

## DEPARTMENT OF REVENUE

### Marijuana Enforcement Division

## COLORADO MARIJUANA RULES

### 1 CCR 212-3

*[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

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#### Part 1 – General Applicability

##### Basis and Purpose – 1-105

The statutory authority for this rule includes, but is not limited to, sections 44-10-102(3), 44-10-202(1)(c), and 44-10-701(2)(a), C.R.S. Unless such activity is authorized by the Colorado Constitution, article XVIII, Section 14 or Section 16, the Colorado Marijuana Code, section 25-1.5-106.5, C.R.S., or these rules, any Person who buys, Transfers, or acquires Regulated Marijuana outside the requirements of the Colorado Marijuana Code is engaging in illegal activity pursuant to Colorado law. This rule clarifies that those engaged in the business of possessing, cultivating, dispensing, Transferring, transporting, or testing Medical Marijuana or Retail Marijuana must be properly licensed to be in compliance with Colorado law. This Rule 1-105 was previously Rules M and R 101, 1 CCR 212-1 and 1 CCR 212-2.

##### 1-105 – Engaging in Business

- A. Except as authorized by the Colorado Constitution, article XVIII, sections 14 or 16, the Colorado Marijuana Code, or section 25-1.5-106.5, C.R.S., no person shall possess, cultivate, dispense, Transfer, transport, offer to sell, manufacture, or test Regulated Marijuana unless said person is duly licensed by the State Licensing Authority and approved by the relevant Local Jurisdiction(s) and/or licensed by the relevant Local Licensing Authority(-ies).
- B. Public Health Orders and Executive Orders.
  - 1. All Licensees, their agents, and their employees shall comply with any applicable public health orders issued by any agency of the State of Colorado including, but not limited to the Colorado Department of Public Health and Environment.
  - 2. All Licensees, their agents, and their employees, shall comply with any and all executive orders issued by the Governor pursuant to the Governor's disaster emergency powers under section 24-33.5-704, C.R.S.
  - 3. A violation of this Rule by a Licensee, or by any of the agents or employees of a Licensee, ~~is a license violation affecting public safety, which~~ may result in disciplinary action up to and including license revocation and summary suspension pursuant to sections 44-10-901(1), C.R.S. and 44-10-901(2), C.R.S., and these Rules.

##### Basis and Purpose – 1-115

The statutory authority for this rule includes, but is not limited to, sections 44-10-202(1)(c), 44-10-202(1)(j), and 44-10-103, C.R.S., and all of the Marijuana Code. The purpose of this rule is to provide necessary definitions of terms used throughout the rules. Defined terms are capitalized where they appear in the rules, to let the reader know to refer back to these definitions. When a term is used in a conventional sense, and is not intended to be a defined term, it is not capitalized. This Rule 1-115 was previously Rules M and R 103, 1 CCR 212-1 and 1 CCR 212-2.

### 1-115 – Definitions

Definitions. The following definitions of terms, in addition to those set forth in section 44-10-103, C.R.S., apply to all rules promulgated pursuant to the Marijuana Code, unless the context requires otherwise:

“Acceptability Criteria” means the specified limits placed on the characteristics of an item or method that are used to determine data quality.

“Audited Product” means a Regulated Marijuana Product with an intended use of: (1) metered dose nasal spray, (2) vaginal administration, or (3) rectal administration. Audited Product types may raise public health concerns requiring additional safeguards and oversight. These product types may only be manufactured and Transferred by a Medical Marijuana Products Manufacturer in strict compliance with Rule 5-325 or Retail Marijuana Products Manufacturer in strict compliance with Rule 6-325. Prior to the first Transfer of an Audited Product to a Medical Marijuana Store, Medical Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit, Retail Marijuana Store or Retail Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit, the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer shall submit to the Division and, if applicable, to the Local Licensing Authority or Local Jurisdiction an independent third-party audit verifying compliance with Rule 5-325 or Rule 6-325. All rules regarding Regulated Marijuana Product apply to Audited Product except where Rules 5-325, 6-325, 4-2154-115, 3-1010, and 3-1015 apply different requirements.

“Cannabinoid” means a class of lipophilic molecules that are naturally occurring in Cannabis sativa ~~any of the chemical compounds that are the active principles of marijuana.~~

“CBD” means cannabidiol.

“CBDA” means cannabidiolic acid.

“Certificate of Analysis” means an official document issued by a Regulated Marijuana Testing Facility that shows results of scientific tests performed on a product.

“Chain of Custody” or “COC” means the chronological documentation that records the sequence of custody, control, transfer, analysis, and disposal of a Test Batch.

“Commercially Reasonable Royalty” means a right to compensation in the form of a royalty payment for the use of intellectual property with a direct nexus to the cultivation, manufacture, Transfer or testing of Regulated Marijuana. A Commercially Reasonable Royalty must be limited to specific intellectual property the Commercially Reasonable

Royalty interest owns or is otherwise authorized to license or to a product or line of products. A Commercially Reasonable Royalty must not cause reasonable consumer confusion or violate any federal copyright, trademark or patent law or regulation will not be approved. To determine whether the Commercially Reasonable Royalty is reasonable, the Division will consider the totality of the circumstances, including but not limited to the following factors:

- a. The percentage of royalties received by the recipient for the licensing of the intellectual property.
- b. The rates paid by the Licensee for the use of other intellectual property.
- c. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the product may be sold.
- d. The licensor's established policy and marketing program to maintain an intellectual property monopoly by not licensing others or by granting licenses under special conditions designed to preserve that monopoly.
- e. The commercial relationship between the recipient and Licensee, such as, whether they are competitors in the same territory in the same line of business.
- f. The effect of selling the intellectual property in promoting sales of other products of the Licensee; the existing value of the intellectual property to the recipient as a generator of sales of ~~his~~their non-intellectual property items; and the extent of such derivative sales.
- g. The duration of the term of the license for use of the intellectual property.
- h. The established or projected profitability of the product made using the intellectual property; its commercial success; and its current popularity.
- i. The utility and advantages of the intellectual property over products or businesses without the intellectual property.
- j. The nature of the intellectual property; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the intellectual property.
- k. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the intellectual property.
- l. The portion of the realizable profit that should be credited to the intellectual property as distinguished from non-intellectual property elements, the manufacturing process, business risks, or significant features or improvements added by the Licensee.

"Controlling Beneficial Owner" or "CBO" means a Person that satisfies one or more of the following criteria:

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- a. A natural person, an Entity that is organized under the laws of and for which its principal place of business is located in one of the states or territories of the United States or District of Columbia, a trust, the trustee of a trust, a Publicly Traded Corporation, or a Qualified Private Fund that is not a Qualified Institutional Investor:
  - i. Acting alone or Acting ~~I~~in Concert, that owns or Acquires Beneficial Ownership of ten percent or more of the Owner's Interest of a Regulated Marijuana Business;
  - ii. That is an Affiliate that Controls a Regulated Marijuana Business and includes, without limitation, any Manager; or
  - iii. That is otherwise in a position to Control the Regulated Marijuana Business except as authorized in section 44-10-506 or 44-10-606, C.R.S.; or
- b. A Qualified Institutional Investor acting alone or Acting ~~I~~in Concert that owns or Acquires Beneficial Ownership of more than thirty percent of the Owner's Interest of a Regulated Marijuana Business.
- c. Unless the context otherwise requires, the defined term Controlling Beneficial Owner includes Direct Beneficial Interest Owner.

"Decontamination" means the process of neutralization or removal of dangerous substances or other contaminants from ~~R~~regulated ~~M~~marijuana without changing the product type of the Regulated Marijuana following a failed test.

"Designated Test Batch Collector" means an Owner Licensee or an Employee Licensee who has been designated by a Regulated Marijuana Business and completed training required by Rule ~~4-2254-110~~ to engage in Sample Increment Collection for the purpose of creating Test Batches.

"Disproportionate Impacted Area" means a census tract in the top 15th percentile for that state in at least two of the following categories as measured by the United States Census Bureau:

- a. the percent of residents in the census tract receiving public assistance;
- b. the percent of residents in the census tract falling below the federal poverty level;
- c. the percent of residents in the census tract failing to graduate from ~~H~~high ~~S~~school; and
- d. the percent of residents in the census tract who are unemployed.

~~"Edible Medical Marijuana Product" means any Medical Marijuana Product for which the intended use is oral consumption, including but not limited to, any type of food, drink, or pill.~~

"Edible Regulated Marijuana Product" means any Regulated Marijuana Product for which the intended use is oral consumption, including but not limited to, any type of food,

drink, or pill. "Medical Marijuana" or "Retail Marijuana" may be substituted for "Regulated Marijuana" when referring exclusively to either Edible Medical Marijuana Product or Edible Retail Marijuana Product.

~~"Edible Retail Marijuana Product" means any Retail Marijuana Product for which the intended use is oral consumption, including but not limited to, any type of food, drink, or pill.~~

~~"Food-Based Medical Marijuana Concentrate" means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of propylene glycol, glycerin, butter, olive oil, or other typical cooking fats.~~

"Food-Based Regulated Marijuana Concentrate" means a Regulated Marijuana Concentrate that was produced by extracting Cannabinoids from Regulated Marijuana through the use of propylene glycol, glycerin, butter, olive oil or other typical cooking fats. "Medical Marijuana" or "Retail Marijuana" may be substituted for "Regulated Marijuana" when referring exclusively to either Food-Based Medical Marijuana Concentrate or Food-Based Retail Marijuana Concentrate.

~~"Food-Based Retail Marijuana Concentrate" means a Retail Marijuana Concentrate that was produced by extracting Cannabinoids from Retail Marijuana through the use of propylene glycol, glycerin, butter, olive oil or other typical cooking fats.~~

"Genetic Material" means cannabis material used to propagate cannabis plants and includes:

- a. ~~Small amounts or fragments of the marijuana plant that are unusable and unrecognizable as marijuana or a consumable marijuana product that are~~Immature Plants containing a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent on a dry-weight basis;
  - i. ~~Intended for use for the purposes of propagation of plants in an artificial environment, also known as tissue culture; or~~
  - ii. ~~Intended for the purposes of genetic testing, such as a hop-latent viroid testing or plant sex testing.~~
- b. ~~Genetic Material does not mean~~Cannabis seeds;
  - i. ~~Immature Plants;~~
  - ii. ~~Marijuana seeds;~~
  - iii. ~~Marijuana plant material that is used for the extraction of cannabinoids or terpenes, or the production of any consumable product or ingredient;~~
  - iv. ~~Genetic Material not extracted directly from marijuana;~~
  - v. ~~Genetic Material derived from artificially genetically modified organisms;~~
  - vi. ~~Any substance derived from or intended for use in biosynthetic substances or processes.~~

- c. Tissue culture; and
- d. Small amounts of fragments of the cannabis plant containing a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent on a dry weight basis.

~~“Heat/Pressure-Based Medical Marijuana Concentrate” means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of heat and/or pressure. The method of extraction may be used by only a Medical Marijuana Products Manufacturer and can be used alone or on a Production Batch that also includes Physical Separation-Based Medical Marijuana Concentrate or Solvent-Based Medical Marijuana Concentrate.~~

“Heat/Pressure-Based Regulated Marijuana Concentrate” means a Regulated Marijuana Concentrate that was produced by extracting Cannabinoids from Regulated Marijuana through the use of heat and/or pressure. The method of extraction may be used by only a Regulated Marijuana Products Manufacturer and can be used alone or on a Production Batch that also includes Physical Separation-Based Medical Marijuana Concentrate, Physical Separation-Based Retail Marijuana Concentrate, or Solvent-Based Regulated Marijuana Concentrate. “Medical Marijuana” or “Retail Marijuana” may be substituted for “Regulated Marijuana” when referring exclusively to either Heat/Pressure-Based Medical Marijuana Concentrate or Heat/Pressure-Based Retail Marijuana Concentrate.

~~“Heat/Pressure-Based Retail Marijuana Concentrate” means Retail Marijuana Concentrate that was produced by extracting Cannabinoids from Retail Marijuana through the use of heat and/or pressure. This method of extraction may be used by only a Retail Marijuana Products Manufacturer and can be used alone or on a Production Batch that also includes Physical Separation-Based Retail Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate.~~

“Hemp” means the plant *Cannabis sativa* L. and any part of the plant, including the seeds of the plant and all derivatives, extracts, e~~C~~annabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent on a dry weight basis.

“Hemp Product” means a finished product that contains Hemp and that:

- a. Is a cosmetic, a dietary supplement, a food, a food additive, or an herb;
- b. Is intended for human use or consumption;
- c. Contains any part of the Hemp plant, including naturally occurring e~~C~~annabinoids, compounds, concentrates, extracts isolates, or resins;
- d. Is produced from Hemp;
- e. Contains no more than 1.75 milligrams of tetrahydrocannabinol (THC) per serving; and
- f. Contains a ratio of cannabidiol (CBD) to THC of greater than or equal to 15 to one (15:1).

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“Identification Badge” means a physical badge issued by the Division to ~~anya~~ natural person possessing an Owner License or Employee License, used to verify the identity and license status of the natural persons on the Licensed Premises of a Regulated Marijuana Business.

“Immature ~~p~~Plant” means a nonflowering marijuana plant that is no taller than ~~fifteeneight~~ inches and no wider than ~~fifteeneight~~ inches produced from a cutting, clipping or seedling, ~~and is in a cultivating container.~~

“Intoxicating Cannabinoid” means a ~~e~~Cannabinoid that is classified as an ~~i~~Intoxicating ~~e~~Cannabinoid in section 44-10-209, C.R.S., or by the State Licensing Authority by rule, in coordination with the Department of Public Health and Environment.

“Inventory Tracking System” means the required seed-to-sale tracking system that tracks Regulated Marijuana from either the seed or ~~i~~lmmature ~~p~~Plant stage until the Regulated Marijuana is sold to a patient at a Medical Marijuana Store or to a consumer at a Retail Marijuana Store, Transferred to a Medical Marijuana Testing Facility or Retail Marijuana Testing Facility, Transferred to a Sampling Manager, Transferred to an Industrial Fiber Products Producer, Transferred to a Pesticide Manufacturer, or destroyed by a Regulated Marijuana Business, or used in a Research Project by a Marijuana Research and Development Facility.

“Inventory Tracking System Trained Administrator” means an Owner Licensee of a Regulated Marijuana Business or an Employee Licensee employed by a Regulated Marijuana Business, each of whom has attended and successfully completed Inventory Tracking System training and has completed any additional training required by the Division.

“Kief” means a subset of Physical Separation-Based Marijuana Concentrate that consists of the resinous crystal-like trichomes that have been physically separated from Regulated Marijuana flower, shake, or trim that results in a higher concentration of ~~e~~Cannabinoids.

“License” means a ~~i~~License, permit, or registration pursuant to the Marijuana Code.

“Marijuana Hospitality Business” means a facility, which may be mobile, licensed to permit the consumption of marijuana pursuant to article 10; rules promulgated pursuant to article 10; and the provisions of an enacted, initiated, or referred ordinance or resolution of the local jurisdiction in which the ~~i~~Licensee operates.

“Material Change” means a change that the Licensee makes to their product’s design, cultivation process, or manufacturing process that a Licensee knows, or should reasonably know, could affect the product’s quality or ability to comply with the requirements set forth in these Rules including, but not limited to, intended use, testing, and product safety. This includes any change that would require a substantive revision to a Regulated Marijuana Business’s ~~S~~standard ~~O~~operating ~~P~~procedures. See Rule ~~4-120(F)(1) 4-230(K)~~ for additional examples of Material Change.

“Medical Marijuana” means marijuana that is grown, processed, and sold pursuant to the provisions of article 10 and for a purpose authorized by section 14 of article XVIII of the state constitution but shall not be considered a nonprescription drug for purposes of



section 12-42.5-102(21), C.R.S. or 39-26-717, C.R.S., or an over-the-counter medication for purposes of section 25.5-5-322, C.R.S. If the context requires, Medical Marijuana includes Medical Marijuana Concentrate and Medical Marijuana Products.

“Medical Marijuana Business Operator” means an Entity or Person that is not an owner and that is licensed to provide professional operational services to a Medical Marijuana Business for direct remuneration from the Medical Marijuana Business(es). A Medical Marijuana Business Operator is not, by virtue of its status as a Medical Marijuana Business Operator, a Controlling Beneficial Owner or a Passive Beneficial Owner of any Medical Marijuana Business it operates.

“Medical Marijuana Concentrate” means a subset of Medical Marijuana that is separated from the Medical Marijuana plant and results in matter with a higher concentration of Cannabinoids than naturally occur in the plant. Medical Marijuana Concentrate contains Cannabinoids and may contain terpenes and other chemicals that are naturally occurring in Medical Marijuana plants that have been separated from Medical Marijuana. Medical Marijuana Concentrate may also include residual amounts of the types of solvents, as permitted by the Marijuana Rules. The State Licensing Authority may further define by rule subcategories of Medical Marijuana Concentrate and authorize limited Ingredients based on the method of production of Medical Marijuana Concentrate. Unless the context otherwise requires, Medical Marijuana Concentrate is included when article 10 of the Colorado Revised Statutes refers to Medical Marijuana Product.

“Medical Marijuana Transporter” means an eEntity or Person licensed to transport Medical Marijuana and Medical Marijuana Products from one Medical Marijuana Business to another Medical Marijuana Business and to temporarily store the transported Medical Marijuana and Medical Marijuana Products at its Licensed Premises, but is not authorized to sell Medical Marijuana or Medical Marijuana Products under any circumstances.

“Microbial Control Step” means a post-harvest process that is intended to reduce the presence of microbial contaminant(s) in a Harvest Batch or Production Batch that is performed prior to testing consistently on all Harvest Batches or Production Batches of a particular type, strain, or intended use, as documented in the Regulated Marijuana Business’s Standard Operating Procedures.

“Penny Stock” means any equity security other than a Security:

- a. That is a National Market System stock, provided that:
  - i. The Security is registered, or approved for registration upon notice of issuance, on a national securities exchange that has been continuously registered as a national securities exchange since April 20, 1992; and the national securities exchange has maintained quantitative listing standards that are substantially similar to or stricter than those listing standards that were in place on that exchange on January 8, 2004; or



- ii. The Security is registered, or approved for registration upon notice of issuance, on a national securities exchange, or is listed, or approved for listing upon notice of issuance on, an automated quotation system sponsored by a registered national securities association, that:
  - A. Has established initial listing standards that meet or exceed the following criteria:
    - 1. The issuer shall have: (a) stockholders' equity of \$5,000,000; (b) market value of listed Securities of \$50 million for 90 consecutive days prior to applying for a listing (market value means the closing bid price multiplied by the number of Securities listed); or (c) net income of \$750,000 (excluding non-recurring items) in the most recently completed fiscal year or in two of the last three most recently completed fiscal years;
    - 2. The issuer shall have an operating history of at least one year or a market value of listed Securities of \$50 million (market value means the closing bid price multiplied by the number of Securities listed);
    - 3. The issuer's stock, common or preferred, shall have a minimum bid price of \$4 per share;
    - 4. In the case of common stock, there shall be at least 300 round lot holders of the Security (a round lot holder means a holder of a normal unit of trading);
    - 5. In the case of common stock, there shall be at least 1,000,000 publicly held shares and such shares shall have a market value of at least \$5 million (market value means the closing bid price multiplied by the number of publicly held shares, and shares held directly or indirectly by an officer or director of the issuer and by any Person who is the Beneficial Owner of more than 10 percent of the total shares outstanding are not considered to be publicly held);
    - 6. In the case of a convertible debt security, there shall be a principal amount outstanding of at least \$10 million;
    - 7. In the case of rights and warrants, there shall be at least 100,000 issued and the underlying security shall be registered on a national securities exchange or listed on an automated quotation

system sponsored by a registered national securities association and shall satisfy the requirements of paragraphs (a) or (e) of this definition;

8. In the case of put warrants (that is, instruments that grant the holder the right to sell to the issuing company a specified number of shares of the company's common stock, at a specified price until a specified period of time), there shall be at least 100,000 issued and the underlying Security shall be registered on a national securities exchange or listed on an automated quotation system sponsored by a registered national securities association and shall satisfy the requirements of paragraphs (a) or (e) of this definition;
  9. In the case of units (that is, two or more Securities traded together), all component parts shall be registered on a national securities exchange or listed on an automated quotation system sponsored by a registered national securities association and shall satisfy the requirements of paragraphs (a) or (e) of this definition; and
  10. In the case of equity Securities (other than common and preferred stock, convertible debt securities, rights and warrants, put warrants, or units), including hybrid products and derivative products, the national securities exchange or registered national securities association shall establish quantitative listing standards that are substantially similar to those found in paragraph (a)(ii) of this definition; and
- B. Has established quantitative continued listing standards that are reasonably related to the initial listing standards set forth in paragraph (a)(ii) of this definition, and that are consistent with the maintenance of fair and orderly markets;
- b. That is issued by an investment company registered under the Federal Investment Company Act of 1940;
  - c. That is a put or call option issued by the Options Clearing Corporation;
  - d. That has a price of five dollars (\$5.00) or more;
    - i. For purposes of this paragraph (d):

- A. A Security has a price of five dollars or more for a particular transaction if the Security is purchased or sold in that transaction at a price of five dollars or more, excluding any broker or dealer commission, commission equivalent, mark-up, or mark-down; and
  - B. Other than in connection with a particular transaction, a Security has a price of five dollars or more at a given time if the inside bid quotation is five dollars or more; provided, however, that if there is no such inside bid quotation, a Security has a price of five dollars or more at a given time if the average of three or more interdealer bid quotations at specified prices displayed at that time in an interdealer quotation system, by three or more market makers in the Security, is five dollars or more.
  - C. The term “inside bid quotation” shall mean the highest bid quotation for the Security displayed by a market maker in the Security on an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Federal Securities Exchange Act of 1934, or such other automated interdealer quotation system designated by the Federal Securities Exchange Commission for purposes of this definition, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotation for the Security at specified prices.
- ii. If a Security is a unit composed of one or more Securities, the unit price divided by the number of shares of the unit that are not warrants, options, rights, or similar Securities must be five dollars or more as determined in accordance with paragraph (d)(i), and any share of the unit that is a warrant, option, right, or similar security, or a convertible security, must have an exercise price or conversion price of five dollars or more;
- e. That is registered, or approved for registration upon notice of issuance, on a national securities exchange that makes transaction reports available provided that:
    - i. Price and volume of information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the national securities exchange;
    - ii. The Security is purchased or sold in a transaction that is effected on or through the facilities of the national securities exchange, or that is part of the distribution of the Security; and
    - iii. The Security satisfies the requirements of paragraphs (a)(i) or (a)(ii);

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- f. That is a security futures product listed on a national securities exchange or an automated quotation system sponsored by a registered national securities association; or
- g. Whose issuer has:
  - i. Net tangible assets in excess of \$2,000,000, if the issuer has been in continuous operation for at least three years, or \$5,000,000 if the issuer has been in continuous operation for less than three years; or
  - ii. Average revenue of at least \$6,000,000 for the last three years.

“Production Batch” means (a) any amount of Regulated Marijuana Concentrate of the same category and produced using the same extraction methods, ~~S~~standard ~~O~~perating ~~P~~rocedures and an identical group of Harvest Batch(es) of Medical Marijuana or Retail Marijuana; or (b) any amount of Regulated Marijuana Product of the same exact type, produced using the same Ingredients, ~~S~~standard ~~O~~perating ~~P~~rocedures, and the same Harvest Batch(es) of Harvested Marijuana (single strain or multiple strain) and/or Production Batch(es) of Regulated Marijuana Concentrate; or (c) any amount of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana of the same exact type, produced using the same ingredients, ~~S~~standard ~~O~~perating ~~P~~rocedures, and the same Harvest Batch(es) of Regulated Marijuana Concentrate.

“Professional Engineer” means a natural person who is licensed by the State of Colorado as a professional engineer pursuant to article 120 of title 12 of the Colorado Revised Statutes, sections 12-25-101 et seq., C.R.S.

“Proficiency Testing” means an assessment of the performance of a Medical Marijuana Testing Facility’s or Retail Marijuana Testing Facility’s methodology and processes. Proficiency Testing is also known as inter-laboratory comparison. The goal of Proficiency Testing is to ensure results are accurate, reproducible, and consistent.

“Propagation” means the reproduction of Regulated Marijuana plants ~~\_by seeds, cuttings, or grafting\_~~.

“Publicly Traded Corporation” means any Person other than an individual that is organized under the laws of and for which its principal place of business is located in one of the states or territories of the United States or District of Columbia or another country that authorizes the sale of marijuana that:

- a. Has a class of Securities registered pursuant to 15 U.S.C. sec. 77a et seq., that:
  - i. Constitutes Covered Securities; or
  - ii. Is qualified and quoted on the OTCQX or OTCQB tier of the OTC markets if:
    - A. The Person is then required to file reports and is filing reports on a current basis with the Federal Securities Exchange Commission pursuant to 15 U.S.C. sec. 78a et

seq., as if the Securities constituted Covered Securities;  
and

- B. The Person has established and is in compliance with corporate governance measures pursuant to corporate governance obligations imposed on Securities qualified and quoted on the OTCQX tier of the OTC markets.
- b. Is an Entity that has a class of Securities listed on the Canadian Securities Exchange, Toronto Stock Exchange, TSX Venture Exchange, or NEO Exchange, if:
  - i. The Entity constitutes a Foreign Private Issuer whose Securities are exempt from registration pursuant to 15 U.S.C. sec. 78a et seq., pursuant to 17 CFR 240.12g3-2; and
  - ii. The Entity has been, for the preceding three hundred sixty-five days or since the formation of the Entity, in compliance with all governance and reporting obligations imposed by the relevant exchange on such Entity; or
- c. Publicly Traded Corporation does not include:
  - i. An Ineligible Issuer, unless such Publicly Traded Corporation satisfies the definition of Ineligible Issuer solely because it is one or more of the following, and the Person is filing reports on a current basis with the Federal Securities and Exchange Commission pursuant to 15 U.S.C. sec. 78a et seq., as if the Securities constituted Covered Securities, and prior to becoming a Publicly Traded Corporation, the Person for at least two years was licensed by the State Licensing Authority as a Regulated Marijuana Business with a demonstrated history of operations in the state of Colorado, and during such time was not subject to suspension or revocation of the business license:
    - A. a Blank Check Company;
    - B. an issuer in an offering of Penny Stock; or
    - C. a Shell Company.
  - ii. A Person disqualified as a Bad Actor.

“Qualified Institutional Investor” means:

- a. A bank as defined in 15 U.S.C. sec. 78c (a)(6), if the bank is current in all applicable reporting and record-keeping requirements under such act and rules promulgated thereunder;
- b. A bank holding company as defined in 12 U.S.C. sec. 1841 (a)(1), if the bank holding company is registered and current in all applicable reporting

and record-keeping requirements under such act and rules promulgated thereunder;

- c. An insurance company as defined in 15 U.S.C. sec. 80a-2 (a)(17), if the insurance company is current in all applicable reporting and record-keeping requirements under such act and rules promulgated thereunder;
- d. An investment company registered and subject to 15 U.S.C. sec. 80a-1, et seq., if the investment company is current in all applicable reporting and record-keeping requirements under such act and rules promulgated thereunder;
- e. An employee benefit plan or pension fund subject to 29 U.S.C. sec. 1001 et seq., excluding an employee benefit plan or pension fund sponsored by a ~~U~~licensee or an intermediary or holding company ~~U~~licensee which directly or indirectly owns ten percent or more of a ~~U~~licensee;
- f. A state or federal government pension plan; or
- g. A group comprised entirely of persons specified in (a) through (g) of this definition; or
- h. Any other entity identified by rule by the state licensing authority.

“Reduced Testing Allowance” means the allowance for a Regulated Marijuana Business to conduct less testing than otherwise required by Rules ~~4-120 and 4-1254-215 and 4-230~~ upon demonstrating that ~~S~~standard ~~O~~perating ~~P~~rocedures and production practices result in consistent passing test results over a time frame established in Rules ~~4-120 and 4-1254-215 and 4-230~~.

“Remediation” means the process of neutralization or removal of dangerous substances or other contaminants from ~~R~~egulated ~~M~~marijuana while changing the product type of the regulated marijuana following a failed test.

“Retail Food Establishment” means a retail operation that stores, prepares, or packages food for human consumption or serves or otherwise provides food for human consumption to consumers directly or indirectly through a delivery service, whether such food is consumed on or off the premises or whether there is a charge for such food.

“Retail food establishment” does not mean:

- a. Any private home;
- b. Private boarding house;
- c. Hospital and health facility patient feeding operations licensed by the department of public health and environment;
- d. Child care centers and other child care facilities licensed by the department of human services;
- e. Hunting camps and other outdoor recreation locations where food is prepared in the field rather than at a fixed based of operation;

- f. Food or beverage wholesale manufacturing, processing, or packaging plants, or portions thereof, that are subject to regulatory controls under state or federal laws or regulations;
- g. Motor vehicles used only for the transport of food;
- h. Establishments preparing and serving only hot coffee, hot tea, instant hot beverages, and non-potentially hazardous doughnuts or pastries obtained from sources complying with all laws related to food and food labeling;
- i. Establishments that handle only non-potentially hazardous prepackaged food and operations serving only commercially prepared, prepackaged foods requiring no preparation other than the heating of the food within its original container or package;
- j. Farmers markets and roadside markets that offer only uncut fresh fruit and vegetables for sale;
- k. Automated food merchandising enterprises that supply only prepackaged non-potentially hazardous food or drink in bottles, cans, or cartons only, and operations that dispense only chewing gum or salted nuts in their natural protective covering;
- l. The donation, preparation, sale, or service of food by a nonprofit or charitable organization in conjunction with an event or celebration if such donation, preparation, sale, or service of food:
  - i. Does not exceed the duration of the event or celebration or a maximum of fifty-two days within a calendar year; and
  - ii. Takes place in the county in which such nonprofit or charitable organization resides or is principally located.
- m. A home, commercial, private, or public kitchen in which a person produces food products sold directly to consumers pursuant to the "Colorado Cottage Foods Act," section 25-4-1614, C.R.S.

"Retail Marijuana Business Operator" means an ~~E~~ntity or ~~P~~erson that is not an owner and that is licensed to provide professional operational services to a Retail Marijuana Businesses for direct remuneration from the Retail Marijuana Business.

"Retail Marijuana Concentrate" means a subset of Retail Marijuana that is separated from the ~~R~~etail ~~M~~arijuana plant and results in matter with a higher concentration of ~~e~~Cannabinoids than naturally occur in the plant. Retail Marijuana Concentrate contains ~~e~~Cannabinoids and may contain terpenes and other chemicals that are naturally occurring in Retail Marijuana plants that have been separated from Retail Marijuana. Retail Marijuana Concentrate may also include residual amounts of the types of solvents, as permitted by the marijuana rules. The State Licensing Authority may further define by rule subcategories of Retail Marijuana Concentrate and authorize limited ~~i~~ngredients based on the method of production of Retail Marijuana Concentrate. Unless the context otherwise requires, Retail Marijuana Concentrate is included when article 10 of the Colorado Revised Statutes refers to Retail Marijuana Product.



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“Retail Marijuana Cultivation Facility” means an ~~E~~ntity licensed to cultivate, prepare, and package Retail Marijuana and sell Retail Marijuana to Retail Marijuana Stores, to Retail Marijuana Products Manufacturers, and to other Retail Marijuana Cultivation Facilities, but not to consumers.

“Retail Marijuana Hospitality and Sales Business” means a facility, which cannot be mobile, licensed to permit the consumption of only the ~~r~~Retail ~~m~~Marijuana or ~~r~~Retail ~~m~~Marijuana ~~P~~roducts it has sold pursuant to the provisions of an enacted, initiated, or referred ordinance or resolution of the local jurisdiction in which the ~~L~~icensee operates.

“Safe Harbor Hemp Product” means a hemp-derived compound or ~~e~~Cannabinoid, whether a finished product or in the process of being produced, that is permitted to be manufactured for distribution, produced for distribution, packaged for distribution, processed for distribution, prepared for distribution, treated for distribution, transported for distribution, or held for distribution in Colorado for export from Colorado but that is not permitted to be sold or distributed in Colorado.

“Semi-synthetic Cannabinoid” means a substance that is created by a chemical reaction that converts one ~~e~~Cannabinoid extracted from a cannabis plant directly into a different ~~e~~Cannabinoid.

- a. Semi-synthetic ~~e~~Cannabinoid includes ~~e~~Cannabinoids, such as cannabinol (CBN) that was produced by the conversion of cannabidiol (CBD).
- b. Semi-synthetic ~~e~~Cannabinoid does not include ~~e~~Cannabinoids produced via decarboxylation of naturally occurring acidic forms of ~~e~~Cannabinoids, such as tetrahydrocannabinolic acid, into the corresponding neutral ~~e~~Cannabinoid, such as THC, through the use of heat or light, without the use of chemical reagents or catalysts, and that results in no other chemical change.

“Social Equity Licensee” means a natural person who:

- a. On or before February 1, 2025, submits an application for a finding of suitability and meets the criteria established pursuant to section 44-10-308(4), C.R.S.; and
- b. On and after February 1, 2025, submits an application for a finding of suitability and meets the criteria established pursuant to section 44-10-308(6), C.R.S.

A person qualified as a Social Equity Licensee may participate in the accelerator program established pursuant to the Marijuana Code or may hold a Regulated Marijuana Business License or permit issued pursuant to the Marijuana Code.

~~“Solvent-Based Medical Marijuana Concentrate” means a Medical Marijuana Concentrate that was produced by extracting Cannabinoids from Medical Marijuana through the use of a solvent approved by the Division pursuant to Rule 5-315.~~

“Solvent-Based Regulated Marijuana Concentrate” means a Regulated Marijuana Concentrate that was produced by extracting Cannabinoids from Regulated Marijuana

through the use of a solvent approved by the Division pursuant to Rule 5-315 and Rule 6-315. “Medical Marijuana” or “Retail Marijuana” may be substituted for “Regulated Marijuana” when referring exclusively to either Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate.

~~“Solvent-Based Retail Marijuana Concentrate” means a Retail Marijuana Concentrate that was produced by extracting Cannabinoids from Retail Marijuana through the use of a solvent approved by the Division pursuant to Rule 6-315.~~

“Standard Operating Procedure” (SOP) means a written document detailing instructions for the methods required to be followed for the routine performance of operations, analysis, or tasks. An SOP must include a clear and unique title, a purpose explaining the reason for the SOP and its scope. It must list all materials and equipment required to complete the procedure and provide definitions for any ambiguous, unclear or abbreviated terms. It must also delegate responsibilities by specifying individuals or job titles responsible for overseeing and completing the procedure. The procedure section must be a detailed step-by-step instruction dictating how and when an operation is routinely performed. Health and safety guidelines or protocols must be outlined. Any additional documents, forms, or references needed to complete the task or used to create the task must be included in an appendix or reference section. The SOP must also document all revisions and updates.

“Synthetic Cannabinoid” means a eCannabinoid-like compound that was produced by using chemical synthesis, chemical modification, or chemical conversion, including by using in-vitro biosynthesis or other bioconversion of such a method.

- a. Synthetic eCannabinoid does not include:
  - i. A compound produced through the decarboxylation of naturally occurring eCannabinoids from their acidic forms; or
  - ii. A semi-synthetic eCannabinoid.

“Target Potency” means the potency that a Medical Marijuana Products Manufacturer intends for an individual Medical Marijuana Product, or a Retail Marijuana Products Manufacturer intends for an individual Retail Marijuana Product, prior to testing, which is also outlined in the Licensee’s Sstandard Operating Procedures.

“Total CBD” means the sum of the percentage by weight of CBDA multiplied by 0.877 plus the percentage by weight of CBD i.e., Total CBD= (%CBDA x 0.877) + %CBD.

“Transfer(s)(ed)(ing)” means to grant, convey, hand over, assign, sell, exchange, donate, or barter, in any manner or by any means, with or without consideration, any Regulated Marijuana from one Licensee to another Licensee, to a patient, ~~or~~ to a consumer, or to any other permitted Persons. A Transfer includes the movement of Regulated Marijuana from one Licensed Premises to another, even if both premises are contiguous, and even if both premises are owned by a single entity or individual or group of individuals and also includes a virtual Transfer that is reflected in the Inventory Tracking System, even if no physical movement of the Regulated Marijuana occurs.

“Vegetative” means the state of the ~~c~~Cannabis plant after it is an Immature Plant but before it is Flowering. ~~d~~During this phase, the ~~which plants is typically developing roots, stems, stalks, and leaves, and is not producing flowers or seeds do not produce resin or flowers and are bulking up to a desired production size for Flowering.~~

### **Basis and Purpose – 1-120**

The statutory authority for this rule includes but is not limited to sections 24-4-105(11) and 44-10-201, C.R.S. The purpose of this rule is to establish a system by which a Licensee may request the Division to issue a formal statement of position and, subsequently, petition the State Licensing Authority for a declaratory order. Typically, a position statement or declaratory order would address matters that are likely to be applicable to other Licensees. The approach is similar to that utilized by other divisions within the Department of Revenue. This Rule 1-120 was previously Rules M and R 104, 1 CCR 212-1 and 1 CCR 212-2.

### **1-120 – Declaratory Orders Concerning the Marijuana Code**

- A. Who May Request a Statement of Position. Any person as defined in section 24-4-102(12), C.R.S., may request the Division to issue a statement of position concerning the applicability to the petitioner of any provision of the Marijuana Code, or any regulation of the State Licensing Authority. The request must include the information set forth in paragraph (C.5)(1) through (C.5)(6) of this Rule.
- B. Division Response. The Division will determine, in its sound discretion, whether to respond with a written statement of position. Following receipt of a proper request, the Division will respond by issuing a written statement of position or by declining to issue such a statement.
- C. Petition for Declaratory Order. Any person who has properly requested a statement of position, and who is dissatisfied with the Division’s response, may petition the State Licensing Authority for a declaratory order pursuant to section 24-4-105(11), C.R.S. The petition shall be filed within 30 days of the Division’s response, or may be filed at any time before the Division’s response if the Division has not responded within 60 days of receiving a proper request for a statement of position. ~~and~~

C.5 Requirements for a Request for Statement of Position or a Petition for a Declaratory Order. Each request for a statement of position or petition for a declaratory order shall set forth the following information:

- 1. The name and address of the petitioner.
- 2. Whether the petitioner is licensed pursuant to the Marijuana Code, and if so, the type of license and address of the Licensed Premises.
- 3. Whether the petitioner is involved in any litigation, including any pending administrative hearings with the State Licensing Authority or relevant Local Jurisdiction.
- 4. The statute, rule, or order to which the petition relates.

5. A concise statement of all of the facts necessary to show the nature of the controversy or the uncertainty as to the applicability to the petitioner of the statute, rule, or order to which the petition relates.
  6. A concise statement of the legal authorities, if any, and such other reasons upon which petitioner relies.
  7. For a petition for a declaratory order, a concise statement of the declaratory order sought by the petitioner.
- D. State Licensing Authority Retains Discretion Whether to Entertain Petition. The State Licensing Authority will determine, in its discretion without prior notice to the petitioner, whether to entertain any petition. If the State Licensing Authority decides it will not entertain a petition, it shall notify the petitioner in writing of its decision and the reasons for that decision. Any of the following grounds may be sufficient reason to refuse to entertain a petition:
1. The petitioner failed to properly request a statement of position from the Division, or the petition for declaratory order was filed with the State Licensing Authority more than 30 days after the Division's response to the request for a statement of position.
  2. A ruling on the petition will not terminate the controversy nor remove uncertainties concerning the applicability to petitioner of the statute, rule, or order in question.
  3. The petition involves a subject, question or issue that is relevant to a pending hearing before the state or any Local Licensing Authority, an on-going investigation conducted by the Division, or a written complaint previously filed with the State Licensing Authority.
  4. The petition seeks a ruling on a moot or hypothetical question.
  5. Petitioner has some other adequate legal remedy, other than an action for declaratory relief pursuant to Colo. R. Civ. Pro. 57, which will terminate the controversy or remove any uncertainty concerning applicability of the statute, rule, or order.
- E. State Licensing Authority May Adopt Division Position Statement. The State Licensing Authority may adopt the Division Position Statement as a Final Agency Order subject to judicial review pursuant to section 24-4-106, C.R.S.
- F. If State Licensing Authority Entertains Petition. If the State Licensing Authority determines that it will entertain the petition for declaratory order, it shall so notify the petitioner within 30 days, and any of the following procedures may apply:
1. The State Licensing Authority may expedite the matter by ruling on the basis of the facts and legal authority presented in the petition, or by requesting the petitioner or the Division to submit additional evidence and legal argument in writing.

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2. In the event the State Licensing Authority determines that an evidentiary hearing is necessary to a ruling on the petition, a hearing shall be conducted in accordance with Rules 8-220 – Administrative Hearings, 8-225 – Administrative Subpoenas, and 8-230 – Administrative Hearing Appeals. The petitioner will be identified as Respondent.
  3. The parties to any proceeding pursuant to this Rule shall be the petitioner/Respondent and the Division. Any other interested person may seek leave of the State Licensing Authority to intervene in the proceeding and such leave may be granted if the State Licensing Authority determines that such intervention will make unnecessary a separate petition for declaratory order by the interested person.
  4. The declaratory order shall constitute a Final Agency Order subject to judicial review pursuant to section 24-4-106, C.R.S.
- G. Public Inspection. Files of all requests, petitions, statements of position, and declaratory orders will be maintained by the Division. Except with respect to any material required by law to be kept confidential, such files shall be available for public inspection.
- H. Posted on Website. The Division shall post a copy of all statements of position and all declaratory orders on the Division's website.

**Part 2 – Applications and Licenses****2-100 Series – Fees****Basis and Purpose – 2-105**

The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of these rules is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division.

**2-105 – Employee License – Initial Fees and Renewal Fees**

- A. Initial Application Fees. Upon application for an Employee License, the Applicant must submit a total fee reflecting an application fee and license fee, as follows:

**2-105(A) 1**

<u>License Type</u>	<u>Total Due at Application</u>
<u>Employee License</u>	<u>\$170.00</u>
<u>Conditional Employee License</u>	<u>\$220.00</u>

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B. License Renewal Fee. Upon application to renew an Employee License, the Applicant must submit the following total fee:

**2-105(B) 1**

<u>License Type</u>	<u>Total Due at Application</u>
<u>Employee License Renewal</u>	<u>\$120.00</u>

C. When Fees Are Due. The application and License fees reflected in this Rule are due at the time of application.

**Basis and Purpose – 2-110**

The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of these rules is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division.

**2-110 – Requests for a Finding of Suitability, Owner License and Temporary Appointees – Initial Application and Renewal Fees.**

A. The following fees apply to all proposed Owners, including natural persons and Entities. The fee for Owner Entities corresponds to the number of Controlling Beneficial Owners of the licensed Regulated Marijuana Business created through the Owner Entity, in accordance with Rule 2-235(A)(2)(a). See Rule 2-115(A).

1. Requests for Finding of Suitability Fees.

a. Application Fees. Upon a request for a finding of suitability, the Applicant must submit a total fee reflecting an application fee, as follows:

**2-110(A)(1)(a) 1**

<u>License Type</u>	<u>Due at Submission of Request for Finding of Suitability</u>
<u>Controlling Beneficial Owner – Natural Person</u>	<u>\$720.00</u>
<u>Passive Beneficial Owner</u>	<u>\$720.00</u>
<u>Controlling Beneficial Owner – Owner Entity:</u>	

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<u>License Type</u>	<u>Due at Submission of Request for Finding of Suitability</u>
<u>Level 1: One (1) to four (4) Controlling Beneficial Owners and/or Owner Entities</u>	<u>\$1,430.00</u>
<u>Level 2: Five (5) to nine (9) Controlling Beneficial Owners and/or Owner Entities</u>	<u>\$2,190.00</u>
<u>Level 3: Ten (10) or more Controlling Beneficial Owners and/or Owner Entities</u>	<u>\$2,860.00</u>
<u>Controlling Beneficial Owner – Publicly Traded Corporation (PTC)</u>	<u>\$35,120.00</u>
<u>Controlling Beneficial Owner – Qualified Private Fund – Qualified Institutional Investor – Trust</u>	<u>\$7,140.00</u>

b. License Fees. Upon application submission to associate a finding of suitability to a Regulated Marijuana Business License, the Applicant must submit the total fee reflecting a License fee, as follows:

**2-110(A)(1)(b) 1**

<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to expiration</u>
<u>Controlling Beneficial Owner – Natural Person</u>	<u>\$180.00</u>	<u>\$180.00</u>
<u>Passive Beneficial Owner</u>	<u>\$180.00</u>	<u>\$180.00</u>
<u>Controlling Beneficial Owner – Owner Entity:</u>		



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<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Level 1: One (1) to four (4) Controlling Beneficial Owners and/or Owner Entities</u>	<u>\$180.00</u>	<u>\$180.00</u>
<u>Level 2: Five (5) to nine (9) Controlling Beneficial Owners and/or Owner Entities</u>	<u>\$275.00</u>	<u>\$275.00</u>
<u>Level 3: Ten (10) or more Controlling Beneficial Owners and/or Owner Entities</u>	<u>\$360.00</u>	<u>\$360.00</u>
<u>Controlling Beneficial Owner – Publicly Traded Corporation (PTC)</u>	<u>\$4,390.00</u>	<u>\$4,390.00</u>
<u>Controlling Beneficial Owner – Qualified Private Fund – Qualified Institutional Investor – Trust</u>	<u>\$895.00</u>	<u>\$895.00</u>

c. When Fees Are Due.

- i. The application fee must be submitted with the request for finding of suitability or application.
- ii. The first payment must be submitted with the application to associate a finding of suitability to a Regulated Marijuana Business License, such as an application for a new Regulated Marijuana Business License pursuant to Rule 2-220 or a Change of Controlling Beneficial Owner application pursuant to Rule 2-245.
- iii. The second payment must be submitted at least twelve (12) months prior to the License expiration date, unless otherwise mandated by the State Licensing Authority or the Division.
- iv. Failure to submit the second payment at least twelve (12) months prior to expiration shall result in disciplinary action, which may include an administrative action, fine, suspension, and revocation of the License.

Marijuana Enforcement DivisionB. Owner License Renewal.

1. Upon application to renew an Owner License or Owner Entity License, the Applicant must submit fees, as follows:

2-110(B)(1) 1

<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to expiration</u>
<u>Controlling Beneficial Owner – Owner Licensee</u>	<u>\$585.00</u>	<u>\$585.00</u>
<u>Controlling Beneficial Owner – Owner Entity:</u>		
<u>Level 1: One (1) to four (4) Controlling Beneficial Owners and/or Owner Entities</u>	<u>\$585.00</u>	<u>\$585.00</u>
<u>Level 2: Five (5) to nine (9) Controlling Beneficial Owners and/or Owner Entities</u>	<u>\$870.00</u>	<u>\$870.00</u>
<u>Level 3: Ten (10) or more Controlling Beneficial Owners and/or Owner Entities</u>	<u>\$1,160.00</u>	<u>\$1,160.00</u>
<u>Controlling Beneficial Owner – Publicly Traded Corporation (PTC)</u>	<u>\$5,250.00</u>	<u>\$5,250.00</u>
<u>Controlling Beneficial Owner – Qualified Private Fund – Qualified Institutional Investor – Trust</u>	<u>\$2,100.00</u>	<u>\$2,100.00</u>

2. When Fees Are Due. The application and License fees reflected in this Rule must be paid as follows:

- a. The first payment must be submitted with the application.

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b. The second payment must be submitted at least twelve (12) months prior to the License expiration date, unless otherwise mandated by the State Licensing Authority or the Division.

c. Failure to submit the second payment at least twelve (12) months prior to expiration shall result in disciplinary action, which may include an administrative action, fine, suspension, and revocation of the License.

C. Temporary Appointee Registration Fees.

1. The following fees apply to an application for an initial Temporary Appointee Registration and renewal of a Temporary Appointee Registration:

**2-110(C)(1) 1**

<u>License Type</u>	<u>Application Fee</u> <u>Due at Application</u>
<u>Temporary Appointee Registration (Natural Person)</u>	<u>\$640.00</u>
<u>Temporary Appointee Registration (Entity)</u>	<u>\$2,220.00</u>
<u>Temporary Appointee Registration (Natural Person) Renewal</u>	<u>\$640.00</u>
<u>Temporary Appointee Registration (Entity) Renewal</u>	<u>\$1,790.00</u>

2. When Fees Are Due. The application and license fees reflected in this Rule are due at the time of application.

**Basis and Purpose – 2-115**

The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of these rules is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division.

**2-115 - Regulated Marijuana Business Initial Application & License Fees**

A. Levels. The following levels apply to Regulated Marijuana Businesses with direct Controlling Beneficial Owners, which includes but is not limited to natural persons, Owner Entities, Publicly Traded Companies, Trusts, Qualified Institutional Investors and Qualified Private Funds. This does not include indirect Controlling Beneficial Owners of the licensed Regulated Marijuana Business, in accordance with Rules 2-235(A)(2)(a) and 2-235(B)(1)(b). The levels are:

1. Level 1: One (1) to four (4) Controlling Beneficial Owners.

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2. Level 2: Five (5) to nine (9) Controlling Beneficial Owners.

3. Level 3: Ten (10) or more Controlling Beneficial Owners.

B. Medical Marijuana Businesses. The following fees apply to an application for a new Medical Marijuana Business license.

