Mycotoxins	Metals	Solvents	Pesticides	Moisture	Water Activity	Vitamin E Acetate	Foreign Organic Matter and Materials
Flower (Product)											
Concentrate (Final Product)											
Concentrate (Ingredient), Vape Base Oil											
Fresh-frozen Flower											
Flower for Extraction											
Edibles											
Topicals, Oromucosal or Sublinguals, powder, Oral Muscosal Ointments, pills or tablets, Rosin											
Beverages											
Liquid Ingredient, Tinctures, Emulsions											
Pre-rolls with Added Distillate or Isolate											
Kief											
Pre-rolls, Solventless-infused Pre-rolls											
Shake and Trim											
Non-oral Muscosal Ointments or Lubricants, Suppositories											
Growth Soil and Medium, Mother Plant, Public Water, Non-public Water, Cannabis Root or Shoot of Plant											
Vape Product											

Exhibit B

Permissible Actions Following a Regulatory Compliance Testing Failure			
Regulatory Compliance Test Failure	Repurpose	Reanalyze	Remediate
Cannabinoid Profile	Yes	Yes*	No
Microbial Contaminants	Yes	Yes	Yes
Mycotoxins	No	Yes	No
Metals and Trace Elements	No	Yes	No
Pesticide Residues and Plant Growth Regulators	No**	No**	No**
Residual Solvents and Processing Chemicals	Yes	Yes	Yes
Water Activity	Yes	Yes	No
Moisture content	Yes	Yes	Yes
Foreign Organic Matter and Materials	Yes	No	Yes

*Authorized only when the Cannabis Product claim is greater than +/-10% of result.
**Pesticide residues and Plant Growth Regulator failures are subject to the exclusive jurisdiction of the Department of Agricultural Resources in accordance with M.G.L. c. 132B..