**2-115(B) 1**

<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Medical Marijuana Store</u>		
<u>Level 1</u>	<u>\$8,460.00</u>	<u>\$8,460.00</u>
<u>Level 2</u>	<u>\$12,710.00</u>	<u>\$12,710.00</u>
<u>Level 3</u>	<u>\$16,910.00</u>	<u>\$16,910.00</u>
<u>Medical Marijuana Products</u> <u>Manufacturer</u>		
<u>Level 1</u>	<u>\$3,210.00</u>	<u>\$3,210.00</u>
<u>Level 2</u>	<u>\$4,835.00</u>	<u>\$4,835.00</u>
<u>Level 3</u>	<u>\$6,410.00</u>	<u>\$6,410.00</u>
<u>Medical Marijuana Cultivation</u> <u>Facility - Class 1 (1-500 plants)</u>		
<u>Level 1</u>	<u>\$3,210.00</u>	<u>\$3,210.00</u>
<u>Level 2</u>	<u>\$4,835.00</u>	<u>\$4,835.00</u>
<u>Level 3</u>	<u>\$6,410.00</u>	<u>\$6,410.00</u>
<u>Medical Marijuana Testing Facility</u>		
<u>Level 1</u>	<u>\$3,210.00</u>	<u>\$3,210.00</u>
<u>Level 2</u>	<u>\$4,835.00</u>	<u>\$4,835.00</u>
<u>Level 3</u>	<u>\$6,410.00</u>	<u>\$6,410.00</u>

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<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Medical Marijuana Transporter</u>	<u>\$3,625.00</u>	<u>\$3,625.00</u>
<u>Medical Marijuana Business Operator</u>		
<u>Level 1</u>	<u>\$4,200.00</u>	<u>\$4,200.00</u>
<u>Level 2</u>	<u>\$6,300.00</u>	<u>\$6,300.00</u>
<u>Level 3</u>	<u>\$8,400.00</u>	<u>\$8,400.00</u>
<u>Marijuana Research and Development Facility</u>		
<u>Level 1</u>	<u>\$3,210.00</u>	<u>\$3,210.00</u>
<u>Level 2</u>	<u>\$4,835.00</u>	<u>\$4,835.00</u>
<u>Level 3</u>	<u>\$6,410.00</u>	<u>\$6,410.00</u>

C. Retail Marijuana Businesses. The following fees apply to an application for a new Retail Marijuana Business license.

1. State Licensing Authority Fees. See subparagraph (C)(2) for the separate fees required to be submitted to the Division with an application for a new Retail Marijuana Business license.

**2-115(C)(1) 1**

<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Retail Marijuana Store</u>		
<u>Level 1</u>	<u>\$3,120.00</u>	<u>\$5,620.00</u>
<u>Level 2</u>	<u>\$5,960.00</u>	<u>\$8,460.00</u>
<u>Level 3</u>	<u>\$8,740.00</u>	<u>\$11,240.00</u>

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<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Retail Marijuana Products Manufacturer</u>		
<u>Level 1</u>	<u>\$2,440.00</u>	<u>\$4,940.00</u>
<u>Level 2</u>	<u>\$4,910.00</u>	<u>\$7,410.00</u>
<u>Level 3</u>	<u>\$7,370.00</u>	<u>\$9,870.00</u>
<u>Retail Marijuana Cultivation Facility - Tier 1 (1-1,800 plants)</u>		
<u>Level 1</u>	<u>\$2,440.00</u>	<u>\$4,940.00</u>
<u>Level 2</u>	<u>\$4,910.00</u>	<u>\$7,410.00</u>
<u>Level 3</u>	<u>\$7,370.00</u>	<u>\$9,870.00</u>
<u>Retail Marijuana Testing Facility</u>		
<u>Level 1</u>	<u>\$2,100.00</u>	<u>\$3,150.00</u>
<u>Level 2</u>	<u>\$3,415.00</u>	<u>\$4,465.00</u>
<u>Level 3</u>	<u>\$4,725.00</u>	<u>\$5,775.00</u>
<u>Retail Marijuana Transporter</u>	<u>\$3,075.00</u>	<u>\$3,600.00</u>
<u>Retail Marijuana Business Operator</u>		
<u>Level 1</u>	<u>\$3,100.00</u>	<u>\$4,150.00</u>
<u>Level 2</u>	<u>\$4,935.00</u>	<u>\$5,985.00</u>
<u>Level 3</u>	<u>\$6,720.00</u>	<u>\$7,770.00</u>
<u>Marijuana Hospitality Business</u>	<u>\$1,420.00</u>	<u>\$2,470.00</u>
<u>Retail Marijuana Hospitality and Sales Business</u>	<u>\$5,745.00</u>	<u>\$8,245.00</u>

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2. Local Portion of Application Fee. In addition to the fees in subparagraph (1) of this Rule, an Applicant must submit a separate check made out to the local jurisdiction as follows:

**2-115(C)(2) 1**

<u>License Type</u>	<u>Application Fee</u> <u>Due at Application</u>
<u>Retail Marijuana Store</u>	<u>\$2,500.00</u>
<u>Retail Marijuana Products Manufacturer</u>	<u>\$2,500.00</u>
<u>Retail Marijuana Cultivation Facility</u>	<u>\$2,500.00</u>
<u>Retail Marijuana Testing Facility</u>	<u>\$1,050.00</u>
<u>Retail Marijuana Transporter</u>	<u>\$525.00</u>
<u>Retail Marijuana Business Operator</u>	<u>\$1,050.00</u>
<u>Marijuana Hospitality Business</u>	<u>\$1,050.00</u>
<u>Retail Marijuana Hospitality and Sales Business</u>	<u>\$2,500.00</u>

- D. When Fees Are Due. The application and License fees reflected in this Rule must be paid as follows.

1. The first payment must be submitted with the application.
2. The second payment must be submitted at least twelve (12) months prior to the License expiration date, unless otherwise mandated by the State Licensing Authority or the Division.
3. Failure to timely submit the second payment at least twelve (12) months prior to expiration shall result in disciplinary action, which may include an administrative action, fine, suspension, or revocation of the License.

**Basis and Purpose – 2-120**

The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of this rule is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division.

**2-120 – Permit Fees**



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A. The following fees apply to permits issued by the State Licensing Authority or the Division and are due at the time of application.

**2-120(A) 1**

<u>License Type</u>	<u>Total Due at Application</u>
<u>Transition Permit</u>	<u>\$370.00</u>
<u>Centralized Distribution Permit</u>	<u>\$60.00</u>
<u>Off-Premises Storage Facility Permit</u>	<u>\$2,100.00</u>
<u>R&amp;D Co-Location Permit</u>	<u>\$110.00</u>

B. Delivery Permit Fees.

1. The following fees apply to delivery permits issued by the State Licensing Authority or the Division.

**2-120(B) 1**

<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Delivery Permit</u>	<u>\$5,515.00</u>	<u>\$5,515.00</u>
<u>Delivery Permit Renewal</u>	<u>\$2,785.00</u>	<u>\$2,785.00</u>

2. When Fees Are Due. The fees reflected in this subparagraph (B) must be paid as follows.

- a. The first payment must be submitted with the application.
- b. The second payment must be submitted at least twelve (12) months prior to the permit expiration date, unless otherwise mandated by the State Licensing Authority or the Division.
- c. Failure to submit the second payment at least twelve (12) months prior to expiration shall result in disciplinary action, which may include an administrative action, fine, suspension, and revocation of the License.

**Basis and Purpose – 2-125**

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The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of this rule is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division.

**2-125 – Regulated Marijuana Business License Renewal Fees****A. Medical Marijuana Businesses.****2-125(A) 1**

<b><u>License Type</u></b>	<b><u>1st Payment</u></b> <i><u>Due at Application</u></i>	<b><u>2nd Payment</u></b> <i><u>Due 12 months prior to expiration</u></i>
<u>Medical Marijuana Store</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>
<u>Medical Marijuana Products Manufacturer</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>
<u>Medical Marijuana Cultivation Facility:</u>		
<u>Class 1 (1-500 plants)</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>
<u>Class 2 (501-1,500 plants)</u>	<u>\$3,520.00</u>	<u>\$3,520.00</u>
<u>Class 3 (1,501-3,000 plants)</u>	<u>\$5,200.00</u>	<u>\$5,200.00</u>
<u>Expanded Production Management (The amount shown is charged in addition to the Class 3 fee for each class of 3,000 plants over Class 3)</u>	<u>\$1,110.00</u>	<u>\$1,110.00</u>
<u>Medical Marijuana Testing Facility</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>
<u>Medical Marijuana Transporter</u>	<u>\$3,195.00</u>	<u>\$3,195.00</u>
<u>Medical Marijuana Business Operator</u>	<u>\$3,365.00</u>	<u>\$3,365.00</u>

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<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to expiration</u>
<u>Marijuana Research and Development Facility</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>

B. Retail Marijuana Businesses.2-125(B) 1

<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to expiration</u>
<u>Retail Marijuana Store</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>
<u>Retail Marijuana Products Manufacturer</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>
<u>Retail Marijuana Cultivation Facility:</u>		
<u>Tier 1 (1-1,800 plants)</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>
<u>Tier 2 (1,801-3,600 plants)</u>	<u>\$3,520.00</u>	<u>\$3,520.00</u>
<u>Tier 3 (3,601-6,000 plants)</u>	<u>\$4,520.00</u>	<u>\$4,520.00</u>
<u>Tier 4 (6,001-10,200 plants)</u>	<u>\$6,565.00</u>	<u>\$6,565.00</u>
<u>Tier 5 (10,201-13,800 plants)</u>	<u>\$9,350.00</u>	<u>\$9,350.00</u>
<u>Expanded Production Management (The amount shown is charged in addition to the Tier 5 fee for each additional tier of 3,600 plants over Tier 5)</u>	<u>\$1,110.00</u>	<u>\$1,110.00</u>
<u>Retail Marijuana Testing Facility</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>
<u>Retail Marijuana Transporter</u>	<u>\$3,210.00</u>	<u>\$3,210.00</u>

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<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Retail Marijuana Business</u> <u>Operator</u>	<u>\$3,365.00</u>	<u>\$3,365.00</u>
<u>Marijuana Hospitality Business</u>	<u>\$1,370.00</u>	<u>\$1,370.00</u>
<u>Retail Marijuana Hospitality and</u> <u>Sales Business</u>	<u>\$2,420.00</u>	<u>\$2,420.00</u>

C. When Fees Are Due. The application and License fees reflected in this Rule must be paid as follows.

1. The first payment must be submitted with the application.
2. The second payment must be submitted at least twelve (12) months prior to the License expiration date, unless otherwise mandated by the State Licensing Authority or the Division.
3. Failure to submit the second payment at least twelve (12) months prior to expiration shall result in disciplinary action, which may include an administrative action, fine, suspension, and revocation of the License.

### **2-130 – Basis and Purpose – 2-130**

The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of these rules is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division.

### **2-130 – Ownership Change Fees**

A. The following fees apply per a Regulated Marijuana Business License and are due at the time of submission.

#### **2-130(A) 1**

<u>License Type</u>	<u>Total Due with Submission</u>
<u>Change of Controlling Beneficial Owner:</u>	

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<b><u>License Type</u></b>	<b><u>Total Due with Submission</u></b>
<u>Involving up to four (4) Controlling Beneficial Owners and/or Owner Entities, (i.e. buyers and sellers)</u>	<u>\$2,940.00</u>
<u>Involving five (5) to nine (9) Controlling Beneficial Owners and/or Owner Entities, (i.e. buyers and sellers)</u>	<u>\$5,150.00</u>
<u>Involving ten (10) or more Controlling Beneficial Owners and/or Owner Entities, (i.e. buyers and sellers)</u>	<u>\$6,670.00</u>
<u>Changes Exempt from a Change of Ownership not involving a reallocation</u>	<u>\$1,210.00</u>
<u>Changes Exempt from a Change of Ownership involving a reallocation</u>	<u>\$2,100.00</u>

**Basis and Purpose – 2-135**

The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of these rules is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division.

**2-135 – Applications to Modify Fees**

A. The following fees apply per a Regulated Marijuana Business License and are due at the time of application.

**2-135(A) 1**

<b><u>License Type</u></b>	<b><u>Total Due at Application</u></b>
<u>Request Fee (for Tier Increase / Class Increase)</u>	<u>\$320.00</u>
<u>Change of Trade Name (COTN)</u>	<u>\$110.00</u>

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<u>License Type</u>	<u>Total Due at Application</u>
<u>Change of Location (COL)</u>	<u>\$690.00</u>
<u>Security Waiver</u>	<u>\$630.00</u>
<u>Security Waiver Renewal</u>	<u>\$320.00</u>
<u>Contingency Plan</u>	<u>\$1,370.00</u>

**Basis and Purpose – 2-140**

The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of these rules is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division.

**2-140 – Other Application Fees**

A. The following fees apply and are due at the time of application.

**2-140(A) 1**

<u>License Type</u>	<u>Total Due at Application</u>
<u>Reduced Testing Allowance Certification</u>	<u>\$4,200.00</u>
<u>Duplicate Business License</u>	<u>\$60.00</u>
<u>Duplicate Owner/Employee License</u>	<u>\$30.00</u>
<u>Request for Reinstatement</u>	<u>\$370.00</u>
<u>Responsible Vendor Program Provider:</u>	
<u>Responsible Vendor Program Provider Initial Application</u>	<u>\$1,160.00</u>
<u>Duplicate Responsible Vendor Program Provider Certificate</u>	<u>\$60.00</u>

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<u>License Type</u>	<u>Total Due at Application</u>
<u>Responsible Vendor Program Provider Renewal Application</u>	<u>\$480.00</u>
<u>R&amp;D Project Proposal</u>	<u>\$690.00</u>

**Basis and Purpose – 2-145**

The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-308(5); 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. The purpose of these rules is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division by Social Equity Licensees.

**2-145 – Social Equity Fees**

A. When Reduced Fees Apply. Reduced fees apply to Licensees who have been found suitable as a Social Equity Licensee pursuant to Rule 2-235(B.5) or (B.6) under the following circumstances:

1. The first Owner Entity initial finding of suitability application submitted by the Social Equity Licensee;
2. The first and second initial Regulated Marijuana Business License applications submitted by the Licensee;
3. The first and second initial delivery permit applications submitted by the Licensee (if applicable);
4. The first renewal after July 1, 2023 of any two Regulated Marijuana Business Licenses issued;
5. The first renewal after July 1, 2023 of any two delivery permits issued;
6. The first renewal after July 1, 2023 of one Owner Entity License issued; and
7. The first renewal after July 1, 2023 of one Owner License issued.

B. Requests for a Finding of Suitability and Owner License – Initial Application and Renewal Fees. The following fees apply to all proposed Owners, including natural persons and Entities.

1. Requests for Finding of Suitability Fees.
  - a. Application Fees. Upon a request for a finding of suitability, the Applicant must submit a total fee reflecting an application fee, as follows:



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**2-145(B)(1)(a) 1**

<u>License Type</u>	<u>Due at Submission of Request for Finding of Suitability</u>
<u>Controlling Beneficial Owner – Natural Person – Social Equity</u>	<u>\$720.00</u>
<u>Controlling Beneficial Owner – Owner Entity</u>	<u>\$170.00</u>

b. License Fees. Upon application submission to associate a finding of suitability to a Regulated Marijuana Business License, the Applicant must submit a total fee reflecting a license fee, as follows:

**2-145(B)(1)(b) 1**

<u>License Type</u>	<u>1st Payment Due at Application</u>	<u>2nd Payment Due 12 months prior to expiration</u>
<u>Controlling Beneficial Owner – Owner License – Social Equity Licensee</u>	<u>\$0.00</u>	<u>\$0.00</u>
<u>Controlling Beneficial Owner – Owner Entity</u>	<u>\$0.00</u>	<u>\$0.00</u>

c. When Fees Are Due.

- i. The application fee must be submitted with the request for finding of suitability or application.
- ii. The first payment must be submitted with the application to associate a finding of suitability to a Regulated Marijuana Business License, such as an application for a new Regulated Marijuana Business License pursuant to Rule 2-220 or a Change of Controlling Beneficial Owner application pursuant to Rule 2-245.
- iii. The second payment must be submitted at least twelve (12) months prior to the License expiration date, unless otherwise mandated by the State Licensing Authority or the Division.
- iv. Failure to submit the second payment at least twelve (12) months prior to expiration shall result in disciplinary action, which may include an administrative action, fine, suspension, and revocation of the License.

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2. Owner License Renewal. Upon application to renew an Owner License or Owner Entity License, the Applicant must submit fees, as follows:

**2-145(B)(2) 1**

<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Controlling Beneficial Owner –</u> <u>Owner License – Social Equity</u> <u>Licensee</u>	<u>\$165.00</u>	<u>\$165.00</u>
<u>Controlling Beneficial Owner –</u> <u>Owner Entity</u>	<u>\$165.00</u>	<u>\$165.00</u>

- a. When Fees Are Due. The application and License fees reflected in this Rule must be paid as follows.
- i. The first payment must be submitted with the application.
  - ii. The second payment must be submitted at least twelve (12) months prior to the License expiration date, unless otherwise mandated by the State Licensing Authority or the Division.
  - iii. Failure to submit the second payment at least twelve (12) months prior to expiration shall result in disciplinary action, which may include an administrative action, fine, suspension, and revocation of the License.

C. Retail Marijuana Business – Initial and Renewal Application and License Fees.

1. Initial Application and License Fees.

**2-145(C)(1) 1**

<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Retail Marijuana Store</u>	<u>\$1,420.00</u>	<u>\$1,420.00</u>
<u>Retail Marijuana Products</u> <u>Manufacturer</u>	<u>\$1,260.00</u>	<u>\$1,260.00</u>
<u>Retail Marijuana Cultivation Facility -</u> <u>Tier 1 (1-1,800 plants)</u>	<u>\$1,260.00</u>	<u>\$1,260.00</u>

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<u><b>License Type</b></u>	<u><b>1st Payment</b></u> <u><i>Due at Application</i></u>	<u><b>2nd Payment</b></u> <u><i>Due 12 months prior to expiration</i></u>
<u>Retail Marijuana Testing Facility</u>	<u>\$685.00</u>	<u>\$685.00</u>
<u>Retail Marijuana Transporter</u>	<u>\$840.00</u>	<u>\$840.00</u>
<u>Retail Marijuana Business Operator</u>	<u>\$895.00</u>	<u>\$895.00</u>
<u>Marijuana Hospitality Business</u>	<u>\$475.00</u>	<u>\$475.00</u>
<u>Retail Marijuana Hospitality and Sales Business</u>	<u>\$1,420.00</u>	<u>\$1,420.00</u>

2. Renewal Application and License Fees.**2-145(C)(2) 1**

<u><b>License Type</b></u>	<u><b>1st Payment</b></u> <u><i>Due at Application</i></u>	<u><b>2nd Payment</b></u> <u><i>Due 12 months prior to expiration</i></u>
<u>Retail Marijuana Store</u>	<u>\$635.00</u>	<u>\$635.00</u>
<u>Retail Marijuana Products Manufacturer</u>	<u>\$635.00</u>	<u>\$635.00</u>
<u>Retail Marijuana Cultivation Facility:</u>		
<u>Tier 1 (1 - 1,800 Plants)</u>	<u>\$635.00</u>	<u>\$635.00</u>
<u>Tier 2 (1,801 – 3,600 Plants)</u>	<u>\$895.00</u>	<u>\$895.00</u>
<u>Tier 3 (3,601 – 6,000 Plants)</u>	<u>\$1,160.00</u>	<u>\$1,160.00</u>
<u>Tier 4 (6,001 – 10,200 Plants)</u>	<u>\$1,635.00</u>	<u>\$1,635.00</u>

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<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Tier 5 (10,201 – 13,800</u> <u>Plants)</u>	<u>\$2,365.00</u>	<u>\$2,365.00</u>
<u>Expanded Production</u> <u>Management (The amount shown</u> <u>is charged in addition to the Tier 5</u> <u>fee for each additional 3,600</u> <u>plants after Tier 5)</u>	<u>\$265.00</u>	<u>\$265.00</u>
<u>Retail Marijuana Testing Facility</u>	<u>\$635.00</u>	<u>\$635.00</u>
<u>Retail Marijuana Transporter</u>	<u>\$820.00</u>	<u>\$820.00</u>
<u>Retail Marijuana Business Operator</u>	<u>\$845.00</u>	<u>\$845.00</u>
<u>Marijuana Hospitality Business</u>	<u>\$370.00</u>	<u>\$370.00</u>
<u>Retail Marijuana Hospitality and</u> <u>Sales Business</u>	<u>\$635.00</u>	<u>\$635.00</u>

3. When Fees Are Due. The application and License fees reflected in this Rule must be paid as follows.

- a. The first payment must be submitted with the application.
- b. The second payment must be submitted at least twelve (12) months prior to the License expiration date, unless otherwise mandated by the State Licensing Authority or the Division.
- c. Failure to timely submit the second payment shall result in disciplinary action, which may include an administrative action, fine, suspension, and revocation of the License.

D. Medical Marijuana Business – Initial and Renewal Application and License Fees.

1. Initial Application and License Fees.

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**2-145(D)(1) 1**

<b><u>License Type</u></b>	<b><u>1st Payment</u></b> <i><u>Due at Application</u></i>	<b><u>2nd Payment</u></b> <i><u>Due 12 months prior to expiration</u></i>
<u>Medical Marijuana Store</u>	<u>\$2,100.00</u>	<u>\$2,100.00</u>
<u>Medical Marijuana Products Manufacturer</u>	<u>\$790.00</u>	<u>\$790.00</u>
<u>Medical Marijuana Cultivation Facility - Class 1 (1-500 plants)</u>	<u>\$790.00</u>	<u>\$790.00</u>
<u>Medical Marijuana Testing Facility</u>	<u>\$790.00</u>	<u>\$790.00</u>
<u>Medical Marijuana Transporter</u>	<u>\$920.00</u>	<u>\$920.00</u>
<u>Medical Marijuana Business Operator</u>	<u>\$1,050.00</u>	<u>\$1,050.00</u>
<u>Marijuana Research and Development Facility</u>	<u>\$790.00</u>	<u>\$790.00</u>

**2. Renewal Application and License Fees.****2-145(D)(2) 1**

<b><u>License Type</u></b>	<b><u>1st Payment</u></b> <i><u>Due at Application</u></i>	<b><u>2nd Payment</u></b> <i><u>Due 12 months prior to expiration</u></i>
<u>Medical Marijuana Store</u>	<u>\$635.00</u>	<u>\$635.00</u>
<u>Medical Marijuana Products Manufacturer</u>	<u>\$635.00</u>	<u>\$635.00</u>
<u>Medical Marijuana Cultivation Facility:</u>		
<u>Class 1 (1-500 plants)</u>	<u>\$635.00</u>	<u>\$635.00</u>
<u>Class 2 (501-1,500 plants)</u>	<u>\$895.00</u>	<u>\$895.00</u>
<u>Class 3 (1,501-3,000 plants)</u>	<u>\$1,315.00</u>	<u>\$1,315.00</u>

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<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Expanded Production Management (The amount shown is charged in addition to the Class 3 fee for each class of 3,000 plants over Class 3)</u>	<u>\$265.00</u>	<u>\$265.00</u>
<u>Medical Marijuana Testing Facility</u>	<u>\$635.00</u>	<u>\$635.00</u>
<u>Medical Marijuana Transporter</u>	<u>\$820.00</u>	<u>\$820.00</u>
<u>Medical Marijuana Business Operator</u>	<u>\$845.00</u>	<u>\$845.00</u>
<u>Marijuana Research and Development Facility</u>	<u>\$635.00</u>	<u>\$635.00</u>

3. When Fees Are Due. The application and License fees reflected in this Rule must be paid as follows.

- a. The first payment must be submitted with the application.
- b. The second payment must be submitted at least twelve (12) months prior to the License expiration date, unless otherwise mandated by the State Licensing Authority or the Division.
- c. Failure to timely submit the second payment shall result in disciplinary action, which may include an administrative action, fine, suspension, and revocation of the License.

E. Delivery Permit Fees.

**2-145(E) 1**

<u>License Type</u>	<u>1st Payment</u> <u>Due at Application</u>	<u>2nd Payment</u> <u>Due 12 months prior to</u> <u>expiration</u>
<u>Delivery Permit</u>	<u>\$1,365.00</u>	<u>\$1,365.00</u>
<u>Delivery Permit Renewal</u>	<u>\$685.00</u>	<u>\$685.00</u>

1. When Fees Are Due. The fees reflected in this Rule must be paid as follows.

- a. The first payment must be submitted with the application.
- b. The second payment must be submitted at least twelve (12) months prior to the permit expiration date, unless otherwise mandated by the State Licensing Authority or the Division.
- c. Failure to submit the second payment at least twelve (12) months prior to expiration shall result in disciplinary action, which may include an administrative action, fine, suspension, and revocation of the License.

## 2-200 Series – Applications and Licenses Rules

### **Basis and Purpose – 2-205**

~~The statutory basis for this rule includes but is not limited to sections 44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(II). The purpose of this rule is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division.~~

### **2-205 – Fees - Repealed**

#### A. ~~Regulated Marijuana Business Initial Application and License Fees.~~

1. ~~Levels.~~ ~~The following levels apply to Regulated Marijuana Businesses with direct Controlling Beneficial Owners, which includes but is not limited to natural persons, Owner Entities, Publicly Traded Companies, Trusts, Qualified Institutional Investors and Qualified Private Funds. This does not include indirect Controlling Beneficial Owners of the licensed Regulated Marijuana Business, in accordance with Rules 2-235(A)(2)(a) and 2-235(B)(1)(b). The levels are:~~
  - a. ~~Level 1: One (1) to four (4) Controlling Beneficial Owners.~~
  - b. ~~Level 2: Five (5) to nine (9) Controlling Beneficial Owners.~~
  - c. ~~Level 3: Ten (10) or more Controlling Beneficial Owners.~~
2. ~~Medical Marijuana Businesses.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Medical Marijuana Store</u>	<u>Level 1:</u>	<u>Level 1:</u>	<u>Level 1:</u>
	\$6,440.00	\$1,610.00	\$8,050.00
	<u>Level 2:</u>	<u>Level 2:</u>	<u>Level 2:</u>
	\$9,680.00	\$2,420.00	\$12,100.00
	<u>Level 3:</u>	<u>Level 3:</u>	<u>Level 3:</u>

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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
	\$12,880.00	\$3,220.00	\$16,100.00
<u>Medical Marijuana Products Manufacturer</u>	<u>Level 1:</u>	<u>Level 1:</u>	<u>Level 1:</u>
	\$2,440.00	\$610.00	\$3,050.00
	<u>Level 2:</u>	<u>Level 2:</u>	<u>Level 2:</u>
	\$3,680.00	\$920.00	\$4,600.00
	<u>Level 3:</u>	<u>Level 3:</u>	<u>Level 3:</u>
	\$4,880.00	\$1,220.00	\$6,100.00
<u>Medical Marijuana Cultivation Facility Class 1 (1-500 plants)</u>	<u>Level 1:</u>	<u>Level 1:</u>	<u>Level 1:</u>
	\$2,440.00	\$610.00	\$3,050.00
	<u>Level 2:</u>	<u>Level 2:</u>	<u>Level 2:</u>
	\$3,680.00	\$920.00	\$4,600.00
	<u>Level 3:</u>	<u>Level 3:</u>	<u>Level 3:</u>
	\$4,880.00	\$1,220.00	\$6,100.00
<u>Medical Marijuana Testing Facility</u>	<u>Level 1:</u>	<u>Level 1:</u>	<u>Level 1:</u>
	\$2,440.00	\$610.00	\$3,050.00
	<u>Level 2:</u>	<u>Level 2:</u>	<u>Level 2:</u>
	\$3,680.00	\$920.00	\$4,600.00
	<u>Level 3:</u>	<u>Level 3:</u>	<u>Level 3:</u>
	\$4,880.00	\$1,220.00	\$6,100.00
<u>Medical Marijuana Transporter</u>	\$5,520.00	\$1,380.00	\$6,900.00
<u>Medical Marijuana Business Operator</u>	<u>Level 1:</u>	<u>Level 1:</u>	<u>Level 1:</u>
	\$3,200.00	\$800.00	\$4,000.00
	<u>Level 2:</u>	<u>Level 2:</u>	<u>Level 2:</u>
	\$4,800.00	\$1,200.00	\$6,000.00
	<u>Level 3:</u>	<u>Level 3:</u>	<u>Level 3:</u>
	\$6,400.00	\$1,600.00	\$8,000.00



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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Marijuana Research and Development Facility</u>	<u>Level 1:</u>	<u>Level 1:</u>	<u>Level 1:</u>
	\$2,440.00	\$610.00	\$3,050.00
	<u>Level 2:</u>	<u>Level 2:</u>	<u>Level 2:</u>
	\$3,680.00	\$920.00	\$4,600.00
	<u>Level 3:</u>	<u>Level 3:</u>	<u>Level 3:</u>
	\$4,880.00	\$1,220.00	\$6,100.00

2. ~~Retail Marijuana Businesses.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Retail Marijuana Store</u>	\$5,000.00	<u>Level 1:</u>	<del>State Check</del>
		\$2,850.00	<u>Level 1:</u>
			\$5,350.00
		<u>Level 2:</u>	<u>Level 2:</u>
		\$5,550.00	\$8,050.00
<u>Retail Marijuana Products Manufacturer</u>	\$5,000.00	<u>Level 3:</u>	<u>Level 3:</u>
		\$8,200.00	\$10,700.00
			<del>Local Check</del>
			\$2,500.00
<u>Retail Marijuana Products Manufacturer</u>	\$5,000.00	<u>Level 1:</u>	<del>State Check</del>
		\$2,200.00	<u>Level 1:</u>
			\$4,700.00
		<u>Level 2:</u>	<u>Level 2:</u>
		\$4,550.00	\$7,050.00
<u>Retail Marijuana Products Manufacturer</u>	\$5,000.00	<u>Level 3:</u>	<u>Level 3:</u>
		\$6,900.00	\$9,400.00
			<del>Local Check</del>
			\$2,500.00

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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Retail Marijuana Cultivation Facility Tier 1 (1-1,800 plants)</u>	\$5,000.00	<u>Level 1:</u> \$2,200.00  <u>Level 2:</u> \$4,550.00  <u>Level 3:</u> \$6,900.00	<del>State Check</del> <del>Level 1:</del> <del>\$4,700.00</del> <del>Level 2:</del> <del>\$7,050.00</del> <del>Level 3:</del> <del>\$9,400.00</del> <b>Local Check</b> <b>\$2,500.00</b>
<u>Retail Marijuana Testing Facility</u>	\$1,000.00	<u>Level 1:</u> \$2,000.00  <u>Level 2:</u> \$3,250.00  <u>Level 3:</u> \$4,500.00	<del>State Check</del> <del>Level 1:</del> <del>\$2,500.00</del> <del>Level 2:</del> <del>\$3,750.00</del> <del>Level 3:</del> <del>\$5,000.00</del> <b>Local Check</b> <b>\$500.00</b>
<u>Retail Marijuana Transporter</u>	\$1,000.00	\$5,850.00	<del>State Check</del> <del>\$6,350.00</del> <b>Local Check</b> <b>\$500.00</b>

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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Retail Marijuana Business Operator</u>	\$1,000.00	<u>Level 1:</u> \$2,950.00 <u>Level 2:</u> \$4,700.00 <u>Level 3:</u> \$6,400.00	<b>State Check</b> <u>Level 1:</u> \$3,450.00 <u>Level 2:</u> \$5,200.00 <u>Level 3:</u> \$6,900.00 <b>Local Check</b> \$500.00
<u>Marijuana Hospitality</u>	\$1,000.00	\$1,350.00	<b>State Check</b> \$1,850.00 <b>Local Check</b> \$500.00
<u>Retail Marijuana Hospitality and Sales Business</u>	\$5,000.00	\$2,850.00	<b>State Check</b> \$5,350.00 <b>Local Check</b> \$2,500.00

B. Regulated Marijuana Business Renewal Application and License Renewal Fees.1. Medical Marijuana Businesses.

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Medical Marijuana Store</u>	\$1,840.00	\$460.00	\$2,300.00
<u>Medical Marijuana Products Manufacturer</u>	\$1,840.00	\$460.00	\$2,300.00
<u>Medical Marijuana Cultivation Facility</u> Class 1 (1-500 plants)	\$1,840.00	\$460.00	\$2,300.00
	\$2,680.00	\$670.00	\$3,350.00

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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Class 2 (501-1,500 plants)</u>	\$3,960.00	\$990.00	\$4,950.00
<u>Class 3 (1,501-3,000 plants)</u>	\$840.00	\$210.00	\$1,050.00
<u>Expanded Production Management (The amount shown is charged in addition to the Class 3 fee for each class of 3,000 plants over Class 3)</u>			
<u>Medical Marijuana Testing Facility</u>	\$1,840.00	\$460.00	\$2,300.00
<u>Medical Marijuana Transporter (every 2 years)</u>	\$4,880.00	\$1,220.00	\$6,100.00
<u>Medical Marijuana Business Operator</u>	\$2,560.00	\$640.00	\$3,200.00
<u>Marijuana Research and Development Facility</u>	\$1,840.00	\$460.00	\$2,300.00

**2. Retail Marijuana Businesses.**

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Retail Marijuana Store</u>	\$1,840.00	\$460.00	\$2,300.00
<u>Retail Marijuana Products Manufacturer</u>	\$1,840.00	\$460.00	\$2,300.00
<u>Retail Marijuana Cultivation Facility</u>	\$1,840.00	\$460.00	\$2,300.00
<u>Tier 1 (1-1,800 plants)</u>			
<u>Tier 2 (1,801-3,600 plants)</u>	\$2,680.00	\$670.00	\$3,350.00
<u>Tier 3 (3,601-6,000 plants)</u>	\$3,440.00	\$860.00	\$4,300.00
<u>Tier 4 (6,001-10,200 plants)</u>	\$5,000.00	\$1,250.00	\$6,250.00
<u>Tier 5 (10,201-13,800 plants)</u>	\$7,120.00	\$1,780.00	\$8,900.00
<u>Expanded Production Management (The amount shown is charged in addition to the Tier 5 fee for each additional tier of 3,600 plants over Tier 5)</u>	\$840.00	\$210.00	\$1,050.00
<u>Retail Marijuana Testing Facility</u>	\$1,840.00	\$460.00	\$2,300.00

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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Retail Marijuana Transporter</u>	\$4,880.00	\$1,220.00	\$6,100.00
<u>Retail Marijuana Business Operator</u>	\$2,560.00	\$640.00	\$3,200.00
<u>Marijuana Hospitality Business</u>	\$1,040.00	\$260.00	\$1,300.00
<u>Retail Marijuana Hospitality and Sales Business</u>	\$1,840.00	\$460.00	\$2,300.00

C. ~~Requests for a Finding of Suitability, Owner License and Owner Identification Badge—Initial Application and Renewal Fees.~~

1. ~~Levels.~~ The fee for Owner Entities corresponds to the number of Controlling Beneficial Owners of the licensed Regulated Marijuana Business created through the Owner Entity, in accordance with Rule 2-235(A)(2)(a).
2. ~~Requests for Finding of Suitability Fees.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<del>Controlling Beneficial Owner—Natural Person</del>	\$680.00	\$170.00	\$850.00
<del>Controlling Beneficial Owner—Natural Person—Social Equity (applies to Applicant seeking to be found suitable as a Social Equity Licensee)</del>	\$680.00	\$170.00	\$850.00
<del>Passive Beneficial Owner</del>	\$680.00	\$170.00	\$850.00
<del>Owner Entity:</del>			
<del>Level 1: One (1) to four (4) Controlling Beneficial Owners and/or Owner Entities</del>	\$680.00	\$170.00	\$850.00
<del>Level 2: Five (5) to nine (9) Controlling Beneficial Owners and/or Owner Entities</del>	\$1,040.00	\$260.00	\$1,300.00

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<del>Level 3: Ten (10) or more Controlling Beneficial Owners and/or Owner Entities</del>	<del>\$1,360.00</del>	<del>\$340.00</del>	<del>\$1,700.00</del>
<del>Controlling Beneficial Owner—Publicly Traded Corporation (PTC)</del>	<del>\$16,720.00</del>	<del>\$4,180.00</del>	<del>\$20,900.00</del>
<del>Controlling Beneficial Owner—Qualified Private Fund—Qualified Institutional Investor</del>	<del>\$3,400.00</del>	<del>\$850.00</del>	<del>\$4,250.00</del>
<del>Controlling Beneficial Owner—Trust</del>	<del>\$3,400.00</del>	<del>\$850.00</del>	<del>\$4,250.00</del>

**3. License Renewal Fees.**

<b><u>License Type</u></b>	<b><u>Application Fee</u></b>	<b><u>License Fee</u></b>	<b><u>Total Due at Application</u></b>
<del>Owner Individual Licensees, Passive Beneficial Owners who elect to be found suitable for licensure as an Owner</del>	<del>\$440.00</del>	<del>\$110.00</del>	<del>\$550.00</del>
<del>Owner Entities</del>			
<del>Level 1: One (1) to four (4) Controlling Beneficial Owners and/or Owner Entities</del>	<del>\$440.00</del>	<del>\$110.00</del>	<del>\$550.00</del>
<del>Level 2: Five (5) to nine (9) Controlling Beneficial Owners and/or Owner Entities</del>	<del>\$660.00</del>	<del>\$165.00</del>	<del>\$825.00</del>
<del>Level 3: Ten (10) or more Controlling Beneficial Owners and/or Owner Entities</del>	<del>\$880.00</del>	<del>\$220.00</del>	<del>\$1,100.00</del>
<del>Controlling Beneficial Owner—Publicly Traded Corporation (PTC)</del>	<del>\$4,000.00</del>	<del>\$1,000.00</del>	<del>\$5,000.00</del>

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<del>Controlling Beneficial Owner—Qualified Private Fund—Qualified Institutional Investor—Trust</del>	<del>\$1,600.00</del>	<del>\$400.00</del>	<del>\$2,000.00</del>
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~~D. Employee License—Initial Fees and Renewal Fees.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<del>Employee License</del>	<del>\$120.00</del>	<del>\$30.00</del>	<del>\$150.00</del>
<del>Conditional Employee License</del>	<del>\$160.00</del>	<del>\$40.00</del>	<del>\$200.00</del>
<del>Employee License Renewal</del>	<del>\$80.00</del>	<del>\$20.00</del>	<del>\$100.00</del>

~~E. Temporary Appointee Registration—Request for Finding of Suitability Fees and Renewal Fees.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<del>Temporary Appointee Registration (Natural Person)</del>	<del>\$240.00</del>	<del>\$60.00</del>	<del>\$300.00</del>
<del>Temporary Appointee Registration (Entity)</del>	<del>\$840.00</del>	<del>\$210.00</del>	<del>\$1,050.00</del>
<del>Temporary Appointee Registration (Natural Person) Renewal</del>	<del>\$240.00</del>	<del>\$60.00</del>	<del>\$300.00</del>
<del>Temporary Appointee Registration (Entity) Renewal</del>	<del>\$680.00</del>	<del>\$170.00</del>	<del>\$850.00</del>

~~F. Other Application Fees. The following other fees apply:~~~~1. Permits.~~

<u>License Type</u>	<u>Total Due at Application</u>
<del>Transition Permit:</del>	<del>\$350.00</del>

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<del>Delivery Permit:</del>	<del>\$5,250.00</del>
<del>Delivery Permit Renewal:</del>	<del>\$2,650.00</del>
<del>Centralized Distribution Permit</del>	<del>\$50.00</del>
<del>Off-Premises Storage Facility Permit</del>	<del>\$2,000.00</del>
<del>R&amp;D Co-Location Permit</del>	<del>\$100.00</del>

~~2. Changes of Ownership Fees: The following fees apply per a Regulated Marijuana Business License.~~

<del><u>License Type</u></del>	<del><u>Total Due with Submission</u></del>
<del>Change of Controlling Beneficial Owner:</del>	
<del>Involving up to four (4) Controlling Beneficial Owners and/or Owner Entities, (i.e. buyers and sellers)</del>	<del>\$2,800.00</del>
<del>Involving five (5) to nine (9) Controlling Beneficial Owners and/or Owner Entities, (i.e. buyers and sellers)</del>	<del>\$4,900.00</del>
<del>Involving ten (10) or more Controlling Beneficial Owners and/or Owner Entities, (i.e. buyers and sellers)</del>	<del>\$6,350.00</del>
<del>Changes Exempt from a Change of Ownership not involving a reallocation</del>	<del>\$1,150.00</del>
<del>Changes Exempt from a Change of Ownership involving a reallocation</del>	<del>\$2,000.00</del>

~~3. Applications to Modify Fees: The following fees apply per a Regulated Marijuana Business License.~~

<del><u>License Type</u></del>	<del><u>Total Due at Application</u></del>
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Modification of Premises Fee (MOP)	\$150.00
Request Fee (for Tier Increase / Class Increase)	\$300.00
Change of Trade Name (COTN)	\$100.00
Change of Location (COL)	\$650.00
Security Waiver	\$600.00
Contingency Plan	\$1,300.00

**4. Other Fees:**

<b><u>License Type</u></b>	<b><u>Application Fee</u></b>	<b><u>License Fee</u></b>	<b><u>Total Due at Application</u></b>
<del>Reduced Testing Allowance Certification (effective January 8, 2024)</del>	<del>\$4,000.00</del>	<del>\$0</del>	<del>\$4,000.00</del>
<del>Duplicate Business License</del>	<del>\$50.00</del>	<del>\$0</del>	<del>\$50.00</del>
<del>Duplicate Owner/Employee License</del>	<del>\$50.00</del>	<del>\$0</del>	<del>\$50.00</del>
<del>Reinstatement Fee</del>	<del>\$350.00</del>	<del>\$0</del>	<del>-\$350.00</del>
<del>Responsible Vendor Program Provider:</del>			
<del>Responsible Vendor Program Provider Initial Application</del>	<del>\$1,100.00</del>	<del>\$0</del>	<del>-\$1,100.00</del>
<del>Duplicate Responsible Vendor Program Provider Certificate</del>	<del>\$100.00</del>	<del>\$0</del>	<del>-\$100.00</del>
<del>Responsible Vendor Program Provider Renewal</del>	<del>\$360.00</del>	<del>\$90.00</del>	<del>\$450.00</del>
<del>R&amp;D Project Proposal Fee</del>	<del>\$650.00</del>	<del>\$0</del>	<del>\$650.00</del>

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Security Waiver Renewal Fee	\$300.00	\$0	\$300.00
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G. ~~When Fees are Due.~~ All fees in this Rule are due at the time the application or request is submitted.

**Basis and Purpose – 2-206**

The statutory basis for this rule includes but is not limited to sections ~~44-10-103, 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(b), 44-10-203(2)(h), 44-10-203(2)(q), 44-10-203(2)(w), 44-10-203(2)(dd)(XII), 44-10-303(2)(b), 44-10-308(5), 44-10-310(7), 44-10-313, 44-10-401, 44-10-801, 44-10-802, 44-10-803, 44-10-1201, 44-10-1202, C.R.S.~~ The purpose of this rule is to establish fees required for applications, renewals, licenses fees, permits, and other fees required to accompany applications and submissions to the Division by Social Equity Licensees.

**2-206 – Social Equity Fees - Repealed**

A. ~~When Reduced Fees Apply.~~ Reduced fees apply to Licensees who have been found suitable as a Social Equity Licensee pursuant to Rule 2-220(C) under the following circumstances:

1. ~~The first Owner Entity initial finding of suitability application submitted by the Social Equity Licensee;~~
2. ~~The first and second initial Regulated Marijuana Business License applications submitted by the Licensee;~~
3. ~~The first and second initial delivery permit applications submitted by the Licensee (if applicable);~~
4. ~~The first renewal after July 1, 2023 of any two Regulated Marijuana Business Licenses issued;~~
5. ~~The first renewal after July 1, 2023 of any two delivery permits issued;~~
6. ~~The first renewal after July 1, 2023 of one Owner Entity License issued; and~~
7. ~~The first renewal after July 1, 2023 of one Owner License issued.~~

B. ~~Finding of Suitability Requests and Owner License – Initial Application and Renewal Fees Renewals.~~

1. ~~Finding of Suitability Requests Fees.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<u>Request for Finding of Suitability – Controlling Beneficial Owner – Natural Person</u>	<u>\$720.00</u>	<u>\$0.00</u>	<u>\$720.00</u>

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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<del>Controlling Beneficial Owner—Natural Person—Social Equity (applies to Applicant seeking to be found suitable as a Social Equity Licensee)</del>	<del>\$0.00</del> \$680.00	<del>\$0.00</del> \$170.00	<del>\$0.00</del> \$850.00
<del>Controlling Beneficial Owner—Owner Entity</del>	<del>\$160.00</del>	<del>\$40.00</del>	<del>\$200.00</del>

~~2. Controlling Beneficial Owner License Renewal Fees.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<del>Controlling Beneficial Owner Licensees, including Passive Beneficial Owners electing to be subject to licensure</del>	<del>\$120.00</del>	<del>\$30.00</del>	<del>\$150.00</del>
<del>Controlling Beneficial Owner—Owner Entity</del>	<del>\$120.00</del>	<del>\$30.00</del>	<del>\$150.00</del>

~~C. Retail Marijuana Business—Initial and Renewal Application and License Fees.~~~~1. Initial Application and License Fees.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<del>Retail Marijuana Store</del>	<del>\$0</del>	<del>\$1,350.00</del>	<del>\$1,350.00</del>
<del>Retail Marijuana Products Manufacturer</del>	<del>\$0</del>	<del>\$1,200.00</del>	<del>\$1,200.00</del>
<del>Retail Marijuana Cultivation Facility—Tier 1</del>	<del>\$0</del>	<del>\$1,200.00</del>	<del>\$1,200.00</del>
<del>Retail Marijuana Testing Facility</del>	<del>\$0</del>	<del>\$650.00</del>	<del>\$650.00</del>
<del>Retail Marijuana Transporter</del>	<del>\$0</del>	<del>\$1,600.00</del>	<del>\$1,600.00</del>
<del>Retail Marijuana Business Operator</del>	<del>\$0</del>	<del>\$850.00</del>	<del>\$850.00</del>

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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
Marijuana Hospitality Business	\$0	\$450.00	\$450.00
Retail Marijuana Hospitality and Sales Business	\$0	\$1,350.00	\$1,350.00

2. ~~Renewal Application and License Fees.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<del>Retail Marijuana Store</del>	<del>\$480.00</del>	<del>\$120.00</del>	<del>\$600.00</del>
<del>Retail Marijuana Products Manufacturer</del>	<del>\$480.00</del>	<del>\$120.00</del>	<del>\$600.00</del>
<del>Retail Marijuana Cultivation Facility</del>	<del>\$480.00</del>	<del>\$120.00</del>	<del>\$600.00</del>
<del>Tier 1 (1 — 1,800 Plants)</del>	<del>\$680.00</del>	<del>\$170.00</del>	<del>\$850.00</del>
<del>Tier 2 (1,801 — 3,600 Plants)</del>	<del>\$880.00</del>	<del>\$220.00</del>	<del>\$1,100.00</del>
<del>Tier 3 (3,601 — 6,000 Plants)</del>	<del>\$1,240.00</del>	<del>\$310.00</del>	<del>\$1,550.00</del>
<del>Tier 4 (6,001 — 10,200 Plants)</del>	<del>\$1,800.00</del>	<del>\$450.00</del>	<del>\$2,250.00</del>
<del>Tier 5 (10,201 — 13,800 Plants)</del>	<del>\$200.00</del>	<del>\$50.00</del>	<del>\$250.00</del>
<del>Expanded Production Management (The amount shown is charged in addition to the Tier 5 fee for each additional 3,600 plans after Tier 5)</del>			
<del>Retail Marijuana Testing Facility</del>	<del>\$480.00</del>	<del>\$120.00</del>	<del>\$600.00</del>

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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<del>Retail Marijuana Transporter (every 2 years)</del>	<del>\$1,240.00</del>	<del>\$310.00</del>	<del>\$1,550.00</del>
<del>Retail Marijuana Business Operator</del>	<del>\$640.00</del>	<del>\$160.00</del>	<del>\$800.00</del>
<del>Marijuana Hospitality Business</del>	<del>\$280.00</del>	<del>\$70.00</del>	<del>\$350.00</del>
<del>Retail Marijuana Hospitality and Sales Business</del>	<del>\$480.00</del>	<del>\$120.00</del>	<del>\$600.00</del>

~~D. Medical Marijuana Business Initial and Renewal Application and License Fees.~~~~1. Initial Application and License Fees.~~

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
<del>Medical Marijuana Store</del>	<del>\$1,600.00</del>	<del>\$400.00</del>	<del>\$2,000.00</del>
<del>Medical Marijuana Products Manufacturer</del>	<del>\$600.00</del>	<del>\$150.00</del>	<del>\$750.00</del>
<del>Medical Marijuana Cultivation Facility—Class 1</del>	<del>\$600.00</del>	<del>\$150.00</del>	<del>\$750.00</del>
<del>Medical Marijuana Testing Facility</del>	<del>\$600.00</del>	<del>\$150.00</del>	<del>\$750.00</del>
<del>Medical Marijuana Transporter</del>	<del>\$1,400.00</del>	<del>\$350.00</del>	<del>\$1,750.00</del>
<del>Medical Marijuana Business Operator</del>	<del>\$800.00</del>	<del>\$200.00</del>	<del>\$1,000.00</del>
<del>Marijuana Research and Development Facility</del>	<del>\$600.00</del>	<del>\$150.00</del>	<del>\$750.00</del>

~~2. Renewal Application and License Fees.~~

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<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
Medical Marijuana Store	\$480.00	\$120.00	\$600.00
Medical Marijuana Products Manufacturer	\$480.00	\$120.00	\$600.00
Medical Marijuana Cultivation Facility— Class 1	\$480.00	\$120.00	\$600.00
Class 2	\$680.00	\$170.00	\$850.00
Class 3	\$1,000.00	\$250.00	\$1,250.00
Expanded Production Management (The amount shown is charged in addition to the Class 3 fee for each class of 3,000 plants over Class 3)	\$200.00	\$50.00	\$250.00
Medical Marijuana Testing Facility	\$480.00	\$120.00	\$600.00
Medical Marijuana Transporter (every 2 years)	\$1,240.00	\$310.00	\$1,550.00
Medical Marijuana Business Operator	\$640.00	\$160.00	\$800.00
Marijuana Research and Development Facility	\$480.00	\$120.00	\$600.00

E. Delivery Permit Fees:

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>	<u>Total Due at Application</u>
Delivery Permit	\$1,300.00	\$0	\$1,300.00
Delivery Permit Renewal	\$650.00	\$0	\$650.00

~~F. When Fees are Due. All fees in this Rule are due at the time the application or request is submitted.~~

### **Basis and Purpose – 2-210**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(w), 44-10-305, 44-10-901(2), and 24-4-105(2) C.R.S. The purpose of this rule is to clarify the duties that Applicants and Licensees have when reporting to the State Licensing Authority information that is necessary for the issuance of a state license. These duties include but are not limited to reporting and keeping a mailing address current, reporting a felony conviction or other disqualifying event, cooperating with the State Licensing Authority and his or her employees, and notifying the State Licensing Authority of any change of registered agent in the State of Colorado. This rule further provides that all communications or notifications that the State Licensing Authority or Division send an Applicant or Licensee will be sent to the last known address. The Applicant's or Licensee's failure to notify the Division of a change of address does not relieve the Applicant or Licensee from timely responding to any correspondence or notification.

### **2-210 – Duties of All Applicants and Licensees**

A. Duty to Keep Mailing Address Current: All Applicants and Licensees.

1. Timing of Notification. An Applicant or Licensee must provide a physical mailing address to the Division and may provide an electronic mailing address to the Division. A Licensee must inform the Division in writing of any change to its physical mailing address and/or electronic mailing address within 28 days of the change. The Division will not change a Licensee's information without written notice from the Licensee or its authorized agent.
2. State Licensing Authority and Division Communications. The State Licensing Authority and Division will send any formal notifications or determinations regarding any application or an administrative action to the last mailing address and to the last electronic mailing address, if any, furnished to the Division by the Applicant or Licensee.
3. Failure to Change Address Does Not Relieve Applicant's or Licensee's Obligations. An Applicant's or Licensee's failure to notify the Division of a change of physical or electronic mailing address does not relieve the Applicant or Licensee from the obligation of responding to a Division communication or a State Licensing Authority communication.

B. Duty to Report Felony - Convictions, Deferred Sentences and Judgments. An Applicant or Licensee must notify the Division in writing of any felony conviction or deferred sentence or judgment regarding a felony against him or her within seven days of the conviction or deferred sentence or judgment. The notification must include disposition documents. Failure to make required notification to the Division may be grounds for administrative action.

C. Duty to Report Any Disqualifying Event. Applicants and Licensees must notify the Division within seven days of any change of fact that would result in the Applicant or

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Licensee being disqualified from holding a license, permit, or registration pursuant to the Marijuana Code, or these Rules.

- D. Duty to Cooperate. Applicants and Licensees must cooperate in any investigation conducted by the Division. Failure to cooperate with a Division investigation may be grounds for denial of an application or for administrative action against a Licensee.
- E. Duty to Report Change of Registered Agent. A Regulated Marijuana Business must disclose any change of its registered agent in the State of Colorado within seven days of the change.

**Basis and Purpose – 2-215**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(a), 44-10-203(2)(c), 44-10-203(2)(k), 44-10-203(2)(w), 44-10-305, 44-10-307, 44-10-308, 44-10-309, 44-10-310, 44-10-311, 44-10-312, 44-10-313, 44-10-314 and 44-10-316, C.R.S. The purpose of this rule is to establish requirements for all applications including: required application fees; complete, accurate and truthful applications; notification of the applicable local licensing authority or local jurisdiction; that the Applicant or Licensee establish he, she or it is not a person prohibited from licensure; submission of additional information or documents upon request by the Division; and notification that all application material may be disclosed consistent with the Marijuana Code.

**2-215 – All Applications Requirements**

- A. Applicability. This Rule 2-215 applies to all applications submitted to the Division for a license, permit, or registration provided by the Marijuana Code.
- B. Division Forms Required. All applications for licenses, registrations, or permits authorized by subsections 44-10-401(2) and (3), C.R.S., must be made on current Division forms.
- C. Application Fees Required. Applications must be accompanied by full remittance of the required ~~application and license~~ fees. Owner Licenses, Regulated Marijuana Business Licenses, and delivery permits are subject to annual payments as described in Rules 2-110, 2-115, 2-120, 2-125 and 2-145 See Rules 2-205 and 2-206.
- D. Complete, Accurate, and Truthful Applications Required. Applications must be complete, accurate, and truthful and include all attachments and supplemental information. Incomplete applications may not be accepted by the Division.
- E. Local Licensing Authority/Local Jurisdiction.
  - 1. Each application must identify the applicable Local Licensing Authority or Local Jurisdiction.
  - 2. If the Local Licensing Authority or Local Jurisdiction requires a physical copy of the application, the Applicant or Licensee must submit the original application and one identical copy to the Division. Otherwise the Applicant or Licensee must submit only the original application to the Division.



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- F. Applicant Not Prohibited From Licensure. Applicants must provide information establishing the Applicant is not a Person prohibited from licensure by section 44-10-307, C.R.S.
- G. Additional Information and Documents May Be Required.
1. Upon request by the Division, an Applicant must provide additional information or documents required to process and investigate the application. The additional information or documents must be provided within seven days of the request, however, this deadline may be extended for a period of time commensurate with the scope of the request.
  2. An Applicant's failure to provide requested information or documents by the deadline may be grounds for denial of the application.
- H. Application Forms Accessible. All application forms provided by the Division and filed by an Applicant for a license, registration, or permit, including attachments and any other documents associated with the investigation, may be used for a purpose authorized by the Marijuana Code, for investigation or enforcement of any international, federal, state, or local securities law or regulation, for any other state or local law enforcement purpose, or as otherwise required by law.

**Basis and Purpose – 2-220**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(k), 44-10-203(2)(a), 44-10-203(2)(w), 44-10-203(2)(ee), 44-10-203(7), 44-10-301, 44-10-305, 44-10-307, 44-10-308, 44-10-309, 44-10-310, 44-10-311, 44-10-312, 44-10-313, and 44-10-316, C.R.S. The purpose of this rule is to establish the general requirements and processes for submission of an initial application for a Regulated Marijuana Business to the State Licensing Authority.

**2-220 – Initial Application Requirements for Regulated Marijuana Businesses**

- A. Documents and Information Requested. Every initial application for a Regulated Marijuana Business License must include all required documents and information including, but not limited to:
1. A copy of the local license application, if required, for a Regulated Marijuana Business.
  2. Certificate of Good Standing from the jurisdiction in which the Entity was formed, which must be one of the states of the United States, territories of the United States, District of Columbia, or another country that authorizes the sale of marijuana.
  3. If the Applicant is an Entity, the identity and physical address of its registered agent in the state of Colorado.
  4. Organizational Documents. Articles of Incorporation, by-laws, and any shareholder agreement for a corporation; articles of organization and operating agreement for a limited liability company; or partnership agreement for a partnership.

5. Corporate Governance Documents.
  - a. A Regulated Marijuana Business that is a Publicly Traded Corporation must maintain corporate governance documents as required by the securities exchange on which its securities are listed and traded, and section 44-10-103(50), C.R.S., and must provide those corporate governance documents with each initial application.
  - b. A Regulated Marijuana Business that is not a Publicly Traded Corporation is not required to maintain any corporate governance documents. However, if the Regulated Marijuana Business that is not a Publicly Traded Corporation voluntarily maintains corporate governance documents, the Division encourages inclusion of such documents with each initial application.
6. The deed, lease, sublease, rental agreement, contract, or any other document(s) establishing the Applicant is, or will be, entitled to possession of the premises for which the application is made.
7. Legible and accurate diagram for the facility. The diagram must include a plan for the Licensed Premises and a separate plan for the security/surveillance plan including camera location, number and direction of coverage. If the diagram is larger than 8.5 x 11 inches, the Applicant must also provide a copy of the diagram in a portable document format (.pdf).
8. All required findings of suitability issued by the Division.
9. If the Applicant is a Publicly Traded Corporation:
  - a. Documents establishing the Publicly Traded Corporation qualifies to hold a Regulated Marijuana Business License including but not limited to disclosure of securities exchange(s) on which its Securities are listed and traded, the stock symbol(s), the identity of all regulators with regulatory oversight over its Securities; and
  - b. Divestiture plan for any Controlling Beneficial Owner that is a Person prohibited by the Marijuana Code, has had her or his Owner License revoked, or has been found unsuitable.
10. Financial Statements. Consolidated financial statements (which may be prepared on either a calendar or fiscal year basis) that were prepared in the preceding 365 days, and which must include a balance sheet, an income statement, and a cash flow statement. If the Applicant or Regulated Marijuana Business is required to have audited financial statements by another regulator (e.g. United States Securities and Exchange Commission or the Canadian Securities Administrators) the financial statements provided to the Division must be audited and must also include all footnotes, schedules, auditors' report(s), and auditor's opinion(s). If the financial statements are publicly available on a website (e.g. EDGAR or SEDAR), the Applicant or Regulated Marijuana Business may provide notification of the website link where the financial statements can be accessed in lieu of hardcopy submission.

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11. Tax Documents. While duplicate tax documentation is not required to be provided with the application, the Applicant shall cooperate with the Division to establish proof of compliant return filing and payment of taxes related to any Regulated Marijuana Business in which the Person is, or was, required to file and pay taxes.

B. Local Licensing/Approval Required.

1. Regulated Marijuana Business Local Licensing Authority Approval Required.

- a. If the Division grants a License to a Regulated Marijuana Business before the Local Licensing Authority or Local Jurisdiction approves the application or grants a local license, the state License will be conditioned upon local approval. If the Local Licensing Authority denies the application, the state License will be revoked.
- b. An Applicant is prohibited from operating a Regulated Marijuana Business prior to obtaining all necessary licenses, registrations, permits, or approvals from both the State Licensing Authority and the Local Licensing Authority or Local Jurisdiction.

2. ~~Repealed. Retail Marijuana Business One Year to Obtain Local Jurisdiction Approval Required.~~

- ~~a. The Applicant has one year from the date of licensing by the State Licensing Authority to obtain approval or licensing from the Local Jurisdiction.~~
- ~~b. If the Applicant fails to obtain Local Jurisdiction approval or licensing within one year from grant of the state License, the state License may be renewed in accordance with Rule 2-225(G)(2).~~

C. Social Equity License Qualification.

1. A natural person who can establish he or she qualifies as a Social Equity Licensee may apply for either a Regulated Marijuana Business License or an Accelerator License.
2. Repealed.
3. Repealed.
4. Repealed.

D. Accelerator License Application and Qualification.

1. License Issuance.

- a. ~~Beginning January 1, 2021, a~~ Social Equity Licensee may apply for an Accelerator License. The application shall be made on Division forms and in accordance with the 2-200 Series Rules.
- b. An Accelerator Licensee may exercise the privileges of a Retail Marijuana Cultivation Facility License, Retail Marijuana Products Manufacturer License, or Retail Marijuana Store License on the Licensed Premises of a

Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, or Retail Marijuana Store that has been approved as an Accelerator-Endorsed Licensee or on a Licensed Premises under the control of the Accelerator-Endorsed Licensee.

2. Qualifications. To qualify for an Accelerator License, an Applicant must:
  - a. Be found suitable for licensure pursuant to Rule 2-235, unless otherwise exempted by these Rules; and
  - b. Be approved as a Social Equity Licensee pursuant to Rule 2-235(B.5) or 2-235(B.6).
3. Information Required to Establish Qualification as an Accelerator Licensee. To establish that an Applicant qualifies as an Accelerator Licensee, he or she must establish:
  - a. Qualification as a Social Equity Licensee; and
  - b. An affirmation that the Applicant has not been the Beneficial Owner of a Regulated Marijuana Business License issued pursuant to the Marijuana Code.

### **Basis and Purpose – 2-225**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(c), 44-10-203(2)(a), 44-10-203(2)(c), 44-10-203(2)(w), 44-10-203(2)(ee), 44-10-203(7), 44-10-305(2)(b)(I)(C), 44-10-307, 44-10-308, 44-10-309, 44-10-313, 44-10-314, and 44-10-316 C.R.S. The purpose of this rule is to establish the requirements and procedures for the license renewal process, including the circumstances under which an expired license may be reinstated.

### **2-225 – Renewal Application Requirements for All Licensees**

- A. License Periods.
  1. Regulated Marijuana Business and Owner Licenses are valid for a period not to exceed two years~~one year~~ from the date of issuance.
  2. ~~Medical Marijuana Transporters, Retail Marijuana Transporters, and~~ Employee Licenses are valid for a period not to exceed two years from the date of issuance.
  3. Licenses issued by a Local Licensing Authority or Local Jurisdiction may have a license term other than two years.
- B. Division Notification Prior to Expiration.
  1. The Division will send a notice of license renewal 90 days prior to the expiration of an existing Regulated Marijuana Business or Owner License by first class mail to the Licensee's mailing address of record.
  2. Failure to receive the Division notification does not relieve the Licensee of the obligation to timely renew the license.

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C. Renewal Deadline.

1. A Licensee must apply for the renewal of an existing license prior to the License's expiration date.
2. A renewal application submitted to the Division prior to the license's expiration date shall be deemed timely pursuant to subsection 24-4-104(7), C.R.S., and the Licensee may continue to operate until Final Agency Order on the renewal application.

D. If License Not Renewed Before Expiration. A License is immediately invalid upon expiration if the Licensee has not filed a renewal application and remitted all of the required ~~application and license~~ fees prior to the ~~l~~license expiration date. A Regulated Marijuana Business that fails to file a renewal application and remit ~~all~~ required ~~application and license~~ fees prior to the ~~l~~license expiration date must not operate unless it first obtains a new state license and any required local license.

1. Reinstatement of Expired Regulated Marijuana Business License. A Regulated Marijuana Business that fails to file a renewal application and remit ~~all~~ required ~~application and license~~ fees prior to the license expiration date may request that the Division reinstate an expired ~~l~~license only in accordance to the following:
  - a. The Regulated Marijuana Business License expired within the previous 30 days;
  - b. The Regulated Marijuana Business License has submitted an initial application pursuant to Rule 2-220. The initial application must be submitted prior to, or concurrently with, the request for reinstatement;
  - c. The Regulated Marijuana Business has paid the reinstatement fee in Rule ~~2-2052-140(A)~~; and
  - d. Any license or approval from the Local Licensing Authority or Local Jurisdiction is still valid or has been obtained.
2. Reinstatement Not Available for Surrendered or Revoked Licenses. A request for reinstatement cannot be submitted and will not be approved for a Regulated Marijuana Business License that was surrendered or revoked.
3. Reinstatement Not Available for Owner Licenses or Employee Licenses. A request for reinstatement cannot be submitted and will not be approved for expired, surrendered, or revoked Owner Licenses or Employee Licenses.
4. Denial of Request for Reinstatement or Administrative Action. The request for reinstatement may be denied if:
  - a. ~~If t~~The Licensee requesting reinstatement of a Regulated Marijuana Business License operated during a period that the license was expired, ~~the request may be subject to denial and t~~The Licensee may be subject to administrative action as authorized by the Marijuana Code or these Rules.

b. The Licensee requesting the reinstatement of a Regulated Marijuana Business License is a person prohibited from licensure pursuant to section 44-10-307 C.R.S.

5. Approval of Request for Reinstatement. Upon approval of any request for reinstatement of an expired Regulated Marijuana Business License, the Licensee may resume operations until the final agency action on the Licensee's initial application for a Regulated Marijuana Business License.
  - a. Approval of a request for reinstatement of an expired Regulated Marijuana Business License does not guarantee approval of the Regulated Marijuana Business Licensee's initial application; and
  - b. Approval of a request for reinstatement of an expired License does not waive the State Licensing Authority's authority to pursue administrative action on the expired License or initial application for a Regulated Marijuana Business License.
6. Final Agency Order on Initial Application for Regulated Marijuana Business.
  - a. If the initial application for a Regulated Marijuana Business License submitted pursuant to this Rule is approved, the new Regulated Marijuana Business License will replace the reinstated license.
  - b. If the initial application for a Regulated Marijuana Business License submitted pursuant to this Rule is denied, the Licensee must immediately cease all operations including but not limited to, Transfer of Regulated Marijuana. See Rule 2-270 – Application Denial and Voluntary Withdrawal; 8-115 – Disposition of Unauthorized Regulated Marijuana; 8-130 – Administrative Warrants.
- E. Voluntarily Surrendered or Revoked Licenses Not Eligible for Renewal. Any License that was voluntarily surrendered or that was revoked by a Final Agency Order is not eligible for renewal. Any Licensee who voluntarily surrendered its license or has had its License revoked by a Final Agency Order may only submit an initial application. The State Licensing Authority will consider the voluntary surrender or the Final Agency Order and all related facts and circumstances in determining approval of any subsequent initial application.
- F. Licenses Subject to Ongoing Administrative Action. Licenses subject to an administrative action are subject to the requirements of this Rule. Licenses that are not timely renewed expire and cannot be renewed.
- G. Documents Required at Renewal. A Regulated Marijuana Business and all Controlling Beneficial Owner-Entities must provide the following documents with every renewal application:
  1. Any document required by Rule 2-220(A)(1) through (9) that has changed since the document was last submitted to the Division. ~~It is a license violation affecting public safety to fail to submit any document that changed since the last~~

~~submission for the purpose of circumventing the requirements of the Marijuana Code, or these Rules;~~

2. A copy of the Local Licensing Authority or Local Jurisdiction approval, licensure, and/or documentation demonstrating timely submission of and pending local license renewal application;
  - a. ~~For renewal applications submitted after August 8, 2023, t~~The State Licensing Authority may renew a License that has not yet received Local Licensing Authority approval prior to the expiration of the state-issued License if:
    - i. The Applicant submits a renewal application in accordance with this Rule; and
    - ii. The Applicant submits written documentation that demonstrates the Licensee has taken action to obtain local approval and demonstrates why local approval has not yet been obtained or a local license issued.
3. A list of any sanctions, penalties, assessments, or cease and desist orders imposed by any securities regulatory agency, including but not limited to the United States Securities and Exchange Commission or the Canadian Securities Administrators;
4. A Regulated Marijuana Business operating under a single Entity name with more than one License may submit the following documents only once each calendar year on the first license renewal in lieu of submission with every license renewal in the same calendar year:
  - a. Financial statements required by Rule 2-220(A)(10);
  - b. If the Regulated Marijuana Business is a Publicly Traded Corporation, the most recent list of Non-Objecting Beneficial Owners possessed by the Regulated Marijuana Business;
  - c. A copy of all management agreement(s) the Regulated Marijuana Business has entered into regardless of whether the Person is licensed or unlicensed; and
  - d. Contracts, agreements, royalty agreements, equipment leases, financing agreements, or security contracts for any Indirect Financial Interest Holder that is required to be disclosed by Rule 2-230(A)(3).
- H. Controlling Beneficial Owner Signature. At least one Controlling Beneficial Owner shall sign the renewal application. However, other Controlling Beneficial Owners may be required to sign authorizations and/or requests to release information.
- I. Accelerator Program Renewal Application Requirements.
  1. Accelerator License Renewal. Accelerator Cultivator, Accelerator Manufacturer, and Accelerator Store Licenses are required to be renewed ~~biennially~~ annually. In

addition to the documents and information required to be submitted with a renewal application, an Accelerator Licensee must also disclose to the Division copies of any agreements between the Accelerator Licensee and the Accelerator-Endorsed Licensee under which it operated during the previous License term~~year~~.

2. Accelerator-Endorsed Licensee Additional Renewal Requirements.

- a. An endorsement issued to an Accelerator-Endorsed Licensee is required to be renewed biennially~~annually~~.
- b. At the time of submitting a renewal application for the endorsement, an Accelerator-Endorsed Licensee must submit the following:
  - i. The name and License number of any Accelerator Licensee for which it served as an Accelerator-Endorsed Licensee during the previous License term~~year~~;
  - ii. The equity assistance proposal if there have been any updates or amendments since the proposal was last submitted to the Division;
  - iii. Copies of any agreements between the Accelerator-Endorsed Licensee and the Accelerator Licensee(s), including the equity partnership agreement; and
  - iv. Any required Local Jurisdiction approvals.
- c. In addition to any other basis for denial of a renewal application, the State Licensing Authority may also consider the following facts and circumstances as additional bases for denial of an endorsement renewal application:
  - i. The Accelerator-Endorsed Licensee violated the terms of any equity partnership agreement it entered into with an Accelerator Licensee;
  - ii. The Accelerator-Endorsed Licensee ended the equity partnership agreement with an Accelerator Licensee prematurely; and
  - iii. The Accelerator-Endorsed Licensee provided false or misleading statements, records, or information to an Accelerator Licensee.

**Basis and Purpose – 2-230**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(c), 44-10-203(2)(t), 44-10-203(2)(u), 44-10-203(2)(w), 44-10-203(2)(ee), 44-10-203(7), 44-10-308, 44-10-309, and 44-10-316, C.R.S. Section 44-10-309, C.R.S., establishes varying disclosure requirements for Applicants and Licensees regarding disclosure of financial interests and ownership in a Regulated Marijuana Business. The purpose of this rule is to clarify information an Applicant or Licensee must disclose to the State Licensing Authority at the various levels, which include mandatory



disclosure, disclosure in the State Licensing Authority's discretion, and disclosure for reasonable cause. This rule also provides factors that will be considered in determining whether a Regulated Marijuana Business exercised reasonable care and whether a Person is in control of a Regulated Marijuana Business.

## **2-230 – Disclosure of Financial Interests in a Regulated Marijuana Business**

- A. Mandatory Disclosures. Information required to be disclosed by section 44-10-309, C.R.S., must be identified in every initial, renewal, and change of owner application. Mandatory disclosures include, but are not limited:
1. All Regulated Marijuana Businesses (including Publicly Traded Corporations and Entities that are not Publicly Traded Corporations) must disclose an organizational chart including the identity and ownership percentages of all Controlling Beneficial Owners;
  2. All Controlling Beneficial Owners.
    - a. For any Controlling Beneficial Owner that is an Entity (including Publicly Traded Corporations and entities that are not Publicly Traded Corporations):
      - i. The Controlling Beneficial Owner's Executive Officers; and
      - ii. Beneficial Owners of ten percent or more of the Controlling Beneficial Owner.
    - b. Natural persons:
      - i. Name;
      - ii. Address;
      - iii. Date of birth;
      - iv. Social Security Number or other Federal Government-issued identification number.
    - c. Qualified Private Fund: Organizational chart reflecting the identity and ownership percentages of the Qualified Private Fund's Executive Officers, investment advisers, investment adviser representatives, any trustee or equivalent, and any other Person that controls the investment in, or management or operations of, a Regulated Marijuana Business.
    - d. Trust: A copy of any documents required to establish the trust, a certification of the trust, and any additional documents necessary to demonstrate the type of trust, the identity and age of the trustee and all beneficiaries of the trust.
  3. Any Person that is an Indirect Financial Interest Holder that:
    - a. Holds two or more indirect financial interests;
    - b. Is also a Passive Beneficial Owner; or

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- c. That is contributing debt financing, secured or unsecured, that has not previously been disclosed and exceeds fifty percent of the operating capital of the Regulated Marijuana Business or if the calculation yields a negative number. Operating capital is defined as total current and fixed assets less total liabilities (as presented on the balance sheet consistent with the business's past practices), measured as of the nearest month's end prior to the date of the applicable loan document(s).
- B. Discretionary Disclosure. In his or her reasonable discretion, the State Licensing Authority may require disclosure following an initial or renewal application for a Regulated Marijuana business as follows:
  1. For a Regulated Marijuana Business or a Controlling Beneficial Owner, neither of which is a Publicly Traded Corporation, its:
    - a. Affiliates;
    - b. Beneficial Owners of a Controlling Beneficial Owner;
  2. Qualified Private Fund's Affiliates; and
  3. Managers of a Controlling Beneficial Owner.
- C. Reasonable Cause Disclosure. An Applicant will be notified by the State Licensing Authority of Reasonable Cause to require additional disclosure. The State Licensing Authority's notification will identify the facts and law supporting Reasonable Cause for the disclosure and the deadline for disclosure. The following may be required to be disclosed by the State Licensing Authority's notification:
  1. An updated list of all Non-objecting Beneficial Owners in a Publicly Traded Corporation that is either a Regulated Marijuana Business or a Controlling Beneficial Owner reflecting ownership as of the date of request;
  2. All Passive Beneficial Owners in a Regulated Marijuana Business that is not a Publicly Traded Corporation. If the Passive Beneficial Owner is not a natural person, the members of the board of directors, general partners, managing members, or Managers or Executive Officers and Beneficial Owners of ten percent or more of the Passive Beneficial Owner;
  3. A list of all Beneficial Owners of a Qualified Private Fund;
  4. All Indirect Financial Interest Holders of a Regulated Marijuana Business, and, for any Indirect Financial Interest Holder that is an Entity, the Beneficial Owners of ten percent or more of the Indirect Financial Interest Holder.
- D. Affirmation of Reasonable Care.
  1. Reasonable Care Affirmation for a Regulated Marijuana Business That is Not a Publicly Traded Corporation. A Regulated Marijuana Business that is not a Publicly Traded Corporation must affirm it exercised reasonable care to confirm its Passive Beneficial Owner(s), including any Qualified Institutional Investor(s), and Indirect Financial Interest Holder(s) are not Persons prohibited from holding

a license under these Rules or the Marijuana Code. A Regulated Marijuana Business exercises reasonable care if it:

- a. Receives documentation from each Passive Beneficial Owner, including any Qualified Institutional Investor, and each Indirect Financial Interest Holder affirming each is not a Person prohibited from holding a license by these Rules or the Marijuana Code; and
- b. The Regulated Marijuana Business does not know or reasonably should not know facts that would contradict the Passive Beneficial Owner or Indirect Financial Interest Holder's affirmation.

2. Reasonable Care Affirmation for a Regulated Marijuana Business That is a Publicly Traded Corporation. A Regulated Marijuana Business that is a Publicly Traded Corporation must affirm it exercised reasonable care to confirm its Passive Beneficial Owners, including any Qualified Institutional Investor(s), both of which are Non-Objecting Beneficial Owners, and Indirect Financial Interest Holder(s) are not Person prohibited from holding a license by these Rules and the Marijuana Code. A Regulated Marijuana Business that is a Publicly Traded Corporation exercises reasonable care if it:

- a. At least once every two years annually, checks a list of its Passive Beneficial Owners, including any Qualified Institutional Investor(s), both of which are Non-Objecting Beneficial Owners, against the Specially Designated Nationals and Blocked Persons List (SDN List) on the United States Treasury Office of Foreign Assets Control (OFAC) website and the Financial Industry Regulatory Authority (FINRA) website for Persons Barred by FINRA to determine if there are any prohibited Persons;
- b. Receives documentation from its Indirect Financial Interest Holder(s) affirming each is not a Person prohibited from holding a license by these Rules or the Marijuana Code; and
- c. The Regulated Marijuana Business does not know or reasonably should not know facts that would contradict the Indirect Financial Interest Holder's affirmation.

- E. Control. The State Licensing Authority will consider all facts and circumstances in determining whether a Person has Control of a Regulated Marijuana Business or is a Controlling Beneficial Owner by virtue of common control.

1. Non-Exhaustive Factors. Non-exhaustive facts and circumstances that will be considered when evaluating Control include, but are not limited to:
  - a. The Person's percentage of ownership, if any;
  - b. The Person's ability to influence the decision of the Regulated Marijuana Business;
  - c. The Person is a Manager of the Regulated Marijuana Business;

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- d. The Person has a close relationship, familial tie, or common purpose or motive with one or more Persons in Control of the Regulated Marijuana Business;
  - e. The Person has substantial business relationship(s) with the Regulated Marijuana Business;
  - f. The Person has the ability to control the proxy machinery or to win a proxy contest;
  - g. The Person is a primary creditor of the Regulated Marijuana Business; or
  - h. The Person is the original incorporator of the Regulated Marijuana Business.
2. Totality of the Evidence. The State Licensing Authority may consider the totality of the evidence when determining whether a Person has Control of a Regulated Marijuana Business or is a Controlling Beneficial Owner by virtue of common control.

**Basis and Purpose – 2-235**

The statutory basis for this rule includes, but is not limited to, sections 44-10-202(1)(e), 44-10-203(2)(c), 44-10-203(2)(ee), 44-10-308(4), 44-10-308(6), 44-10-309, 44-10-310, and 44-10-312(4), C.R.S. Section 44-10-310, C.R.S., requires that persons disclosed or who should have been disclosed to the State Licensing Authority obtain a finding of suitability from the State Licensing Authority. The purpose of this rule is to explain the conditions under which a Person is subject to either a mandatory finding of suitability or a finding of suitability for reasonable cause, to identify exemptions from an otherwise required finding of suitability and to identify the information and documents that, at a minimum, must be submitted in connection with any Person's request for a finding of suitability.

**2-235 – Suitability**

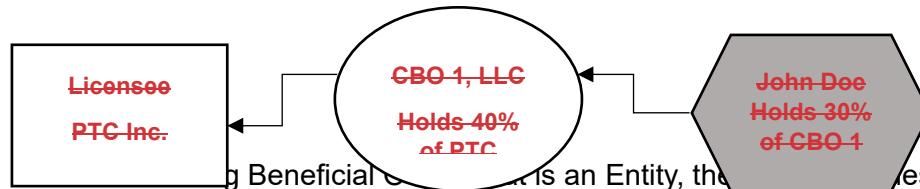
- A. Persons Subject to a Mandatory Finding of Suitability for Regulated Marijuana Businesses That Are Not Publicly Traded Corporations.
- 1. Except as provided in subparagraph (A)(1)(a), any Person intending to become a Controlling Beneficial Owner by submitting an initial application for any Regulated Marijuana Business that is not a Publicly Traded Corporation must first obtain a finding of suitability from the State Licensing Authority.
    - a. Members of the Board of Directors and Executive Officers of a Regulated Marijuana Business. An individual who is a Controlling Beneficial Owner because he or she is a member of the board of directors or an Executive Officer of a Regulated Marijuana Business or is Controlling a Regulated Marijuana Business but who does not possess ten percent or more of the Owner's Interest in a Regulated Marijuana Business must submit a request for a finding of suitability to the State Licensing Authority within 45 days of becoming such a Controlling Beneficial Owner.

2. Indirect Ownership of Ten-Percent or More Owner's Interests in a Regulated Marijuana Business.
  - a. For a Controlling Beneficial Owner that is an Entity, the Entity's request for finding of suitability must include all information necessary for the State Licensing Authority to determine whether that Entity's Executive Officers and any Person that directly or indirectly owns ten percent or more of the Owner's Interest in the Regulated Marijuana Business are suitable. For example, assuming the scenario depicted below, Licensee RMB LLC has one-thousand outstanding ownership interests and CBO 1, LLC owns 400 of those ownership interests. John Doe owns 30% of CBO 1, LLC. Therefore, John Doe indirectly owns 12% of the outstanding ownership interests of Licensee RMB LLC, and must apply to the State Licensing Authority for a finding of suitability.



3. Any Person that has not received a finding of suitability and who intends to become a Controlling Beneficial Owner of a Regulated Marijuana Business that is not a Publicly Traded Corporation must submit their request for a finding of suitability prior to or contemporaneously with the change of owner application, unless exempt from the change of owner application requirement under Rule 2-245(C).
  4. For a Controlling Beneficial Owner that is a trust, the trust's request for a finding of suitability must include all documents and information required or requested by the State Licensing Authority to permit a determination of whether or not the trustee and any beneficiary who may exercise control over the trust is suitable. A trust will not be found suitable if any person prohibited by section 44-10-307 is the trustee, otherwise controls the trust, or is positioned to receive distributions from the trust while a person prohibited.
  5. Any Passive Beneficial Owner who elects to apply for an Owner's License in accordance with Rule 2-265(B)(3).
- B. Persons Subject to a Mandatory Finding of Suitability for Regulated Marijuana Businesses That Are Publicly Traded Corporations.
1. The following Persons must apply to the State Licensing Authority for a finding of suitability:
    - a. Any Person that becomes a Controlling Beneficial Owner of any Regulated Marijuana Business that is a Publicly Traded Corporation; and
    - b. Any Person that indirectly Beneficially Owns ten percent or more of the Regulated Marijuana Business that is a Publicly Traded Corporation

through direct or indirect ownership of its Controlling Beneficial Owner. For example, assuming the scenario depicted below, Licensee PTC Inc. has one-million shares of outstanding Securities and CBO 1 owns 400,000 of those securities. John Doe owns 30% of CBO 1. Therefore, John Doe indirectly owns 12% of the outstanding securities of Licensee PTC Inc., and must apply to the State Licensing Authority for a finding of suitability.



2. If the Controlling Beneficial Owner is an Entity, the request for finding of suitability must include all information necessary for the State Licensing Authority to determine whether its Executive Officers and any Person that indirectly owns ten percent or more of the Owner's Interest in the Regulated Marijuana Business are suitable.

3. Timing of Request for Finding of Suitability Involving Publicly Traded Corporation.

- a. Unless exempted under Rule 2-235(E), all Persons that will be a Controlling Beneficial Owner in a Regulated Marijuana Business that is entering into a Publicly Traded Corporation transaction described in Rule 2-245(B)(1) must first obtain a finding of suitability by the State Licensing Authority before the transaction can close or the public offering can occur.
- b. A Person who becomes a Controlling Beneficial Owner in a Regulated Marijuana Business that is a Publicly Traded Corporation must submit a request for a finding of suitability to the State Licensing Authority within 45 days of becoming a Controlling Beneficial Owner.
- c. An individual who is a Controlling Beneficial Owner because he or she is a member of the board of directors or an Executive Officer of a Regulated Marijuana Business or is Controlling a Regulated Marijuana Business but who does not possess ten percent or more of the Owner's Interest in a Regulated Marijuana Business must submit a request for a finding of suitability to the State Licensing Authority within 45 days of becoming such a Controlling Beneficial Owner.

B.5. Persons Subject to Mandatory Finding of Suitability: Social Equity Licensees. [Effective through February 1, 2025.](#)

1. Qualifications. To qualify as a Social Equity Licensee, the Applicant must be found suitable for licensure pursuant to Rule 2-235, unless otherwise exempted by these Rules, and must meet the following minimum eligibility requirements:
  - a. The Applicant is a Colorado Resident and has established Colorado residency by providing the items required by Rule 2-265(H).

- b. The Applicant has not been the Beneficial Owner of a License subject to administrative action issued by the State Licensing Authority resulting in the revocation of a license issued pursuant to the Marijuana Code;
- c. The Applicant has demonstrated at least one of the following:
  - i. The Applicant has resided for at least fifteen years between the years 1980 and 2010 in a census tract designated by the ~~Office~~ of ~~E~~conomic ~~D~~evelopment and ~~I~~nternational ~~T~~rade as an opportunity zone or a census tract designated as a Disproportionate Impacted Area;
  - ii. The Applicant or the Applicant's parent, legal guardian, sibling, spouse, child, or minor in their guardianship was arrested for a marijuana offense, convicted of a marijuana offense, or was subject to civil asset forfeiture related to a marijuana investigation; or
  - iii. The Applicant's household income in the year prior to application did not exceed 50% of the state median income as measured by the number of people who reside in the Applicant's household.
- d. The Social Equity Licensee, or collectively one or more Social Equity Licensees, holds at least fifty-one percent of the Beneficial Ownership of the Regulated Marijuana Business License.

2. Information Required to Establish Qualification as a Social Equity Licensee.

- a. To demonstrate qualification as a Social Equity Licensee based on residence during the relevant time period, the Applicant must demonstrate the Applicant's residency which may include either:
  - i. Providing information or documents including but not limited to a copy of school records, rental agreements, lease agreements, utility bills, mortgage statements, loan documents, bank records, tax returns, or any other document which proves the Applicant's place of residence; or
  - ii. Affirming, under penalty of perjury, the Applicant's place of residence and provide the name(s) and contact information for at least one individual who can verify the Applicant's place of residence during the time period at issue.
- b. To demonstrate that an Applicant qualifies as a Social Equity Licensee based on a prior marijuana conviction of a family member, the Applicant must provide affirmation of the familial relationship and court or other documents demonstrating the family member's arrest or conviction for a marijuana offense or that the family member was subject to a civil asset forfeiture related to a marijuana investigation.
- c. To demonstrate that an Applicant qualifies as a Social Equity Licensee based on the Applicant's income, the Applicant must provide the

Applicant's tax return for the prior year. If an Applicant applies between January 1 and April 15 but has not yet filed a tax return, the application may be delayed or denied until the tax return is filed and provided to the Division. The Division cannot accept tax returns for previous years.

3. Denial on the Sole Basis of a Marijuana Conviction. The State Licensing Authority will not deny an application for a Social Equity License or a related request for a finding of suitability on the sole basis of a marijuana conviction.

B.6 Persons Subject to Mandatory Finding of Suitability: Social Equity Licensees. Effective February 1, 2025.

1. Qualifications. To qualify as a Social Equity Licensee, the Applicant must be found suitable for licensure pursuant to Rule 2-235, unless otherwise exempted by these Rules, and must meet the following minimum eligibility requirements:
  - a. The Applicant has not been the Beneficial Owner of a License subject to administrative action issued by the State Licensing Authority resulting in the revocation of a license issued pursuant to the Marijuana Code;
  - b. The Applicant has demonstrated at least one of the criteria established in section 44-10-308(6)(b), C.R.S.; and
  - c. The Applicant for a Social Equity License, or collectively one or more Social Equity Licensees, holds, or will hold, at least fifty-one percent of the Beneficial Ownership of the Regulated Marijuana Business License.
  - d. The Applicant is not a Controlling Beneficial Owner of any combination of more than three Retail Marijuana Store Licenses, Medical Marijuana Store Licenses, Retail Marijuana Cultivation Facility Licenses, or Medical Marijuana Cultivation Facility Licenses, unless the Beneficial Ownership of the listed Licenses for which the Applicant is a Controlling Beneficial Owner are at least fifty-one percent held by the Applicant as a Social Equity Licensee, or collectively one or more Social Equity Licensees.
    - i. For the purposes of subparagraph (d), co-located Retail Marijuana Store and Medical Marijuana Store Licenses, or co-located Retail Marijuana Cultivation Facility and Medical Marijuana Cultivation Facility Licenses constitute one license.
2. Information Required to Establish Qualification as a Social Equity Licensee.
  - a. To demonstrate qualification as a Social Equity Licensee based on the Applicant's residence during the relevant time period, the Applicant must demonstrate the Applicant's residency, which may include either:
    - i. Providing information or documents including, but not limited to, a copy of school records, rental agreements, lease agreements, utility bills, mortgage statements, loan documents, bank records, tax returns, or any other document which proves the Applicant's place of residence; or



- ii. Affirming, under penalty of perjury, the Applicant's place of residence and provide the name(s) and contact information for at least one individual who can verify the Applicant's place of residence during the time period at issue.
    - b. To demonstrate qualification as a Social Equity Licensee based on the Applicant receiving government assistance, the Applicant must either:
      - i. Provide information or documentation, including, but not limited to, a copy of a benefit verification letter, award letter, or other official communication from the program providing assistance during the time period at issue; or
      - ii. Affirming, under penalty of perjury, the Applicant's participation in an appropriate government assistance program during the time period at issue.
    - c. To demonstrate that an Applicant qualifies as a Social Equity Licensee based on a prior marijuana arrest and conviction of the Applicant or the Applicant's spouse, parent, or legal guardian, the Applicant must provide affirmation of the familial relationship and court or other documents demonstrating the Applicant or the Applicant's spouse, parent, or legal guardian's arrest and conviction for a marijuana offense.
    - d. To demonstrate that an Applicant qualifies as a Social Equity Licensee based on a prior marijuana arrest or conviction of the Applicant's sibling or child or minor in the Applicant's guardianship, the Applicant must provide affirmation of the familial relationship and court or other documents demonstrating the arrest or conviction of the Applicant's sibling or child or minor in the Applicant's guardianship for a marijuana offense.
      - i. In order for an Applicant to qualify as a Social Equity Licensee pursuant to 44-10-308(6)(b)(III)(A) C.R.S., the Applicant shall provide documentation demonstrating qualification pursuant to this subparagraph (d) and subparagraph (a) of Rule 2-235(B.6)(2) as applied to the Applicant's sibling or child or minor in the Applicant's guardianship residence.
      - ii. In order for an Applicant to qualify as a Social Equity Licensee pursuant to 44-10-308(6)(b)(III)(B) C.R.S., the Applicant shall provide documentation demonstrating qualification pursuant to this subparagraph (d) and subparagraph (b) of Rule 2-235(B.6)(2) as applied to the Applicant's sibling or child or minor in the Applicant's guardianship receiving assistance.
  - 3. Denial on the Sole Basis of a Marijuana Conviction. The State Licensing Authority will not deny an application for a Social Equity License or a related request for a finding of suitability on the sole basis of a marijuana conviction.
- C. Finding of Suitability for Reasonable Cause. For Reasonable Cause, any other Person that was disclosed or should have been disclosed pursuant to subsections 44-10-309(1)

or (2) or that was required to be disclosed based on previous notification of Reasonable Cause must submit a request to the State Licensing Authority for a finding of suitability. Any Person required to submit a request for a finding of suitability pursuant to this Rule must submit such request within 45 days from notice of the State Licensing Authority's determination of Reasonable Cause for the finding of suitability.

- D. Information Required in Connection with a Request for a Finding of Suitability. When determining whether a Person is suitable or unsuitable for licensure, the State Licensing Authority may consider the Person's criminal character or record, licensing character or record, or financial character or record. To consider a Person's criminal character or record, licensing character or record, and financial character or record, all requests for a finding of suitability must, at a minimum, be accompanied by the following information:
1. Criminal Character or Record:
    - a. A set of the natural person's fingerprints for purposes of a fingerprint-based criminal history record check.
  2. Licensing Character or Record:
    - a. Affirmation that the Person is not prohibited from holding a license under section 44-10-307, C.R.S.
    - b. A list of all Colorado Department of Revenue-issued business licenses held in the three years prior to submission of the request for a finding of suitability;
    - c. A list of all Department of Regulatory Agencies business, professional, or occupational licenses held in the three years prior to submission of the request for a finding of suitability;
    - d. A list of any marijuana business or personal license(s) held in any other state or territory of the United States or District of Columbia or another country, where such license is or was at any time subject to a denial, suspension, revocation, surrender, or equivalent action by the licensing agency, commission, board, or similar authority; and
    - e. Disclosure of any civil lawsuits in which the Person was named a party where pleadings included allegations involving any Regulated Marijuana Business.
  3. Financial Character or Record:
    - a. Disclosure of any sanctions, penalties, assessments, or cease and desist orders imposed by any securities regulatory agency other than the United States Securities Exchange Commission;
    - b. Account Statements or Property Ownership Documents Required.
      - i. If a Person is submitting a request for a finding of suitability to acquire ten percent or more of the Owner's Interest in a Regulated Marijuana Business and has identified both the source of funds or

property and the Regulated Marijuana Business License that will be acquired at the time of the request for the finding of suitability, then the Person shall also include, copies of the Person's financial account statements for the preceding one-hundred eighty days for any accounts serving as a source of funding used to acquire the Owner's Interest in the Regulated Marijuana Business; or, if the Person is contributing one or more asset(s) to the Regulated Marijuana Business in exchange for the Owner's Interests, documents establishing the Person has owned such asset(s) for the preceding one-hundred eighty days.

- ii. If a Person has not identified both the source of funding or property and the Regulated Marijuana Business License that will be acquired, then the Person can submit a request for a finding of suitability without account statements or property ownership documents.
- iii. When a Person submits a Change of Controlling Beneficial Owner or new Regulated Marijuana Business License application, the Person shall also provide account statements for the funds that will be used to acquire the Owner's Interest in the Regulated Marijuana Business License or the property ownership documents for the preceding one hundred eighty (180) days.

E. Exemptions from a Finding of Suitability.

1. The following Persons are exempt from an otherwise required finding of suitability:
  - a. Any Person that currently possesses an approved Owner License issued by the State Licensing Authority and such Owner License has not, in the preceding 365 days, been subject to suspension or revocation.
2. Exemptions from an otherwise required finding of suitability are limited to those listed in this Rule. The State Licensing Authority will consider other factors that may inform amendments to this Rule through the Department's formal rulemaking session.

F. Timing to Approve or Deny a Request for Finding of Suitability. Absent Reasonable Cause, the State Licensing Authority must approve or deny a request for a finding of suitability within 120 days from the date of submission of the request for such finding, where such request was accompanied by all information required under sub~~paragraph~~~~section~~ (D) of this Rule.

G. Executive Officer Considerations. Whether an individual is an Executive Officer subject to a mandatory finding of suitability is based on the definition in these rules and the facts and circumstances. In determining whether an individual is an Executive Officer, the State Licensing Authority will consider the following, non-exhaustive factors:

1. ~~Executive Officers include~~~~Title is not dispositive, however,~~ the Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, president, and the

General Counsel. ~~Title alone is not dispositive and an individual with a title that is not included in the list above may also be an Executive Officer where they have and any individual with similar policy making authority are Executive Officers;~~

2. The level of decision-making authority the individual possesses;
3. The Controlling Beneficial Owner and/or Regulated Marijuana Business's organizational chart; and
4. Any relevant guidance from the United States Securities and Exchange Commission or similar securities regulator, securities rules or securities case law.

H. Findings of Suitability Expiration.

1. Finding of Suitability. A finding of suitability other than for a Social Equity Licensee is valid for one year from the date it is issued by the State Licensing Authority. If more than one year has passed since the State Licensing Authority issued a finding of suitability to a Person other than for a Social Equity Licensee and such Person has not during that time applied to become a Controlling Beneficial Owner of a Regulated Marijuana Business pursuant to an initial business license application or change of owner application, then such Person shall submit a new request for finding of suitability to the State Licensing Authority and obtain a new finding of suitability before submitting any application to become a Controlling Beneficial Owner of a Regulated Marijuana Business. Upon approval and issuance of an Owner License, a finding of suitability is no longer valid.
2. Finding of Suitability for Social Equity Licensees. A finding of suitability for Social Equity License Applicants under Rule 2-220(C) is valid for two years from the date it is issued by the State Licensing Authority. If more than two years has passed since the State Licensing Authority issued the finding of suitability and such Social Equity Licensee has not during that time applied to become a Controlling Beneficial Owner of a Regulated Marijuana Business, then such Social Equity Licensee shall submit a new request for finding of suitability to the State Licensing Authority and obtain a new finding of suitability before submitting any application to become a Controlling Beneficial Owner of a Regulated Marijuana Business. Upon approval and issuance of an Owner License, a finding of suitability is no longer valid.

**Basis and Purpose – 2-240**

The statutory basis for this rule includes but is not limited to sections 44-10-103(53), 44-10-203(2)(ee)(C), 44-10-309(3), and 44-10-310(10), C.R.S. The purpose of this rule is to clarify factors the State Licensing Authority will consider when determining whether reasonable cause exists to require disclosure, to require a finding of suitability or to extend the 120-day deadline for granting or denying a request for a finding of suitability.

**2-240 – Factors Considered in Determining Reasonable Cause for Disclosure, Finding of Suitability, and Extension of 120 Day Deadline for Finding of Suitability**

- A. Non-Exhaustive Factors Informing Reasonable Cause Considerations. The State Licensing Authority may consider the following non-exhaustive factors when evaluating whether Reasonable Cause exists for disclosure, requiring a reasonable cause finding of suitability or extension of time to provide a finding of suitability:
1. The Person provided materially inaccurate or incomplete documents to the Division;
  2. The Person failed to provide required documents to the Division;
  3. The request for a finding of suitability is sufficiently complex such that a determination cannot be completed within the 120-day deadline specified;
  4. Information that an undisclosed Person is controlling or has the ability to control the Regulated Marijuana Business;
  5. Information indicating one or more Persons prohibited holds an interest in the Regulated Marijuana Business;
  6. Inability to obtain documents or information expected to be available from third-parties or publicly available sources;
  7. The Person interfered with, obstructed, or impeded a Division investigation; or
  8. The Person failed to make any filing required by a securities regulator or securities exchange that has regulatory oversight over the Person.

### **Basis and Purpose – 2-245**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(e), 44-10-203(1)(d), 44-10-203(1)(k), 44-10-203(2)(ee)(I)(A) and (E), 44-10-203(7), 44-10-308(3)(b), 44-10-309, 44-10-310, 44-10-311, 44-10-312, 44-10-505(1)(a), and 44-10-605(1)(a), C.R.S. The purpose of this rule is to define the application process and conditions an Applicant or Licensee must meet when changing Beneficial Ownership in a Regulated Marijuana Business. This rule further describes requirements in the event of a dispute between the Controlling Beneficial Owners of a Regulated Marijuana Business.

### **2-245 – Change of Controlling Beneficial Owner Application or Notification**

- A. Application for Change of Controlling Beneficial Owner(s) – Not a Publicly Traded Corporation.
1. Division Approval Required Prior to Transfer of Owner's Interest. Unless excepted pursuant to subparagraph (C) of this Rule, a Regulated Marijuana Business that is not a Publicly Traded Corporation must obtain Division approval before it transfers the Owner's Interests of any Controlling Beneficial Owner(s) or before a trust that is a Controlling Beneficial Owner changes its trustee.
  2. Documents Required. Any change of owner application(s) regarding a Controlling Beneficial Owner of a Regulated Marijuana Business that does not involve a Publicly Traded Corporation must include the following documents:

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- a. Asset purchase agreement, merger, sales contract, agreement, or any other document necessary to effectuate the change of owner;
  - b. Request for a finding of suitability for each proposed Controlling Beneficial Owner(s) who has not already submitted a request for a finding of suitability, who has not already been found suitable, or who does not already hold an Owner License;
  - c. Operating agreement, by-laws, partnership agreement, or other governing document(s) as will apply to the Regulated Marijuana Business if the change of owner application is approved;
  - d. Request for voluntary surrender form of the Owner License of any Controlling Beneficial Owner that will not remain a Controlling Beneficial Owner, or Passive Beneficial Owner electing to hold an Owner License in a Regulated Marijuana Business if the change of owner application is approved;
  - e. Copy of current Medical Marijuana or Retail Marijuana State Sales Tax or Wholesale license and any other documents necessary to verify tax compliance; and
  - f. An affirmation and consent signed by any Controlling Beneficial Owner whose Owner's Interest is decreasing as a result of the Change of Controlling Beneficial Owner application, unless otherwise specified in the Licensee's bylaws, operating agreement, or purchase agreement signed by a Controlling Beneficial Owner whose Owner's Interest is decreasing.
3. Licensee Initiates Change of Owner for Permitted Economic Interests Issued Prior to January 1, 2020. All natural persons holding a Permitted Economic Interest who seek to become a Controlling Beneficial Owner are subject to this Rule. The Regulated Marijuana Business must initiate the change of owner process for a natural person holding a Permitted Economic Interest who seeks to convert its interest and become a Controlling Beneficial Owner in a Regulated Marijuana Business. Prior to submitting a change of owner application, the Permitted Economic Interest holder must obtain a finding of suitability pursuant to Rule 2-235 including any required criminal history record check. Permitted Economic Interest holders who fail to obtain a finding of suitability to become a Controlling Beneficial Owner may remain as a Permitted Economic Interest holder.
- B. Change of Owner Involving a Publicly Traded Corporation. This Rule applies to transactions involving any Publicly Traded Corporation.
  1. Publicly Traded Corporation Transactions. A Regulated Marijuana Business may transact with a Publicly Traded Corporation in the following ways:
    - a. Merger with a Publicly Traded Corporation. A Regulated Marijuana Business or a Controlling Beneficial Owner that intends to receive, directly or indirectly, an investment from a Publicly Traded Corporation, or that intends to merge or consolidate with a Publicly Traded Corporation,

whether by way of merger, combination, exchange, consolidation, reorganization, sale of assets or otherwise, including but not limited to any shell company merger.

- b. Investment by a Publicly Traded Corporation. A Regulated Marijuana Business that intends or that has a Controlling Beneficial Owner that intends to transfer, directly or indirectly, ten percent or more of the Securities in the Regulated Marijuana Business to a Publicly Traded Corporation, whether by sale or other transfer of outstanding Securities, issuance of new Securities, or otherwise.
  - c. Public Offering. A Regulated Marijuana Business that intends or that has a Controlling Beneficial Owner that intends to become, directly or indirectly, a Publicly Traded Corporation, whether by effecting a primary or secondary offering of its Securities, uplisting of outstanding Securities, or otherwise.
- 2. Required Finding(s) of Suitability.
  - a. Pre-Transaction Findings of Suitability Required. Any Person intending to become a Controlling Beneficial Owner in a Regulated Marijuana Business in connection with any transaction identified in subparagraph (B)(1)(a) through (c) above, must obtain a finding of suitability prior to the Publicly Traded Corporation transaction closing or becoming effective.
  - b. Ongoing Suitability Requirements. Any Person who becomes a Controlling Beneficial Owner of a Publicly Traded Corporation that is a Regulated Marijuana Business must apply to the State Licensing Authority for a finding of suitability or an exemption from a finding of a suitability pursuant to Rule 2-235 within forty-five days of becoming a Controlling Beneficial Owner. A Publicly Traded Corporation that is a Regulated Marijuana Business must notify any Person that becomes a Controlling Beneficial Owner of the suitability requirements as soon as the Regulated Marijuana Business becomes aware of the ownership subjecting the Person to this requirement; however, the Controlling Beneficial Owner's obligation to timely request the required finding of suitability is independent of, and unaffected by, the Regulated Marijuana Business's failure to make the notification.
- 3. Change of Owner Application(s) Required. A Licensee entering into a transaction permitted in subparagraph (B)(1)(a)-(c) above with Publicly Traded Corporation must submit any required change of owner application to the Division prior to the transaction closing. The change of owner application(s) may be submitted simultaneously with the requests for finding(s) of suitability required by subparagraph (B)(2) or after the request(s) for findings of suitability were submitted to the Division.
- 4. Mandatory Disclosure of Required, United States Securities and Exchange Commission, Canadian Securities Administrators and/or Securities Exchange Filings. A Regulated Marijuana Business and any Controlling Beneficial Owner

that is required to file any document with the United States Securities and Exchange Commission, the Canadian Securities Administrators, any other similar securities regulator or any securities exchange regarding any change of owner in subparagraphs (B)(1)(a) through (c) above must also provide a notice to the Division at the same time as the filing with the United States Securities and Exchange Commission, the Canadian Securities Administrators or the securities exchange.

5. Ordinary Broker Transactions. Resales or transfers of Securities of a Publicly Traded Corporation that is a Regulated Marijuana Business or Controlling Beneficial Owner or Passive Beneficial Owner in ordinary broker transactions through an established trading market do not require a change of owner application or prior approval from the State Licensing Authority.

C. Exemptions to the Change of Owner Application Requirement.

1. Entity Conversions or Change of Legal Name. A Regulated Marijuana Business or a Controlling Beneficial Owner may combine with or convert, including but not limited to under sections 7-90-201 et seq., C.R.S., for the exclusive purpose of changing its Entity jurisdiction to one of the states or territories of the United States or the District of Columbia, its Entity type or change the legal name of an Entity without filing a change of owner application. These exemptions apply only if the Controlling Beneficial Owners and their Owner's Interests will remain the same after the combination, conversion, or change of legal name, and there will not be any new Controlling Beneficial Owners (individuals or Entities). Within fourteen days of the combination, conversion, or change of legal name the Regulated Marijuana Business must submit the following to the Division:
  - a. A copy of the transaction documents;
  - b. Documents submitted to the Colorado Secretary of States;
  - c. Any document submitted to the secretary of state or similar regulator if the Entity is organized under the laws of a state of the United States other than Colorado, a territory of the United States, or the District of Columbia;
  - d. Identification of the Regulated Marijuana Business's or Controlling Beneficial Owner's registered agent;
  - e. Identification of any Passive Beneficial Owner and Indirect Financial Interest Holder for which disclosure is required by Rule 2-230; and
  - f. The fee required by Rule ~~2-205(F)(2)(b)~~-2-130(A).
2. Change of Owner's Interests For Controlling Beneficial Owners. A Regulated Marijuana Business may reallocate Owner's Interests among existing Controlling Beneficial Owners holding valid Owner Licenses if it provides notification of the change to the Division with its next application submission as long as there are no new Controlling Beneficial Owners. A Regulated Marijuana Business may also issue new or additional shares to one or more existing Controlling Beneficial Owners subject to the requirements of this Rule. Changes that are solely a result



of adding, removing, or changing Passive Beneficial Owners are not subject to this Rule 2-245(C)(2), but are subject to the requirements in Rule 2-245(C)(5). Changes of Controlling Beneficial Owners' Owner's Interest under this Rule is subject to the following requirements:

- a. All Owner's Interests of a Controlling Beneficial Owner may be changed to other existing Controlling Beneficial Owners;
  - b. Only consensual changes where all Controlling Beneficial Owners whose ownership percentages will change agree to the changes are permitted under this Rule. Proof that the transfer was consensual may include:
    - i. ~~a~~ Affirmation from all Controlling Beneficial Owners for which the Owner's Interests were changed in the required disclosure at the next application submission; ~~or-~~
    - ii. Changes permitted by the Licensee's bylaws, operating agreement, or purchase agreement signed by a Controlling Beneficial Owner whose Owner's Interest were changed.
  - c. If any Controlling Beneficial Owner will not hold any Owner's Interest in a Regulated Marijuana Business following the change, that Controlling Beneficial Owner shall voluntarily surrender ~~his or her~~their Owner's License and identification badge within 30 days of the change;
  - d. All Controlling Beneficial Owners remain responsible for all actions of the Regulated Marijuana Business while they were a Controlling Beneficial Owner and are subject to administrative action based on the same regardless of the change; and
  - e. Disclosure and submission of the fee required by Rule ~~2-205(F)(2)(b)-2-130(A)~~ at the next application submission ~~-which shall not be longer than 365 days.~~
3. Passive Beneficial Owner Licensed Prior to August 1, 2019. A Passive Beneficial Owner who was issued an Owner License prior to August 1, 2019, and who has continuously maintained that license, is not required to submit a change of owner application if ~~he or she~~they becomes a Controlling Beneficial Owner in the business license(s) with which the Owner License is associated but must disclose and submit the fee required by Rule ~~2-205(F)(2)(b)-2-130(A)~~ at the next application submission, ~~-which shall not be longer than 365 days.~~
  4. Change of Executive Officer or Member of the Board of Directors. A change of owner application is not required for a change of an Executive Officer or member of the board of directors of a Regulated Marijuana Business or an Owner Entity License of a Regulated Marijuana Business so long as the new Executive Officer or member of the board of directors does not possess ten percent or more of the Owner's Interest in the Regulated Marijuana Business or is otherwise Controlling the Regulated Marijuana Business. A Licensee must notify the Division within forty-five (45) days of any removal of Executive Officers or Members of the Board

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of Directors. However, a change of Executive Officer or member of the board of directors is subject to the following requirements:

- a. Any such Executive Officer or member of the board of directors of the Regulated Marijuana Business must notify the Division of the new Controlling Beneficial Owner, Executive Officer, or member of the board of directors and submit a request for a finding of suitability as required by Rule 2-235(A)(1)(a) unless exempt under subparagraph (b) of this Rule 2-245(C)(4); or,
  - b. If exempt from a finding of suitability pursuant to Rule 2-235(E), the Regulated Marijuana Business subject to any such change of the Executive Officer or members of their board of directors, whether adding or removing, must provide notice to the Division of the new Controlling Beneficial Owner within forty-five (45) days.
  - c. The fee required by Rule ~~2-205(F)(2)(b)~~ 2-130(A).
5. Change of Passive Beneficial Owner. Persons are not required to submit an application or obtain prior approval of their ownership, or provide notification, if: (1) the person was not a Direct Beneficial Interest Owner prior to November 1, 2019, (2) the Person will remain a Passive Beneficial Owner after the acquisition of Owner's Interests is complete, (3) the transfer will not create any previously undisclosed Controlling Beneficial Owner, and (4) disclosure is not otherwise required by section 44-10-309, C.R.S., or Rule 2-230.

D. Change of Owner Requirements, Restrictions and Procedures Applicable to All Regulated Marijuana Businesses.

1. Application Signature Requirements. All applications for change of Controlling Beneficial Owner(s) must be executed by every Controlling Beneficial Owner of the involved Licensees where that Controlling Beneficial Owner is being removed or added by the change of ownership application, unless otherwise specified in the Licensee's bylaws or operating agreement, or purchase agreement signed by a Controlling Beneficial Owner whose Owners Interest is decreasing. Controlling Beneficial Owners whose Owner's Interest will not change are not required to execute the change of owner application; however, at least one Controlling Beneficial Owner and all Persons proposed to become a Controlling Beneficial Owner must execute every change of owner application.
2. Process for Approval. Upon completion of the investigation of a change of owner application, the State Licensing Authority will issue a contingent approval letter. However, the State Licensing Authority will not issue the state license until:
  - a. Local Approval Required. If local approval is required, the proposed Controlling Beneficial Owner(s) demonstrates to the State Licensing Authority that local approval has been obtained and notifies the State Licensing Authority of the date by which the change of owner will be completed, which must be within three to thirty days of the notification. The proposed Controlling Beneficial Owner's notification to the Division

must be within 365 days of the issuance of the Division's contingent approval letter.

- i. If a Local Licensing Authority or Local Jurisdiction requires a change of owner application and that application is denied, the State Licensing Authority will deny the State change of owner application;
  - b. No Local Approval Required. If local approval is not required, the proposed Controlling Beneficial Owner(s) demonstrates that such approval is not required and notifies the State Licensing Authority of the date by which the change of owner will be completed, which must be within three to thirty days of the notification. However, the proposed Controlling Beneficial Owner's notification to the Division must be made within 365 days of issuance of the Division's contingent approval letter.
  - c. Contingent Approval. Contingent approval pursuant to this subparagraph (D)(2) is valid for one year from the date it is issued by the State Licensing Authority. If more than one year has passed since the State Licensing Authority issued contingent approval to a Person and such Person during that time has not met the requirements of Rule 2-245(D)(2)(a) or 2-245(D)(2)(b) to complete the Change of Beneficial Owner Application, then such Person shall submit a new Change of Controlling Beneficial Owner Application. The State Licensing Authority in their discretion may extend the contingent approval upon written request.
3. Operational Restrictions Pending All Required Approvals. Unless otherwise provided under these Rules, any proposed new Controlling Beneficial Owner cannot operate the Regulated Marijuana Business for which it intends to become a Controlling Beneficial Owner until it receives any required finding of suitability and is issued all approvals and/or license(s) pursuant to any change of owner application required by this Rule. Controlling Beneficial Owners that have already been approved in connection with ownership of the Regulated Marijuana Business may continue to operate the Regulated Marijuana Business. A violation of this requirement is grounds for denial of the change of owner application, ~~may be a violation affecting public safety,~~ and may result in disciplinary action against existing license(s).
4. Modifications to Change of Owner Applications. If anything in a change of owner application is modified or changed after the Division approves the application, the Licensee must submit a new change of owner application, unless exempted by the Division prior to completing the change of owner.
5. Regulated Marijuana Business Subject to Investigation or Administrative Action. If a Regulated Marijuana Business or any of its Controlling Beneficial Owner(s) apply for a change of owner and is involved in an administrative investigation or administrative action, the following may apply:
  - a. The change of owner application may be delayed or denied until the administrative action is resolved; or

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- b. If the change of owner application is approved by the Division, the transferor, the transferee, or both may be responsible for the actions of the Regulated Marijuana Business and its prior Controlling Beneficial Owner(s), and subject to discipline based upon the same.
- 6. Repealed.
- E. Refundable and Nonrefundable Deposits Permitted. A proposed Controlling Beneficial Owner may provide a selling Controlling Beneficial Owner with a refundable or nonrefundable deposit in connection with a change of owner application.
- F. Controlling Beneficial Owner Dispute.
  - 1. In the event of a dispute between Controlling Beneficial Owner(s) not involving divestiture under Rule 2-275 and precluding or otherwise impeding the ability to comply with these Rules, a Regulated Marijuana Business that is not a Publicly Traded Corporation must submit a change of owner application, notification pursuant to subparagraph (C) of this Rule, or initiate mediation, arbitration, or a judicial proceeding within 90 days of the dispute. The 90-day period may be extended for an additional 90 days upon a showing of good cause by the Regulated Marijuana Business.
  - 2. A Regulated Marijuana Business that is not a Publicly Traded Corporation must submit a change of owner application or notification pursuant to subparagraph (C) of this Rule within forty-five days of entry of a final court order, final arbitration award, or full execution of a settlement agreement altering the Controlling Beneficial Owner(s) of a Regulated Marijuana Business. Any change of owner application or notification based on a final court order, final arbitration award, or fully executed settlement agreement must include a copy of the order or settlement agreement and remains subject to approval by the Division. In this circumstance, the change of owner application or notification needs to be executed by at least one remaining Controlling Beneficial Owner.
  - 3. If mediation, arbitration, or a judicial proceeding is not timely initiated, or if a change of owner application or notification pursuant to subparagraph (C) of this Rule is not timely submitted following entry of a final court order, final arbitration award, or full execution of a settlement agreement altering the Controlling Beneficial Owner(s) of a Regulated Marijuana Business that is not a Publicly Traded Corporation, the Regulated Marijuana Business and its Owner Licensee(s) may be subject to fine, suspension, or revocation of their license(s).

**Basis and Purpose – 2-250**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(e), 44-10-203(2)(ee)(I), 44-10-203(7), and 44-10-309(6), C.R.S. The purpose of this rule is to require notification to the State Licensing Authority of any filing with a securities regulator by an Applicant or Licensee.

**2-250 – Regulated Marijuana Business that is a Publicly Traded Corporation – Notification of Non-Confidential Securities Filings**

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- A. A Regulated Marijuana Business that is a Publicly Traded Corporation must provide notice on Division forms within two business days of any non-confidential filing with the United States Securities and Exchange Commission, the Canadian Securities Administrators, any other securities regulator, or any security exchange on which the Securities are listed or traded. The notice must identify the title of the document and include a hyperlink to the website where the document is publicly available (example EDGAR or SEDAR link for the Publicly Traded Corporation).
- B. In addition to any other administrative or investigative requests or inquiries, the Division may contact a Regulated Marijuana Business that is a Publicly Traded Corporation to obtain clarification of a securities filing.
- C. This Rule is currently limited to require notice of securities filings that are not confidential. However, this Rule may be evaluated during subsequent rulemaking proceedings and/or in connection with development of a policy regarding confidential securities filings.

**Basis and Purpose – 2-255**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(2)(a), 44-10-203(2)(e), 44-10-203(2)(w), 44-10-203(2)(cc), 44-10-305, 44-10-313(8), and 44-10-313(13), C.R.S. The purpose of this rule is to clarify the application process for changing location of a Licensed Premises. This rule also provides the requirements for a Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility to obtain a transition permit.

**2-255 – Change of Location of a Regulated Marijuana Business**

- A. Application Required Before Changing Location of Licensed Premises.
  - 1. A Regulated Marijuana Business must apply for and receive Division approval before changing the location of its Licensed Premises.
  - 2. Changing the location of a Licensed Premises includes:
    - a. Changing addresses; and
    - b. Expanding or decreasing the physical size of the Licensed Premises, including, but not limited to, adding or removing contiguous units or areas or changing suite numbers.
- B. Application Requirements. A change of location application must include the following:
  - 1. At least one signature of a Controlling Beneficial Owner and representation that the signing Controlling Beneficial Owner(s) is/are authorized to submit the application on behalf of the Regulated Marijuana Business.
  - 2. Evidence the Local Licensing Authority and/or Local Jurisdiction in which the Regulated Marijuana Business proposes to move have approved the proposed new location.

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3. The deed, lease, sublease, rental agreement, contract, or any other document(s) establishing the Licensee is, or will be, entitled to possession of the premises for which the application is made.
4. Legible and accurate diagram for the proposed licensed Premises that complies with the requirements of the 3-200 Series Rules. The diagram must include a plan for the proposed Licensed Premises and a separate plan for the security/surveillance plan including camera location, number and direction of coverage. If the diagram is larger than 8.5 inches x 11 inches, the Applicant must also provide the diagram in a portable document format (.pdf).

C. Change of Location Permit Required.

1. A Regulated Marijuana Business cannot change the location of its Licensed Premises until it receives a change of location permit from the Division.
2. The permit is effective on the date of issuance, and the Licensee must, within 120 days, change the location of its Regulated Marijuana Business to the place specified in the change of location permit and at the same time cease to operate a Regulated Marijuana Business at the former location. For good cause shown, the 120-day deadline may be extended an additional 120 days.
3. If the Regulated Marijuana Business does not change the location of its Licensed Premises within the time period granted by the Division, including any extension, the Regulated Marijuana Business must submit a new application, pay the change of location fee, and receive a new change of location permit prior to changing the location of its Licensed Premises.
4. A Regulated Marijuana Business cannot operate or exercise any of the privileges of its license(s) in both locations, unless a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility has received a transition permit.
5. Licensees with a valid change of location permit shall notify the Division within forty-eight (48) hours upon completion of the change of location.

D. Medical Marijuana Cultivation Facilities and Retail Marijuana Cultivation Facilities - Transition Permit. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility that has obtained an approved change of location from the State Licensing Authority may operate one License at two geographical locations for the purpose of transitioning operations from one location to the other, subject to the following requirements:

1. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility may apply for a transition permit and a change of location at the same time. The Division will not accept an application for a transition permit unless it is submitted prior to or concurrently with a change of location application. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility is prohibited from exercising the privileges of a transition permit until it has also received all required approvals for a change of location.

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2. A Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility that has an approved change of location and a transition permit must comply with the following requirements:
    - a. The total plants cultivated at both locations do not exceed any plant count limit imposed on the Licensee by the Marijuana Code and these rules;
    - b. The Licensed Premises of both geographical locations comply with all surveillance, security, and inventory tracking requirements imposed by the Marijuana Code and these rules at the Rule 3-200 Series and 3-800 Series;
    - c. Both geographical locations shall track all Regulated Marijuana plants in transition in the Inventory Tracking System to ensure proper tracking for taxation purposes;
    - d. Operation at both geographical locations does not exceed 180 days, unless Licensee demonstrates good cause to extend the deadline an additional 180 days; and
    - e. The Licensee obtains a transition permit pursuant to this Rule and any local permit or license, as required by the Local Licensing Authority or Local Jurisdiction.
  3. Change of Location in the Same Local Jurisdiction. If the change of location is within the same local jurisdiction, the Licensee must:
    - a. First obtain a transition permit pursuant to this Rule; and
    - b. If required by the Local Licensing Authority or Local Jurisdiction, obtain a transition permit or other form of approval from the Local Licensing Authority or Local Jurisdiction.
  4. Change of Location to a Different Local Jurisdiction. If the change of location is to a different local jurisdiction, the Licensee must:
    - a. First obtain a license from the Local Licensing Authority or Local Jurisdiction where the Licensee intends to locate;
    - b. Obtain a transition permit pursuant to this Rule; and
    - c. If required by the Local Licensing Authority or Local Jurisdiction, obtain a transition permit or other form of approval from the Local Licensing Authority or Local Jurisdiction for the local jurisdiction where it intends to locate.
  5. Conduct at either location may be basis for fine, suspension, revocation, or other sanction against the License.
- E. ~~Repealed. Violation Affecting Public Safety. It is a violation affecting public safety if a Regulated Marijuana Business changes the location of its Licensed Premises without first obtaining a change of location permit from the Division, and any required approval(s) from the Local Licensing Authority and/or Local Jurisdiction.~~



- F. Application Required to Change Mobile Premises. After obtaining a License, a Marijuana Hospitality Business Licensee must apply for Division approval to change the Mobile Premises. The Licensee whose Mobile Premises is to be changed is responsible for filing an application for approval on current forms provided by the Division.
1. The Application to change Mobile Premises must include the following:
    - a. Documentation that the Mobile Premises is owned or leased by the Marijuana Hospitality Business;
    - b. The vehicle manufacturer/make, model, and model year associated with the Mobile Premises;
    - c. The vehicle identification number (VIN) associated with the Mobile Premises;
    - d. The Colorado license plate number and copy of the registration associated with the Mobile Premises;
    - e. If applicable, the automatic vehicle identification tag associated with the Mobile Premises; and
    - f. Information demonstrating the Mobile Premises meets the requirements in Rule 6-940(E).
  2. Prior to operating the Mobile Premises, the Licensee must obtain a valid permit issued by the Public Utilities Commission for the Marijuana Hospitality Business.

### Basis and Purpose – 2-260

The statutory authority for this rule includes, but is not limited to, sections 44-10-202(1)(c), 44-10-203(1)(c), ~~44-10-203(1)(e)~~, 44-10-203(1)(k), 44-10-203(2)(a), ~~44-10-203(2)(e)~~, 44-10-203(2)(h), 44-10-203(2)(w), 44-10-305, 44-10-313(8)(b), and 44-10-313(2) C.R.S. The purpose of this rule is to establish guidelines for changing, altering, modifying, or transitioning the Licensed Premises. This Rule 2-260 was previously Rules M and R 303, 1 CCR 212-1 and 1 CCR 212-2.

### 2-260 – Changing, Altering, or Modifying Licensed Premises

- A. Notification of Application Required to Change, Alteration, or Modification of Licensed Premises. After obtaining a license, the Licensee shall make no physical change, alteration, or modification of the Licensed Premises that significantly alters the Licensed Premises or the usage of the Licensed Premises from the plans originally approved, without the Division's prior written approval and, written approval or written acknowledgement from the relevant Local Licensing Authority or Local Jurisdiction. The Licensee whose Licensed Premises are to be significantly changed is responsible for filing an application for approval on current forms provided by the Division. Licensees must report any change, modification, or alteration of Licensed Premises. Changes to the Licensed Premises which do not require an application must be disclosed on a floorplan submitted with the Licensee's biennial renewal application. The biennial notification must also include information demonstrating that any required Local Licensing Authority or



Local Jurisdiction approval was obtained and conforms to any local restrictions related to the time, manner, and place of Regulated Marijuana Business operations.

- B. Local Approval may be Required. What Constitutes a Significant Change. This Rule does not exempt Licensees are required to comply from complying with any Local Licensing Authority or Local Jurisdiction requirements regarding changes, alterations, or modifications to the Licensed Premises. Significant changes, alterations, or modifications requiring Division approval include, but are not limited to, the following:

1. Repealed. Any increase or decrease in the total physical size or capacity of the Licensed Premises;
2. Repealed. The sealing off, creation of or relocation of a common entryway, doorway, passage or other such means of public ingress and/or egress, walk-up window or drive-up window, when such common entryway, doorway, passage, walk-up or drive-up window alters or changes Limited Access Areas, such as the cultivation, harvesting, manufacturing, testing, or sale of Regulated Marijuana within the Licensed Premises; or
3. Repealed. Any physical modification of the Licensed Premises which would require the installation of additional video surveillance cameras. See Rule 3-225 —Video Surveillance.

- C. Repealed. Attachments to Application. The Division and relevant Local Licensing Authority or Local Jurisdiction may grant approval for the types of changes, alterations, or modifications described herein upon the filing of an application by the Licensee and payment of any applicable fee. The Licensee must submit all information requested by the Division, including but not limited to, documents that verify the following:

1. The Licensee will continue to have possession of the Licensed Premises, as changed, by ownership, lease, or rental agreement; and
2. The proposed change conforms to any local restrictions related to the time, manner, and place of Regulated Marijuana Business regulation.

- D. Repealed. Application Required to Change Mobile Premises. After obtaining a License, a Marijuana Hospitality Business Licensee must apply for Division approval to change the Mobile Premises. The Licensee whose Mobile Premises is to be changed is responsible for filing an application for approval on current forms provided by the Division.

1. The Application to change Mobile Premises must include the following:
  - a. Documentation that the Mobile Premises is owned or leased by the Marijuana Hospitality Business;
  - b. The vehicle manufacturer/make, model, and model year associated with the Mobile Premises;
  - c. The vehicle identification number (VIN) associated with the Mobile Premises;

- ~~d. The Colorado license plate number and copy of the registration associated with the Mobile Premises;~~
  - ~~e. If applicable, the automatic vehicle identification tag associated with the Mobile Premises; and~~
  - ~~f. Repealed.~~
  - ~~g. Information demonstrating the proposed Mobile Premises meets the requirements in Rule 6-940(E).~~
- ~~2. Prior to operating the Mobile Premises, the Licensee must obtain a valid permit issued by the Public Utilities Commission for the Marijuana Hospitality Business.~~

### **Basis and Purpose – 2-265**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(2)(b)-(c), 44-10-203(2)(e), 44-10-203(2)(t)-(u), 44-10-203(2)(w), 44-10-307, 44-10-308(2), 44-10-313(6), 44-10-401(2)(c), 44-10-901(1), 24-76.5-101 *et seq.*, C.R.S. Historically, natural persons who held an Owner's Interest in a Regulated Marijuana Business were required to hold an Associated Key License. This Rule transitions the Associated Key designation to an Owner License designation after August 1, 2019. The purpose of this rule is to clarify the requirements and procedures a Person must follow when applying for or possessing either an Owner License or an Employee License. This rule also identifies factors the State Licensing Authority will consider in determining whether a natural person is a resident and whether such person possess good moral character.

### **2-265 – Owner and Employee License: License Requirements, Applications, Qualifications, and Privileges**

- A. Repealed.
- B. Owner Licenses Required.
  - 1. Each Controlling Beneficial Owner must hold a valid Owner License.
  - 2. If a Controlling Beneficial Owner is an Entity, then its Executive Officer(s) and any natural person who indirectly holds ten percent or more of the Owner's Interests in the Regulated Marijuana Business must also hold a valid Owner's License.
    - a. The existence of an Owner Entity does not relieve the Owner Licensees from responsibility for acts and violations of the Regulated Marijuana Business.
  - 3. A Passive Beneficial Owner who is a natural person may elect to hold an Owner License and obtain an Owner Identification Badge provided that such Person agrees to be disclosed as holding an Owner's Interest in the Regulated Marijuana Business.
  - 4. Only Controlling Beneficial Owners and Passive Beneficial Owners can obtain an Owner License.

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C. Owner License and Identification Badge or Employee License and Identification Badge Required. The following natural persons must possess a valid Owner License and Identification Badge or an Employee License and Identification Badge:

1. Any natural person who works in and possesses, cultivates, manufactures, tests, dispenses, sells, serves, transports, or delivers Regulated Marijuana or Regulated Marijuana Products as permitted by privileges of a Regulated Marijuana Business license; and
2. ~~Repealed. Any natural person who has access to the Inventory Tracking System or a Regulated Marijuana Business point-of-sale system; and~~
3. Any natural person with unescorted access in the Limited Access Area.

D. Escort or Monitoring Required.

1. Any natural person in a Limited Access Area that does not have a valid Owner License and Identification Badge or an Employee License and Identification Badge is a visitor and must be escorted at all times by a person who holds a valid Owner License and Identification Badge or Employee License and Identification Badge. ~~Failure by a Regulated Marijuana Business to continuously escort an individual who does not have a valid Owner License and Identification Badge or an Employee License and Identification Badge in the Limited Access Area is a license violation affecting public safety.~~
2. Patients, their caregiver, and consumers in a Restricted Access Area and third-party vendors in a Limited Access Area do not need to be escorted at all times but must be reasonably monitored to ensure compliance with these rules.

E. Employee License Required to Commence or Continue Employment. Any natural person required to obtain an Employee License by these rules must obtain such license before commencing activities permitted by an Employee License.

1. Conditional License. Applicants for an Employee License may be issued a conditional License and Identification Badge upon results of an initial investigation that demonstrates the Applicant is qualified to hold such License in compliance with Rule 2-215, subject to the following requirements:
  - a. Applications for a conditional Employee License must be submitted in person to the Division to facilitate the issuance and physical transfer of the conditional License to the Applicant. Applications for a conditional Employee License must be accompanied by the Conditional Employee License Fee in Rule 2-105(A)2-205.
  - b. The Employee's application remains subject to a Notice of Denial pending the complete results of the Applicant's initial fingerprint-based criminal history record check.
  - c. If the Division issues the Applicant a Notice of Denial, the Employee License Applicant shall return the conditional License and Identification Badge within seven (7) days of the Division's mailing of the Notice of Denial.

- F. Owner License and Employee License Identification Badges Are Property of the State Licensing Authority. All Owner Licenses and Employee Licenses, and all Identification Badges are property of the State Licensing Authority.
- G. Owner and Employee Initial and Renewal Applications Required. Owner Licensees and Employee Licensees must submit initial license applications and renewal applications on Division forms and in accordance with this Rule and Rules 2-215, 2-220, and 2-225.
- H. Licenses Requiring Proof of Residency. Where a license issued by the State Licensing Authority requires the Applicant to establish Colorado residency, an Applicant may demonstrate residency by the following methods including, but are not limited to:
1. Current valid Colorado driver's license or current Colorado identification card with a current address; or
  2. A government issued photo identification and two of the following documents showing the Applicant's correct name, current date, and current Colorado address:
    - a. Utility bill or phone bill;
    - b. Car registration;
    - c. Voter registration card;
    - d. Statement from a major creditor;
    - e. Bank statement;
    - f. Recent County tax notice;
    - g. Recent contract/mortgage statement.
- I. Owner License Qualifications and Privileges.
1. Owner License Qualifications. Each Controlling Beneficial Owner, or Passive Beneficial Owner who elects to be subject to disclosure and licensure, must meet the following criteria before receiving an Owner License:
    - a. The Applicant is not prohibited from licensure pursuant to section 44-10-307, C.R.S.;
    - b. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for Persons licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application;
    - c. The Division has not received notice that the Applicant has failed to comply with a court or administrative order for current child support, child support debt, retroactive child support, or child support arrearages. If the Division receives notice of the Applicant's noncompliance pursuant to sections 24-35-116 and 26-13-126, C.R.S., the application may be denied or delayed until the Applicant has established compliance with the order to the satisfaction of the state child support enforcement agency.

- d. Each Controlling Beneficial Owner required to hold an Owner License, and any Passive Beneficial Owner that elects to hold an Owner License, must be fingerprinted at each renewal~~least once every two years~~, and may be fingerprinted more often at the Division's discretion.
      - i. Repealed.
      - e. An Owner Licensee who exercises day-to-day operational control on the Licensed Premises of a Regulated Marijuana Business must possess an Identification Badge and must establish and maintain Colorado residency. Proof of residency may be accomplished by submission of the documents identified in Rule 2-265(H). A Controlling Beneficial Owner will not be deemed to exercise day-to-day operational control by reason of holding a title defined as an Executive Officer.
  - 2. Owner License Exercising Privileges of an Employee License. A natural person who holds an Owner License and Identification Badge may exercise the privileges of an Employee License in a Regulated Marijuana Business, subject to the following limitations:
    - a. If the Owner Licensee is not a Controlling Beneficial Owner of the Regulated Marijuana Business for which he or she is seeking to exercise the privileges of an Employee License, the Owner Licensee may exercise such Employee License privileges regardless of that Person's residency.
    - b. If the Owner Licensee is a Controlling Beneficial Owner of the Regulated Marijuana Business for which he or she is seeking to exercise the privileges of an Employee License, the Owner Licensee may only exercise such Employee License privileges if he or she is a Colorado resident.
  - 3. Business License Required. A natural person cannot hold an Owner License without holding a Regulated Marijuana Business license, or without at least submitting an application for a Regulated Marijuana Business license. An Entity cannot hold an Owner Entity License without holding a Regulated Marijuana Business License, or without at least submitting an application for a Regulated Marijuana Business License.
- J. Employee License Qualifications and Privileges.
- 1. Employee License Qualifications and Requirements. An Employee License Applicant must meet the following criteria before receiving an Employee License:
    - a. The Applicant is not prohibited from licensure pursuant to section 44-10-307, C.R.S.;
    - b. The Applicant has not been a State Licensing Authority employee with regulatory oversight responsibilities for Persons licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.

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- c. The Division has not received notice that the Applicant has failed to comply with a court or administrative order for current child support, child support debt, retroactive child support, or child support arrearages. If the Division receives notice of the Applicant's noncompliance pursuant to sections 24-35-116 and 26-13-126, C.R.S., the application may be denied or delayed until the Applicant has established compliance with the order to the satisfaction of the state child support enforcement agency.
    - d. The Applicant's licensing character or record demonstrates the Applicant is suitable for licensure under the Marijuana Code.
  - 2. Medical and Retail Employee Licenses. A natural person who holds a current, valid Employee License and Identification Badge issued pursuant to the Marijuana Code may work in any Regulated Marijuana Business.
- K. Owner Licensees and Employee Licensees Required to Maintain Licensing Qualification. An Owner Licensee or Employee Licensee's failure to maintain qualifications for licensure may constitute grounds for discipline, including but not limited to, suspension, revocation, or fine.
- L. Evaluating a Natural Person's Good Moral Character Based on Criminal History.
  - 1. In evaluating whether a Person is prohibited from holding a license pursuant to subsections 44-10-307(1)(b) or (c), C.R.S., based on a determination that the person's criminal history indicates she or he is not of Good Moral Character, the Division will not consider the following:
    - a. The mere fact a person's criminal history contains an arrest(s) or charge(s) of a criminal offense that is not actively pending;
    - b. A conviction of a criminal offense in which the Applicant/Licensee received a pardon;
    - c. A conviction of a criminal offense which resulted in the sealing or expungement of the record;
    - d. A conviction of a criminal offense in which a court issued an order of collateral relief specific to the application for state licensure;
    - e. A civil judgment or criminal conviction, discipline, or other sanction imposed under the laws of another state regarding consumption, possession, cultivation, or processing of marijuana that is lawful and consistent with professional conduct and standards of care within the State of Colorado; or
    - f. The Applicant has been adjudicated for committing a delinquent act in a juvenile proceeding.
  - 2. In evaluating whether a Person is prohibited from holding a license pursuant to subsections 44-10-307(1)(b) or (c), C.R.S., based on a determination that the person's criminal history indicates he or she is not of Good Moral Character, the Division may consider the following history:

- a. Any felony conviction(s), except as set forth in Rule 2-265(L)(1)(e) and 2-265(L)(1)(f);
  - b. Any conviction(s) of crimes involving moral turpitude;
  - c. Pertinent circumstances connected with the conviction(s); and
  - d. Conduct underlying arrest(s) or charge(s) or a criminal offense for which the criminal case is not actively pending.
- 3. When considering criminal history in subparagraph (L)(2) above, the Division will consider:
  - a. Whether there is a direct relationship between the conviction(s) and the duties and responsibilities of holding a state license issued pursuant to the Marijuana Code;
  - b. Any information provided to the Division regarding the person's rehabilitation, which may include but is not limited to the following non-exhaustive considerations:
    - i. Character references;
    - ii. Educational, vocational, and community achievements, especially those achievements occurring during the time between the person's most recent criminal conviction and the application for a state license;
    - iii. Successful participation in an alcohol and drug treatment program;
    - iv. That the person truthfully and fully reported the criminal conduct to the Division;
    - v. The person's employment history after conviction or release, including but not limited to whether the person was vetted and approved to hold a state or out-of-state license for the purposes of employment in a regulated industry;
    - vi. The person's successful compliance with any conditions of parole or probation imposed after conviction or release; or
    - vii. Any other facts or circumstances tending to show the Applicant has been rehabilitated and is ready to accept the responsibilities of a law-abiding and productive member of society.

**Basis and Purpose – 2-270**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(2)(a), 44-10-203(2)(l)-(m), 44-10-203(2)(w), 44-10-305, 44-10-306, 44-10-307, 44-10-313(8), 24-4-104, and 24-4-105, C.R.S. The purpose of this rule is to clarify the procedures and factors governing the denial process and voluntary withdrawal process for all licenses issued by the State Licensing Authority. This Rule 2-270 is similar to the previous Rules M and R 251, 1 CCR 212-1 and 1 CCR 212-2.

**2-270 – Application Denial, Voluntary Withdrawal, and Effect of License Surrender, ~~or~~ Revocation, or Expiration on Related Applications**

- A. Applicant Bears the Burden of Proving It Meets Licensure Requirements. A License issued to a Person or a Regulated Marijuana Business is a revocable privilege. At all times during the application process, an Applicant must be capable of establishing it is qualified to hold a License.
- B. Applicants Must Provide Information to the Division in a Full, Faithful, Truthful, and Fair Manner. An application may be denied where the Applicant made misstatements, omissions, misrepresentations, or untruths in the application or in connection with the Applicant's suitability investigation. Providing misstatements, misrepresentations, omissions, or untruths to the Division may be the basis for administrative action, or the basis of criminal charges against the Applicant.
- C. Grounds for Denial.
1. The State Licensing Authority will deny an application for Good Cause.
  2. The State Licensing Authority will deny an application from an Applicant that is statutorily disqualified from holding a license.
  3. The State Licensing Authority will deny an application where the Applicant failed to provide all required information or documents, failed to obtain all required findings of suitability prior to submitting the application, provided inaccurate, incomplete, or untruthful information or documents, or failed to cooperate with the Division.
- D. Voluntary Withdrawal of Application.
1. The Division and Applicant may mutually agree to allow the voluntary withdrawal of an application in lieu of a denial proceeding.
  2. Applicants must first submit a form to the Division requesting the voluntary withdrawal of the application. Applicants will submit the form with the understanding that they were not obligated to request the voluntary withdrawal and that any right to a hearing in the matter is waived once the voluntary withdrawal is approved.
  3. The Division will consider the request along with any circumstances at issue with the application in making a decision to accept the voluntary withdrawal. The Division may at its discretion grant the request with or without prejudice or deny the request.
  4. The Division will notify the Applicant of its acceptance of the voluntary withdrawal and the terms thereof.
  5. If the Applicant agrees to a voluntary withdrawal granted with prejudice, then the Applicant is not eligible to apply again for licensing or approval until after expiration of one year from the date of such voluntary withdrawal.



- E. A Denied Applicant May Appeal a Denial. A Denied Applicant may appeal a denial pursuant to the Administrative Procedure Act.
- F. Effect of License Surrender, ~~or~~ Revocation, or Expired on Related Applications. If a License is voluntarily surrendered, ~~or~~ revoked, or expired and are not eligible for reinstatement, and there are related applications that are seeking some change to that License (including, but not limited to, renewal, change of Controlling Beneficial Owner, modification of Licensed Premises, or change of location) pending Final Agency Order, the related applications become moot and those moot applications will be closed by the Division without further action or notification to the Applicant.

### **Basis and Purpose – 2-275**

The statutory basis for this rule includes but is not limited to sections 44-10-202(1)(b)-(c), 44-10-203(1)(k), 44-10-203(2)(q), 44-10-203(2)(t), 11-10-310, 44-10-401(3)(a)-(d), C.R.S. The purpose of this rule is to establish procedures and requirements for any Person appointed by a court as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person acting in accordance with sections 44-10-401(3)(a)-(d), C.R.S., and authorized by court order to take possession of, operate, manage, or control a Regulated Marijuana Business. This Rule 2-275 was previously Rules M and R 253, 1 CCR 212-1 and 1 CCR 212-2.

### **2-275 – Temporary Appointee Registrations for Court Appointees**

- A. Notice and Application Requirements for All Court Appointees.
1. Notice to the State and Local Licensing Authorities. Within seven days of accepting an appointment as a Court Appointee pursuant to sections 44-10-401(3), C.R.S., such Court Appointee must file a notice to the State Licensing Authority and the applicable Local Licensing Authority on a form required by the State Licensing Authority which must include at least:
    - a. A copy of the order appointing the Court Appointee;
    - b. A statement affirming the Court Appointee complied with the certification required by section 44-10-401(3)(a), C.R.S.;
    - c. If the Court Appointee is an entity, a list of all natural persons responsible for taking possession of, operating, managing, or controlling the Regulated Marijuana Business; and
    - d. A complete list of all Regulated Marijuana Businesses for which the Court Appointee was appointed and the respective dates during which the Court Appointee is currently serving, or has previously served, as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person.
  2. Application for Finding of Suitability. Within 14 days of accepting an appointment as a Court Appointee pursuant to section 44-10-401(3), C.R.S., each Court Appointee must file either an application for a finding of suitability or a change of ownership application if the Court Appointee has applied for a finding of suitability or has already been found suitable with the State Licensing Authority on forms

required by the State Licensing Authority. Each entity and natural person for whom a notice was filed pursuant to Rule 2-275(A) must file an application for a finding of suitability. The Division may in its discretion extend the 14-day deadline to file an application for a finding of suitability upon a showing of good cause. The Division may also in its discretion rely upon a recent licensing background investigation for Court Appointees that currently hold a license or Temporary Appointee Registration issued by the State Licensing Authority and may waive all or part of the application fee accordingly.

3. Effective Date. The Temporary Appointee Registration will be issued following the State Licensing Authority's receipt of the notice required by Rule 2-275(A)(1) and is effective as of the date of the court appointment.

B. Temporary Appointee Registration.

1. Entities. If the Court Appointee is an entity, the entity and all natural persons responsible for taking possession of, operating, managing, or controlling the Regulated Marijuana Business must receive a Temporary Appointee Registration. Every Court Appointee that is an entity must have at least one natural person with a Temporary Appointee Registration.
2. Temporary Appointee Registrations. Every Temporary Appointee Registration issued to a Person will be treated as an Owner License except where inconsistent with section 44-10-401(3), C.R.S., or this Rule.
3. Other employees. Any other person working under the direction of a Court Appointee who possesses, cultivates, manufactures, tests, dispenses, sells, serves, transports, researches, or delivers Regulated Marijuana as permitted by privileges granted under a Regulated Marijuana Business license must have a valid Employee License.
4. Licensed Premises. A Court Appointee cannot establish an independent Licensed Premises but is authorized to exercise the privileges of the Temporary Appointee Registration in the Licensed Premises of the Regulated Marijuana Business for which it is appointed.
5. Medical Marijuana Business Operators or Retail Marijuana Business Operators. A Court Appointee may retain a Medical Marijuana Business Operator or a Retail Marijuana Business Operator. If the Medical Marijuana Business Operator or Retail Marijuana Business Operator is the Court Appointee, see subparagraph E of this Rule.
6. Marijuana Code and Rules Applicable. Court Appointees are subject to the requirements of the Marijuana Code and the rules promulgated thereto. Except where inconsistent with section 44-10-401(3), C.R.S., or this Rule, the State Licensing Authority may take any action with respect to a Temporary Appointee Registration that it could take with respect to any license issued under the Marijuana Code. In any action involving a Temporary Appointee Registration, these rules will be read to include the terms "registered", "registration", "registrant", or any other similar terms in lieu of "licensed", "licensee", and any

other similar terms as the context requires when applied to a Temporary Appointee Registration.

C. Administrative Actions.

1. Suspension, Revocation, Fine, or Other Administrative Action Regarding a Regulated Marijuana Business. In addition to any other basis for suspension, revocation, fine, or other administrative action, a Regulated Marijuana Business's license may, pursuant to subsections 44-10-202(1)(b), 44-10-401(3)(b), and 44-10-901(1), C.R.S., be suspended, revoked, fined, or subject to other administrative action based upon its Court Appointee's violations of the Marijuana Code, the rules promulgated pursuant to the Marijuana Code, the terms, conditions, or provisions of the Temporary Appointee Registration issued by the State Licensing Authority, or any order of the State Licensing Authority. Grounds for discipline include, but are not limited to, the Court Appointee's failure to timely notify the Division of the appointment or failure to timely apply for and obtain a finding of suitability. Such administrative action may occur even after the Temporary Appointee Registration is expired or surrendered, if the action is based upon an act or omission that occurred while the Temporary Appointee Registration was in effect.
2. Suspension, Revocation, Fine, or Other Administrative Action Regarding a Temporary Appointee Registration. In addition to any other basis for suspension, revocation, fine, or other administrative action, a Temporary Appointee Registration may, pursuant to subsections 44-10-202(1)(b), 44-10-401(3)(b), and 44-10-901(1), C.R.S., be suspended, revoked, or subject to other administrative action based upon the Court Appointee's violations of the Marijuana Code or the Rules promulgated pursuant to the Marijuana Code, the terms, conditions, or provisions of the Temporary Appointee Registration issued by the State Licensing Authority, or any order of the State Licensing Authority. Grounds for discipline include, but are not limited to, the Court Appointee's failure to timely notify the Division of the appointment or failure to timely apply for and obtain a finding of suitability. Such administrative action may occur even after the Temporary Appointee Registration is expired or surrendered, if the action is based upon an act or omission that occurred while the Temporary Appointee Registration was in effect. If a Person holding a Temporary Appointee Registration also holds any other Owner License or Employee License, the Owner License, the Employee License, and the Temporary Appointee Registration may be suspended, revoked, fined, or subject to other administrative action for any violations of the Marijuana Code or the rules promulgated pursuant to the Marijuana Code, the terms, conditions, or provisions of the Temporary Appointee Registration, Owner License, and/or Employee License issued by the State Licensing Authority, or any order of the State Licensing Authority.
3. Suitability. If the State Licensing Authority denies an application for a finding of suitability because the Court Appointee failed to timely apply for a finding of suitability, failed to timely provide all information requested by the Division in connection with an application for a finding of suitability, or was found unsuitable,

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the State Licensing Authority may also pursue administrative action as set forth in this Rule.

4. Court Appointee's Responsibility to Notify Appointing Court. The Court Appointee must notify the appointing court of any action taken against the Temporary Appointee Registration by the State Licensing Authority pursuant to sections 44-10-901 or 24-4-104, C.R.S., within two business days. Such actions include, without limitation, the issuance of an Order to Show Cause, the issuance of an Administrative Hold, the issuance of an Order of Summary Suspension, the issuance of an Initial Decision by the Department's Hearings Division, or the issuance of a Final Agency Order by the State Licensing Authority. The Court Appointee must forward a copy of such notification to the Division at the same time the notification is made to the appointing court.

D. Expiration and Renewal.

1. Conclusion of Court Appointment. A Court Appointee's Temporary Appointee Registration expires upon the conclusion of a Court Appointee's court appointment. Each Court Appointee and each Regulated Marijuana Business that has a Court Appointee must notify the State Licensing Authority within two business days of the date on which a Court Appointee's court appointment ends, whether due to termination of the appointment by the court, substitution of another Court Appointee, closure of the court case, or otherwise. For a Court Appointee that is appointed in connection with multiple court cases, the notice must be filed with the State Licensing Authority with respect to each such case.
2. ~~Biennial~~Annual Renewal. If it has not yet expired pursuant to Rule 2-270(D)(1), each Temporary Appointee Registration is valid for ~~one-two~~ years, after which it must be subject to ~~biennial~~annual renewal in accordance with the Marijuana Code and the rules promulgated pursuant to the Marijuana Code. If a Court Appointee is appointed in connection with multiple court cases, the Temporary Appointee Registration is subject to ~~biennial~~annual renewal unless all such appointments have ended, whether due to termination of the appointments by the courts, substitution of other Court Appointees, closure of the court cases, or otherwise.
3. Other Termination. A Temporary Appointee Registration may be valid for less than the applicable term if surrendered, revoked, suspended, or subject to similar action.

E. Medical Marijuana Business Operators and/or Retail Marijuana Business Operators as Court Appointees. By virtue of its privileges of licensure, a Medical Marijuana Business Operator, a Retail Marijuana Business Operator, and their respective Owner Licensees may serve as Court Appointees without a Temporary Appointee Registration subject to the following terms:

1. Notice to the State Licensing Authority of Appointment. The Medical Marijuana Business Operator or the Retail Marijuana Business Operator, and its Owner Licensee(s) are responsible for notifying the State Licensing Authority within seven days of any court appointment to serve as a receiver, personal

representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person and take possession of, operate, manage, or control a Regulated Marijuana Business. Such notice must be accompanied by a copy of the order making the appointment and must identify each Regulated Marijuana Business regarding which the Medical Marijuana Business Operator and/or Retail Marijuana Business Operator is appointed.

2. Notice to the Appointing Court of State Licensing Authority Action. The Medical Marijuana Business Operator or the Retail Marijuana Business, and its Owner Licensee(s) are responsible for notifying the appointing court of any action taken against the Medical Marijuana Business Operator license, the Retail Marijuana Business Operator license and/or the Owner License by the State Licensing Authority pursuant to sections 44-10-901 or 24-4-104, C.R.S., within two business days. Such actions include, without limitation, the issuance of an Order to Show Cause, the issuance of an Administrative Hold, the issuance of an Order of Summary Suspension, the issuance of an Initial Decision by the Department's Hearings Division, or the issuance of a Final Agency Order by the State Licensing Authority. The Medical Marijuana Business Operator, the Retail Marijuana Business Operator and its Owner Licensee(s) must forward a copy of such notification to the Division at the same time the notification is made to the appointing court.

### **Basis and Purpose – 2-280**

The statutory basis for this rule includes but is not limited to sections 44-10-203(2)(c), 44-10-203(2)(l), 44-10-203(2)(t), 44-10-203(2)(ee)(D), 44-10-203(7), 44-10-307, 44-10-309(4)-(5), 44-10-310(5) and (11), 44-10-313(8)(a), and 44-10-901, C.R.S. The purpose of this rule is to clarify the conditions and procedures for divestiture of any Person prohibited from holding a license under section 44-10-307, C.R.S., or who is found unsuitable by the State Licensing Authority. This rule also requires that every Regulated Marijuana Business have at least one Controlling Beneficial Owner and provides what happens in the event of suspension of a Regulated Marijuana Business's Controlling Beneficial Owner(s). Finally, this rule provides that Licensees cannot have unlicensed persons take actions on their behalf or for their benefit that the Licensees themselves are prohibited from taking under these rules or the Marijuana Code.

### **2-280 – Controlling Beneficial Owners that are Persons Prohibited, Unsuitable, Revoked, or Suspended; At Least One Controlling Beneficial Owner Holding a Valid Owner License Required; and Prohibited Third-Party Acts**

- A. Controlling Beneficial Owners That Are Persons Prohibited, Unsuitable, or Revoked.
  1. Less than 100% of all Controlling Beneficial Owners – Divestiture. If less than 100% of a Regulated Marijuana Business's Controlling Beneficial Owners are or become a Person prohibited from holding a license by these Rules or the Marijuana Code, have his or her Owner License revoked by a Final Agency Order, or are found unsuitable, the Regulated Marijuana Business must divest all of the Beneficial Ownership of that Controlling Beneficial Owner.
    - a. Unless extended for good cause, within 90 days of a Controlling Beneficial Owner becoming a Person prohibited from holding a license,

having his or her Owner License revoked, or being found unsuitable, the Regulated Marijuana Business must either:

- i. Submit a change of owner application, where required, and any document(s) necessary to transfer all of that Controlling Beneficial Owner's Interests to one or more Persons that are not prohibited from holding a license or unsuitable. Any required change of owner application is subject to approval by the Division; or
    - ii. Where a change of owner application is not required, transfer all of that Controlling Beneficial Owner's Interests to one or more Persons that are not a Person prohibited from holding a license or unsuitable.
  - b. In determining whether good cause for an extension exists, the Division will consider whether there is any Owner Interest buy-back provision with the Controlling Beneficial Owner. If mediation, arbitration, or a legal proceeding has been initiated regarding the required divestiture, the 90-day deadline is extended until 90 days following execution of a settlement agreement, arbitration order, or final judgment concluding the mediation, arbitration, or legal proceeding.
  - c. A Regulated Marijuana Business that is a Publicly Traded Corporation must have a divestiture plan with its Controlling Beneficial Owners which must be disclosed to the Division pursuant to Rule 2-220(A).
  - d. A Regulated Marijuana Business that fails to divest a Controlling Beneficial Owner as required by this Rule may be subject to denial, fine, suspension, or revocation of its license(s). The State Licensing Authority may consider aggravating and mitigating factors surrounding measures taken to divest the unsuitable or Person prohibited from holding a license when determining the imposition of a penalty. However, a Regulated Marijuana Business that is unable to divest a Controlling Beneficial Owner that is a Person prohibited from holding a license or found unsuitable is prohibited from being issued or holding a license.
2. All Controlling Beneficial Owners are Unsuitable, Revoked, or Persons Prohibited From Holding a License. A Regulated Marijuana Business's License may be revoked if 100% of its Controlling Beneficial Owners are found unsuitable, have his or her Owner's License revoked, or are Persons prohibited from holding a license by these Rules or the Marijuana Code.

**B. Suspension of Controlling Beneficial Owners.**

1. Suspension of Less than 100% of the Controlling Beneficial Owner(s) of a Regulated Marijuana Business. In the event of the suspension of the Owner License of a Controlling Beneficial Owner, either (i) the Regulated Marijuana Business must comply with all requirements of Rule 8-210 – Disciplinary Process: Summary Suspensions, or (ii) the non-suspended Owner Licensee(s)

must control the Regulated Marijuana Business without participation from the suspended Controlling Beneficial Owner(s).

2. Suspension of 100% of the Controlling Beneficial Owners of a Regulated Marijuana Business. A Regulated Marijuana Business cannot operate or Transfer Regulated Marijuana if all Controlling Beneficial Owners are suspended.
- C. At Least One Controlling Beneficial Owner Holding a Valid Owner License Required. No Regulated Marijuana Business or Owner Entity may operate or be licensed unless it has at least one Controlling Beneficial Owner who holds a valid Owner License.
- D. Loss Of Owner License As A Controlling Beneficial Owner Of Multiple Businesses. If an Owner License is suspended, revoked, or found unsuitable as to one Regulated Marijuana Business, that Owner License is automatically suspended, revoked, or found unsuitable as to any other Regulated Marijuana Business in which that Person is a Controlling Beneficial Owner.
- E. Prohibited Third-Party Acts. No Licensee may employ, contract with, hire, or otherwise retain any Person, including but not limited to an employee, agent, or independent contractor, to perform any act or conduct on the Licensee's behalf or for the Licensee's benefit if the Licensee is prohibited by law or these rules from engaging in such conduct itself.
  1. A Licensee may be held responsible for all actions and omissions of any Person the Licensee employs, contracts with, hires, or otherwise retains, including but not limited to an employee, agent, or independent contractor, to perform any act or conduct on the Licensee's behalf or for the Licensee's benefit.
  2. A Licensee may be subject to license denial or administrative action, including but not limited to fine, suspension, or revocation of its license(s), based on the act and/or omissions of any Person the Licensee employs, contracts with, hires, or otherwise retains, including but not limited to an employee, agent, or independent contractor, to perform any act or conduct on the Licensee's behalf or for the Licensee's benefit.

### **Basis and Purpose – 2-285**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(aa), 44-10-310(2), and 44-10-311(2), 44-10-401(2)(b)(I), 44-10-401(2)(b)(VII), 44-10-401(2)(b)(VIII), 44-10-607, 44-10-608, 44-10-611 C.R.S. The purpose of this rule is to establish requirements for Accelerator-Endorsed Licensees participating in the accelerator program.

### **2-285 – Accelerator Endorsement Application, Qualification, and Eligibility**

- A. Beginning January 1, 2021, Retail Marijuana Store Licensees, Retail Marijuana Cultivation Facility Licensees, and Retail Marijuana Products Manufacturers Licensees may apply for an endorsement to participate in the accelerator program. The application shall be made on Division forms and in accordance with the 2-200 Series Rules.

- B. Qualifications and Eligibility. The State Licensing Authority may consider the following facts and circumstances for purposes of determining a Licensees' qualifications and eligibility to be an Accelerator-Endorsed Licensee.
1. The Applicant has not, in the previous two years, been subject to a license revocation or active suspension issued by the State Licensing Authority, any Local Licensing Authority or Local Jurisdiction, or any other state in which it operated.
  2. Information demonstrating the Applicant operated its license for at least two years prior to the date of application; or if the Applicant is unable to demonstrate operations for a period of at least two years, it must satisfy at least one of the following:
    - a. The Applicant possesses a valid commercial marijuana license issued in another state and has operated such license for the preceding two years;
    - b. For the preceding two years the Applicant has participated in an accelerator, incubator, or social equity program that may, but is not required to be, associated with the commercial marijuana industry;
    - c. The Applicant has at least two years of regulated cannabis industry experience at a managerial or executive level; or
    - d. The Applicant has at least two years of business experience in a highly regulated industry other than the marijuana industry.
- C. Application Requirements. In addition to all other application requirements outlined in the 2-200 Series Rules, an application to become an Accelerator-Endorsed Licensee must include the Applicant's equity assistance proposal, containing the information required by the 3-1100 Series Rules.
- D. The Division will maintain a list of Accelerator-Endorsed Licensees on its website. By submitting an application to become an Accelerator-Endorsed Licensee, the Applicant authorizes the State Licensing Authority to publish the Applicant's name on the Division's website.

### **Part 3 – Regulated Marijuana Business Operations**

#### **3-100 Series – General Privileges and Limitations**

#### **3-200 Series – Licensed Premises**

##### **Basis and Purpose – 3-205**

The statutory authority for this rule includes but is not limited to sections 44-10-103(14), 44-10-103(26), 44-10-202(1)(c), 44-10-202(1)(e), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(p), and 44-10-203(2)(t), C.R.S. The purpose of this rule is to establish Limited Access Areas for Licensed Premises under the control of the Licensee to only individuals licensed by the State Licensing Authority. In addition, this rule clarifies that businesses and individuals cannot use the visitor system as a means to employ an individual who does not possess a valid and current



Employee License. This Rule was previously Rules M and R 301, 1 CCR 212-1 and 1 CCR 212-2.

### 3-205 – Limited Access Areas

- A. Proper Display of Identification Badge. All Persons in a Limited Access Area as provided for in section 44-10-103(26) C.R.S., shall be required to hold and properly display a current Identification Badge issued by the Division at all times. Proper display of the Identification Badge shall consist of wearing the badge in a plainly visible manner, at or above the waist. If the Identification Badge does not have a photo, the Licensee must be in possession of valid government-issued photo identification. The Licensee shall not alter, obscure, damage, or deface the badge in any manner.
- B. Visitors in Limited Access Areas.
1. Prior to entering a Limited Access Area, all visitors, including outside vendors, contractors or others, must obtain a visitor identification badge from ~~management~~licensed personnel of the ~~Licensee~~Regulated Marijuana Business that shall remain visible while in the Limited Access Area.
  2. Visitors shall be escorted by the Regulated Marijuana Business's licensed personnel at all times. No more than five visitors may be escorted by a single employee. Except that trade craftspeople, including but not limited to ancillary business operators, not normally engaged in the business of cultivating, processing, or selling Regulated Marijuana need not be accompanied on a full-time basis, but only reasonably monitored.
  3. A Regulated Marijuana Business and all Licensees employed by the Regulated Marijuana Business shall report to the Division any discovered plan or other action of any Person to (1) commit theft, burglary, underage sales, diversion of marijuana or marijuana product, or other crime related to the operation of the subject Regulated Marijuana Business; or (2) compromise the integrity of the Inventory Tracking System. A report shall be made as soon as possible after the discovery of the action, but not later than 14 days. Nothing in this paragraph (B) alters or eliminates any obligation a Regulated Marijuana Business or Licensee may have to report criminal activity to a local law enforcement agency.
  4. The Licensee shall maintain a log of all visitor activity, for any purpose, within the Limited Access Area and shall make such logs available for inspection by the Division and relevant Local Licensing Authority or Local Jurisdiction.
  5. All visitors admitted into a Limited Access Area must provide acceptable proof of age and must be at least 21 years of age. See Rule 3-405 – Acceptable Forms of Identification.
  6. The Licensee shall check the identification for all visitors to verify that the name on the identification matches the name in the visitor log. See Rule 3-405 – Acceptable Forms of Identification.
  7. A Licensee may not receive consideration or compensation for permitting a visitor to enter a Limited Access Area.

8. ~~Repealed. Use of a visitor badge to circumvent the Employee License requirements of Rule 2-265 is prohibited and may constitute a license violation affecting public safety.~~
- C. Required Signage. All areas of ingress and egress to Limited Access Areas on the Licensed Premises shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, "Do Not Enter - Limited Access Area – Access Limited to Licensed Personnel and Escorted Visitors." A Licensee may comply with this paragraph (C) when that sign is conspicuously placed immediately within an exterior entrance that is locked against public entry and only accessible to limited, licensed personnel and escorted visitors.
- D. Diagram for Licensed Premises. All Limited Access Areas shall be clearly identified to the Division and relevant Local Licensing Authority or Local Jurisdiction and described in a diagram of the Licensed Premises reflecting walls, partitions, counters and all areas of ingress and egress. The diagram shall also reflect all Propagation, cultivation, manufacturing, testing, consumption, and Restricted Access Areas. See Rule 3-905 – Business Records Required.
- E. ~~Repealed. Modification of Limited Access Area. A Licensee's proposed modification of designated Limited Access Areas must be approved by the Division, the Local Licensing Authority, and, if required, the relevant Local Jurisdiction prior to any modifications being made. See Rule 2-260 – Changing, Altering, or Modifying Licensed Premises.~~
- F. Law Enforcement Personnel Authorized. Notwithstanding the requirements of sub~~paragraph~~section (A) of this Rule, nothing shall prohibit investigators and employees of the Division, authorities from relevant Local Jurisdiction or state or local law enforcement, for a purpose authorized by the Marijuana Code or for any other state or local law enforcement purpose, from entering a Limited Access Area upon presentation of official credentials identifying them as such.
- G. When the Limited Access Area within a Licensed Premises of a Regulated Marijuana Business can only be accessed from outside the Licensed Premises, the movement of Regulated Marijuana and Regulated Marijuana Product between and within the Licensed Premises must comply with the following requirements:
1. Any Regulated Marijuana or Regulated Marijuana Product must be moved by a person holding a valid Owner License or Employee License and who must be an employee of the Regulated Marijuana Business;
  2. Any Regulated Marijuana or Regulated Marijuana Product must be in a sealed, opaque Container;
  3. Any movement of Regulated Marijuana or Regulated Marijuana Product must remain on video surveillance;
  4. The Owner Licensee or Employee Licensee moving the Regulated Marijuana or Regulated Marijuana Product must not enter the property of any other business, vehicle, residence, or building that is not controlled by the Licensee; and

5. Any movement must not be by a self-propelled vehicle that is designed primarily for travel on the public highways, that is generally and commonly used to transport persons and property over the public highways or a low-speed electric vehicle.

### **Basis and Purpose – 3-210**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-311(1)(b), and 44-10-311(2), C.R.S. The purpose of this rule is to establish and clarify the means by which the Licensee has lawful possession of the Licensed Premises. This Rule 3-210 was previously Rules M and R 302, 1 CCR 212-1 and 1 CCR 212-2.

### **3-210 – Possession of Licensed Premises**

- A. Evidence of Lawful Possession. Persons licensed pursuant to sections 44-10-501, 44-10-502, 44-10-503, 44-10-504, 44-10-507, 44-10-601, 44-10-602, 44-10-603, 44-10-604, 44-10-607, 44-10-608, 44-10-609, 44-10-610 C.R.S., or those applying for such licenses, must demonstrate proof of lawful possession of the premises to be licensed or Licensed Premises. Evidence of lawful possession consists of properly executed deeds of trust, leases, or other written documents acceptable to state and local licensing authorities.
- B. Relocation Prohibited. The Licensed Premises shall only be those geographical areas that are specifically and accurately described in executed documents verifying lawful possession. Licensees are not authorized to relocate to other areas or units within a building structure without first filing a change of location application and obtaining approval from the Division and the relevant Local Jurisdiction. Licensees shall not add additional contiguous units or areas, thereby altering the initially-approved premises, without filing an application and receiving approval to ~~change the location~~ modify the Licensed Premises on current forms prepared by the Division, including any applicable processing fee. ~~See Rule 2-260 – Changing, Altering, or Modifying Licensed Premises~~
- C. Subletting Not Authorized. Licensees are not authorized to sublet any portion of Licensed Premises for any purpose, unless all necessary applications to modify the existing Licensed Premises to accomplish any subletting have been approved by the Division and the relevant Local Licensing Authority or Local Jurisdiction.

### **Basis and Purpose – 3-215**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(d)(I)-(VI), 44-10-313(14), 44-10-401, 44-10-501, 44-10-502, 44-10-503, 44-10-504, 44-10-601, 44-10-602, 44-10-603, 44-10-604, C.R.S. The purpose of this rule is to establish guidelines for the manner in which a Medical Marijuana Business may share its existing Licensed Premises with a Retail Marijuana Business, and to ensure the proper separation of Regulated Marijuana Business operation operations. This Rule 3-215 was previously Rules M and R 304.1, 1 CCR 212-1 and 1 CCR 212-2.

### **3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation**

- A. Shared Licensed Premises for Medical Marijuana Stores and Retail Marijuana Stores.

1. Medical Marijuana Store that authorizes only patients that are over the age of 21. A Medical Marijuana Store that authorizes only Medical Marijuana patients who are over the age of 21 years to be on the Licensed Premises may also hold a Retail Marijuana Store license and operate at the same location under the following circumstances:
  - a. The relevant Local Licensing Authority and Local Jurisdiction permit a dual operation at the same location;
  - b. The Medical Marijuana Store and Retail Marijuana Store are commonly owned;
  - c. The Medical Marijuana Store and Retail Marijuana Store shall maintain physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory;
  - d. The Medical Marijuana Store and Retail Marijuana Store shall maintain separate displays between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory, but the displays may be on the same sale floor;
  - e. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Store and Retail Marijuana Store shall enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Store from the inventories and business transactions of the Retail Marijuana Store; and
  - f. The Medical Marijuana Store shall post and maintain signage that clearly conveys that persons under the age of 21 years may not enter.
2. Medical Marijuana Store that authorizes patients under the age of 21. A Medical Marijuana Store that authorizes Medical Marijuana patients under the age of 21 years to be on the Licensed Premises may operate in the same location with a Retail Marijuana Store under the following conditions:
  - a. The relevant Local Licensing Authority and Local Jurisdiction permit a dual operation at the same location;
  - b. The Medical Marijuana Store and Retail Marijuana Store are commonly owned;
  - c. The Medical Marijuana Store and Retail Marijuana Store maintain physical separation, including separate entrances and exits, between their respective Restricted Access Areas;

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- d. No point of sale operations occur at any time outside the physically separated Restricted Access Areas;
- e. All Medical Marijuana, Medical Marijuana Concentrate, and Medical Marijuana Product in a Restricted Access Area must be physically separated from all Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product in a Restricted Access Area, and such physical separation must include separate entrances and exits;
- f. Any display areas shall be located in the physically separated Restricted Access Areas;
- g. In addition to the physically separated sales and display areas, the Medical Marijuana Store and Retail Marijuana Store shall maintain physical or virtual separation for storage of Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory from storage of Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory; and
- h. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Store and Retail Marijuana Store shall enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Store from the inventories and business transactions of the Retail Marijuana Store.

B. Shared Licensed Premises For Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility. A Medical Marijuana Cultivation Facility and a Retail Marijuana Cultivation Facility may share a single Licensed Premises and operate at the same location under the following circumstances:

- 1. The relevant Local Licensing Authority and Local Jurisdiction permit a dual operation at the same location;
- 2. The Medical Marijuana Cultivation Facility and the Retail Marijuana Cultivation Facility are commonly owned;
- 3. The Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility shall maintain either physical or virtual separation between (i) Medical Marijuana and Medical Marijuana Concentrate and (ii) Retail Marijuana and Retail Marijuana Concentrate; and
- 4. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility must enable the Division and relevant Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Cultivation Facility from the Retail Marijuana Cultivation Facility.

C. Shared Licensed Premises For Medical Marijuana Products Manufacturer and Retail Marijuana Products Manufacturer. A Medical Marijuana Products Manufacturer and a

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Retail Marijuana Products Manufacturer may share a single Licensed Premises and operate at the same location under the following circumstances:

1. The relevant Local Licensing Authority and Local Jurisdiction permit a dual operation at the same location;
2. The Medical Marijuana Products Manufacturer and the Retail Marijuana Products Manufacturer are commonly owned;
3. The Medical Marijuana Products Manufacturer and Retail Marijuana Products Manufacturer shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory. Nothing in this Rule prohibits a Retail Marijuana Products Manufacturer and Medical Marijuana Products Manufacturer from sharing raw Ingredients in bulk, for example flour or sugar, except Retail Marijuana and Medical Marijuana may not be shared under any circumstances; and
4. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Products Manufacturer and Retail Marijuana Products Manufacturer must enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Products Manufacturer from the Retail Marijuana Products Manufacturer.

D. Shared Licensed Premises For Medical Marijuana Store, Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, Retail Marijuana Store, Retail Marijuana Cultivation Facility, and Retail Marijuana Products Manufacturer. A Medical Marijuana Store, Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, Retail Marijuana Store, Retail Marijuana Cultivation Facility, or Retail Marijuana Products Manufacturer may share the common areas of a Licensed Premises where the cultivation, manufacture, packaging, storing, or Transfers to patients and consumers of Regulated Marijuana does not occur. For example, the shared common areas may include hallways, break rooms, bathrooms, etc. Licensees must maintain physical separation of all Regulated Marijuana inventory. Nothing in this paragraph D prohibits Licensees sharing premises in accordance with paragraphs (B) and (C) of this Rule.

E. Shared Licensed Premises For Medical Marijuana Testing Facility and Retail Marijuana Testing Facility. A Medical Marijuana Testing Facility and a Retail Marijuana Testing Facility may share a single Licensed Premises and operate at the same location under the following circumstances:

1. The relevant Local Licensing Authority and Local Jurisdiction permit dual operation at the same location;
2. The Regulated Marijuana Testing Facilities are identically owned;
3. The Regulated Marijuana Testing Facilities shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate,

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Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory; and

4. Record-keeping, inventory tracking, packaging and labeling for the Regulated Marijuana Testing Facilities must enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Testing Facility from the Retail Marijuana Testing Facility.
- F. Shared Licensed Premises Medical Marijuana Transporter and Retail Marijuana Transporter. A Medical Marijuana Transporter and a Retail Marijuana Transporter may share a single Licensed Premises and operate dual transporting, logistics, and temporary storage business operation at the same location under the following circumstances:
1. The relevant Local Licensing Authority and Local Jurisdiction permit dual operation at the same location;
  2. The Medical Marijuana Transporter and Retail Marijuana Transporter are identically owned;
  3. The Medical Marijuana Transporter and Retail Marijuana Transporter shall maintain either physical or virtual separation between (i) Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Products, and other Medical Marijuana-related inventory and (ii) Retail Marijuana, Retail Marijuana Concentrate, Retail Marijuana Products, and other Retail Marijuana-related inventory; and
  4. Record-keeping, inventory tracking, packaging and labeling for the Medical Marijuana Transporter and Retail Marijuana Transporter must enable the Division and Local Licensing Authority or Local Jurisdiction to clearly distinguish the inventories and business transactions of the Medical Marijuana Transporter from the Retail Marijuana Transporter.
- G. Shared Licensed Premises Marijuana Research and Development Facility. A Marijuana Research and Development Facility that has obtained an R&D Co-Location Permit pursuant to Rule 5-705(B) may share a single Licensed Premises and operate at the same location as another Regulated Marijuana Business to the extent permitted by the R&D Co-Location Permit and otherwise in compliance with all applicable rules. See 5-700 Series Rules.
- H. ~~Repealed. Violation Affecting Public Safety. Violation of this Rule may be considered a license violation affecting public safety.~~

**Basis and Purpose – 3-225**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(h), 44-10-203(1)(k), 44-10-203(2)(e), 44-10-313(14), and 44-10-1001, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure adequate control of the Licensed Premises and Regulated Marijuana contained therein.

This rule also establishes the minimum guidelines for security requirements for video surveillance systems for maintaining adequate security. This Rule 3-225 was previously Rules M and R 306, 1 CCR 212-1 and 1 CCR 212-2.

### 3-225 – Video Surveillance

- A. Minimum Requirements. The following video surveillance requirements shall apply to all Regulated Marijuana Businesses, unless stated otherwise in these rules.
1. Prior to exercising the privileges of a Regulated Marijuana Business, an Applicant must install a fully operational video surveillance and camera recording system. The recording system must record in digital format and meet the requirements outlined in this Rule.
  2. All video surveillance records and recordings must be stored in a secure area that is only accessible to a Licensee's ~~management staff~~employees.
  3. Video surveillance records and recordings must be made available upon request to the Division, the relevant Local Licensing Authority or Local Jurisdiction, or any other state or local law enforcement agency for a purpose authorized by the Marijuana Code or for any other state or local law enforcement purpose. A Licensee may access video surveillance records and recordings remotely to meet the requirements of this rule.
  4. Video surveillance records and recordings of point-of-sale areas shall be held in confidence by all employees and representatives of the Division, except that the Division may provide such records and recordings to the Local Licensing Authority or Local Jurisdiction, or any other state or local law enforcement agency for a purpose authorized by the Marijuana Code, or for any other state or local law enforcement purpose.
- B. Video Surveillance Equipment.
1. Video surveillance equipment shall, at a minimum, consist of digital or network video recorders, cameras capable of meeting the recording requirements described in this Rule, and a minimum of one on-premises video monitors, ~~digital archiving devices, and a color printer capable of delivering still photos.~~
  2. ~~Repealed All video surveillance systems must be equipped with a failure notification system that provides prompt notification to the Licensee of any prolonged surveillance interruption and/or the complete failure of the surveillance system.~~
  3. Licensees are responsible for ensuring that all surveillance equipment is properly functioning, ~~and maintained,~~ and equipped with a failure notification system that provides prompt notification to the Licensee of any prolonged surveillance interruption and/or the complete failure of the surveillance system. ~~so that t~~ The playback quality ~~is~~ must be suitable for viewing and the surveillance equipment is capturing the identity of all individuals and activities in the monitored areas.
  4. All video surveillance equipment shall have sufficient battery backup or other uninterrupted power supply to support a minimum of two hours of recording in the



event of a power outage. Licensees must notify the Division of any loss of video surveillance capabilities that extend beyond four hours.

C. Placement of Cameras and Required Camera Coverage.

1. Camera coverage is required for all areas identified as Restricted Access Areas or Limited Access Areas, point-of-sale areas, security rooms, all points of ingress and egress to Limited Access Areas, all areas where Regulated Marijuana is displayed for sale, and all points of ingress and egress to the exterior of the Licensed Premises.
2. Camera placement shall be capable of identifying activity occurring within 20 feet of all points of ingress and egress and shall allow for the clear and certain identification of any individual and activities on the Licensed Premises.
3. At each point-of-sale location, camera coverage must enable recording of the facial features of patients, caregivers or consumer(s), and employee(s) with sufficient clarity to determine identity.
4. All entrances and exits to the facility shall be recorded from both indoor and outdoor vantage points.
5. The system shall be capable of recording all pre-determined surveillance areas in any lighting conditions. If the Licensed Premises has a Regulated Marijuana cultivation area, a rotating schedule of lighted conditions and zero-illumination can occur as long as ingress and egress points to Flowering areas remain constantly illuminated for recording purposes.
6. Areas where Regulated Marijuana is grown, sampled, tested, cured, manufactured, researched, or stored shall have camera placement in the room facing the primary entry door at a height which will provide a clear unobstructed view of activity without sight blockage from lighting hoods, fixtures, or other equipment.
7. Cameras shall also be placed at each location where weighing, packaging, transport preparation, processing, or tagging activities occur.
8. At least one camera must be dedicated to record the access points to the secured surveillance recording area.
9. All outdoor cultivation areas must meet the same video surveillance requirements applicable to any other indoor Limited Access Areas.

D. Location and Maintenance of Surveillance Equipment.

1. The surveillance room or surveillance area shall be a Limited Access Area.
2. Surveillance recording equipment must be housed in a designated, locked, and secured room or other enclosure with access limited to authorized employees, agents of the Division, and the relevant Local Licensing Authority or Local Jurisdiction, state or local law enforcement agencies for a purpose authorized by

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the Marijuana Code or for any other state or local law enforcement purpose, and service personnel or contractors.

3. Licensees must keep a current list of all authorized employees and service personnel who have access to the surveillance system and/or room on the Licensed Premises. Licensees must keep a surveillance equipment maintenance activity log on the Licensed Premises to record all service activity including the identity of the individual(s) performing the service, the service date and time and the reason for service to the surveillance system.
4. Off-site Monitoring and video recording storage of the areas identified in this Rule 3-225(C) by the Licensee or an independent third-party is authorized as long as standards exercised at the remote location meet or exceed all standards for on-site Monitoring.
5. Each Regulated Marijuana Business Licensed Premises located in a common or shared building, or commonly owned Regulated Marijuana Businesses located in the same Local Jurisdiction, must have a separate surveillance room/area that is dedicated to that specific Licensed Premises. Commonly-owned Regulated Marijuana Businesses located in the same Local Jurisdiction may have one central surveillance room located at one of the commonly owned Licensed Premises which simultaneously serves all of the commonly-owned Licensed Premises. The facility that does not house the central surveillance room is required to have a review station, printer, and map of camera placement on the premises. All minimum requirements for equipment and security standards as set forth in this section apply to the review station.
6. Licensed Premises that combine both a Medical Marijuana Business and a Retail Marijuana Business may have one central surveillance room located at the shared Licensed Premises. See Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation.

E. Video Recording and Retention Requirements.

1. All camera views of all Limited Access Areas must be continuously recorded 24 hours a day. The use of motion detection is authorized when a Licensee can demonstrate that monitored activities are adequately recorded.
2. All surveillance recordings must be kept for a minimum of 30 days and be in a format that can be easily accessed for viewing. Video recordings must be archived in a format that ensures authentication of the recording as legitimately captured video and guarantees that no alteration of the recorded image has taken place.
3. ~~Repealed~~~~The Licensee's surveillance system or equipment must have the capabilities to produce a color still photograph from any camera image, live or recorded, of the areas identified in this Rule 3-225(C).~~
4. The date and time must be embedded on all surveillance recordings without significantly obscuring the picture. The date and time must synchronize with any point-of-sale system.

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5. Time is to be measured in accordance with the official United States time established by the National Institute of Standards and Technology and the U.S. Naval Observatory at: <http://www.time.gov>.
6. After the 30-day surveillance video retention schedule has lapsed, surveillance video recordings must be erased or destroyed prior to: sale or transfer of the facility or business to another Licensee; or being discarded or disposed of for any other purpose. Surveillance video recordings may not be destroyed if the Licensee knows or should have known of a pending criminal, civil, or administrative investigation, or any other proceeding for which the recording may contain relevant information.

**F. Other Records.**

1. All records applicable to the surveillance system shall be maintained on the Licensed Premises. At a minimum, Licensees shall maintain a map of the camera locations, direction of coverage, camera numbers, surveillance equipment maintenance activity log, user authorization list, and operating instructions for the surveillance equipment.
2. A chronological point-of-sale transaction log must be made available to be used in conjunction with recorded video of those transactions.

**Basis and Purpose – 3-230**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), and 44-10-203(2)(h), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish waste disposal requirements for Regulated Marijuana Businesses and to provide more sustainable options including for Regulated Marijuana waste including composting, anaerobic digestion, pyrolyzing into biochar or biomass gasification. This Rule 3-230 was previously Rules M and R 307, 1 CCR 212-1 and 1 CCR 212-2.

**3-230 – Waste Disposal**

- A. All Applicable Laws Apply. Regulated Marijuana waste must be stored, secured, locked, and managed in accordance with all applicable federal, state, and local statutes, regulations, ordinances, or other requirements, including but not limited to the “Regulations Pertaining to Solid Waste Sites and Facilities” (6 CCR 1007-2, Part 1) established by the Colorado Department of Public Health and Environment pursuant to the “Solid Wastes Disposal Sites and Facilities Act”, Title 30, Article 20, Part 1, C.R.S. and “Regulation No. 100 – Water and Wastewater Facility Operations Certification Requirements” (5 CCR 1003-2) established by the Colorado Department of Public Health and Environment pursuant to the Title 25, Article 9, Part 1, C.R.S.
- B. Liquid Waste. Liquid waste from Regulated Marijuana Businesses shall be disposed of in compliance with all applicable federal, state and local laws, regulations, rules, and other requirements.
- C. Chemical, Dangerous and Hazardous Waste. Disposal of chemical, dangerous, and hazardous waste must be conducted in a manner consistent with federal, state and local

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laws, statutes, regulations, rules, and other requirements. This may include, but is not limited to, the disposal of all Pesticide and other agricultural chemicals, certain solvents and other chemicals used in the production of Regulated Marijuana Concentrate and any Regulated Marijuana soaked in a Flammable Solvent for purposes of producing a Regulated Marijuana Concentrate.

1. Elemental Impurities Remediation. All post extraction plant material generated from the elemental impurities Remediation process, and other Regulated Marijuana waste products (including but not limited to, still bottoms, lipids removed during winterization) generated from the Remediation process have the potential to be hazardous waste. Therefore, all such post extraction plant material must be subject to one of the following actions prior to leaving the Licensed Premises:

- ia. Treated as hazardous waste in regard to storage, labeling, and disposal; or

- ii.b. Tested for elemental impurities content.

- ia. Materials that meet the definition of hazardous waste, as defined by the Resource Conservation and Recovery Act or other applicable federal, state, or local regulations, must be treated as hazardous waste. Accordingly, they must be properly labeled, contained, stored, and disposed of in accordance with the Environmental Protection Agency, the Resource Conservation and Recovery Act, and other applicable regulations for hazardous waste.

- ii.b. Materials that contain elemental impurities concentrations less than the allowable concentration limits specified in the Resource Conservation and Recovery Act, and are not designated hazardous waste by other applicable federal, state, or local regulations, may be disposed of in accordance with this rule.

- D. Regulated Marijuana Waste Must Be Made Unusable and Unrecognizable. Unless expressly exempt by these rules, all Regulated Marijuana waste must be made unusable and Unrecognizable prior to leaving the Licensed Premises.

1. A Regulated Marijuana Business may Transfer Vaporizer Delivery Device waste prior to being made unusable and Unrecognizable for purposes of grinding or compacting the Vaporizer Delivery Device waste at the Licensed Premises of another Regulated Marijuana Business.

- E. Methods to Make Waste Unusable and Unrecognizable. Regulated Marijuana waste shall be rendered unusable and Unrecognizable through one of the following methods:

1. Grind or Compact and Mix with Non-Marijuana Waste. A Regulated Marijuana Business may render its Regulated Marijuana waste unusable and Unrecognizable by grinding or compacting and incorporating the marijuana waste with non-consumable, solid wastes listed below such that the resulting mixture is

at least 50 percent non-marijuana waste, and such that the resulting mixture cannot easily be separated and sorted:

- a. Paper waste;
- b. Plastic waste;
- c. Cardboard waste;
- d. Food waste;
- e. Grease or other compostable oil waste;
- f. Bokashi or other compost activators;
- g. Soil;
- h. Sawdust;
- i. Manure; and
- j. Other wastes approved by the Division that will render the Regulated Marijuana waste unusable and Unrecognizable.

2. Other Permitted and Sustainable Methods for Rendering Regulated Marijuana Waste Unusable and Unrecognizable. A Regulated Marijuana Business may render its Regulated Marijuana waste unusable and Unrecognizable through the following methods and subject to the following requirements and restrictions:

- a. The following methods are exempt from the 50/50 waste mixing requirement in subparagraph E(1) above and can be used to render Regulated Marijuana unusable and Unrecognizable:
  - i. On-site composting;
  - ii. Anaerobic digestion;
  - iii. Pyrolyze into biochar; or
  - iv. Biomass gasification.
- b. Requirements for Other Permitted and Sustainable Methods to Render Regulated Marijuana Waste Unusable and Unrecognizable. A Regulated Marijuana Business using other methods of rendering Regulated Marijuana waste unusable and Unrecognizable must comply with the requirements of this rule.
  - i. A Regulated Marijuana Business may utilize on its own Licensed Premises or may Transfer Regulated Marijuana waste to another Regulated Marijuana Business for on-site composting, anaerobic digestion, pyrolyzing into biochar or biomass gasification.
  - ii. A Regulated Marijuana Business may transfer only the stalks, stems, fan leaves, and roots from Regulated Marijuana to an area outside the Licensed Premises that is under the Licensee's

possession and control or to an unlicensed third-party that is registered and in good standing with the Colorado Secretary of State for composting, anaerobic digestion, pyrolyzing into biochar or biomass gasification.

- iii. Regulated Marijuana waste that is transferred to a location under the Licensee's possession and control, to another Regulated Marijuana Business, or to a third-party pursuant to this Rule is not required to comply with the 3-800 Series Rules - Inventory Tracking or the 3-1000 Series Rules - Labeling, Packaging, and Product Safety but must be recorded on the Transferring Regulated Marijuana Business' waste log.
- iv. A Regulated Marijuana Business or an unlicensed third-party providing composting, anaerobic digestion, pyrolyzing into biochar or biomass gasification shall ensure that the organic composition of the Regulated Marijuana waste is permanently altered so that it is rendered unusable and Unrecognizable.
- v. Waste Management Plan. A Regulated Marijuana Business using on-site composting, anaerobic digestion, pyrolyzing into biochar or biomass gasification to render Regulated Marijuana waste unusable and Unrecognizable must establish and maintain on its Licensed Premises a waste management plan that includes at least the following information: A description of the Regulated Marijuana Business's methods for on-site composting, anaerobic digestion, pyrolyzing into biochar or biomass gasification and identification of the areas that will be used for these activities. The location of these activities may include areas used for other operational activities of the Regulated Marijuana Business or may be areas outside the Licensed Premises so long as such areas are within the Licensee's possession and control.
- vi. Written Contract for Transfers to Unlicensed Third Parties. A Regulated Marijuana Business that is transferring stalks, stems, fan leaves, or roots from Regulated Marijuana to an unlicensed third-party for composting, anaerobic digestion, pyrolyzing into biochar or biomass gasification must have a written contract with that third-party. The Regulated Marijuana Business must maintain on its Licensed Premises a copy of the written contract and copies of receipts and invoices related to such third-party services. The written contract with the third-party must document at least the following information:
  - A. The identity of the unlicensed third party receiving any transfer of Regulated Marijuana waste pursuant to this Rule;
  - B. A description of the services provided by the unlicensed third party and the agreed-upon methods for managing the

Regulated Marijuana waste, including the end-use of such waste; and

- C. A requirement that the third-party is registered with the Colorado Secretary of State and must remain in in good standing during the contract term.

F. Mobile Waste Rendering. A Licensee or a third party vendor may also render Regulated Marijuana waste unusable and Unrecognizable outside of the Licensed Premises, subject to the following requirements and restrictions:

1. The waste must be rendered unusable and Unrecognizable in accordance with subparagraph (E) of this Rule, and unless otherwise expressly exempt by this Rule 3-230, mobile waste rendering must occur on property under the control of the Licensee that is immediately adjacent to the Licensed Premises;
2. Unless otherwise expressly exempt by this Rule 3-230, the waste must be taken from the Licensed Premises by an Owner Licensee or Employee Licensee directly to the vehicle where the rendering will occur;
3. Unless otherwise expressly exempt by this Rule 3-230, an Owner Licensee or Employee Licensee must monitor and observe the rendering to ensure the waste is made unusable and Unrecognizable;
4. Unless otherwise expressly exempt by this Rule 3-230, the Licensee shall ensure the rendering of any Regulated Marijuana waste unusable and Unrecognizable by a third party is recorded on the Licensee's video surveillance system; and
5. Any other restrictions imposed by the Local Licensing Authority or Local Jurisdiction.

G. After Waste is Made Unusable and Unrecognizable. After Regulated Marijuana waste is made unusable and Unrecognizable, the rendered waste shall be disposed of or otherwise managed as follows:

1. Disposed of at a solid waste site and disposal facility that has a Certificate of Designation from the local governing authority; or
2. Deposited at a compost facility that is permitted or approved by the Colorado Department of Public Health and Environment; or
3. Regulated Marijuana waste that has been rendered unusable and Unrecognizable by composting, anaerobic digestion, pyrolyzing into biochar or biomass gasification and pursuant to the Licensee's waste management plan(s) may be transferred to a Regulated Marijuana Business or an unlicensed third-party for further processing or use.
4. A Regulated Marijuana Business with cultivation privileges may reintroduce its own or Regulated Marijuana waste obtained from another Regulated Marijuana Business that has been rendered unusable and Unrecognizable into its Regulated Marijuana cultivation operations subject to its Standard Operating Procedures. For example, a Medical Marijuana Cultivation Facility or Retail

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Marijuana Cultivation Facility may use such waste as a soil amendment, potting media, or fertilizer

- H. Proper Disposal of Waste. A Licensee shall only dispose of Regulated Marijuana waste in a secured waste receptacle in possession and control of the Licensee.
- I. Inventory Tracking Requirements.
1. In addition to all other tracking requirements set forth in these rules, a Licensee shall utilize the Inventory Tracking System to ensure its post-harvest waste and Fibrous Waste materials are identified, weighed, and tracked while on the Licensed Premises until disposed of.
  2. All Regulated Marijuana waste must be weighed before leaving any Regulated Marijuana Business. A scale used to weigh Regulated Marijuana waste prior to entry into the Inventory Tracking System shall be tested and approved in accordance with section 35-14-127, C.R.S. See Rule 3-805 – Regulated Marijuana Businesses: Inventory Tracking System.
  3. A Licensee is required to maintain accurate and comprehensive records regarding Regulated Marijuana waste that accounts for, reconciles, and evidences all waste activity related to the disposal of Regulated Marijuana. See Rule 3-905 – Business Records Required.
  4. A Licensee is required to maintain accurate and comprehensive records regarding any waste material produced through the trimming or pruning of a Regulated Marijuana plant prior to harvest, which must include weighing and documenting all waste, including Fibrous Waste. Unless required by an Inventory Tracking System procedure, records of waste produced prior to harvest must be maintained on the Licensed Premises. Waste, excluding Fibrous Waste and Marijuana Consumer Waste, whether produced prior or subsequent to harvest, must be disposed of in accordance with this Rule and be made unusable and Unrecognizable. See Rule 3-235 – Transfers of Fibrous Waste and Rule 3-240 – Collection of Marijuana Consumer Waste.

**Basis and Purpose – 3-235**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-203(1)(k), and 44-10-203(2)(x), C.R.S. The purpose of this rule is to establish conditions under which a Licensee is authorized to transfer Fibrous Waste to a Person for the purpose of producing only Industrial Fiber Products. This Rule 3-235 was previously Rules M and R 307.5, 1 CCR 212-1 and 1 CCR 212-2.

**3-235 – Transfers of Fibrous Waste**

- A. All Applicable Laws Apply. Fibrous Waste must be stored and managed in accordance with all applicable state and local statutes, regulations, ordinances, or other requirements, including but not limited to the “Regulations Pertaining to Solid Waste Sites and Facilities” (6 CCR 1007-2, Part 1) established by the Colorado Department of Public Health and Environment pursuant to the “Solid Wastes Disposal Sites and Facilities Act”, Title 30, Article 20, Part 1, C.R.S. and “Regulation No. 100 – Water and



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Wastewater Facility Operations Certification Requirements” (5 CCR 1003-2) established by the Colorado Department of Public Health and Environment pursuant to the Title 25, Article 9, Part 1, C.R.S.

- B. Regulated Marijuana Cultivation Facilities and Regulated Marijuana Manufacturers may Transfer Fibrous Waste to an Industrial Fiber Products Producer in accordance with the requirements of this Rule 3-235.
- C. Contract Requirements. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, Accelerator Cultivators, Retail Marijuana Products Manufacturers and Accelerator Manufacturers that transfer Fibrous Waste to an Industrial Fiber Products Producer shall enter into a written contract prior to transferring any Fibrous Waste.
1. The written contract must be complete, and must fully incorporate all terms and conditions.
  2. The written contract shall include the following terms:
    - a. The identity of the Industrial Fiber Products Producer;
    - b. A requirement that the Industrial Fiber Products Producer shall be and shall remain in good standing with the Colorado Secretary of State during the contract term; and
    - c. A requirement that the Industrial Fiber Products Producer shall ensure the security of Fibrous Waste during transport from the Licensed Premises to the point of processing by the Industrial Fiber Products Producer.
  3. The Licensee and Industrial Fiber Products Producer shall sign an affirmation that the Fibrous Waste is being transferred only for the purpose of producing Industrial Fiber Products. The affirmation may be incorporated into a purchase order, invoice, or manifest.
- D. Business Records. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, Accelerator Cultivators, Retail Marijuana Products Manufacturers and Accelerator Manufacturers that transfer Fibrous Waste to an Industrial Fiber Products Producer shall keep all contracts, receipts, and inventory records relating to the transfer of any Fibrous Waste in accordance with Rule 3-905, including but not limited to Rule 3-905(A)(2).
- E. Security Measures.
1. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, Accelerator Cultivators, and Retail Marijuana Products Manufacturers, and Accelerator Manufacturers that transfer Fibrous Waste to an Industrial Fiber Products Producer shall comply with all security requirements pursuant to Rules 3-220 and 3-225.
  2. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, Accelerator Cultivators, Retail Marijuana Products Manufacturers and Accelerator Manufacturers

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preparing Fibrous Waste for transfer to an Industrial Fiber Products Producer must separate Fibrous Waste from other Regulated Marijuana plant material and waste within the Limited Access Area and on video surveillance.

3. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, Accelerator Cultivators Retail Marijuana Products Manufacturers, and Accelerator Manufacturers shall physically segregate all Fibrous Waste from other waste and Regulated Marijuana.
4. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, Accelerator Cultivators, Retail Marijuana Products Manufacturers and Accelerator Manufacturers shall affix a label to all receptacles holding Fibrous Waste that has already been separated from other Regulated Marijuana plant material and waste within the Limited Access Area prior to transfer to an Industrial Fiber Products Producer. The label must identify the receptacle as "Contains Fibrous Waste."
5. An Industrial Fiber Products Producer, or its employee or agent, must sign the visitor log, unless such individual has a valid Division-issued Employee License, to enter the Limited Access Area for any transfer of Fibrous Waste.
6. The Licensee remains responsible for all Fibrous Waste until the Industrial Fiber Products Producer takes possession and removes Fibrous Waste from the Licensed Premises.
7. The Licensee shall ensure that only Fibrous Waste and waste that has been made unusable and Unrecognizable pursuant to Rule 3-320 is transferred to the Industrial Fiber Products Producer.

F. Inventory Tracking Requirements.

1. A Licensee shall utilize the Inventory Tracking System to ensure its post-harvest Fibrous Waste materials are identified, weighed, and tracked while on the Licensed Premises until transferred.
2. A scale used to weigh Fibrous Waste prior to entry into the Inventory Tracking System shall be tested and approved in accordance with section 35-14-127, C.R.S. See Rule 3-805 – Regulated Marijuana Business: Inventory Tracking System.
3. A Licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all Fibrous Waste transfers. See Rule 3-905 – Business Records Required.

- G. Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, Accelerator Cultivators, Retail Marijuana Products Manufacturers and Accelerator Manufacturers shall not transfer contaminated Fibrous Waste to an Industrial Fiber Products Producer and shall handle contaminated Fibrous Waste using the same reasonable protocols used to handle waste.

- H. ~~Repealed. Violation Affecting Public Safety. It may be considered a violation of public safety for a Licensee to transfer anything to an Industrial Fiber Products Producer other than in accordance with this Rule 3-235.~~

### **Basis and Purpose – 3-240**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), and 44-10-203(2)(bb), C.R.S. The purpose of this rule is to establish conditions under which Regulated Marijuana Businesses are permitted to collect Marijuana Consumer Waste for purposes of reuse and recycling.

### **3-240 – Collection of Marijuana Consumer Waste**

- A. All Applicable Laws Apply. Marijuana Consumer Waste must be stored and managed in accordance with all applicable state and local statutes, regulations, ordinances, or other requirements, including but not limited to the “Regulations Pertaining to Solid Waste Sites and Facilities” (6 CCR 1007-2, Part 1) established by the Colorado Department of Public Health and Environment pursuant to the “Solid Wastes Disposal Sites and Facilities Act”, Title 30, Article 20, Part 1, C.R.S. and “Regulation No. 100 – Water and Wastewater Facility Operations Certification Requirements” (5 CCR 1003-2) established by the Colorado Department of Public Health and Environment pursuant to the Title 25, Article 9, Part 1, C.R.S.
- B. Regulated Marijuana Businesses may collect, reuse, and recycle Marijuana Consumer Waste in accordance with the requirements of this Rule 3-240.
- C. Collection, Separation, and Processes.
1. Collection. A Licensee must comply with the following requirements when collecting Marijuana Consumer Waste pursuant to this Rule:
    - a. Only Medical Marijuana Stores, Retail Marijuana Stores, and Licensed Hospitality Businesses may collect Marijuana Consumer Waste from patients and consumers. Medical Marijuana Stores, Retail Marijuana Stores, and Licensed Hospitality Businesses collecting Marijuana Consumer Waste pursuant to this Rule are not limited to collecting Marijuana Consumer Waste from patients or consumers who purchased Regulated Marijuana from the Medical Marijuana Store, Retail Marijuana Store, or Licensed Hospitality Business.
    - b. A Regulated Marijuana Business may collect Marijuana Consumer Waste from any of its Owner Licensees or Employee Licensees who purchased the Regulated Marijuana from the Regulated Marijuana Business, or may collect Marijuana Consumer Waste from other Regulated Marijuana Businesses pursuant to paragraph (E) of this Rule.
    - c. The Licensee must utilize receptacles that are locked, sealed and designed to require a key or specialized tools in order to open and access the contents of the receptacle used for collection of Marijuana Consumer Waste;

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- d. All receptacles used for collection of Marijuana Consumer Waste shall be located in a secured area on the Licensed Premises and shall be reasonably supervised by a Licensee to ensure any Marijuana Consumer Waste collected is only removed by a Licensee;
    - e. All receptacles used for collection of Marijuana Consumer Waste shall be recorded on video surveillance; and
    - f. All receptacles used for collection of Marijuana Consumer Waste shall be labeled. The label must at least identify the receptacle as "Contains Marijuana Consumer Waste." A Licensee may choose to include additional information on the receptacle label.
  2. Separation. Regulated Marijuana Businesses collecting Marijuana Consumer Waste pursuant to this Rule must separate any electronic and battery components from the Marijuana Consumer Waste.
  3. Processes. Regulated Marijuana Businesses collecting Marijuana Consumer Waste pursuant to this Rule must establish Standard Operating Procedures that ensure at a minimum any remaining Regulated Marijuana in Marijuana Consumer Waste is removed and destroyed to the extent practicable.
- D. Reuse of Marijuana Consumer Waste. Once any remaining Regulated Marijuana has been removed and destroyed pursuant to these rules, a Regulated Marijuana Business may reuse Marijuana Consumer Waste as follows and subject to the following requirements and restrictions:
  1. Sanitizing. The Containers have been sanitized and disinfected either by a Regulated Marijuana Business or by a third-party to ensure that they do not contain any harmful residue or contaminants.
  2. Child-Resistant Containers. Either the Containers can be reused with new child resistant packaging that complies with 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995); or if new child resistant packaging is not being used, based on a visual inspection, the existing Child-Resistant packaging appears to be in good working order and does not appear to pose a risk of unintended exposure or ingestion of Regulated Marijuana. The visual inspection must ensure such Containers are not brittle or have chips, cracks, or other imperfections that could compromise the child-resistant properties of the Container or otherwise pose a threat of harm to a patient or consumer.
- E. Transfers of Marijuana Consumer Waste. Once any remaining Regulated Marijuana has been removed and destroyed pursuant to these rules, a Regulated Marijuana Business may transfer Marijuana Consumer Waste as follows:
  1. A Licensee may Transfer Marijuana Consumer Waste to another Regulated Marijuana Business for purposes of further processing and recycling or for reuse pursuant to this Rule; or
  2. A Licensee may transfer Marijuana Consumer Waste, excluding the electronic components and battery components, to a Person for purposes of recycling or for

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reuse pursuant to this Rule. To the extent required, such Person shall be registered as required by the Colorado Department of Public Health and Environment's regulations at 6 CCR 1007-2, Part 1, Section 8; or

3. A Licensee may transfer the electronic and battery components of Marijuana Consumer Waste to a Person for purposes of recycling in accordance with the Colorado Department of Public Health and Environment's regulations at 6 CCR 1007-3.
- F. Business Records. Regulated Marijuana Businesses that collect and Transfer Marijuana Consumer Waste pursuant to this Rule 3-240 shall keep all contracts, ~~S~~standard ~~O~~perating ~~P~~rocedures, and receipts relating to the collection and Transfer of any Marijuana Consumer Waste in accordance with Rule 3-905, including but not limited to Rule 3-905(A)(2).
- G. ~~Repealed. Violation Affecting Public Safety. It may be considered a violation affecting public safety for a Licensee to Transfer Marijuana Consumer Waste that has remaining Regulated Marijuana and in a manner other than in accordance with this Rule 3-240.~~

**3-300 Series – Health and Safety Regulations****Basis and Purpose – 3-305**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(3)(f), and 44-10-1001(2), C.R.S. The purpose of this rule is to clarify the conditions under which a Regulated Marijuana Business may be subject to an inspection of its Licensed Premises by a county or municipal employee, specifically but not exclusively a fire safety inspection.

**3-305 – Local Safety Inspections**

A Regulated Marijuana Business~~es~~ may be subject to inspection of its Licensed Premises by the local fire department, building inspector, or code enforcement officer to inspect for compliance with local health and safety regulations. The inspection could result in additional specific standards to meet Local Jurisdiction restrictions related to Regulated Marijuana or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety

**Basis and Purpose – 3-310**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(k), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), and 44-10-313(14), C.R.S. The purpose of this rule is to clarify the minimum health and sanitary conditions under which a Regulated Marijuana Business must maintain its Licensed Premises.

**3-310 – General Sanitary Requirements**

- A. The Licensee shall ensure the Licensed Premises is kept in a sanitary condition and the Regulated Marijuana is produced in a sanitary manner~~, take all reasonable measures and precautions to ensure~~ This includes, but is not limited to, the following:

1. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with Regulated Marijuana shall be excluded from any operations which may be expected to result in contamination until the condition is corrected;
2. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;
3. That all persons working in direct contact with Regulated Marijuana shall conform to hygienic practices while on duty, including but not limited to:
  - a. Maintaining adequate personal cleanliness;
  - b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of Regulated Marijuana Product, and at any other time when the hands may have become soiled or contaminated; and
  - c. Refraining from having direct contact with Regulated Marijuana if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.
4. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Regulated Marijuana are exposed;
5. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned, and each is kept clean and in good repair;
6. That there is adequate lighting in all areas where Regulated Marijuana is stored or sold, and where equipment or utensils are cleaned;
7. That the Licensee provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;
8. That any buildings, fixtures, and other facilities are maintained in a sanitary condition, including but not limited to the prevention of microorganism growth;
9. That toxic cleaning compounds, sanitizing agents, and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Regulated Marijuana and in a manner that is in accordance with any applicable local, state or federal law, rule, regulation, or ordinance;

10. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Regulated Marijuana shall be conducted in accordance with adequate sanitation principles;
11. That each Regulated Marijuana Business provides its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
12. That Regulated Marijuana that can support the rapid growth of undesirable microorganisms are held in a manner that prevents the growth of these microorganisms.

**Basis and Purpose – 3-315**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(1)(g), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), and 44-10-1001(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). It sets forth general standards and basic sanitary requirements for Retail Marijuana Stores. It covers the physical premises where the products are made as well as the individuals handling the products. This rule authorizes the State Licensing Authority to require an independent consultant to conduct a health and sanitary audit of a Regulated Marijuana Business. The purpose of this rule is to establish the conditions under an independent health and safety audit may be required. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Regulated Marijuana Businesses refusal to cooperate or pay for the audit. The State Licensing Authority intends for this rule to reduce any product contamination, which will benefit both the Licensees and consumers. The State Licensing Authority modeled this rule after those adopted by the Colorado Department Revenue for Medical Marijuana and those adopted by the Colorado Department of Public Health and Environment. Overall, the State Licensing Authority intends this rule to help maintain the integrity of Colorado's Retail Marijuana businesses and the safety of the public.

**3-315 – Independent Health and Safety Audit****A. State Licensing Authority May Require A Health and Sanitary Audit.**

1. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Regulated Marijuana Business to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Regulated Marijuana Business is in compliance with the requirements set forth in this Rule and other applicable health, sanitary, or food handling laws, rules, and regulations.
2. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Regulated Marijuana Business. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.
3. The Regulated Marijuana Business will be responsible for all costs associated with the independent health and sanitary audit.

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- B. When Independent Health and Sanitary Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:
1. The Division has reasonable grounds to believe that the Regulated Marijuana Business is in violation of one or more of the requirements set forth in this Rule or other applicable public health or sanitary laws, rules, or regulations;
  2. The Division has reasonable grounds to believe that the Regulated Marijuana Business was the cause or source of contamination of Regulated Marijuana;
  3. A Regulated Marijuana Cultivation Facility does not provide requested records related to the use of Pesticide or other agricultural chemicals used in the cultivation process;
  4. Multiple Harvest Batches or Production Batches produced by a Regulated Marijuana Cultivation Facility failed contaminant testing;
  5. A Regulated Marijuana Products Manufacturer does not provide requested records related to the production of Regulated Marijuana Products, including but not limited to, certification of its Licensed Premises, equipment or ~~Standard~~ ~~Operating~~ ~~Procedures~~, food handling training required for Owner Licensees and Employee Licensees engaged in the production of Regulated Marijuana Products, or Production Batch specific records to the Division;
  6. Multiple Production Batches of Regulated Marijuana Products produced by the Regulated Marijuana Products Manufacturer failed contaminant testing.
- C. Compliance Required. A Regulated Marijuana Business must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent health and sanitary audit in accordance with this Rule.
- D. Suspension of Operations.
1. If the State Licensing Authority has objective and reasonable grounds to believe and finds upon reasonable ascertainment of the underlying facts that the Licensee committed a deliberate and willful violation or there is a substantial danger to public health and safety and incorporates such findings into its order, it may order summary suspension of the Regulated Marijuana Business's license. See Rule 8-210 – Disciplinary Process: Summary Suspensions.
  2. Prior to or following the issuance of such an order, the Regulated Marijuana Business may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.
    - a. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety, or welfare, then the State Licensing Authority will promptly institute license suspension or revocation



procedures. See Rule 8-210 – Disciplinary Process: Summary Suspensions.

- b. If an agreement to suspend operations is reached, then the Regulated Marijuana Business may continue to care for its inventory and conduct any necessary internal business operations, but it may not Transfer any Regulated Marijuana or Regulated Marijuana Product to another Regulated Marijuana Business, a patient, or a consumer during the period of time specified in the agreement

### **Basis and Purpose – 3-320**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(dd)(X), and 44-10-203(3)(c), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). This rule prohibits a Regulated Marijuana Business from Transferring any contaminated Regulated Marijuana or Regulated Marijuana Product to any Person or another Regulated Marijuana Business. Additionally, this rule provides permitted Microbial Decontamination or Microbial Control Step methods that a Licensee may utilize in the course of their business. These provisions outline the minimum requirements a Licensee must comply with to utilize approved Microbial Decontamination or Microbial Control Step methods and do not reflect an endorsement of these methods.

### **3-320 – Contaminated Product: Approved Microbial Decontamination and Microbial Control Step Methods**

- A. A Regulated Marijuana Business shall not accept or Transfer to any Person any Regulated Marijuana that has failed required testing pursuant to Rule ~~4-2104-120~~ or Rule ~~4-2154-125~~, unless otherwise permitted in these rules. See Rule ~~4-2404-135~~. If, despite the prohibitions in these ~~R~~rules, another Regulated Marijuana Business Transfers any Regulated Marijuana that has failed or subsequently fails required testing pursuant to Rule ~~4-1204-210~~ or Rule ~~4-1254-215~~, the receiving Regulated Marijuana Business shall ensure that all Regulated Marijuana that failed required testing are safely disposed of in accordance with Rule 3-230.
- B. Approved Microbial Decontamination and Microbial Control Step Methods. Licensees are permitted to use only the following Microbial Decontamination or Microbial Control Step techniques to treat an entire Harvest Batch or Production Batch and are not approved for use on plants that have not been harvested. Licensees must not use a technique to treat a Test Batch alone. Inclusion of a technique in this Rule does not imply that a substance or a device is compliant with other requirements or regulations. Regulated Marijuana Businesses must comply with any applicable state and federal requirements regarding the use of any substance or device used for Microbial Decontamination or Microbial Control Step. Any substance or device used for Microbial Decontamination or Microbial Control Step must be registered in accordance with state and federal requirements. Any substance that would be considered a pesticide must meet all criteria at 8 CCR 1203-2 Part 17.
  1. Ozone treatment.

- a. Equipment requirements: Non-enclosed ozone generating device. A Licensee who seeks to use a non-enclosed ozone generating device for Decontamination, or Microbial Control Step must comply with the following safety requirements, which must be documented in a Sstandard Operating Procedure:
    - i. Sufficient air filtration and/or handling systems to protect worker safety, meet manufacturer safety recommendations, and comply with any federal, state, or local regulations; and
    - ii. Review by an Industrial Hygienist that includes, at a minimum:
      - A. Consideration of volume and storage of chemicals;
      - B. Fire safety considerations;
      - C. Ambient levels of chemicals (e.g. ozone, flammable liquids); and
      - D. Environmental monitoring.
    - iii. Any Material Change in the Licensee's Sstandard Operating Procedures or processes requires subsequent Industrial Hygienist review and approval.
  - b. Equipment requirements: Sealed enclosure ozone generating device. A Licensee who seeks to use a sealed enclosure ozone generating device for Decontamination or Microbial Control Steps must comply with the following safety requirements, which must be documented in a Sstandard Operating Procedure:
    - i. Sufficient air filtration and/or handling systems to protect worker safety, meet manufacturer safety recommendations, and comply with any federal, state, or local regulations; and
    - ii. To be considered a sealed enclosure ozone generating device, the ozone must be contained in an enclosed space not intended for human occupancy and capture the ozone or reactive oxygen species generated by the device and degrade it into molecular oxygen (O<sub>2</sub>) or other components that are safe for human exposure.
2. X-ray irradiation in a sealed enclosure device. A Licensee who uses x-ray irradiation in a sealed enclosure device for Decontamination or Microbial Control Steps must require the use of personal protective equipment and safety procedures to prevent human exposure to UV radiation and to comply with the following safety requirements, which must be documented in a Sstandard Operating Procedure:
    - a. Radiation survey and dosimeter badges for operators; and

- b. Inspection by a Colorado registered qualified inspector and certification by the Colorado Department of Public Health and Environment X-ray Certification Unit.
- 3. Ultraviolet light (UV) irradiation. A Licensee who seeks to use UV light irradiation for Decontamination or Microbial Control Steps must require the use of personal protective equipment and safety procedures to prevent human exposure to UV radiation.
- 4. Microwave Irradiation. A Licensee who seeks to use microwave irradiation for Decontamination or Microbial Control Steps must only use a microwave device that is constructed, inside and outside, in a manner that it may be adequately cleaned.
- 5. Vaporized hydrogen peroxide in a sealed enclosure device.
  - a. A Licensee who seeks to use vaporized hydrogen peroxide in a sealed enclosure device for Decontamination or Microbial Control Steps must have sufficient air filtration and/or handling systems to protect worker safety, meet manufacturer safety recommendations, and comply with all federal, state or local regulations, which must be documented in a Standard Operating Procedure.
  - b. To be considered a sealed enclosure device, the vaporized hydrogen peroxide and any reactive oxygen species must be contained in an enclosed space not intended for human occupancy and capture the hydrogen peroxide or reactive oxygen species generated by the device and degrade it into molecular oxygen (O<sub>2</sub>), water, or other components that are safe for human exposure.
- 6. Pasteurization. A Licensee who seeks to use pasteurization must have sufficient air filtration and/or handling systems to protect worker safety, meet manufacturer safety recommendations, and comply with all federal, state, or local regulations.
- 7. Radio Frequency. A Licensee who seeks to use radio frequency for Decontamination or Microbial Control Steps must comply with the following safety requirements, which must be documented in a Standard Operating Procedure:
  - a. Follow manufacturer safety recommendations and steps for operation of the unit; and
  - b. Comply with all federal, state, or local regulations, including but not limited to, regulations pertaining to fire safety and prevention programs for electrical devices in the workplace.
- C. Required Safety Measures. A Licensee who conducts Decontamination or seeks to use any of the above approved Microbial Control Step methods must:
  - 1. Ensure proper training of personnel operating the equipment or working in the vicinity of the equipment;

2. Ensure proper use of appropriate personal protective equipment (PPE) and requiring that PPE be worn by anyone working in the vicinity of the Decontamination or Microbial Control Step equipment;
  3. Comply with all manufacturer safety recommendations;
  4. Comply with any additional safety mitigation measures recommended by the manufacturer;
  5. Include signage clearly indicating areas where Decontamination or Microbial Control Steps are taking place;
  6. If compressed gasses or other simple asphyxiants are present, a device must be used that monitors oxygen levels and alarms if an oxygen deficient environment exists; and
  7. Document all training, safety, and other operating processes in Sstandard Operating Procedures.
- D. The Microbial Decontamination method must be accurately documented in the Inventory Tracking System for packages that have been Decontaminated.
1. Uniform treatment of Harvest Batches prior to Sample Increment Collection is required. Storage of Test Batches after collection and prior to Transfer to a Licensed Marijuana Testing Facility shall be consistent with storage conditions of the Harvest Batch that they were pulled from, including but not limited to temperature, airflow, and humidity. Equipment used for Decontamination or Microbial Control Steps shall be located in a Limited Access Area of the Licensed Premises.
  2. Equipment used for Decontamination or Microbial Control Steps shall be used exclusively for the purpose of Decontamination or Microbial Control Steps.
  3. No other activity is permitted to be used with the equipment including, but not limited to preparing food.
- E. Microbial Decontamination and Microbial Control Step Methods Approval Process. A Licensee may submit a request to the Division to consider approval of a Decontamination or Microbial Control Step method not permitted under this Rule. The request must include scientific data and evidence on the principles and efficacy of the method and detail all aspects of the Decontamination or Microbial Control Step method including associated safety risks and appropriate safety mitigation steps including training requirements, use of personal protective equipment (PPE), and the appropriate occupational, environmental, and product/consumer safety precautions, including any safety-related manufacturer recommendations.

**Basis and Purpose – 3-325**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(dd)(X), and 44-10-203(3)(c), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to clarify that a Regulated Marijuana Business engaged

in the cultivation of Regulated Marijuana is prohibited from using certain chemicals or pesticides that may cause harm to employees or consumers.

### 3-325 – Prohibited Chemicals

- A. Applicability. This Rule 3-325 applies to Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturer, Retail Marijuana Cultivation Facilities, Retail Marijuana Products Manufacturer, Accelerator Cultivator, Accelerator Manufacturer, and Marijuana Research and Development Licensees.
- B. The following chemicals are prohibited and shall not be used in the production of Regulated Marijuana. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises is a violation of this Rule. Additionally, possession of Regulated Marijuana, Regulated Marijuana Concentrate, Regulated Marijuana Product, or Hemp Product on which any of the following chemicals is detected is a violation of this Rule.
1. Any Pesticide the use of which would constitute a violation of the Pesticide Act, section 35-9-101 *et seq.*, C.R.S., the Pesticide Applicators' Act, section 35-10-101 *et seq.*, C.R.S., or the rules and regulations pursuant thereto.
  2. Other chemicals: ~~(listed by chemical name and CAS Registry Number (or EDF Substance ID)):~~

~~ALDRIN~~

~~309-00-2~~

~~ARSENIC OXIDE (3)~~

~~1327-53-3~~

~~ASBESTOS (FRIABLE)~~

~~1332-21-4~~

~~AZODRIN~~

~~6923-22-4~~

~~1,4 BENZOQUINONE, 2,3,5,6-TETRACHLORO-~~

~~118-75-2~~

~~BINAPACRYL~~

~~485-31-4~~

~~2,3,4,5-BIS (2-BUTENYLENE) TETRAHYDROFURFURAL~~

~~126-15-8~~

~~BROMOXYNIL-BUTYRATE~~

~~EDF-186~~

CADMIUM COMPOUNDS~~CAE750~~CALCIUM ARSENATE [2ASH3O4.2CA]~~7778-44-1~~CAMPHECHLOR~~8001-35-2~~CAPTAFOL~~2425-06-1~~CARBOFURAN~~1563-66-2~~CARBON TETRACHLORIDE~~56-23-5~~CHLORDANE~~57-74-9~~CHLORDECONE (KEPONE)~~143-50-0~~CHLORDIMEFORM~~6164-98-3~~CHLOROBENZILATE~~510-15-6~~CHLOROMETHOXYPROPYLMERCURIC ACETATE [CPMA] EDF-~~183~~COPPER ARSENATE~~10103-61-4~~2,4-D, ISOOCTYL ESTER~~25168-26-7~~DAMINOZIDE~~1596-84-5~~DDD~~72-54-8~~

~~DDT~~

~~50-29-3~~

~~DI(PHENYLMERCURY)DODECENYLSUCCINATE (PMDS) EDF-~~

~~187~~

~~1,2-DIBROMO-3-CHLOROPROPANE (DBCP)~~

~~96-12-8~~

~~1,2-DIBROMOETHANE~~

~~106-93-4~~

~~1,2-DICHLOROETHANE~~

~~107-06-2~~

~~DIELDRIN~~

~~60-57-1~~

~~4,6-DINITRO-O-CRESOL~~

~~534-52-1~~

~~DINITROBUTYL PHENOL~~

~~88-85-7~~

~~ENDRIN~~

~~72-20-8~~

~~EPN~~

~~2104-64-5~~

~~ETHYLENE OXIDE~~

~~75-21-8~~

~~FLUOROACETAMIDE~~

~~640-19-7~~

~~GAMMA-LINDANE~~

~~58-89-9~~

~~HEPTACHLOR~~

~~76-44-8~~

~~HEXACHLOROBENZENE~~

~~118-74-1~~

~~1,2,3,4,5,6-HEXACHLOROCYCLOHEXANE (MIXTURE OF ISOMERS)~~

~~608-73-1~~

~~1,3-HEXANEDIOL, 2-ETHYL-~~

~~94-96-2~~

~~LEAD ARSENATE~~

~~7784-40-9~~

~~LEPTOPHOS~~

~~21609-90-5~~

~~MERCURY~~

~~7439-97-6~~

~~METHAMIDOPHOS~~

~~10265-92-6~~

~~METHYL PARATHION~~

~~298-00-0~~

~~MEVINPHOS~~

~~7786-34-7~~

~~MIREX~~

~~2385-85-5~~

~~NITROFEN~~

~~1836-75-5~~

~~OCTAMETHYLDIPHOSPHORAMIDE~~

~~152-16-9~~

~~PARATHION~~

~~56-38-2~~

~~PENTACHLOROPHENOL~~

~~87-86-5~~

~~PHENYLMERCURIC OLEATE [PMO]~~

~~EDF-185~~

~~PHOSPHAMIDON~~

~~13171-21-6~~



PYRIMINIL~~53558-25-1~~SAFROLE~~94-59-7~~SODIUM ARSENATE~~13464-38-5~~SODIUM ARSENITE~~7784-46-5~~~~2,4,5-T~~~~93-76-5~~TERPENE POLYCHLORINATES (STROBANE6)~~8001-50-1~~THALLIUM(I) SULFATE~~7446-18-6~~~~2,4,5-TP ACID (SILVEX)~~~~93-72-1~~TRIBUTYL TIN COMPOUNDS~~EDF-184~~~~2,4,5-TRICHLOROPHENOL~~~~95-95-4~~VINYL CHLORIDE~~75-01-4~~**3-325(B)(2) 1**

<u>Chemical Name</u>	<u>CAS Registry Number (or EDF Substance ID)</u>
<u>ALDRIN</u>	<u>309-00-2</u>
<u>ARSENIC OXIDE (3)</u>	<u>1327-53-3</u>
<u>ASBESTOS (FRIABLE)</u>	<u>1332-21-4</u>
<u>AZODRIN</u>	<u>6923-22-4</u>

## Marijuana Enforcement Division

<u>Chemical Name</u>	<u>CAS Registry Number (or EDF Substance ID)</u>
<u>1,4-BENZOQUINONE, 2,3,5,6-TETRACHLORO-</u>	<u>118-75-2</u>
<u>BINAPACRYL</u>	<u>485-31-4</u>
<u>2,3,4,5-BIS (2-BUTENYLENE) TETRAHYDROFURFURAL</u>	<u>126-15-8</u>
<u>BROMOXYNIL BUTYRATE</u>	<u>EDF-186</u>
<u>CADMIUM COMPOUNDS</u>	<u>CAE750</u>
<u>CALCIUM ARSENATE [2ASH3O4.2CA]</u>	<u>7778-44-1</u>
<u>CAMPHECHLOR</u>	<u>8001-35-2</u>
<u>CAPTAFOL</u>	<u>2425-06-1</u>
<u>CARBOFURAN</u>	<u>1563-66-2</u>
<u>CARBON TETRACHLORIDE</u>	<u>56-23-5</u>
<u>CHLORDANE</u>	<u>57-74-9</u>
<u>CHLORDECONE (KEPONE)</u>	<u>143-50-0</u>
<u>CHLORDIMEFORM</u>	<u>6164-98-3</u>
<u>CHLOROBENZILATE</u>	<u>510-15-6</u>
<u>CHLOROMETHOXYPROPYLMERCURIC ACETATE [CPMA]</u>	<u>EDF-183</u>
<u>COPPER ARSENATE</u>	<u>10103-61-4</u>
<u>2,4-D, ISOOCTYL ESTER</u>	<u>25168-26-7</u>
<u>DAMINOZIDE</u>	<u>1596-84-5</u>
<u>DDD</u>	<u>72-54-8</u>
<u>DDT</u>	<u>50-29-3</u>
<u>DI(PHENYLMERCURY)DODECENYLSUCCINATE [PMDS]</u>	<u>EDF-187</u>

## Marijuana Enforcement Division

<u>Chemical Name</u>	<u>CAS Registry Number (or EDF Substance ID)</u>
<u>1,2-DIBROMO-3-CHLOROPROPANE (DBCP)</u>	<u>96-12-8</u>
<u>1,2-DIBROMOETHANE</u>	<u>106-93-4</u>
<u>1,2-DICHLOROETHANE</u>	<u>107-06-2</u>
<u>DIELDRIN</u>	<u>60-57-1</u>
<u>4,6-DINITRO-O-CRESOL</u>	<u>534-52-1</u>
<u>DINITROBUTYL PHENOL</u>	<u>88-85-7</u>
<u>ENDRIN</u>	<u>72-20-8</u>
<u>EPN</u>	<u>2104-64-5</u>
<u>ETHYLENE OXIDE</u>	<u>75-21-8</u>
<u>FLUOROACETAMIDE</u>	<u>640-19-7</u>
<u>GAMMA-LINDANE</u>	<u>58-89-9</u>
<u>HEPTACHLOR</u>	<u>76-44-8</u>
<u>HEXACHLOROBENZENE</u>	<u>118-74-1</u>
<u>1,2,3,4,5,6-HEXACHLOROCYCLOHEXANE (MIXTURE OF ISOMERS)</u>	<u>608-73-1</u>
<u>1,3-HEXANEDIOL, 2-ETHYL-</u>	<u>94-96-2</u>
<u>LEAD ARSENATE</u>	<u>7784-40-9</u>
<u>LEPTOPHOS</u>	<u>21609-90-5</u>
<u>MERCURY</u>	<u>7439-97-6</u>
<u>METHAMIDOPHOS</u>	<u>10265-92-6</u>
<u>METHYL PARATHION</u>	<u>298-00-0</u>
<u>MEVINPHOS</u>	<u>7786-34-7</u>
<u>MIREX</u>	<u>2385-85-5</u>

## Marijuana Enforcement Division

<u>Chemical Name</u>	<u>CAS Registry Number (or EDF Substance ID)</u>
<u>NITROFEN</u>	<u>1836-75-5</u>
<u>OCTAMETHYLDIPHOSPHORAMIDE</u>	<u>152-16-9</u>
<u>PARATHION</u>	<u>56-38-2</u>
<u>PENTACHLOROPHENOL</u>	<u>87-86-5</u>
<u>PHENYLMERCURIC OLEATE [PMO]</u>	<u>EDF-185</u>
<u>PHOSPHAMIDON</u>	<u>13171-21-6</u>
<u>PYRIMINIL</u>	<u>53558-25-1</u>
<u>SAFROLE</u>	<u>94-59-7</u>
<u>SODIUM ARSENATE</u>	<u>13464-38-5</u>
<u>SODIUM ARSENITE</u>	<u>7784-46-5</u>
<u>2,4,5-T</u>	<u>93-76-5</u>
<u>TERPENE POLYCHLORINATES (STROBANE6)</u>	<u>8001-50-1</u>
<u>THALLIUM(I) SULFATE</u>	<u>7446-18-6</u>
<u>2,4,5-TP ACID (SILVEX)</u>	<u>93-72-1</u>
<u>TRIBUTYLTIN COMPOUNDS</u>	<u>EDF-184</u>
<u>2,4,5-TRICHLOROPHENOL</u>	<u>95-95-4</u>
<u>VINYL CHLORIDE</u>	<u>75-01-4</u>

- C. DMSO. Except for R&D Licensees, the use of Dimethylsulfoxide (DMSO) in the production of Regulated Marijuana and the possession of DMSO upon the Licensed Premises is prohibited.

### Basis and Purpose – 3-330

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-203(3)(c), 44-10-203(3)(e), and 44-10-1001, C.R.S. The purpose of this rule is to clarify the minimum health and safety requirements imposed on a Medical or Retail Marijuana Cultivation Facility. The State Licensing Authority has determined the cultivation of Medical or Retail Marijuana requires the application of processes and procedures, and the use of materials, chemicals, and

pesticides which, if improperly used, may be potentially harmful to employees and consumers. Therefore, the cultivation of Medical or Retail Marijuana must be performed in a manner that reduces the likelihood of exposure to such materials, chemicals and pesticides, or other microbials or molds. The State Licensing Authority intends for this rule to reduce any product contamination, which will benefit both the Licensees and consumers. The State Licensing Authority modeled this rule after those adopted by the Colorado Department Revenue for Medical Marijuana and those adopted by the Colorado Department of Public Health and Environment. Overall, the State Licensing Authority intends this rule to help maintain the integrity of Colorado's Retail Marijuana businesses and the safety of the public.

### **3-330 – Cultivation of Regulated Marijuana: Specific Health and Safety Requirements**

- A. Additional Sanitary Requirements. In addition to the general sanitary requirements in Rule 3-310, a Regulated Marijuana Cultivation Facility shall take all reasonable measure and precautions to ensure the following:
1. That all contact surfaces, including utensils and equipment used for the preparation of Regulated Marijuana, Physical Separation-Based Medical Marijuana Concentrate, or Physical Separation-Based Retail Marijuana Concentrate, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in a Regulated Marijuana Cultivation Facility;
  2. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises' needs. Reclaimed water may also be used only for the cultivation of Regulated Marijuana to the extent authorized under the Reclaimed Water Control Regulations (5 CCR 1002-84), and subject to approval of the Water Quality Control Division of the Colorado Department of Public Health and Environment and the local water provider;
  3. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable water, reclaimed water, and waste water lines; and
  4. That any room used for the cultivation of Regulated Marijuana has measures to prevent the accumulation of dangerous levels of CO<sub>2</sub>.
- B. Pesticide Application. A Regulated Marijuana Cultivation Facility may only use Pesticide in accordance with the "Pesticide Act" sections 35-9-101 et seq., C.R.S., the "Pesticides Applicators' Act," sections 35-10-101 et seq., C.R.S., and all other applicable federal, state, and local laws, statutes, rules and regulations. This includes, but shall not be limited to, the prohibition on detaching, altering, defacing or destroying, in whole or in part, any label on any Pesticide. The Colorado Department of Agriculture's determination

that the Licensee used any quantity of a Pesticide that would constitute a violation of the Pesticide Act or the Pesticide Applicators' Act shall constitute prima facie evidence of a violation of this Rule.

- C. Application of Other Agricultural Chemicals. A Regulated Marijuana Cultivation Facility may only use agricultural chemicals, other than a Pesticide, in accordance with all applicable federal, state, and local laws, statutes, rules, and regulations.

- D. Required Documentation.

1. Standard Operating Procedures. A Regulated Marijuana Cultivation Facility must establish written Sstandard Operating Procedures for the cultivation, harvesting, drying, curing, trimming, packaging, storing, and sampling for testing of Regulated Marijuana, and the processing, packaging, storing, and sampling for testing of Regulated Marijuana Concentrate, and the processing, rolling, filling or similar process, packaging, storing and sampling for testing of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana made from Physical Separation-Based Concentrate. A copy of all Sstandard Operating Procedures must be maintained on the Licensed Premises of the Regulated Marijuana Cultivation Facility.
  - a. The Sstandard Operating Procedures must include when, and the manner in which, all Pesticides and other agricultural chemicals are to be applied during its cultivation process.
  - b. The Sstandard Operating Procedures of the Licensee conducting Microbial Decontamination or Microbial Control Steps must also include any methods and processes related to Decontamination or Microbial Control Steps of Harvest Batches.
    - i. The Sstandard Operating Procedures must also include detailed descriptions of any methods and processes related to Decontamination or Microbial Control Steps of Harvest Batches including steps to meet safety mitigation requirements associated with the Decontamination or Microbial Control Step method in use. This documentation must demonstrate that appropriate occupational, environmental, and product / consumer safety procedures are in place, including any safety-related manufacturer recommendations. Sstandard Operating Procedures must also document steps to ensure uniformity of treatment of the entire Harvest Batch or Production Batch during the Decontamination or Microbial Control Steps process.
    - ii. Use of Decontamination and Remediation techniques must be accurately documented in the Inventory Tracking System.
    - iii. For Licensees sending Harvest Batches for Decontamination to a third party to conduct Decontamination procedures, Sstandard Operating Procedures must include detailed descriptions of methods and processes related to handling Harvest Batches in

such a manner as to ensure uniformity of treatment of the entire Harvest Batch or Production Batch prior to and after the completion of the Decontamination process conducted by a third party.

- c. If a Regulated Marijuana Cultivation Facility produces Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana made from Physical Separation-Based Concentrate, the Sstandard Operating Procedures must include all methods and processes related to the creation of each type of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana product, including but not limited to, the strains used, where strains are sourced, which parts of Harvest Batches are used (e.g. flower, shake, trim), the size of the product (e.g. 1 gram pre-rolls), and how much and what type of Regulated Marijuana Concentrate is added (if applicable) for each type of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana it produces.
- d. Provide adequate training to every Owner Licensee and Employee Licensee who performs a task or set of tasks that are referenced in the Sstandard Operating Procedures. Adequate training must include, but need not be limited to, providing a copy of the Sstandard Operating Procedures for that Licensed Premises detailing at least all of the topics required to be included in the Sstandard Operating Procedures.
- e. A Regulated Marijuana Cultivation Facility seeking to achieve and maintain Reduced Testing Allowance for microbial contamination on Regulated Marijuana flower, shake, trim, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana, the Licensee's Sstandard Operating Procedures must include:
  - i. Cleaning Records. Cleaning records must include cleaning methods, frequency specifications for cleaning, and record keeping requirements of cleaning occurrence for areas that contain Regulated Marijuana and surfaces that contact Regulated Marijuana. Specifications shall be reasonable and adequate to control microbial contaminants. Licensees must verify cleaning records at least every seven days, and a Licensee may choose to verify cleaning records more frequently.
  - ii. Maintenance Records. Maintenance record keeping must include requirements for facility maintenance occurrence logs that affect areas containing Regulated Marijuana and surfaces that contact Regulated Marijuana stating what maintenance was performed, what affects the maintenance had on areas containing Regulated Marijuana and surfaces that contact Regulated Marijuana, what measures were taken to avoid contamination of the Regulated Marijuana, and record keeping requirements of these logs. Specifications must be reasonable and adequate to control microbial contaminants. Licensees must verify maintenance

records at least every 30 days, and a Licensee may choose to verify maintenance records more frequently.

2. Material Change. If a Regulated Marijuana Cultivation Facility makes a Material Change to its cultivation procedures, it must document the change and revise its ~~S~~standard ~~O~~perating ~~P~~rocedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.
  3. Safety Data Sheet. A Regulated Marijuana Cultivation Facility must obtain a safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. A Regulated Marijuana Cultivation Facility must maintain a current copy of the safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.
  4. Labels of Pesticide and Other Agricultural Chemicals. A Regulated Marijuana Cultivation Facility must have the original label or a copy thereof at its Licensed Premises for all Pesticide and other agricultural chemicals used during its cultivation process.
  5. Pesticide Application Documentation. A Regulated Marijuana Cultivation Facility that applies any Pesticide to any portion of a Regulated Marijuana plant during cultivation or generally within the Licensed Premises must document, and maintain a record on its Licensed Premises of, the following information:
    - a. The name, signature, and Employee License number of the individual who applied the Pesticide;
    - b. Applicator certification number if the applicator is licensed through the Department of Agriculture in accordance with the "Pesticides Applicators' Act," sections 35-10-101 et seq., C.R.S.;
    - c. The date and time of the application;
    - d. The EPA registration number of the Pesticide applied;
    - e. Any of the active ingredients of the Pesticide applied;
    - f. Brand name and product name of the Pesticide applied;
    - g. The restricted entry interval from the product label of any Pesticide applied;
    - h. The Inventory Tracking System tag number of the Regulated Marijuana plant(s) that the Pesticide was applied to or if applied to all plants, a statement to that effect; and
    - i. The total amount of each Pesticide applied.
- E. Adulterants. A Regulated Marijuana Cultivation Facility may not treat or otherwise adulterate Regulated Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight, or smell.



**Basis and Purpose – 3-335**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-202(2)(y), 44-10-203(3)(b), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-203(3)(g), and 44-10-1001, C.R.S. The State Licensing Authority has determined the manufacturing of Medical or Retail Marijuana Infused Products involves the application of processes and procedures, materials, chemicals, and additives, which, if improperly applied, may cause harm to employees and consumers. Therefore, the purpose of this Rule is to clarify the minimum and specific health and safety requirements imposed on a Medical or Retail Marijuana Products Manufacturing Facility. This Rule clarifies which Edible Medical or Retail Marijuana Products, due to their specific composition, are *per se* practicable to mark with the Universal Symbol but exempts certain Liquid Products from the Universal Symbol requirements. Additionally, the Rule imposes manufacturing and production requirements (e.g. prohibiting products from being shaped like fruit or humans), identifies the standard THC portion, prohibits licensees from using commercial food products to remanufacture Medical or Retail Marijuana Products, and prohibits the use of toxic additives.

**3-335 – Production of Regulated Marijuana Concentrate and Regulated Marijuana Products: Specific Health and Safety Requirements****A. Training.**

1. Prior to engaging in the manufacture of any Edible Medical Marijuana Product or Edible Retail Marijuana Product each Owner Licensee or Employee Licensee must:
  - a. Have a currently valid Food Handler Certificate obtained through the successful completion of an online assessment or print exam; or
  - b. Take a food safety course that includes basic food handling training and is comparable to, or is a course given by, the Colorado State University extension service or a state, county, or district public health agency, and must maintain a status of good standing in accordance with the course requirements, including attending any additional classes if necessary. Any course taken pursuant to this rule must last at least two hours and cover the following subjects:
    - i. Causes of foodborne illness, highly susceptible populations and worker illness;
    - ii. Personal hygiene and food handling practices;
    - iii. Approved sources of food;
    - iv. Potentially hazardous foods and food temperatures;
    - v. Sanitization and chemical use; and
    - vi. Emergency procedures (fire, flood, sewer backup).

2. A Medical Marijuana Products Manufacturer, an Accelerator Manufacturer, or Retail Marijuana Products Manufacturer must obtain documentation evidencing that each Owner Licensee or Employee Licensee has successfully completed the examination or course required by this Rule and is in good standing. A copy of the documentation must be kept on file at any Licensed Premises where that Owner Licensee or Employee Licensee is engaged in the manufacturing of an Edible Medical Marijuana Product or Edible Retail Marijuana Product.
- B. Other State and Local Health and Safety Standards Apply. A Medical Marijuana Products Manufacturer, an Accelerator Manufacturer, or Retail Marijuana Products Manufacturer that manufactures Edible Medical Marijuana Products or Edible Retail Marijuana Products shall comply with all kitchen-related health and safety standards of the relevant Local Licensing Authority or Local Jurisdiction and, to the extent applicable, with all Colorado Department of Public Health and Environment health and safety regulations applicable to retail food establishments, as set forth in 6 CCR 1010-2.
- C. Additional Sanitary Requirements. A Medical Marijuana Products Manufacturer, an Accelerator Manufacturer, or Retail Marijuana Products Manufacturer shall take all reasonable measures and precautions to ensure the following:
1. That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of Regulated Marijuana or Regulated Marijuana Products;
  2. That all contact surfaces, including utensils and equipment used for the preparation of Regulated Marijuana or Regulated Marijuana Product, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used by a Medical Marijuana Products Manufacturer, an Accelerator Manufacturer, or Retail Marijuana Products Manufacturer, and used in accordance with labeled instructions;
  3. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs;
  4. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable and waste water lines; and
  5. That storage and transport of finished Regulated Marijuana Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any Container.
- D. Product Safety.

1. A Regulated Marijuana Products Manufacturer that manufactures Edible Regulated Marijuana Product shall create and maintain standard production procedures and detailed manufacturing processes for each Edible Medical Marijuana Product or Edible Retail Marijuana Product it manufactures. These procedures and processes must be documented and made available on the Licensed Premises for inspection by the Division, the Colorado Department of Public Health & Environment, and local licensing authorities.
2. Universal Symbol Marking Requirements.
  - a. The following categories of Edible Medical Marijuana Products and Edible Retail Marijuana Products are considered to be per se practicable to mark, and shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the Regulated Marijuana Product:
    - i. Chocolate;
    - ii. Soft confections;
    - iii. Hard confections or lozenges;
    - iv. Consolidated baked goods (e.g. cookie, brownie, cupcake, granola bar);
    - v. Pressed pills and capsules.
  - b. The Universal Symbol marking shall:
    - i. Be marked, stamped, or otherwise imprinted in its entirety on at least one side of the Edible Medical Marijuana Product or Edible Retail Marijuana Product. The shape of the product shall not be included or take place of any part of the Universal Symbol;
    - ii. Be centered either horizontally or vertically on the Edible Medical Marijuana Product or Edible Retail Marijuana Product;
    - iii. If centered horizontally on the Edible Medical Marijuana Product or Edible Retail Marijuana Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's height, but not less than  $\frac{1}{4}$  inch by  $\frac{1}{4}$  inch.
    - iv. If centered vertically on the Edible Medical Marijuana Product or Edible Retail Marijuana Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's height, but not less than  $\frac{1}{4}$  inch by  $\frac{1}{4}$  inch.
  - c. The following categories of Edible Medical Marijuana Product and Edible Retail Marijuana Product are considered to be per se impracticable to mark with the Universal Symbol marking requirements, provided that they comply with labeling and Container requirements of 3-1000 Series Rules.
    - i. Loose bulk goods (e.g. granola, cereals, popcorn);

- ii. Powders;
  - iii. Liquid Edible Medical Marijuana Products;
  - iv. Liquid Edible Retail Marijuana Products.
- d. Soft confections such as caramel, taffy, and soft chew Edible Medical Marijuana Products and Edible Retail Marijuana Products that are not able to hold its original shape after production may be printed with the Universal Symbol on the Regulated Marijuana Product's wrapper to satisfy Rule 3-335(D)(2)(a) so long as:
  - i. The wrapper is opaque;
  - ii. Each serving of Edible Medical Marijuana Product or Edible Retail Marijuana Product is individually wrapped and placed in a Child Resistant Container pursuant to Rule 3-1005(C)(1); and
  - iii. The Universal Symbol is fully visible in its entirety and complies with measurement requirements pursuant to this Rule 3-335(D)(2)(b).

3. Medical Marijuana Products Manufacturer Specific Requirements.

- a. Standard Portion of THC. A Medical Marijuana Products Manufacturer may determine a standard portion of THC for each Edible Medical Marijuana Product it manufactures. If a Medical Marijuana Products Manufacturer determines a standard portion for an Edible Medical Marijuana Product, that information must be documented in the product's standard production procedure.
- b. Documentation. For each Edible Medical Marijuana Product, the total amount of active THC contained within the product must be documented in the standard production procedures.
- c. If a Medical Marijuana Products Manufacturer elects to determine standard portions for an Edible Medical Marijuana Product, then the Universal Symbol shall be applied to each portion in accordance with the requirements of subparagraph (D)(2)(b) of this Rule 3-335. Except that the size of the Universal Symbol marking shall be determined by the size of the portion instead of the overall product size and shall not be less than ¼ inch by ¼ inch.
- d. Medical Marijuana Concentrate Recommended Serving Size and Visual Representation.
  - i. The recommended serving size for Medical Marijuana Concentrate in Vaporized Delivery Devices should not exceed one (1) inhalation lasting two (2) seconds per serving.
  - ii. The recommended serving size for Medical Marijuana Concentrate intended to be inhaled in any manner other than a

Vaporizer Delivery Device is a sphere identified in the tangible educational resource, the diameter of which can be reproduced using a “period” in Microsoft Word “Calibri” font, size 54. The tangible educational resource is required to be provided to a patient pursuant to Rule 5-125(D) and Rule 5-115(C.5).

4. Retail Marijuana Products Manufacturer Specific Requirements.

- a. Standardized Serving of Marijuana. The size of a Standardized Serving of Marijuana shall be no more than 10mg of active THC. A Retail Marijuana Products Manufacturer or an Accelerator Manufacturer that manufactures Edible Retail Marijuana Product shall determine the total number of Standardized Servings of Marijuana for each product that it manufactures. No individual Edible Retail Marijuana Product unit packaged for Transfer to a consumer shall contain more than 100 milligrams of active THC.
- b. Documentation. The following information must be documented in the standard production procedures for each Edible Retail Marijuana Product: the amount in milligrams of Standardized Serving of Marijuana, the total number of Standardized Servings of Marijuana, and the total amount of active THC contained within the product.
- c. Notwithstanding the requirement of subparagraph (D)(2)(b), an Edible Retail Marijuana Product shall contain no more than 10 mg of active THC per Container and the Retail Marijuana Products Manufacturer or an Accelerator Manufacturer must ensure that the product is packaged in accordance with the Rules 3-1005(C)(1) and 1010(D)(1), when:
  - i. The Edible Retail Marijuana Product is of the type that is impracticable to mark, stamp, or otherwise imprint with the Universal Symbol directly on the product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable; or
  - ii. The Edible Retail Marijuana Product is of the type that is impracticable to clearly demark each Standardized Serving of Marijuana or to make each Standardized Serving of Marijuana separable.
- d. Liquid Edible Retail Marijuana Product.
  - i. Pursuant to 44-10-603(4)(b), C.R.S., Liquid Edible Retail Marijuana Products are impracticable to mark with the Universal Symbol and are exempt from the provision in subparagraph (D)(4)(c) of this Rule 3-335 that requires Edible Retail Marijuana Products that are impracticable to mark with the Universal Symbol to contain 10mg or less active THC per Container.
  - ii. This exemption permits the manufacture and Transfer of Multi-Serving Liquid Edible Retail Marijuana Products so long as the product is packaged in accordance with Rules 3-1005(C)(1) and 3-1010(D)(1)(c)(ii).

- e. Multiple-Serving Edible Retail Marijuana Product.
  - i. A Retail Marijuana Products Manufacturer or an Accelerator Manufacturer must ensure that each single Standardized Serving of Marijuana of a Multiple-Serving Edible Retail Marijuana Product is physically demarked in a way that enables a reasonable person to intuitively determine how much of the product constitutes a single serving of active THC.
  - ii. Each demarked Standardized Serving of Marijuana must be easily separable in order to allow an average person 21 years of age and over to physically separate, with minimal effort, individual servings of the product.
  - iii. Each single Standardized Serving of Marijuana contained in a Multiple-Serving Edible Retail Marijuana Product shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable. The Universal Symbol marking shall comply with the requirements of subparagraph (D)(2)(b) of this Rule 3-335.
  - iv. A Multiple-Serving Edible Retail Marijuana Product that is a Liquid Edible Retail Marijuana Product shall comply with the requirements in subparagraph (D)(4)(d)(ii) of this Rule 3-335 and is exempt from subparagraphs (i)-(iii) of this subparagraph (D)(4)(e)(iv).
- f. Retail Marijuana Concentrate Recommended Serving Size and Visual Representation.
  - i. The recommended serving size for Retail Marijuana Concentrate in Vaporized Delivery Devices should not exceed one (1) inhalation lasting two (2) seconds per serving.
  - ii. The recommended serving size for Retail Marijuana Concentrate intended to be inhaled in any manner other than a Vaporizer Delivery Device is a sphere identified in the tangible educational resource, the diameter of which can be reproduced using a “period” in Microsoft Word “Calibri” font, size 54. The tangible educational resource is required to be provided to a consumer pursuant to Rule 6-110(C.5) and Rule 6-1110(C.5).

E. Remanufactured Products Prohibited. A Regulated Marijuana Products Manufacturer shall not utilize a commercially manufactured food product as its Edible Medical Marijuana Product or Edible Retail Marijuana Product. The following exceptions to this prohibition apply:

- 1. A food product that was commercially manufactured specifically for use by a Regulated Marijuana Products Manufacturer to infuse with Regulated Marijuana shall be allowed. The Licensee shall have a written agreement with the

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commercial food product manufacturer that declares the food product's exclusive use by the Regulated Marijuana Products Manufacturer.

2. Commercially manufactured food products may be used as Ingredients in an Edible Medical Marijuana Product or Edible Retail Marijuana Product so long as: (1) they are used in a way that renders them unrecognizable as the commercial food product in the final Edible Medical Marijuana Product or Edible Retail Marijuana Product, and (2) the Regulated Marijuana Products Manufacturer does not state or advertise to the consumer that the final Edible Medical Marijuana Product or Edible Retail Marijuana Product contains the commercially manufactured food product.
- F. Trademarked Food Products. Nothing in this Rule alters or eliminates a Regulated Marijuana Products Manufacturer's responsibility to comply with the trademarked food product provisions required by the Marijuana Code per section 44-10-503(9)(a-c), C.R.S. and 44-10-603(1)(d), C.R.S.
- G. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit.
1. The production, Transfer, and donation of Edible Medical Marijuana Products or Edible Retail Marijuana Products in the following shapes is prohibited:
    - ai. The distinct shape of a human, animal, or fruit; or
    - bii. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
  2. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Regulated Marijuana Business. Nothing in this subparagraph (G)(2) alters or eliminates a Licensee's obligation to comply with the requirements of the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
  3. Edible Medical Marijuana Products and Edible Retail Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
  4. Edible Medical Marijuana Products and Edible Retail Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible.
- G.5. Production of Semi-Synthetic Cannabinoids and Synthetic Cannabinoids.
1. Semi-Synthetic Cannabinoids. Only a Marijuana Research and Development Licensee may manufacture semi-synthetic eCannabinoids.
  2. Synthetic Cannabinoids Prohibited. Licensees are prohibited from manufacturing, producing, possessing, or Transferring any Synthetic Cannabinoid.
- H. Inactive Ingredients.
1. Only non-cannabis derived inactive Ingredients listed in the Federal Food and Drug Administration Inactive Ingredient Database <https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>, or approved by

another equivalent international government agency, may be used in the manufacture of Audited Product and Regulated Marijuana Concentrate intended for use through a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.

2. All non-cannabis derived inactive Ingredients contained in any Audited Product or in any Regulated Marijuana Concentrate intended for use through a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler must be less than or equal to the concentration listed in the Federal Food and Drug Administration Inactive Ingredient Database, or approved by another equivalent international government agency for:
  - a. The inhalation route of administration for any Audited Product to be used in a metered dose nasal spray, or any Regulated Marijuana Concentrate to be used in a Vaporizer Delivery Device or pressurized metered dose inhaler;
  - b. The vaginal route of administration for any Audited Product to be used for vaginal administration; or
  - c. The rectal route of administration for any Audited Product to be used for rectal administration.
- I. Other Permitted Ingredients. Nothing in paragraph H above prohibits a Regulated Marijuana Products Manufacturer from using marijuana-derived ingredients or Botanically Derived Compounds and/or terpenoids.
- J. Processing Aids and Additives. A Regulated Marijuana Products Manufacturer shall not include any Processing Aid or Additive that is toxic, prohibited, or present at levels over the acceptable limits pursuant to Rule ~~4-215(J)~~~~4-115(D)~~ within a Regulated Marijuana Product; nor include any Additive for the purposes of making the product more addictive, appealing to children, or misleading to patients or consumers.
- K. Prohibited Ingredients.
  1. A Regulated Marijuana Products Manufacturer shall not use the following Ingredients in the production or Transfer of Regulated Marijuana Concentrate and Regulated Marijuana Product for which the inhaled product is the intended use in accordance with Rule 3-1015:
    - a. Polyethylene glycol (PEG);
    - b. Vitamin E Acetate;
    - c. Medium Chain Triglycerides (MCT Oil);
  2. A Licensee authorized to manufacture Regulated Marijuana Concentrate or Regulated Marijuana Product shall not use ingredients, other than Regulated Marijuana, with over 0.3% combined D8-THC, D9-THC, D10-THC, Exo-THC or other THC isomers, salts, or salt isomers of tetrahydrocannabinol in the manufacture, production, or Transfer of Regulated Marijuana Concentrate or Regulated Marijuana Product.



L. Required Documentation~~Standard Operating Procedures.~~

1. A Regulated Marijuana Products Manufacturer must have written ~~S~~standard ~~O~~perating ~~P~~rocedures for each category and type of Medical Marijuana Product or Retail Marijuana Product that it produces.
  - a. All ~~S~~standard ~~O~~perating ~~P~~rocedures for the production of a Medical Marijuana Concentrate or Retail Marijuana Concentrate must follow the requirements in Rules 5-315 and 6-315.
  - b. A copy of all ~~S~~standard ~~O~~perating ~~P~~rocedures must be maintained on the Licensed Premises of the Regulated Marijuana Products Manufacturer.
  - c. If a Regulated Marijuana Products Manufacturer produces Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana, the ~~S~~standard ~~O~~perating ~~P~~rocedures must include all methods and processes related to the creation of each type of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana product, including but not limited to, the strains used, where strains are sourced, which parts of Harvest Batches are used (e.g. flower, shake, trim), the size of the product (e.g. 1 gram pre-rolls), and how much and what type of Regulated Marijuana Concentrate is added (if applicable) for each type of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana it produces.
  - d. Provide adequate training to every Owner Licensee and Employee Licensee who performs a task or set of tasks that are referenced in the ~~S~~standard ~~O~~perating ~~P~~rocedures. Adequate training must include, but need not be limited to, providing a copy of the ~~S~~standard ~~O~~perating ~~P~~rocedures for that Licensed Premises detailing at least all of the topics required to be included in the ~~S~~standard ~~O~~perating ~~P~~rocedures.
2. If a Regulated Marijuana Products Manufacturer makes a Material Change to its standard Medical Marijuana Product production process or Retail Marijuana Product production process, it must document the change and revise its ~~S~~standard ~~O~~perating ~~P~~rocedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

- M. Expiration Date for Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers.  
~~Effective July 1, 2022, a~~~~A~~ Regulated Marijuana Products Manufacturer that produces a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler shall establish an expiration date upon which the Vaporized Delivery Device or Pressurized Metered Dose Inhaler will no longer be fit for consumption. The Licensee shall determine the expiration date by conducting potency and contaminant testing pursuant to Rules ~~4-2104-120~~ and ~~4-2154-125~~ on the final Vaporizer Delivery Device or Pressurized Metered Dose Inhaler prior to Transfer to ensure the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler can pass potency and contaminant testing prior to the established expiration date.

1. When determining the expiration date for a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler pursuant to this rule, the Licensee shall also consider the following:
    - ia. Any expiration dates of additives used to produce the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler;
    - ib. The interaction with hardware;
    - ic. The final formulation within the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler; and
    - id. The ideal storage conditions for the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.
  2. The License may, but is not required to, use accelerated stability tests to demonstrate compliance with this rule.
  3. Expiration date determinations, along with any data used to establish the expiration date, shall be documented and maintained in the Licensee's business records pursuant to these rules.
  4. Expiration dates must be entered into the Inventory Tracking System.
- N. DMSO. Except for R&D Licensees, the use of Dimethylsulfoxide (DMSO) in the production of Regulated Marijuana Product and possession of DMSO upon the Licensed Premises is prohibited.

### **Basis and Purpose – 3-336**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(b)-(c), 44-10-203(1)(k), 44-10-203(2)(d)(I)-(VI), 44-10-203(2)(m), 44-10-401(2)(a)(III), 44-10-503, and 44-10-901(1), C.R.S. The purpose of this rule is to establish minimum requirements for a recall plan, the process by which the Division or a Regulated Marijuana Business initiates a product recall, the requirements any recall must meet, and how such recall is terminated.

### **3-336 – Recall of Regulated Marijuana**

- A. Effective Date. This Rule is effective January 1, 2021.
- B. Applicability. This Rule 3-336 applies to Medical Marijuana Stores, Medical Marijuana Products Manufacturers, Medical Marijuana Cultivation Facilities, Medical Marijuana Research and Development Facilities, Retail Marijuana Stores, Retail Marijuana Products Manufacturers, Retail Marijuana Cultivation Facilities, Licensed Hospitality Businesses, Accelerator Cultivators, Accelerator Manufacturers, and Accelerator Stores.
- C. Initiating a Recall. A Regulated Marijuana Business subject to this Rule 3-336 may voluntarily initiate a recall at any time or a recall may be initiated at the request of the Division. A Regulated Marijuana Business subject to this rule must comply with the requirements of this Rule 3-336.
  1. Division Requests for Recalls:

**ai.** If the Division requests a Regulated Marijuana Business to initiate a recall pursuant to this rule, the Division's correspondence, which may be electronic, must include the reasons for the recall request and any other information necessary for the Regulated Marijuana Business to initiate a recall pursuant to this rule.

**bii.** A recall request issued by the Division does not require that a Regulated Marijuana Business initiate a recall. However, if the Division has reasonable grounds to believe a Licensee's Regulated Marijuana is contaminated or otherwise presents a risk to public safety, the Division may require a Regulated Marijuana Business to quarantine affected Regulated Marijuana Inventory pursuant to Rules 4-205, 4-215, ~~4-115~~ and 4-2404-135.

D. **Recall Plan Required.** A Regulated Marijuana Business subject to this Rule 3-336 must have a written recall plan. A recall plan shall include, but is not limited to the following:

1. **Evaluation of a Complaint or Condition.** A Regulated Marijuana Business subject to this rule must maintain a record of all complaints it receives regarding the quality of Regulated Marijuana that has any potential negative impact to health or regarding an adverse reaction. To the extent known after reasonable diligence to ascertain the information, the record must contain the name of the complainant, the purchase date, the location of where the product was purchased, the date the complaint was received, the nature of the complaint, the steps taken to investigate the complaint, the response to the complaint, and the name and Production or Harvest Batch number for the Regulated Marijuana subject to the complaint.

a. If an initial assessment indicates a recall may be necessary, the Regulated Marijuana Business shall take the following measures:

i. Determine the hazard and evaluate the safety concerns with the product;

ii. Undertake necessary product quarantine measures for any affected Regulated Marijuana in the Licensee's possession or control; and

iii. Determine the product removal strategy appropriate to the threat and location in commerce.

2. **Identification of Affected Regulated Marijuana.** A recall plan must establish a process for identifying affected Regulated Marijuana subject to a recall, which shall include the following:

a. **Distribution List.** When identifying Regulated Marijuana subject to a recall, the Licensee shall create a distribution list that includes the following information:

- i. The name, license number, and address of the Regulated Marijuana Business(es) that received the Regulated Marijuana subject to the recall;
    - ii. Ship or Transfer date(s) for the Regulated Marijuana subject to the recall; and
    - iii. Business contact information for each Regulated Marijuana Business that received Regulated Marijuana subject to the recall, including names and telephone numbers.
  - b. Product Information. When identifying Regulated Marijuana subject to a recall, the Licensee shall document the following product information:
    - i. The category of Regulated Marijuana (e.g. Medical Marijuana flower; Medical Marijuana Concentrate; Medical Marijuana Product; Retail Marijuana flower; Retail Marijuana Concentrate, Retail Marijuana Product);
    - ii. Product description;
    - iii. Net contents;
    - iv. Production or Harvest Batch number;
    - v. The license number(s) for the Regulated Marijuana Business(es) that cultivated or manufactured the product(s) subject to the recall; and
    - vi. To the extent known after reasonable diligence to ascertain the information, the recall plan must also include the following additional product information: The amount of affected Regulated Marijuana returned in response to the recall and the amount of affected Regulated Marijuana that remains in the marketplace.
- 3. Notification to Affected Parties.
  - a. A Licensee initiating a recall pursuant to this rule shall issue a recall notice to Regulated Marijuana Businesses identified on the Licensee's distribution list.
  - b. No later than 48 hours from issuing a recall notice to Regulated Marijuana Businesses on the Licensee's distribution list, the Licensee shall issue the following additional notifications:
    - i. The Licensee shall notify the Division and the Colorado Department of Public Health and Environment;
    - ii. The Licensee shall notify the Local Licensing Authority or Local Jurisdiction in which the Licensee issuing the recall is located; and
    - iii. The Licensee shall notify patients or consumers using the most effective method available, which may include any of the following

methods: an email to the patient or customer list serve, an alert on the Regulated Marijuana Business' website, a warning that is clearly and visibly posted on the Regulated Marijuana Business' Licensed Premises, or a press release to notify patients or consumers.

- c. Recall Notice. A recall notice issued by a Regulated Marijuana Business pursuant to this rule shall include at least the following information:
- i. The reason for recall and related hazards, if any. If the Regulated Marijuana is being removed for quality rather than health reasons, the notice may state that the Regulated Marijuana does not meet internal company specifications and is being removed from distribution;
  - ii. The category of Regulated Marijuana (e.g. Medical Marijuana flower; Medical Marijuana Concentrate; Medical Marijuana Product; Retail Marijuana flower; Retail Marijuana Concentrate, Retail Marijuana Product);
  - iii. Regulated Marijuana Businesses that received the Medical Marijuana Concentrate, Medical Marijuana Product, Retail Marijuana Concentrate or Retail Marijuana Product;
  - iv. The license number(s) and name(s), including trade name(s), of the Regulated Marijuana Business(es) that cultivated or manufactured the product(s) subject to the recall;
  - v. Product description(s) for Regulated Marijuana subject to the recall;
  - vi. Production or Harvest Batch number(s) for the Regulated Marijuana subject to the recall;
  - vii. Expiration date(s) for the Regulated Marijuana subject to the recall, if applicable;
  - viii. Ship or Transfer date(s) for the Regulated Marijuana subject to the recall; and
  - ix. Instructions regarding the disposition of the Regulated Marijuana subject to the recall.

4. Removal of Affected Regulated Marijuana.

- a. Removal. A Regulated Marijuana Business subject to this Rule 3-336 shall make all reasonable efforts to remove the affected Regulated Marijuana from commerce. Affected Regulated Marijuana that is either still in control of the originating Regulated Marijuana Business or in commerce shall be, secured, segregated, clearly labeled not for sale or distribution and separated from any other Medical Marijuana Concentrate,

Medical Marijuana Product(s), Retail Marijuana Concentrate, or Retail Marijuana Product(s).

- b. Final Product Disposition. At the discretion of the Regulated Marijuana Business contaminated product must be disposed by either:
  - i. Destroying and documenting the destruction of the affected Regulated Marijuana pursuant to Rule 3-230; or
  - ii. If possible, Decontaminating the affected Regulated Marijuana pursuant to Rule ~~4-240(C)(2)~~~~4-135(B)(2)~~ or Remediating the Regulated Marijuana Product pursuant to Rule 4-240(C)(3). If the Regulated Marijuana cannot be decontaminated, it must be destroyed pursuant to Rule ~~4-240(C)(1)~~~~4-135(B)(3)(e)~~ and 3-230.
- c. Recall Effectiveness. A Regulated Marijuana Business initiating a recall pursuant to this rule is responsible for determining whether the recall is effective. The Licensee shall complete recall effectiveness checks to verify that all receiving Licensees have been notified and have taken the appropriate action.
  - i. Effectiveness checks shall determine:
    - A. If the receiving Licensee received the recall notification;
    - B. If the recalled Regulated Marijuana was handled as instructed in the recall notification; and
    - C. If the Regulated Marijuana was further distributed or sold by the receiving Licensee before receipt of the recall notification, and if so, were these additional Licensees notified.
  - ii. If 100 percent of the affected Regulated Marijuana has been accounted for, then no effectiveness checks are required.
- d. Termination of Recall. A Regulated Marijuana Business initiating a recall pursuant to this rule may terminate the recall when the Licensee determines that all reasonable efforts have been made to remove or correct the affected Regulated Marijuana in accordance with the recall plan, and when it is reasonable to assume that the Regulated Marijuana subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled Regulated Marijuana.
  - i. Upon termination of the recall, the Regulated Marijuana Business shall provide notice to the Division with a recall status report and a description of the disposition of the recalled Regulated Marijuana. The recall status report shall contain the following information:
    - A. Number of receiving Licensees notified of the recall, the date and method of notification;

- B. Number of receiving Licensees who responded to the recall notice and both the quantity of affected Regulated Marijuana in the possession of the Licensee at the time of response, and quantity of affected Regulated Marijuana returned or corrected;
- C. Number and results of the effectiveness checks that were made; and
- D. Approximate time that was required to complete the recall.

**Basis and Purpose – 3-340**

~~The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(b)-(c), 44-10-203(1)(k), 44-10-203(2)(l), 44-10-203(2)(m), and 44-10-901(1), C.R.S. The purpose of this Rule is to clarify that a Regulated Marijuana Businesses failure to comply with the requirements of 3-300 Rules Series may jeopardize the public health and safety.~~

**3-340 – Violation Affecting Public Safety - Repealed**

~~A violation of these 3-300 Rules may be considered a license violation affecting public safety.~~

**Basis and Purpose – 3-345 [Emergency rule expired 05/11/2021]****Rule 3-345 – [Emergency rule expired 05/11/2021]****3-400 Series – Acceptable Forms of Identification for Regulated Marijuana Sales****Basis and Purpose – 3-405**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(v), 44-10-203(2)(z), 44-10-401(2)(a)(I), 44-10-401(2)(b)(I), 44-10-501(3)(b), 44-10-501(3)(c), 44-10-501(3)(d), 44-10-501(4), 44-10-501(10)(b)(II), 44-10-601(3)(b), 44-10-701(1)(b), 44-10-701(2)(a), 44-10-701(4)(a), and 44-10-701(5)(a), C.R.S. The purpose of this rule is to establish guidelines for the acceptable forms of identification for verifying the lawful sale of Regulated Marijuana. This Rule 3-405 was previously Rule M 405, 1 CCR 212-1, and Rule R 404, 1 CCR 212-2.

**3-405 – Identification****A. Medical Marijuana Transfers.**

1. Necessary Identification. Medical Marijuana Stores may only Transfer Medical Marijuana to any patient or primary caregiver who is permitted to deliver Medical Marijuana to homebound patients or minor patients as permitted by section 25-1.5-106(9)(e), C.R.S., if the patient or caregiver can produce:
  - a. Proof of identification that complies with subparagraphs (C) and (D) of this Rule; and
  - b. Either a valid patient registry card, including any valid and verified digital registry card, or a copy of a current and complete new application for the Medical Marijuana registry that is documented by proof of submittal to the

Colorado Department of Public Health and Environment within the preceding 35 days.

2. Physical Inspection Required. A Licensee must physically view and inspect the patient or primary caregiver's registry card, including any valid and verified digital registry card, physician certification, and proof of identification to confirm the information contained on the documents and also to judge the authenticity of the documents presented.
  - a. If the Medical Marijuana Store Licensee maintains the physician certification on behalf of a patient, and the record has not expired, the Medical Marijuana Store Licensee may review the record in their possession rather than requiring the patient to present the physician certification before each sale.
3. Valid and Verified Registry Card. For the purposes of these rules, a valid and verified digital registry card may include:
  - a. A hard copy of the patient's registry card; or
  - b. A portable document format (PDF) of the patient's registry card presented on a phone or other portable device.
    - i. If a patient is presenting his or her registry card on a phone or other portable device, the PDF of the registry card must be presented.
    - ii. A screen shot of the patient's profile, text image of a blank card, or photo of the hard copy is unacceptable.
- B. Retail Marijuana Transfers. An Accelerator Store, a Retail Marijuana Store, or a Retail Marijuana Hospitality and Sales Business may only Transfer Retail Marijuana to a consumer that first produces a form of identification that complies with subparagraphs (C) and (D) of this Rule establishing the consumer is 21 years of age or older.
  1. Fraudulent Identification and Licensee's Burden. Pursuant to section 44-10-601(3)(b)(I), C.R.S., if a person under 21 years of age presents a fraudulent proof of age to a Retail Marijuana Store, or an Accelerator Store any action based upon the fraudulent proof of age shall not be grounds for the revocation or suspension of a license. To establish that the identification presented by the minor was a fraudulent proof of age, the Licensee must establish that:
    - a. The minor presented fraudulent identification of the type established in subparagraph (C) below;
    - b. During the transaction in which Retail Marijuana was Transferred to the minor, the Licensee inspected the identification provided, compared the identification to the person presenting the identification, and:
      - i. Inspected an identification book issued within the past three years;
      - ii. Used an electronic scanner;



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- iii. Used an ID checking software or other device used in the inspection of identification; or
  - iv. Used other ID security features.
- C. Forms of Valid Identification. The kind and type of identification deemed adequate shall be limited to the following, including any valid and verified digital identification:
  - 1. An operator's, chauffeur's, or similar type driver's license, including a temporary license issued by any state within the United States, District of Columbia, or any U.S. territory;
  - 2. An identification card, including a temporary identification card, issued by any state within the United States, District of Columbia, or any U.S. territory, for the purpose of proof of age using requirements similar to those in sections 42-2-302 and 42-2-303, C.R.S.;
  - 3. A United States military identification card or any other identification card issued by the United States government including but not limited to a permanent resident card, alien registration card, or consular card;
  - 4. A passport or passport identification card; or
  - 5. An Enrollment card issued by the governing authority of a federally recognized Indian tribe, if the enrollment card incorporates proof of age requirements similar to sections 42-2-302 and 42-2-303, C.R.S.
- D. Identification Must Be Valid. A Licensee shall refuse the Transfer of Regulated Marijuana if a person produces identification that is invalid or expired.

**3-600 Series – Transport and Storage****Basis and Purpose – 3-605**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-313(5)(b), 44-10-505, and 44-10-605 C.R.S. The purpose of the rule is to provide clarity as to the requirements associated with the transport and delivery of Regulated Marijuana between Licensed Premises. It also prescribes the manner in which licensed entities will track inventory in the transport process to prevent diversionary practices. This Rule 3-605 was previously Rules M and R 801, 1 CCR 212-1 and 1 CCR 212-2.

**3-605 – Transport: All Regulated Marijuana Businesses**

- A. Persons Authorized to Transport. Except as provided in these 3-600 Series Rules, any individual who transports Regulated Marijuana, Regulated Marijuana Vegetative plants, Regulated Marijuana Immature ~~P~~plants, Regulated Marijuana, or Regulated Marijuana Product on behalf of a Regulated Marijuana Business must hold a valid Owner License or Employee License and must be an employee of the Regulated Marijuana Business. An individual who does not possess a current and valid Owner's License or Employee License from the State Licensing Authority may not transport Regulated Marijuana, Regulated Marijuana Vegetative plants, Regulated Marijuana Immature ~~P~~plants,

Regulated Marijuana Concentrate, or Regulated Marijuana Product between Licensed Premises.

B. Transport Between Licensed Premises.

1. Regulated Marijuana. Regulated Marijuana shall only be transported by Licensees between Licensed Premises; between Licensed Premises and a permitted off-premises storage facility; and between Licensed Premises and a Pesticide Manufacturer. Licensees transporting Regulated Marijuana are responsible for ensuring that all Regulated Marijuana are secured at all times during transport.
2. Regulated Marijuana Vegetative Plants and Regulated Marijuana Immature Plants.
  - a. Regulated Marijuana Vegetative plants may only be transported between Licensed Premises and such transport shall only be permitted due to an approved change of location pursuant to Rule 2-255.
  - b. Regulated Marijuana Immature ~~P~~plants shall only be transported between Licensed Premises; and between Licensed Premises and a Pesticide Manufacturer.
  - c. Licensees transporting Regulated Marijuana Vegetative plants and Regulated Marijuana Immature ~~P~~plants are responsible for ensuring that all Regulated Marijuana Vegetative ~~P~~plants and Regulated Marijuana Immature ~~P~~plants are secure at all times during transport. Transportation of Regulated Marijuana Vegetative plants and Regulated Marijuana Immature ~~P~~plants to a permitted off-premises storage facility shall not be allowed. Transport of Regulated Marijuana plants other than Vegetative Plants and Immature ~~P~~plants shall not be allowed.

C. Inventory Tracking System-Generated Transport Manifest Required. A Licensee may only transport Regulated Marijuana if ~~he or she has~~they have a copy of an Inventory Tracking System-generated transport manifest that contains all the information required by this Rule and shall be in the format prepared by the State Licensing Authority.

1. A Licensee may elect to use a hard copy or digital copy of an Inventory Tracking System-generated transport manifest. Licensees are required to ensure all information is preserved ~~with valid and verified signatures~~ on any digital copy of an Inventory Tracking System-generated transport manifest. A copy of an Inventory Tracking System-generated transport manifest may be maintained in and obtained directly from the Inventory Tracking System.
2. Regulated Marijuana. A Licensee may transport Regulated Marijuana from an originating location to multiple destination locations so long as the transport manifest correctly reflects the specific inventory destined for specific Regulated Marijuana Businesses and/or Pesticide Manufacturers.
3. Regulated Marijuana Vegetative Plants. A Licensee shall transport Regulated Marijuana Vegetative plants only from the originating Licensed Premises to the

destination Licensed Premises due to a change of location that has been approved by the Division pursuant to Rule 2-255.

4. Manifest for Transfers to Pesticide Manufacturers. A Licensee may not transport or permit the transportation of Regulated Marijuana to a Pesticide Manufacturer unless an Inventory Tracking System-generated transport manifest has been generated.
- D. Motor Vehicle Required. Transport of Regulated Marijuana shall be conducted by a motor vehicle that is properly registered in the state of Colorado pursuant to motor vehicle laws, but need not be registered in the name of the Licensee. Except that when a rental truck is required for transporting Regulated Marijuana Vegetative plants or Regulated Marijuana Immature ~~P~~plants, Colorado motor vehicle registration is not required.
- E. Documents Required During Transport. Transport of Regulated Marijuana shall be accompanied by a copy of the originating Regulated Marijuana Business's business license, the driver's valid Owner's License or Employee License, the driver's valid motor vehicle operator's license, and all required vehicle registration and insurance information.
- F. Use of Colorado Roadways. State law does not prohibit the transport of Regulated Marijuana on any public road within the state of Colorado as authorized in this Rule. However, nothing herein authorizes a Licensee to violate specific local ordinances or resolutions enacted by any city, town, city and county, or county related to the transport of Regulated Marijuana.
- G. Preparation of Regulated Marijuana for Transport.
  1. Final Weighing and Packaging. A Regulated Marijuana Business shall comply with the specific rules associated with the final weighing and packaging of Regulated Marijuana before such items are prepared for transport pursuant to this Rule. The scale used to weigh product to be transported shall be tested and approved in accordance with measurement standards established in 35-14-127, C.R.S.
  2. Preparation in Limited Access Area. Regulated Marijuana shall be prepared for transport in a Limited Access Area, including the packaging and labeling of Containers or Shipping Containers.
  3. Shipping Containers. Licensees may Transfer multiple Containers of Regulated Marijuana in a Shipping Container. The contents of Shipping Containers shall be easily accessible and may be inspected by the State Licensing Authority, Local Licensing Authorities, Local Jurisdictions, and state and local law enforcement agency for a purpose authorized by the Marijuana Code or for any other state or local law enforcement purpose.
    - a. Licensees shall ensure that either the multiple Containers placed within a Shipping Container each have an Inventory Tracking System tag, or the Shipping Container itself must have an Inventory Tracking System tag. If the Licensee elects to place the Inventory Tracking System tag on the

Shipping Container, the Shipping Container shall contain only one Harvest Batch, or Production Batch of Regulated Marijuana. If a Shipping Container consists of more than one Harvest Batch or Production Batch, then each group of multiple Containers shall be affixed with an Inventory Tracking System tag

- b. Regulated Marijuana Vegetative Plants and Regulated Marijuana Immature Plants. Each Regulated Marijuana Vegetative plant that is transported pursuant to this Rule must have a Inventory Tracking System tag affixed to it prior to transport. Each receptacle containing Regulated Marijuana Immature ~~P~~plants transported pursuant to this Rule must have an Inventory Tracking System tag affixed prior to transport.

H. Creation of Records and Inventory Tracking.

1. Use of Inventory Tracking System – Generated Transport Manifest.

- a. Regulated Marijuana. Licensees who transport or permit the transportation of Regulated Marijuana shall create an Inventory Tracking System-generated transport manifest to reflect inventory that leaves the Licensed Premises destined for another Licensed Premises or Pesticide Manufacturers. The transport manifest may either reflect multiple destination locations within a single trip or separate transport manifests may reflect each single destination location. In either case, no inventory shall be transported without an Inventory Tracking System-generated transport manifest.
- b. Use of a Medical Marijuana Transporter or Retail Marijuana Transporter. In addition to subparagraph (H)(1)(a), Licensees shall also follow the requirements of this subparagraph (H)(1)(b) when a Licensee utilizes the services of a Medical Marijuana Transporter or Retail Marijuana Transporter.
  - i. When a Medical Marijuana Business utilizes a Medical Marijuana Transporter for transporting its Medical Marijuana, the originating Licensee shall input the requisite information on the Inventory Tracking System-generated transport manifest for the final destination Licensee or Pesticide Manufacturer who will be receiving the Medical Marijuana.
  - ii. When a Retail Marijuana Business utilizes a Retail Marijuana Transporter for transporting its Retail Marijuana the originating Licensee shall input the requisite information on the Inventory Tracking System-generated transport manifest for the final destination Licensee or Pesticide Manufacturer who will be receiving the Retail Marijuana.
  - iii. A Medical Marijuana Transporter or Retail Marijuana Transporter is prohibited from being listed as the final destination Licensee.

- iv. A Medical Marijuana Transporter or Retail Marijuana Transporter shall not alter the information of the final destination Licensee or Pesticide Manufacturer after the information has been entered on the Inventory Tracking System-generated transport manifest by the Licensee.
    - v. If the Medical Marijuana Transporter or Retail Marijuana Transporter is not delivering the originating Licensee's Regulated Marijuana directly to the final destination Licensee or Pesticide Manufacturer, the Medical Marijuana Transporter or Retail Marijuana Transporter shall communicate to the originating Licensee which of the Medical Marijuana Transporter's or Retail Marijuana Transporter's Licensed Premises or off-premises storage facilities will receive and temporarily store the Regulated Marijuana. The originating Licensee shall input the Medical Marijuana Transporter's or Retail Marijuana Transporter's location address and license number on the Inventory Tracking System-generated transport manifest.
  - c. Medical Marijuana Vegetative Plants and Retail Marijuana Vegetative Plants.
    - i. Licensees who transport Medical Marijuana Vegetative or Retail Marijuana Vegetative plants shall create an Inventory Tracking System-generated transport manifest to reflect inventory that leaves the originating Licensed Premises to be transported to the destination Licensed Premises due to a change of location approved by the Division pursuant to Rule 2-255, or a one-time Transfer pursuant to Rule 3-805.
    - ii. Retail Marijuana Transporters are permitted to transport Retail Marijuana Vegetative plants on behalf of other Licensees due to a change of location approved by the Division pursuant to Rule 2-255, or a one-time Transfer pursuant to Rule 3-805. The Retail Marijuana Transporter shall transport the Retail Marijuana Vegetative Plants directly from the originating Licensed Premises to the final destination Licensed Premises.
    - iii. Medical Marijuana Transporters are permitted to transport Medical Marijuana Vegetative plants on behalf of other Licensees due to a change of location approved by the Division pursuant to Rule 2-255, or a one-time Transfer pursuant to Rule 3-805. The Medical Marijuana Transporter shall transport the Medical Marijuana Vegetative plants directly from the originating Licensed Premises to the final destination Licensed Premises.
- 2. Copy of Transport Manifest to Recipient. A Licensee shall provide a copy of the transport manifest to each Regulated Marijuana Business, or Pesticide Manufacturer receiving the inventory described in the transport manifest. In order to maintain transaction confidentiality, the originating Licensee may prepare a

separate Inventory Tracking System-generated transport manifest for each recipient Regulated Marijuana Business or Pesticide Manufacturer.

3. The Inventory Tracking System-generated transport manifest shall include the following:
  - a. Departure date and approximate time of departure;
  - b. Name, location address, and license number of the originating Regulated Marijuana Business;
  - c. Name, location address, and license number of the destination Regulated Marijuana Business(es) or name and location address of the destination Pesticide Manufacturer;
  - d. Name, location address, and license number of the Medical Marijuana Transporter or Retail Marijuana Transporter if applicable pursuant to Rule 3-605(H)(1)(b)(iv).
  - e. Product name and quantities (by weight and unit) of each product to be delivered to each specific destination location(s);
  - f. Arrival date and estimated time of arrival;
  - g. Transport vehicle make and model and license plate number; and
  - h. Name, ~~and~~ Employee or Owner License number, ~~and signature~~ of the Licensee accompanying the transport.
- I. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a Regulated Marijuana Business shall be responsible for all the procedures associated with the tracking of inventory that is transported between Licensed Premises. See Rule 3-905 – Business Records Required.
  1. Responsibilities of Originating Licensee.
    - a. Regulated Marijuana. Prior to departure, the originating Regulated Marijuana Business shall adjust its records to reflect the removal of Regulated Marijuana. The scale used to weigh product to be transported shall be tested and approved in accordance with measurement standards established in 35-14-127, C.R.S. Entries to the records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.
    - b. Regulated Marijuana Vegetative Plants and Regulated Marijuana Immature Plants. Prior to departure, the originating Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility shall adjust its records to reflect the removal of Medical Marijuana Vegetative plants and Medical Marijuana Immature ~~P~~plants, or Retail Marijuana Vegetative plants and Retail Marijuana Immature ~~P~~plants. Entries to the records shall note the Inventory Tracking System-generated transport manifest and

shall be easily reconciled, by product name and quantity, with the applicable transport manifest.

2. Responsibilities of Recipient Licensee.

- a. Regulated Marijuana. Upon receipt, the receiving Licensee shall ensure that the Regulated Marijuana received are as described in the transport manifest and shall immediately adjust its records to reflect the receipt of inventory. The scale used to weigh product being received shall be tested and approved in accordance with measurement standards established in 35-14-127, C.R.S. Entries to the inventory records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest. Medical Marijuana Transporters and Retail Marijuana Transporters shall comply with all requirements of this subparagraph (l)(2)(a) except that they are not required to weigh Regulated Marijuana.

- i. When a Regulated Marijuana Business transfers Regulated Marijuana to a Pesticide Manufacturer, the originating Licensee is responsible for confirming receipt of the Regulated Marijuana in the Inventory Tracking System.

- b. Regulated Marijuana Vegetative Plants and Regulated Marijuana Immature Plants. Upon receipt, the recipient Licensee shall ensure that the Regulated Marijuana Vegetative plants received are as described in the transport manifest, accounting for all Inventory Tracking System tags and each associated plant, and shall immediately adjust its records to reflect the receipt of inventory. Upon Receipt, the recipient Licensee shall ensure that the Regulated Marijuana Immature ~~P~~plants received are as described in the transport manifest, accounting for all Inventory Tracking System tags and each receptacle containing Regulated Marijuana Immature ~~P~~plants, and shall immediately adjust its records to reflect the receipt of inventory.

- i. When a Regulated Marijuana Business transfers Regulated Marijuana Immature ~~P~~plants to a Pesticide Manufacturer, the originating Licensee is responsible for confirming receipt of the Retail Marijuana Immature ~~P~~plants in the Inventory Tracking System.

3. Discrepancies.

- a. Licensees. A recipient Licensee shall separately document any differences between the quantity specified in the transport manifest and the quantities received. Such documentation shall be made in the Inventory Tracking System and in any relevant business records.
- b. Pesticide Manufacturers. In the event of a discrepancy between the quantity specified in a transport manifest and the quantity received by a Pesticide Manufacturer, the originating Licensee shall document the



discrepancy in the Inventory Tracking System and in any relevant business records, and account for the discrepancy.

- J. Adequate Care of Perishable Regulated Marijuana Product. A Regulated Marijuana Business must provide adequate refrigeration for perishable Regulated Marijuana Product during transport.
- K. Failed Testing. In the event Regulated Marijuana has failed required testing, has been contaminated, or otherwise presents a risk of cross-contamination to other Regulated Marijuana, such Regulated Marijuana may only be transported if it is physically segregated and contained in a sealed package that prevents cross-contamination.

### **Basis and Purpose – 3-615**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(2)(dd), C.R.S. The purpose of this rule is to provide requirements for a Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter or Retail Marijuana Transporter to apply for and conduct deliveries to private residences pursuant to a delivery permit. This rule provides application and renewal requirements for a delivery permit. Additionally, the rule describes requirements for responsible vendor training, requirements for use of the inventory tracking system, Delivery Motor Vehicles requirements including security, requirements for delivery orders, requirements prior to completing a delivery to a patient or consumer at a private residence and requirements for maintaining the confidentiality of all patient and customer information.

### **3-615 – Regulated Marijuana Delivery Permits**

#### **A. Application, Qualification, and Eligibility for Delivery Permit.**

- 1. ~~Beginning January 2, 2020, a~~ Medical Marijuana Store may apply for a delivery permit. The application shall be made on Division forms and in accordance with the 2-200 Series Rules. The delivery permit application can be submitted simultaneously with a Medical Marijuana Store initial or renewal application or it can be separate from a Medical Marijuana Store application but the application must identify the Medical Marijuana Store(s) seeking to obtain the delivery permit.
- 2. ~~Beginning January 2, 2021, a~~ Retail Marijuana Store, an Accelerator Store, a Medical Marijuana Transporter, and a Retail Marijuana Transporter may apply for a delivery permit. The delivery permit application can be submitted simultaneously with a Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter initial or renewal application or it can be separate from a Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter application but the application must identify the Retail Marijuana Store(s), Medical Marijuana Transporter(s), or Retail Marijuana Transporter(s) seeking to obtain the delivery permit.
- 3. Prior to the State Licensing Authority issuing an Applicant a delivery permit, the Applicant must establish the Local Licensing Authority and/or Local Jurisdiction where the Applicant is located, or for a Medical Marijuana Transporter or Retail



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Marijuana Transporter without a Licensed Premise, the Local Licensing Authority or Local Jurisdiction for the location where they intend to operate:

- a. By ordinance or resolution has permitted delivery of Regulated Marijuana in the jurisdiction, and
  - b. Is currently accepting applications for delivery permits in the jurisdiction, if required.
4. Multiple Medical Marijuana Stores, Retail Marijuana Stores, Accelerator Stores, Medical Marijuana Transporters, or Retail Marijuana Transporters with identical Controlling Beneficial Owners that are in the same local jurisdiction may obtain one delivery permit that allows all Medical Marijuana Stores, all Retail Marijuana Stores, all Medical Marijuana Transporters, or all Retail Marijuana Transporters in that jurisdiction to make deliveries to patients or consumers.
5. Delivery Permit Renewal.
  - a. A delivery permit issued by the State Licensing Authority must be renewed ~~biennially~~annually. A Medical Marijuana Store, Accelerator Store, or Retail Marijuana Store must disclose to the Division any online platform provider that the Licensee has utilized during the previous License term~~year~~ at the time of renewal.
  - b. Length of Delivery Permit.
    - i. A delivery permit issued by the State Licensing Authority and issued with an initial or renewal license application is valid for two years ~~and a period not to exceed one year and~~ will expire at the same time as the license for the associated Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, Medical Marijuana Transporter, or Retail Marijuana Transporter.
    - ii. A delivery permit issued by the State Licensing Authority that is not issued with an initial or renewal application will ~~be valid for less than one year to~~ align the license expiration date of the related Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, Medical Marijuana Transporter, or Retail Marijuana Transporter. In all terms after the first License term~~In all years after the first year~~, such a delivery permit will be valid for a period not to exceed two years~~one year~~.
  - c. In addition to any other basis for denial of renewal application, the State Licensing Authority may also consider the following facts and circumstances as an additional basis for denial of a delivery permit renewal application:
    - i. The Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store failed to collect the one-dollar surcharge on every delivery or failed to timely remit the one-dollar surcharge to the municipality where the Medical Marijuana Store, Retail

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Marijuana Store, or Accelerator Store is located, or to the county if the Medical Marijuana Store, Retail Marijuana Store, Accelerator Store is in an unincorporated area.

- B. Delivery to Private Residence. Private residence includes, but is not limited to, a private premises where a person lives such as a private dwelling, place of habitation, a house, a multi-dwelling unit for residential occupants, or an apartment unit. Private residence does not include any premises located at a school, on the campus of an institution of higher education, public property, or any commercial property unit such as offices or retail space.
- C. Responsible Vendor Certification Required. A Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, Medical Marijuana Transporter, or Retail Marijuana Transporter must obtain a valid responsible vendor designation pursuant to section 44-10-1202, C.R.S., and the 3-500 Series Rules including the delivery curriculum prior to conducting its first delivery.
- D. Inventory Tracking System Required. A Regulated Marijuana Business possessing a valid delivery permit must use the inventory tracking system and transport manifests to track all Regulated Marijuana delivered to the intended patient or consumer. This includes the use of a transport manifest.
- E. Delivery Motor Vehicle Requirements.
  - 1. Any Delivery Motor Vehicle must be owned or leased by the Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, Medical Marijuana Transporter, Retail Marijuana Transporter, or an Owner Licensee of the Regulated Marijuana Business that holds the delivery permit, must be registered in the State of Colorado, and must be insured.
  - 2. Any Delivery Motor Vehicle must have a vehicle tracking system that is capable of real-time tracking and recording of the route taken by the Delivery Motor Vehicle while conducting deliveries that can be accessed remotely in real-time by the Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, Medical Marijuana Transporter, or Retail Marijuana Transporter. The vehicle tracking system may be an application installed on a mobile device. The real-time location of the Delivery Motor Vehicle shall not be displayed to any patients or consumers.
  - 3. Any Delivery Motor Vehicle must not have any external markings, words, or symbols that indicate the Delivery Motor Vehicle is used for delivery of Regulated Marijuana or is owned or leased by a Medical Marijuana Business or a Retail Marijuana Business.
  - 4. Regulated Marijuana must not be visible from outside the Delivery Motor Vehicle.
  - 5. Delivery Motor Vehicle security requirements include but are not limited to:
    - a. A security alarm system, and

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- b. A secure, locked, opaque storage compartment that is securely affixed to the Delivery Motor Vehicle for the purpose of securing Regulated Marijuana.

6. Video Surveillance Requirements.

- a. The Delivery Motor Vehicle must be equipped with video surveillance equipment that digitally records during all deliveries. The video surveillance shall record at least the secured, locked, opaque storage compartment containing the Regulated Marijuana and the front view of the Delivery Motor Vehicle (e.g. dash camera).
  - b. Video surveillance shall be kept for a minimum of 30 days, must be capable of being embedded with the date and time, must be reproducible upon request from law enforcement, the Division, a Local Licensing Authority or a Local Jurisdiction and must be archived in a format that ensures authentication and guarantees no alteration of the video.
7. An enclosed Delivery Motor Vehicle shall not contain more than \$10,000.00 in retail value of Regulated Marijuana. A Delivery Motor Vehicle that is not enclosed shall not contain more than \$2,000.00 in retail value of Regulated Marijuana.
8. A Delivery Motor Vehicle must not leave the State of Colorado while any amount of Regulated Marijuana is in the Delivery Motor Vehicle.
9. Only persons licensed by the State Licensing Authority and identified on the transport manifest may occupy a Delivery Motor Vehicle while conducting deliveries of Regulated Marijuana.

F. Delivery Order Requirements.

1. A Medical Marijuana Store, an Accelerator Store, or a Retail Marijuana Store that has a valid delivery permit may accept orders for delivery of Regulated Marijuana to patients who are at least 21 years of age, parents or guardians of patient under 18 years of age, or consumers who are at least 21 years of age at a private residence. Delivery orders to patients ages 18 to 20 are not permitted.
2. For a Medical Marijuana Store, a Retail Marijuana Store, or an Accelerator Store that utilizes an online platform provider:
- a. The online platform provider must require that the patient or consumer choose a Medical Marijuana Store, Retail Marijuana Store, or an Accelerator Store before displaying the price of Regulated Marijuana to the patient or consumer; and
  - b. The Medical Marijuana Store, Retail Marijuana Store, or an Accelerator Store must receive verification that there has not already been a delivery of Regulated Marijuana to that private residence through the online platform provider that same business day.

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3. All delivery orders must document the following information which must be maintained pursuant to Rule 3-905 by the Medical Marijuana Store, the Retail Marijuana Store, or the Accelerator Store:
    - a. The name and date of birth of the patient or consumer placing the delivery order;
    - b. The address of the private residence where the order will be delivered;
    - c. For Medical Marijuana delivery orders only, the registration number reflecting on the patient's registry identification card; and
    - d. For Medical Marijuana delivery orders only, if the patient is under 18 years of age, the parent or guardian designated as the patient's primary caregiver, and if applicable, the registration number of the primary caregiver.
  4. A Medical Marijuana Store, a Retail Marijuana Store, or an Accelerator Store may accept payment for delivery orders using any legal method of payment, gift card pre-payments or payment on delivery, or pre-payment accounts established with a Medical Marijuana Store, Retail Marijuana Store, or an Accelerator Store except that any payment with an Electronic Benefits Transfer Services Card is not permitted. A Medical Marijuana Transporter or Retail Marijuana Transporter may accept payment on behalf of a Medical Marijuana Store, Retail Marijuana Store, or an Accelerator Store at the point of Transfer to the patient or consumer.
    - a. A Local Licensing Authority or Local Jurisdiction may further restrict legal methods of payment not expressly permitted by section 44-10-203(2)(dd)(XV), C.R.S.
  5. Regulated Marijuana must be weighed, packaged, prepared, and labeled for delivery on the Licensed Premises of a Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store or at their off-premises storage facility after receipt of a delivery order. Regulated Marijuana cannot be placed into a Delivery Motor Vehicle until after an order has been received and the Regulated Marijuana has been packaged and labeled for delivery to the patient or consumer as required by the 3-1000 Series Rules.
  6. Medical Marijuana Transporters and Retail Marijuana Transporters shall not take delivery orders but may deliver Regulated Marijuana on behalf of Medical Marijuana Stores, Retail Marijuana Stores, and Accelerator Stores pursuant to a contract with the Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store provided that the store also holds a valid delivery permit. The Medical Marijuana Store and Medical Marijuana Transporter must maintain copies of all contracts for delivery pursuant to Rule 3-905. The Retail Marijuana Store or Accelerator Store and Retail Marijuana Transporter must maintain copies of all contracts for delivery pursuant to Rule 3-905.
- G. Regulated Marijuana Delivery Requirements.

1. A Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, Medical Marijuana Transporter, or Retail Marijuana Transporter shall not deliver Regulated Marijuana to patients, parents, guardians, or consumers while also transporting Regulated Marijuana between Licensed Premises in the same Delivery Motor Vehicle.
2. Delivery of Medical Marijuana and Retail Marijuana.
  - a. A Medical Marijuana Store and Retail Marijuana Store or Accelerator Store, both of which hold a valid delivery permit, and which have identical Controlling Beneficial Owners, may complete deliveries of Medical Marijuana and Retail Marijuana using the same Delivery Motor Vehicle and without returning to the Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store between deliveries.
  - b. A Medical Marijuana Transporter and Retail Marijuana Transporter, both of which hold a valid delivery permit, and which have identical Controlling Beneficial Owners may complete deliveries of Medical Marijuana and Retail Marijuana using the same Delivery Motor Vehicle and without returning to the Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store between deliveries.
  - c. A Medical Marijuana Transporter holding a valid delivery permit may make deliveries for multiple Medical Marijuana Stores that also hold valid delivery permits using the same Delivery Motor Vehicle and without returning to a Medical Marijuana Store between deliveries.
  - d. A Retail Marijuana Transporter holding a valid delivery permit may make deliveries for multiple Retail Marijuana Stores and Accelerator Stores that also hold valid delivery permits using the same Delivery Motor Vehicle and without returning to a Retail Marijuana Store or Accelerator Store between deliveries.
3. An Owner Licensee or Employee Licensee delivering Regulated Marijuana shall not open any Container of Regulated Marijuana in the Delivery Motor Vehicle and is prohibited from packaging or re-packaging Regulated Marijuana once the Delivery Motor Vehicle has departed from the Licensed Premises of a Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store.
4. A Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store shall not accept delivery orders for Regulated Marijuana Product that is perishable unless the Delivery Motor Vehicle that will make the delivery has the ability to secure the Regulated Marijuana Product in climate-controlled storage.
5. A Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, Medical Marijuana Transporter, or Retail Marijuana Transporter must maintain a transport manifest that documents the following:
  - a. The time of delivery;

- b. The name, and identification number of the valid, acceptable identification (e.g. driver's license) presented by the patient or consumer;
- c. Address of the private residence;
- d. Acknowledgement of receipt of delivery by the person receiving the delivery;
- e. If applicable, patient registry number;
- f. If applicable, primary caregiver registry number of the patient's parent or guardian; and
- g. For every Regulated Marijuana delivery that could not be completed, the reason the delivery could not be completed.

6. Proof of Patient Medical Registry and Identification.

- a. Prior to Transferring possession of the order, the Owner Licensee or Employee Licensee delivering Medical Marijuana to a patient or a patient's parent or guardian must:
  - i. Inspect the patient's or parent's or guardian's identification and registry identification card;
  - ii. Verify the possession of a valid registry identification card;
  - iii. Verify that the information provided at the time of order match the name and age on the patient's or parent or guardian's identification; and
  - iv. Verify that the identification and registry identification card belong to the person receiving the delivery.
- b. The Owner Licensee or Employee Licensee must refuse delivery of Medical Marijuana if the person attempting to accept the delivery order cannot establish all of the requirements of subparagraph (G)(6)(a)(i) through (iv) above.

7. Proof of Consumer Identification.

- a. The Owner Licensee or Employee Licensee delivering Retail Marijuana to a consumer must first verify that the natural person accepting the delivery has an acceptable form of identification demonstrating the person is at least 21 years of age and that the person is the same as the person that placed the order for delivery with the Retail Marijuana Store or Accelerator Store.
- b. The Owner Licensee or Employee Licensee must refuse delivery of Retail Marijuana if the natural person attempting to accept the delivery order cannot establish all the requirements of subparagraph (G)(7)(a) above.

8. Daily Delivery Limits.

- a. A Medical Marijuana Store or Medical Marijuana Transporter must not deliver individually or in any combination, more than two ounces of Medical Marijuana, eight (8) grams of Medical Marijuana Concentrate, or Medical Marijuana Products containing more than 20,000 milligrams of THC to a patient in a single business day.
  - b. A Medical Marijuana Store or Medical Marijuana Transporter must not deliver to a patient, parent, or guardian or private residence where the Licensee knows or reasonably should know that the patient, parent or guardian, or private residence has already received a delivery during that same business day. This does not prohibit delivery to more than one patient at the same time and private residence.
  - c. A Retail Marijuana Store, Accelerator Store, or Retail Marijuana Transporter must not deliver individually or in any combination, more than one ounce of Retail Marijuana, 8 grams of Retail Marijuana Concentrate, or Retail Marijuana Products containing more than ten 80 milligram servings of THC to a customer in a single business day.
  - d. A Retail Marijuana Store, Accelerator Store, or Retail Marijuana Transporter must not deliver to a consumer or private residence where the Licensee knows or reasonably should know that the consumer or private residence has already received a delivery during that same business day. This does not prohibit delivery to more than one consumer at the same time and private residence.
9. An Owner Licensee or Employee Licensee who cannot complete a delivery order for any reason must return the Regulated Marijuana to the Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, or off-premises storage facility from which the delivery order originated. If the Container is unopened and has not been tampered with, the Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, or off-premises storage facility may return the Regulated Marijuana into its inventory and reconcile it with the Inventory Tracking System by the close of business that same day. Otherwise, the Regulated Marijuana must be destroyed in accordance with this Rule and Rule 3-235..
- H. Confidentiality of Patient and Consumer Personal Identifying Information. A Medical Marijuana Store, a Retail Marijuana Store, an Accelerator Store, a Medical Marijuana Transporter, a Retail Marijuana Transporter, and their respective Owner Licensees and Employee Licensees must keep all personal identifying information and any health care information obtained from patients and consumers confidential and must not disclose such personally identifiable information and any health care information to any person other than those who need that information to take, process, or deliver the order or otherwise as required by the Marijuana Code, or Title 18, or Title 25 of the Colorado Revised Statutes.

### **3-800 Series – Inventory Tracking Requirements**

#### **Basis and Purpose – 3-805**

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The statutory authority for this rule includes but is not limited to sections, 44-10-201(1), 44-10-202(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-501(1)(b), 44-10-502(2), 44-10-503(1)(b), 44-10-505(3), 44-10-601(1)(d), 44-10-602(3), 44-10-603(1)(b), 44-10-605(3), and 44-10-610(3)(a), C.R.S. The purpose of this rule is to establish a system that will allow the State Licensing Authority and the industry to jointly track Regulated Marijuana from ~~either seed or immature plant~~ Genetic Material stage until the Regulated Marijuana is sold to a patient or consumer, or destroyed.

The Inventory Tracking System is a web-based tool coupled with RFID technology that allows both the Inventory Tracking System User and the State Licensing Authority the ability to identify and account for all Regulated Marijuana. Through the use of RFID technology, a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility will tag either the seed or ~~immature~~ Plant with an individualized number, which will follow the Regulated Marijuana through all phases of production and final sale to a patient or consumer. This will allow the State Licensing Authority and the Inventory Tracking System User the ability to monitor and track Regulated Marijuana inventory. The Inventory Tracking System will also provide a platform for the State Licensing Authority to exchange information and provide compliance notifications to the industry.

The State Licensing Authority finds it essential to regulate, monitor, and track all Regulated Marijuana to eliminate diversion, inside and outside of the state, and to ensure that all marijuana grown, processed, sold, and disposed of in the Regulated Marijuana market is transparently accounted for.

The State Licensing Authority will engage the industry and provide training opportunities and continue to evaluate the Inventory Tracking System to promote an effective means for this industry to account for and monitor its Regulated Marijuana inventory, which may include reevaluating the benefits of and alternatives to certain aspects of the current Inventory Tracking System such as RFID technology requirements. This Rule 3-805 was previously Rules M and R 309, 1 CCR 212-1 and 1 CCR 212-2.

**3-805 – Regulated Marijuana Businesses: Inventory Tracking System**

- A. Inventory Tracking System Required. ~~Licensees are~~ A Regulated Marijuana Business is required to use the Inventory Tracking System as the primary inventory tracking system of record. A Regulated Marijuana Business, except for a Medical Marijuana Business Operator or Retail Marijuana Business Operator, must have an Inventory Tracking System account activated and functional prior to operating or exercising any privileges of a License. Medical Marijuana Businesses converting to or adding a Retail Marijuana Business must follow the inventory transfer guidelines detailed in Rule 3-805(C) below. Because Marijuana Hospitality Businesses are not authorized to receive or conduct Transfers of Regulated Marijuana, this Rule does not apply to Marijuana Hospitality Businesses.
- B. Inventory Tracking System Access - Inventory Tracking System ~~Trained~~ Administrator.
  - 1. Inventory Tracking System ~~Trained~~ Administrator Required. A Regulated Marijuana Business must have at least one Owner Licensee or Owner Licensee designee who is an Inventory Tracking System Trained Administrator. A Regulated Marijuana Business may also designate additional Owner Licensees



and Employee Licensees to obtain Inventory Tracking System Trained Administrator accounts.

2. Training for Inventory Tracking System Trained Administrator Account. In order to obtain an Inventory Tracking System Trained Administrator account, a Person must attend and successfully complete all required Inventory Tracking System training. The Division may also require additional ongoing, continuing education for an individual to retain ~~his or her~~their Inventory Tracking System Trained Administrator account.
3. Inventory Tracking System Access - Inventory Tracking System User Accounts. A Regulated Marijuana Business may designate licensed Owners and employees who hold valid Employee Licenses as Inventory Tracking System Users. A Regulated Marijuana Business shall ensure that all Owner Licensees and Employee Licensees who are granted Inventory Tracking System User account access for the purposes of conducting inventory tracking functions in the system are trained by Inventory Tracking System Trained Administrators in the proper and lawful use of Inventory Tracking System.

C. Medical Marijuana Business License Conversions - Declaring Inventory Prior to Exercising Licensed Privileges as a Retail Marijuana Business.

1. Medical Marijuana Inventory Transfer to Retail Marijuana Business.
  - a. Except pursuant to Rules 5-205 and 6-205:
    - i. The only allowed Transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Business is Medical Marijuana and Medical Marijuana Concentrate that was produced at the Medical Marijuana Cultivation Facility, from the Medical Marijuana Cultivation Facility to a Retail Marijuana Cultivation Facility.
    - ii. Each Medical Marijuana Cultivation Facility that is either converting to or adding a Retail Marijuana Cultivation Facility license must create a Retail Marijuana Inventory Tracking System account for each license it is converting or adding.
    - iii. A Medical Marijuana Cultivation Facility must Transfer all relevant Medical Marijuana and Medical Marijuana Concentrate into the Retail Marijuana Cultivation Facility's Inventory Tracking System account and affirmatively declare those items as Retail Marijuana or Retail Marijuana Concentrate as appropriate.
    - iv. The marijuana subject to the one-time Transfer is subject to the excise tax upon the first Transfer from the Retail Marijuana Cultivation Facility to another Retail Marijuana Business.
    - v. All other Transfers are prohibited, including but not limited to Transfers from a Medical Marijuana Store or Medical Marijuana Products Manufacturer to any Retail Marijuana Business.

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2. No Further Transfer Allowed. Once a Licensee has declared any portion of its Medical Marijuana inventory as Retail Marijuana, no further Transfers of inventory from Medical Marijuana to Retail Marijuana shall be allowed.

D. Inventory Tracking System Tags Required.

1. Authorized Tags Required and Costs. Licensees are required to use Inventory Tracking System tags issued by a Division-approved vendor that is authorized to provide Inventory Tracking System tags for the Inventory Tracking System. Each Licensee is responsible for the cost of all Inventory Tracking System tags and any associated vendor fees.
2. Use of Inventory Tracking System Tags Required. A Licensee is responsible to ensure its inventories are properly tagged where the Inventory Tracking System requires Inventory Tracking System tag use. A Regulated Marijuana Business must ensure it has an adequate supply of Inventory Tracking System tags to properly tag Regulated Marijuana as required by the Inventory Tracking System. An Inventory Tracking System tag must be physically attached to every Regulated Marijuana plant being cultivated that is greater than fifteen inches tall or wide. Any plant greater than ~~fifteen~~~~eight~~ inches that is not assigned a tag must be fully accounted for in the Inventory Tracking System. Prior to a plant reaching a viable point to support the weight of the Inventory Tracking System tag and attachment strap, the Inventory Tracking System tag may be securely fastened to the stalk. An Inventory Tracking System tag must be assigned to all Regulated Marijuana. See Rule 3-805(D); Rule 3-1005(G) – Shipping Containers.
3. Reuse of Inventory Tracking System Tags Prohibited. A Licensee shall not reuse any Inventory Tracking System tag that has already been affixed or assigned to any Regulated Marijuana.
4. When plants reach a viable point to support the weight of the Inventory Tracking System tag and attachment strap, the Inventory Tracking System tag shall be securely fastened to a lower supporting branch.

E. General Inventory Tracking System Use.

1. Reconciliation with Inventory. All inventory tracking activities at a Regulated Marijuana Business must be tracked through use of the Inventory Tracking System. A Licensee must reconcile all on-premises and in-transit Regulated Marijuana inventories each day in the Inventory Tracking System at the close of business.
2. Common Weights and Measures.
  - a. A ~~Regulated Marijuana Business~~Licensee must utilize a standard of measurement that is supported by the Inventory Tracking System to track all Regulated Marijuana.
  - b. A scale used to weigh product prior to entry into the Inventory Tracking System shall be tested and approved in accordance with section 35-14-127, C.R.S.

3. Inventory Tracking System ~~Trained~~ Administrator and User Accounts – Security and Record.
  - a. A Regulated Marijuana Business shall maintain an accurate and complete list of all Inventory Tracking System ~~Trained~~ Administrators and Inventory Tracking System Users for each Licensed Premises. A Regulated Marijuana Business shall update this list when a new Inventory Tracking System User is trained. A Regulated Marijuana Business must train and authorize any new Inventory Tracking System Users before those Owners or employees may access Inventory Tracking System or input, modify, or delete any information in the Inventory Tracking System.
  - b. A Regulated Marijuana Business must cancel any Inventory Tracking System ~~Trained~~ Administrators and Inventory Tracking System Users from their associated Inventory Tracking System accounts once any such individuals are no longer employed by the Licensee or at the Licensed Premises.
  - c. A Regulated Marijuana Business is accountable for all actions employees take while logged into the Inventory Tracking System or otherwise conducting Regulated Marijuana inventory tracking activities.
  - d. Each individual user is also accountable for all of his or her actions while logged into the Inventory Tracking System or otherwise conducting Regulated Marijuana inventory tracking activities, and shall maintain compliance with all relevant laws.
4. Secondary Software Systems ~~Allowed~~.
  - a. Nothing in this Rule prohibits a Regulated Marijuana Business from using separate, ~~secondary systems software applications~~ to collect information to be used by the business. ~~This~~ includ~~es~~~~ing~~ secondary inventory tracking or point-of-sale systems.
  - b. A Licensee must ensure that all relevant Inventory Tracking System data is accurately transferred to and from the Inventory Tracking System for the purposes of reconciliations with any secondary systems.
  - c. A Regulated Marijuana Business must preserve original Inventory Tracking System data when transferred to and from a secondary ~~system application(s)~~. Secondary ~~systems software applications~~ must use the Inventory Tracking System data as the primary source of data and must be compatible with updating to the Inventory Tracking System.
  - d. Each Licensee is accountable for all their actions while using the secondary systems or point-of-sale.
  - e. A Licensee shall not intentionally or knowingly make misstatements or omissions in a secondary system that would prevent the Inventory Tracking System from fully and transparently accounting for all inventory tracking activities.

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5. Regulated Marijuana Cultivations: Inventory Tracking System. A Manicure Batch may be combined with a Harvest Batch containing the same plants, provided that the Regulated Marijuana is homogenized prior to sampling and testing, uniform in strain, cultivated utilizing the same Pesticide and other agricultural chemicals. Manicure and Harvest Batches must be clearly identified at the Licensed Premises with the Manicure Batch and Harvest Batch name and date as it appears in the Inventory Tracking System.
- F. Conduct While Using Inventory Tracking System.
1. Misstatements or Omissions Prohibited. A ~~Regulated Marijuana Business and its designated Inventory Tracking System Administrator(s) and Inventory Tracking System User(s)~~ Licensee shall enter data into the Inventory Tracking System that fully and transparently accounts for all inventory tracking activities. Both the Regulated Marijuana Business and the individuals using the Inventory Tracking system are responsible for the accuracy of all information entered into the Inventory Tracking System. ~~Any misstatements or omissions may be considered a license violation affecting public safety.~~
  2. Use of Another User's Login Prohibited. Individuals entering data into the Inventory Tracking System shall only use that individual's Inventory Tracking System account.
  3. Loss of System Access. If at any point a Regulated Marijuana Business loses access to the Inventory Tracking System for any reason, the Regulated Marijuana Business must keep and maintain comprehensive records detailing all Regulated Marijuana tracking inventory activities that were conducted during the loss of access. See Rule 3-905 – Business Records Required. Once access is restored, all Regulated Marijuana inventory tracking activities that occurred during the loss of access must be entered into the Inventory Tracking System. A Regulated Marijuana Business must document when access to the system was lost and when it was restored. A Regulated Marijuana Business shall not Transfer any Regulated Marijuana to another Regulated Marijuana Business until such time as access is restored and all information is recorded into the Inventory Tracking System.
- G. System Notifications.
1. Compliance Notifications. A Regulated Marijuana Business must monitor all compliance notifications from the Inventory Tracking System. The Licensee must resolve the issues detailed in the compliance notification in a timely fashion. Compliance notifications shall not be dismissed in the Inventory Tracking System until the Regulated Marijuana Business resolves the compliance issues detailed in the notification.
  2. Informational Notifications. A Regulated Marijuana Business must take appropriate action in response to informational notifications received through the Inventory Tracking System, including but not limited to notifications related to Inventory Tracking System billing, enforcement alerts, and other pertinent information.

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- H. Lawful Activity Required. Proper use of the Inventory Tracking System does not relieve a Licensee of its responsibility to maintain compliance with all laws, rules, and other requirements at all times.
- I. Inventory Tracking System Procedures Must Be Followed. A Regulated Marijuana Business must utilize Inventory Tracking System in conformance with these rules and Inventory Tracking System procedures, including but not limited to:
1. Properly indicating the creation of a Harvest Batch and/or Production Batch including the assigned Harvest Batch and/or Production Batch Number;
  2. Accurately identifying the cultivation rooms and location of each plant within those rooms on the Licensed Premises;
  3. Accurately identifying when inventory is no longer on the Licensed Premises;
  4. Properly indicating that a Test Batch is being used as part of achieving a Reduced Testing Allowance;
  5. Accurately indicating the Inventory Tracking System category for all Regulated Marijuana; and
  6. Accurately including a note explaining the reason for any destruction of Regulated Marijuana, and reason for any adjustment of weights to Inventory Tracking System packages.
  7. Properly designating one or more Sampling Managers before Transferring any Sampling Units;
  8. Fully and accurately tracking the Transfer of any Sampling Unit from a Regulated Marijuana Business to a Sampling Manager identified by name and license number; and
  9. When entering into the Inventory Tracking System a unit of Regulated Marijuana the Inventory Tracking System Trained Administrator or Inventory Tracking System User shall also identify the net contents of each unit consistent with Rules 3-1005(B)(2)(e) and (C)(2)(a)(iv). For example, if the Inventory Tracking System User enters 1 unit of Retail Marijuana Product that contains 100 milligrams of Retail Marijuana Product, then the Inventory Tracking System User shall also identify that each unit contains 100 milligrams. Further, if the Inventory Tracking System User enters 1 unit of Medical Marijuana Product that contains 200 mg of Medical Marijuana Product, the Inventory Tracking System User shall also identify that each unit contains 200 mg.
  10. Licensees shall enter all expiration dates and use-by dates into the Inventory Tracking System.

**Basis and Purpose – 3-810**

The statutory authority for this rule includes but is not limited to sections, 44-10-201, 44-10-202(1)(a), 44-10-202(1)(c), 44-10-203(2)(n), 44-10-501(1)(b), 44-10-502(2), 44-10-503(1)(b), 44-10-505(3), 44-10-601(1)(d), 44-10-601(4), 44-10-602(1), 44-10-602(6)(f), 44-10-603(1)(b),

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and 44-10-605(3), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to maintain a system that will allow the State Licensing Authority and the industry to jointly track Regulated Marijuana from ~~either seed or immature plant stage~~ Genetic Material until the Regulated Marijuana is sold to the patient or consumer or destroyed.

**3-810 – Minimum Tracking Requirements****A. Requirement to Track Regulated Marijuana From Seed-to-Sale.**

1. Licensees must use the Inventory Tracking System to ensure Regulated Marijuana is identified and tracked from the point the Regulated Marijuana is Propagated ~~from seed or cutting~~ to the point when it is Transferred to another Regulated Marijuana Business, the Medical Marijuana Transporter or Retail Marijuana Transporter takes control of the Regulated Marijuana by removing it from the originating Licensee's Licensed Premises and placing the Regulated Marijuana in the transport vehicle, or it is Transferred to a Sampling Manager as a designated Sampling Unit, and through the delivery, point-of-sale, or the Regulated Marijuana is otherwise disposed of. See Rule 3-805 – Inventory Tracking System.
2. Licensees must immediately input ~~any~~ Genetic Material that is received in accordance with Rules 5-~~32~~05 and 6-~~32~~05 into the Inventory Tracking System following Inventory Tracking System procedures as directed by the 3-800 series. ~~as an Immature Plant batch.~~

**B. Ability to Reconcile Required.** Licensees must have the ability to reconcile transported and on-hand Regulated Marijuana inventory with the Inventory Tracking System and the associated transaction history and transportation order receipts. See Rule 3-905 – Business Records Required.**C. Decontamination.** Licensees must input any Decontamination method utilized into the Inventory Tracking System.**Basis and Purpose – 3-825**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-203(2)(d)(I), 44-10-504, and 44-10-604 The Purpose of this rule is to establish reporting standards for Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities.

**3-825 – Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities Specific Tracking Requirements**

- A. Required Procedures. A Regulated Marijuana Testing Facility must establish procedures to ensure that results are accurate, precise, and scientifically valid prior to reporting such results.
- B. Reports. Every final report, whether submitted to the Division, to a Regulated Marijuana Business, or to any other Person authorized to receive the report, must include the following:

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1. Report quantitative results that are only above the lowest concentration of calibrator or standard used in the analytical run;
2. Verify results that are below the lowest concentration of calibrator or standard and above the LOQ by using a blank and a standard that falls below the expected value of the analyte in the sample-Test Batch in duplicate prior to reporting a quantitative result;
3. Qualitatively report results below the lowest concentration of calibrator or standard and above the LOD as either trace or using a non-specific numerical designation;
4. Adequately document the available external chain of custody information;
5. Ensure all final reports contain the name and location of the Regulated Marijuana Testing Facility that performed the test, name, and unique identifier of Sample-Test Batch, submitting client, Sample-Test Batch received date, date of report, type of Sample-Test Batch tested, test result, units of measure, and any other information or qualifiers needed for interpretation when applicable to the test method and results being reported, to include any identified and documented discrepancies; and
6. Provide the final report to the Division, as well as the Regulated Marijuana Business, and/or any other Person authorized to receive the report in a timely manner.

C. Inventory Tracking System. Each Regulated Marijuana Testing Facility shall:

1. Report all test results to the Division as part of daily reconciliation by the close of business and in accordance with all Inventory Tracking System Procedures under Rule 3-805 – All Regulated Marijuana Businesses: Inventory Tracking System. The requirement to report all test results includes:
  - a. Both positive and negative test results;
  - b. Results from both mandatory and voluntary testing, including Certificates of Analysis; and
  - c. For quantitative tests, a quantitative value.
2. As part of Inventory Tracking System reporting, when results of tested Test Batches exceed maximum levels of allowable potency or contamination, or otherwise result in failed potency, homogeneity, or contaminant testing, the Regulated Marijuana Testing Facility shall, in the Inventory Tracking System, indicate failed test results for the Inventory Tracking System package associated with the failed Test Batches. This requirement only applies to testing of Test Batches that are comprised of Regulated Marijuana.
3. Report all Transfers of Genetic Material to a Regulated Marijuana Cultivation Facility in the Inventory Tracking System.



- D. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

### 3-900 Series – Business Records

#### Basis and Purpose – 3-905

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-301, and 44-10-1001(1) and (3), C.R.S. This rule explains what business records a Licensee must maintain and clarifies that such records must be made available to the Division on demand. This Rule 3-905 was previously Rules M and R 901, 1 CCR 212-1 and 1 CCR 212-2.

#### 3-905 – Business Records Required

A. General Requirements.

1. A Regulated Marijuana Business must maintain the information required in this Rule in a format that is readily understood by a reasonably prudent business person and may be stored electronically.
2. Location of Required Records
  - a. On premises records: The Regulated Marijuana Business's books and records for the preceding six months (or complete copies of such records) must be maintained on the Licensed Premises at all times. Electronic records that are accessible from, but not physically located at, a Licensee's Licensed Premises may also satisfy the requirements of this Rule 3-905.
  - b. On- or off-premises records: Books and records associated with older periods may be archived on or off of the Licensed Premises.
3. Books and records necessary to fully account for the business transactions conducted under its License shall be made available to the State Licensing Authority or Division upon request.

B. The books and records that are required to be maintained for the current calendar year and the preceding calendar year are:

1. Secure Facility Information – For its Licensed Premises and any associated permitted off-premises storage facility, a Regulated Marijuana Business must maintain the business contact information for vendors that maintain video surveillance systems and Security Alarm Systems.
2. Security Alarm Systems documents required by Rule 3-220(A)(3).
3. Advertising Records – All records related to Advertising and marketing, including, but not limited to, audience composition data.
4. Child Resistance Certificates – A copy of the certificate that each Container into which a Licensee places Regulated Marijuana is Child Resistant.



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5. Diagram for the Licensed Premises – Diagram of all approved Limited Access Areas, Restricted Access Areas, and any permitted off-premises storage facilities.
6. Visitor Log – List of all visitors entering Limited Access Areas or Restricted Access Areas.
7. Repealed.
8. Waste Log and Fibrous Waste Records – Comprehensive records regarding all waste and Fibrous Waste material that accounts for, reconciles, and evidences all waste and Fibrous Waste activity related to the disposal of marijuana.
9. Consumer Waste Records – All contracts, ~~S~~standard ~~O~~perating ~~P~~rocedures, and receipts relating to collection and Transfer of Marijuana Consumer Waste as required by Rule 3-240.
10. Surveillance Logs – Surveillance logs identify all authorized employees and service personnel who have access to the surveillance system and maintenance and activity log as required by Rule 3-225.
11. Every Licensee shall maintain a record of its identity statement and Standardized Graphic Symbol. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule.
12. Testing Records Required to be Maintained by Regulated Marijuana Testing Facilities:
  - a. All testing records required by Rule 5-450 and Rule 6-450.
  - b. Digital photographs of each Test Batch.
  - c. Any delegation of responsibilities from the laboratory director to ~~a~~ qualified ~~supervisory analyst personnel~~ as permitted by Rule 5-~~420(B) or 6-420(B)~~240(B)9 or 6-240(B).
13. Testing Records Required to be Maintained by Regulated Marijuana Businesses and Accelerator Licensees:
  - a. Documentation of Designated Test Batch Collector Training required by Rule ~~4-225(D)(3)4-110(C)(3)~~.
  - b. Records regarding wet whole plant that was not tested for microbials pursuant to Rule ~~4-230(N)(1)(b)4-121(F)(3)~~.
  - c. Evidence of any achieved Reduced Testing Allowance – If a Licensee utilizes any Reduced Testing Allowances, then they must maintain documentation demonstrating how it was obtained and maintained throughout the allowance with all applicable rules.
14. Sampling Unit Records – All records related to designated Sampling Managers, identified Sampling Units, and Transfers of Sampling Units. See Rules 3-810, 5-230, 5-320, 6-225, 6-320. This includes, but is not limited to, ~~S~~standard ~~O~~perating ~~P~~rocedures that explain the requirements of sections 44-10-502(5),

- 44-10-503(10), 44-10-602(6) and 44-10-603(10), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements imposed by Rules 5-230, 5-320, 6-225, 6-320, 6-725, and 6-280.
15. License Application Records – All records provided by the Licensee to both the state and local licensing authorities in connection with an application for licensure pursuant to the Marijuana Code and these Rules.
  16. Repealed.
  17. Audited Product and/or Alternative Use Product Records – All records required to demonstrate compliance with Rule 5-325 and 6-325.
  18. Repealed.
  19. Certificates of analysis or other records demonstrating the full composition of each Ingredient used in the manufacture of Vaporizer Delivery Devices or Pressurized Metered Dose Inhalers as required by Rule 5-310(F).
  20. Records required to be maintained by Delivery Permit holders including delivery order requirements and contracts for delivery pursuant to Rule 3-615.
  21. Recall records required by Rule 3-336 including the recall plan, recall notice, and results of any action taken pursuant to the recall plan.
  22. All records related to Material Changes as required by Rules 3-330(D) and 3-335(L).
  23. Records related to Adverse Health Events as required by Rule 3-920.
  24. Internal Security Controls – Licensees must establish and maintain a security plan for each Licensed Premises, including at a minimum:
    - a. Protocols for the end-of-day handling of Regulated Marijuana and cash;
    - b. Protocols for reporting theft or burglaries when they are discovered to Local Law Enforcement, the Division, and Local Licensing Authority or Local Jurisdiction;
    - c. Protocols for reconciling inventory after a theft or burglary has been discovered;
    - d. Identification of exterior lighting of the Licensed Premises and any exterior camera angles, and protocols for maintenance of the lighting and cameras; and
    - e. Identification of ingress and egress routes for the property and identification of any access control measures taken outside of the Licensed Premises.
  25. Patient Documents – Documents required for a patient to register a primary Medical Marijuana Store as required by Rule 5-1~~25(A)(2.5)40(D)~~.

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26. Regulated Marijuana Concentrate Production Records – All records required by Rules 5-315, 6-315, and 6-815 regarding production of Regulated Marijuana Concentrate.
27. Marijuana Research and Development Facility Records – Documents and correspondence sent to or received from an independent reviewer or the Scientific Advisory Council and any testing records if required by Rule 5-725.
28. Documents Related to Pesticide Manufacturers – Affidavit from a Pesticide Manufacturer that it meets the requirements of the Rule and the written agreement between the Licensee and the Pesticide Manufacturer as required by Rule 7-115.
29. Expiration date and use-by date documents required by Rule 3-335(M), 3-1005, and 3-1015.
30. ~~Repealed. Written report of change of management personnel as required by Rule 3-920(A)(2).~~
31. Current Owner and Employee List – This list must provide the full name and License number of all Owner Licensees and every employee who works for a Regulated Marijuana Business. The list shall include all employees who work for the Regulated Marijuana Business, whether or not they report to the Licensed Premises as part of their employment. A Regulated Marijuana Business can fulfill the requirements of this Rule by listing all employees in the Inventory Tracking System for each Licensed Premises. If a Regulated Marijuana Business does not use the Inventory Tracking System to list all employees, it must maintain a separate record for employees who do not report to the Licensed Premises.
32. Repealed.
33. ~~Source~~ Genetic Material Records - Licensees ~~receiving~~ selling, transferring, or shipping Genetic Material in accordance with Rules 5-~~3205~~, and 6-3205, and 6-705 must establish and maintain Standard Operating Procedures to confirm that the purchasing or receiving individual is twenty-one years of age or older, pursuant to 44-10-502(7)(b)(III) and 44-10-602(12)(b)(III), C.R.S. ~~maintain the following records:~~
  - a. ~~The name, address, and license/registration/permit identification of the source of the Genetic Material;~~
  - b. ~~All certificates of analysis associated with the Genetic Material, if available; and~~
  - c. ~~Any other records that clearly document the chain of custody of the Genetic Material, such as an invoice, packing slip, or other document showing the origin of the Genetic Material.~~
34. Procedures for compliance with online sales.
35. All other records required by these Rules.

- B.5 Each Regulated Marijuana Business shall retain the following records for the current year and three immediate prior tax years:
1. Tax documents in accordance with section 44-10-1001(3), C.R.S.;
  2. All books and records necessary to fully account for the business transactions conducted under its license;
  3. Standard Operating Procedures and Training Documentation - All ~~S~~standard ~~O~~perating ~~P~~rocedures, including revision date, as required by these Rules must be maintained for the current year and three previous calendar years. In addition to maintaining ~~S~~standard ~~O~~perating ~~P~~rocedures, Regulated Marijuana Businesses must maintain up-to-date records of employee training as follows:
    - a. Identification of required training of employees;
    - b. Documentation of training topic, training method, date of initial training, date of any necessary re-training, name and signature of trainer, and name and signature of employee;
    - c. Competency and effectiveness of employee training shall be adequately assessed in an appropriate manner determined by the Licensee that is described in the ~~S~~standard ~~O~~perating ~~P~~rocedures.
  4. Corrective Action and Preventive Action records required by Rules 5-115, 5-210, 5-310, 6-110, 6-210, 6-310, 6-710, 6-810, and 6-1110.
  5. Documentation required to demonstrate valid responsible vendor designation(s).
  6. Cleaning records and Maintenance records required under Rule 3-330(D)(1)(e).
- C. Records Required to be Maintained in the Inventory Tracking System. The following records must be maintained by Licensees in the Inventory Tracking System:
1. Records Related to Inventory Tracking. A Regulated Marijuana Business must maintain accurate and comprehensive inventory tracking records that account for, reconcile, and evidence all inventory activity for Regulated Marijuana from ~~either seed or Immature Plant stage~~Genetic Material until the Regulated Marijuana is destroyed or Transferred to another Regulated Marijuana Business, a consumer, a patient, or a Pesticide Manufacturer.
  2. Records Related to Transport. A Regulated Marijuana Business must maintain adequate records for the transport of all Regulated Marijuana. See Rule 3-605 – Transport: All Regulated Marijuana Businesses.
  3. Employees Required to be Listed in the Inventory Tracking System. A Regulated Marijuana Business must use the Inventory Tracking System to list all employees who report to the Licensed Premises. The employee list in the Inventory Tracking System must include the full name and Employee License number of every employee who works on the premises. The Regulated Marijuana Business is responsible for updating its list of employees who work at the Licensed Premises

in the Inventory Tracking System within 10 days of an employee commencing or ceasing employment.

4. Testing results.
- D. Loss of Records and Data. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this Rule. Licensees are required to exercise due diligence in preserving and maintaining all required records.
- E. ~~Repealed. Violation Affecting Public Safety. Violation of this Rule may constitute a license violation affecting public safety.~~
- F. Provision of Any Requested Record to the Division. A Licensee must provide on-demand access to on-premises records following a request from the Division during normal business hours or hours of apparent operation, and must provide access to off-premises records within three business days following a request from the Division.

### **Basis and Purpose – 3-915**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), and 44-10-1001(1), C.R.S. The Marijuana Code mandates that a Regulated Marijuana Business must pay for an audit when the State Licensing Authority deems an audit necessary. This rule explains when an audit may be deemed necessary and sets forth possible consequences of a Regulated Marijuana Business's refusal to cooperate or pay for the audit. This Rule 3-915 was previously Rules M and R 903, 1 CCR 212-1 and 1 CCR 212-2.

### **3-915 – Independent Audit May Be Required**

- A. State Licensing Authority May Require Independent Audit.
  1. When the State Licensing Authority deems it necessary, it may require a Regulated Marijuana Business to undergo an audit by an independent accountant. The scope of the audit may include, but need not be limited, to financial transactions and inventory control measures.
  2. In such instances, the Division may attempt to mutually agree upon the selection of the independent accountant with a Regulated Marijuana Business. However, the Division always retains the right to select the independent accountant regardless of whether mutual agreement can be reached. The independent accountant shall be a certified public accountant licensed by, and in good standing with, the Colorado State Board of Accountancy.
  3. The Regulated Marijuana Business will be responsible for all direct costs associated with the independent audit.
- B. When Independent Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent accountant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:
  1. A Regulated Marijuana Business does not provide requested records to the Division;

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2. The Division has reason to believe that the Regulated Marijuana Business does not properly maintain its business records;
  3. A Regulated Marijuana Business has a prior violation related to recordkeeping or inventory control;
  4. A Regulated Marijuana Business has a prior violation related to diversion.
  5. As determined by the Division, the scope of an audit conducted by the Division would be so extensive as to jeopardize the regular duties and responsibilities of the Division's audit or enforcement staff.
- C. Compliance Required. A Regulated Marijuana Business must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an audit in accordance with this Rule.
- D. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 3-920**

The statutory authority for this rule includes but is not limited to sections 44-10-201(4), ~~44-10-204(1)(a)~~, 44-10-202(1)(c), 44-10-202(1)(a), 44-10-204(1)(a), 44-10-203(1)(k), 44-10-313(12), and 44-10-701(2)(a), C.R.S. The State Licensing Authority must be able to immediately access information regarding a Regulated Marijuana Business's managing individual. Accordingly, this rule reiterates the statutory mandate that Licensees provide any management change to the Division within seven days of any change, and also clarifies that a Licensee must save a copy of any management change report to the Division, and clarifies that failure to follow this rule can result in discipline.

The State Licensing Authority finds it essential to the stringent and comprehensive enforcement of the Marijuana Code to regulate, monitor, and track all Regulated Marijuana in order to prevent diversion and to ensure that all Regulated Marijuana grown, processed, sold, and disposed of in the Regulated Marijuana market is accounted for transparently in accordance with the Marijuana Code.

Requiring Licensees to report instances when the Regulated Marijuana they cultivate, manufacture, distribute, sell, test, or dispose of is stolen, unlawfully Transferred, or otherwise diverted from the regulated market, or when Licensees discover plans to divert the Regulated Marijuana, emphasizes that Licensees are accountable for their Regulated Marijuana at all times and contributes to the transparency of the regulated market.

In addition to maintaining transparency in the regulated marijuana industry, the State Licensing Authority also must ensure the confidentiality of certain Licensee information and records, including information in the Inventory Tracking System. Requiring Licensees to report instances where the Inventory Tracking System was compromised or planned to be compromised through unlawful access, use for unlawful purposes, the deliberate alteration or deletion of data, or deliberately entering false data, contributes to ensuring the accuracy and transparency of the system and therefore the regulated market, and aids in maintaining the confidentiality of Licensee data.

This Rule 3-920 was previously Rules M and R 904, 1 CCR 212-1 and 1 CCR 212-2.

**3-920 – Regulated Marijuana Business Reporting Requirements****A. Management Personnel Change Must Be Reported.**

1. When Required. A Regulated Marijuana Business shall ~~provide the Division a written~~ report within seven days after any change in management personnel occurs through the Inventory Tracking System. In addition, a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer shall report any designation or change of Sampling Manager(s) through the Inventory Tracking System.
2. Licensee Must ~~Maintain Record of Reported Change~~ Regulated Marijuana Business Operator. A Regulated Marijuana Business must ~~also maintain a copy of this written report with its business records as required in Rule 3-905 reported to the Division in writing within seven days any change or engagement of a~~ Regulated Marijuana Business Operator.
3. Consequence of Failure to Report. Failure to report a change in a timely manner may result in discipline.

**B. Reporting of Crime on the Licensed Premises or Otherwise Related to a Regulated Marijuana Business.** A Regulated Marijuana Business and all Licensees employed by the Regulated Marijuana Business shall report to the Division any discovered plan or other action of any Person to (1) commit theft, burglary, underage sales, diversion of marijuana or marijuana product, or other crime related to the operation of the subject Regulated Marijuana Business; or (2) compromise the integrity of the Inventory Tracking System. A report shall be made as soon as possible after the discovery of the action, but not later than 14 days. Nothing in this paragraph (B) alters or eliminates any obligation a Regulated Marijuana Business or Licensee may have to report criminal activity to a local law enforcement agency.**C. Adverse Health Event Reporting.** If a Regulated Marijuana Business is notified of any possible Adverse Health Event, as defined by Rule 1-115, associated with Regulated Marijuana, it must report the Adverse Health Event to the Division within 48 hours from its receipt of notification of the Adverse Health Event. To the extent known after reasonable diligence to ascertain the information, the report must contain the name and contact information of the complainant, the date the complaint was received, the nature of the complaint, the Production Batch or Harvest Batch number, and any other identifying information found on the label of the Regulated Marijuana. The Regulated Marijuana Business must maintain records of reports of Adverse Health Events in accordance with Business Records Rule 3-905.**D. Reporting of Fire on the Licensed Premises.** A Regulated Marijuana Business and all Licensees employed by the Regulated Marijuana Business shall report to the local fire department any fire that occurs on the Licensed Premises in the time frame required by the Local Jurisdiction or Local Licensing Authority. The Regulated Marijuana Business and all Licensees employed by the Regulated Marijuana Business shall report to the Division any fire that occurs on the Licensed Premises within 48 hours.



**3-1000 Series – Labeling, Packaging, and Product Safety****Basis and Purpose – 3-1005**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(f), 44-10-203(1)(k), 44-10-203(3)(a)-(b), 44-10-601(2)(a), 44-10-601(5), 44-10-603(1)(d), 44-10-603(4)(a), and 44-10-603(8), C.R.S. The purpose of this rule is to define minimum packaging and labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product Transferred between Regulated Marijuana Businesses. The State Licensing Authority finds it essential to regulate and establish labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product and that this is in the interest of the health and safety of the people of Colorado. This rule identifies information that is required on all labels to provide information necessary for the Division to regulate the cultivation, production, and sale of Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. This rule also seeks to minimize, to the extent practicable, the burden of labeling compliance to Licensees. The labeling requirements in this rule apply to all Containers immediately containing Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. This Rule 3-1005 was previously Rules M and R 1001-1, 1 CCR 212-1 and 1 CCR 212-2.

**3-1005 - Packaging and Labeling: Minimum Requirements Prior to Transfer to a Regulated Marijuana Business, except to a Regulated Marijuana Testing Facility**

- A. Applicability. This Rule establishes minimum requirements for packaging and labeling Regulated Marijuana prior to Transfer to a Regulated Marijuana Business, except to a Regulated Marijuana Testing Facility. See Rule 3-1025 for minimum requirements for packaging and labeling Regulated Marijuana prior to Transfer to a Regulated Marijuana Testing Facility. The labeling requirements in this Rule apply to all Containers immediately containing Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, and Retail Marijuana Product.
- B. Packaging and Labeling of Regulated Marijuana Flower, Trim, Wet Whole Plant, and Regulated Marijuana Concentrate, Prior to Transfer to a Regulated Marijuana Business. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana flower, trim, wet whole plant, or Medical Marijuana Concentrate to another Medical Marijuana Business, or Retail Marijuana flower, trim, wet whole plant, or Retail Marijuana Concentrate to another Retail Marijuana Business:
1. Packaging of Regulated Marijuana Flower and Trim, and Regulated Marijuana Concentrate.
    - a. Prior to Transfer to a Regulated Marijuana Business, Regulated Marijuana flower, trim, wet whole plant, or Regulated Marijuana Concentrate shall be placed into a Container. The Container may but is not required to be Child-Resistant.
    - b. Each Container of Regulated Marijuana flower or trim that is Transferred to a Regulated Marijuana Business shall not exceed 50 pounds of



Regulated Marijuana flower or trim, but may include pre-weighed units that are within the sales limit in Rules 5-115(C), 6-110(C), and 6-925(G).

- c. A Container of wet whole plant that is Transferred to a Regulated Marijuana Business may exceed 50 pounds, but shall not exceed 100 pounds.
  - d. Each Container of Medical Marijuana Concentrate that is Transferred to a Medical Marijuana Business, or Retail Marijuana Concentrate that is Transferred to a Retail Marijuana Business, shall not exceed 50 pounds of Medical Marijuana Concentrate or Retail Marijuana Concentrate, but may include pre-weighed units that are within the applicable sales limit in Rules 5-115(C), 6-110(C), and 6-925(G).
2. Labeling of Regulated Marijuana Flower, Trim, Wet Whole Plant, and Regulated Marijuana Concentrate. Prior to Transfer to a Regulated Marijuana Business, every Container of Regulated Marijuana flower, trim, wet whole plant, or Regulated Marijuana Concentrate shall be affixed with a label that includes at least the following information:
- a. The license number of the Medical Marijuana Cultivation Facility where the Medical Marijuana was grown, the Retail Marijuana Cultivation Facility where the Retail Marijuana was grown, or the Accelerator Cultivator where the Retail Marijuana was grown;
  - b. The Harvest Batch Number(s) assigned to the Regulated Marijuana or the Production Batch Number(s) assigned to the Regulated Marijuana Concentrate;
  - c. If applicable, the license number of the Medical Marijuana Cultivation Facility(ies) that produced the Physical Separation-Based Medical Marijuana Concentrate, the Retail Marijuana Cultivation Facility(ies) that produced the Physical Separation-Based Retail Marijuana Concentrate, or the license number of the Accelerator Cultivator;
  - d. If applicable, the license number of the Medical Marijuana Products Manufacturer(s) where the Medical Marijuana Concentrate was produced, the Retail Marijuana Products Manufacturer(s) where the Retail Marijuana Concentrate was produced, or the Accelerator Manufacturer(s) where the Retail Marijuana Concentrate was produced;
  - e. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Regulated Marijuana or Regulated Marijuana Concentrate prior to its placement in the Container; and
  - f. Potency test results as required to permit the receiving Regulated Marijuana Business to label the Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, or Retail Marijuana Concentrate as required by these rules.

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- g. Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers. A list of all Ingredients, including Additives, used to manufacture the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.
    - h. Expiration/Use-By Date. Beginning January 1, 2024, the expiration or use-by date as required in Rule 3-1015.
    - i. Storage Conditions. Beginning January 1, 2024, if a Licensee establishes a use-by date that is longer than nine months based on shelf stability testing in accordance with Rule 3-1015(B)(2)(a.5), then the label for the Regulated Marijuana shall include storage conditions as determined by the Regulated Marijuana Business that cultivated or manufactured the Regulated Marijuana.
- C. Packaging and Labeling of Regulated Marijuana Product Prior to Transfer to a Regulated Marijuana Business. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana Product to another Medical Marijuana Business, or Transferring Retail Marijuana Product to another Retail Marijuana Business:
  - 1. Packaging of Regulated Marijuana Product.
    - a. Transfer to a Regulated Marijuana Business Other Than a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Regulated Marijuana Business other than a Medical Marijuana Store or Retail Marijuana Store, Regulated Marijuana Product shall be placed into a Container. The Container may but is not required to be Child-Resistant.
    - b. Transfer to a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Medical Marijuana Store or Retail Marijuana Store, all Regulated Marijuana Product shall be packaged in a Child-Resistant Container that is ready for sale to the patient or consumer as required by the Rule 3-1010(D).
  - 2. Labeling of Regulated Marijuana Product.
    - a. Transfer to a Regulated Marijuana Business other than a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Regulated Marijuana Business other than a Medical Marijuana Store or Retail Marijuana Store, every Container of Regulated Marijuana Product shall be affixed with a label that includes at least the following information:
      - i. ~~Repealed~~The license number of the Regulated Marijuana Cultivation Facility(ies) where the Medical Marijuana or Retail Marijuana was grown;
      - ii. The license number of the Regulated Marijuana Products Manufacturer that produced the Medical Marijuana Product or Retail Marijuana Product;
      - iii. The Production Batch Number(s) assigned to the Regulated Marijuana Product;

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- iv. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Regulated Marijuana Product prior to its placement in the Container; and
    - v. Potency test results as required to permit the receiving Regulated Marijuana Business to label the Regulated Marijuana Product as required by these rules.
  - b. Transfer to a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Regulated Marijuana Store, every Container of Regulated Marijuana Product shall be affixed with a label ready for sale to the patient or consumer including all information required by Rules 3-1010(D)(2) and 3-1015(B).
- D. Packaging and Labeling of ~~Regulated Marijuana Seeds, Immature Plants, and~~ Genetic Material Prior to Transfer. ~~to a Regulated Marijuana Business.~~ A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring ~~Regulated Marijuana seeds, Immature Plants, or~~ Genetic Material ~~to another Regulated Marijuana Business:~~
  - 1. ~~Repealed. Packaging of Regulated Marijuana Seeds.~~
    - a. ~~—Prior to Transfer to a Regulated Marijuana Business, Regulated Marijuana seeds shall be placed into a Container. The Container may but is not required to be Child-Resistant.~~
    - b. ~~—Each Container of Regulated Marijuana seeds that is Transferred to a Regulated Marijuana Business shall not exceed 10 pounds of Regulated Marijuana seeds.~~
  - 2. Packaging of ~~Immature Plants and~~ Genetic Material. Prior to Transfer to a Regulated Marijuana Business, ~~Immature Plants and~~ Genetic Material shall be placed into a receptacle. The receptacle may but is not required to be Child-Resistant.
  - 3. ~~Repealed. Labeling of Regulated Marijuana Seeds and Immature Plants. Prior to Transfer to a Regulated Marijuana Business, every Container of Regulated Marijuana seeds and all receptacles holding an Immature Plant shall be affixed with a label that includes at least the license number of the Regulated Marijuana Cultivation Facility where the Regulated Marijuana that produced the seeds or the Immature Plant was grown.~~
  - 4. Labeling of Genetic Material. Prior to Transfer to another Regulated Marijuana Business, every receptacle of Genetic Material shall be affixed with a label that includes at least the license number of the Regulated Marijuana Cultivation Facility Transferring the Genetic Material ~~and must be accompanied with records required in Rule 3-905.~~
- E. Packaging and Labeling of Sampling Units. Regulated Marijuana Cultivation Facilities and Regulated Marijuana Products Manufacturers shall comply with the following

minimum packaging and labeling requirements prior to Transferring any Sampling Unit to a Sampling Manager.

1. Packaging of Sampling Units. Prior to Transfer to a Sampling Manager, a Sampling Unit must be placed in a Container. If the Sampling Unit is Regulated Marijuana flower, trim, Medical Marijuana Concentrate, or Retail Marijuana Concentrate, the Container may, but is not required to, be Child-Resistant; however, the Container shall be placed into a Child-Resistant Exit Package at the point of Transfer to the Sampling Manager. If the Sampling Unit is composed of Regulated Marijuana Product, the Sampling Unit shall be packaged in a Child-Resistant Container.
2. Labeling of Sampling Units. Prior to Transfer to a Sampling Manager, every Container for a Sampling Unit shall be affixed with a label that includes at least the following information:
  - a. Required License Number. The license number for the Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer Transferring the Sampling Unit.
  - b. Batch Number(s). The relevant Harvest Batch number and/or Production Batch number from which the Sampling Unit was designated.
  - c. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than  $\frac{1}{2}$  of an inch by  $\frac{1}{2}$  of an inch, with the following statement directly below the Universal Symbol:  
**"Contains Marijuana. Keep away from children."**
  - d. Required Potency Statement.
    - i. For a Sampling Unit composed of Regulated Marijuana, Medical Marijuana Concentrate, or Retail Marijuana Concentrate, the potency of the Sampling Unit's active THC and CBD expressed as a percentage.
    - ii. For a Sampling Unit composed of Regulated Marijuana Product, the potency of the Sampling Unit's active THC and CBD expressed in milligrams. If the potency of the Sampling Unit's active THC or CBD is less than 1 milligram, the potency may be expressed as "<1 mg."
    - iii. The required potency statement shall be displayed either: (1) In a font that is bold, and enclosed within an outlined shape such as a circle or square; or (2) highlighted with a bright color, such as yellow.
  - e. Date of Transfer. The label shall include the date of Transfer to the Sampling Unit.
  - f. Patient Number. If the Sampling Unit contains Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product, the label must also

include the patient registration number of the recipient Sampling Manager.

- g. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:

- i. “This product was received as a Sampling Unit and may have been produced with undisclosed allergens, solvents, or pesticides, and may pose unknown physical or mental health risks. This product is not for resale and should not be used by anyone else.”

- F. Prohibited Transfers – All Regulated Marijuana Businesses. A Regulated Marijuana Business shall not Transfer to a Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, or Retail Marijuana Hospitality and Sales Business—and a Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, or Retail Marijuana Hospitality and Sales Business shall not accept nor offer for sale—any Regulated Marijuana that is not packaged and labeled in conformance with the requirements of these rules or that does not provide all information necessary to permit the Medical Marijuana Store, Retail Marijuana Store, Accelerator Store or Retail Marijuana Hospitality and Sales Business to package and label the Regulated Marijuana prior to Transfer to a patient or consumer. However, a Medical Marijuana Store or Retail Marijuana Store is not required to open any tamper evident Marketing Layer received from a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or a Retail Marijuana Products Manufacturer to verify the Container is Child-Resistant or labeled.

- G. Shipping Containers. Licensees may Transfer multiple Containers of Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product to a Regulated Marijuana Business in a Shipping Container.

1. Inventory Tracking System Tag Required. Licensees shall ensure that either the multiple Containers placed within a Shipping Container each have an Inventory Tracking System tag, or the Shipping Container itself must have an Inventory Tracking System tag. If the Licensee elects to place the Inventory Tracking System tag on the Shipping Container, the Shipping Container shall contain only one Harvest Batch of Regulated Marijuana, one Production Batch of Regulated Marijuana Concentrate, or one Production Batch of Regulated Marijuana Product. If a Shipping Container consists of more than one Harvest Batch or Production Batch, then each group of multiple Containers shall be affixed with an Inventory Tracking System tag. See Rule 3-805 – Inventory Tracking System; Rule 3-605 – Transport: All Regulated Marijuana Businesses.
2. Labeling of Shipping Containers. Any Shipping Container that will not be displayed to the consumer is not required to be labeled according to these rules.

- H. Packaging and Labeling of Regulated Marijuana Flower and Trim Prior to Transfer to a Pesticide Manufacturer or a Marijuana Research and Development Facility. The packaging and labeling requirements in these 3-1000 Series Rules also apply to any Transfer of Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated

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Marijuana Product to a Pesticide Manufacturer or a Marijuana Research and Development Facility.

- I. Marijuana Research and Development Facility Transfers to Persons as Part of an Approved Research Project. Any Marijuana Research and Development Facility conducting research as part of an approved Research Project involving human subjects shall comply with all packaging and labeling requirements that are applicable to a Medical Marijuana Store prior to Transfer to a patient, unless the Marijuana Research and Development Facility requests and receives in advance a waiver of specific packaging or labeling requirements in connection with the approved Research Project.
- J. Research Transfers Prohibited. A Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store shall not Transfer any Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Product, Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product to a Pesticide Manufacturer or a Licensed Research Business.
- K. ~~Repealed. Violation Affecting Public Safety. A violation of any rule in these 3-1000 Series Rules may be considered a license violation affecting public safety.~~

**Basis and Purpose – 3-1010**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(f), 44-10-203(1)(k), 44-10-203(3)(a)-(b), 44-10-601(2)(a), 44-10-601(5), 44-10-603(1)(d), 44-10-603(4)(a), and 44-10-603(8), C.R.S. The purpose of this rule is to define general packaging and labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product prior to Transfer to a patient or consumer. The labeling requirements in this rule apply to all Containers immediately containing Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. The State Licensing Authority finds it essential to regulate and establish labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product and that this is in the interest of the health and safety of the people of Colorado. This rule identifies information that is required on all labels to provide necessary information to patients and consumers to make informed decisions and first responders in the event of accidental ingestion, over ingestion or allergic reaction. This rule also seeks to minimize, to the extent practicable, the burden of labeling compliance to Licensees. This Rule 3-1010 was previously Rules M and R 1002-1, 1 CCR 212-1 and 1 CCR 212-2.

**3-1010 – Packaging and Labeling: General Requirements Prior to Transfer to a Patient or Consumer**

- A. Applicability. This Rule establishes general requirements for packaging and labeling Regulated Marijuana prior to Transfer to a patient or consumer. The labeling requirements in this Rule apply to all Containers immediately containing any Regulated Marijuana. The labeling requirements based on intended use in Rule 3-1015 are in addition to, not in lieu of, the requirements in this Rule.
  - 1. Exemption for Transfers to Consumers by a Retail Marijuana Hospitality and Sales Business. Unless otherwise provided by these rules, a Retail Marijuana Hospitality and Sales Business Transferring Retail Marijuana to consumers in

compliance with the packaging and labeling requirements of Rule 3-1020 is exempt from the requirements of this Rule.

B. Labeling Requirements – All Regulated Marijuana.

1. Font Size. Required labeling text on the Container and any Marketing Layer must be no smaller than 1/16 of an inch.
2. Labels Shall Not Be Designed to Appeal to Children. A Regulated Marijuana Business shall not place any content on a Container or the Marketing Layer in a manner that reasonably appears to target individuals under the age of 21, including but not limited to, cartoon characters or similar images.
3. False or Misleading Statements. Label(s) on a Container and any Marketing Layer shall not include any false or misleading statements.
4. Trademark Infringement Prohibited. No Container or Marketing Layer shall be intentionally or knowingly labeled so as to cause a reasonable consumer confusion as to whether the Regulated Marijuana is a trademarked product or labeled in a manner that violates any federal trademark law or regulation.
5. Health and Benefit Claims. The label(s) on the Container and any Marketing Layer shall not make any claims regarding health or physical benefits to the patient or consumer.
6. Use of English Language. Labeling text on the Container and any Marketing Layer must be clearly written or printed and in the English language. In addition to the required English label, Licensees may include an additional, accurate foreign language translation on the label that otherwise complies with these rules.
7. Unobstructed and Conspicuous. Labeling text on the Container and any Marketing Layer must be unobstructed and conspicuous. A Licensee may affix multiple labels to the Container, provided that none of the information required by these rules is obstructed and permanently hidden from view. For example and not by means of limitation, labels may be accordion, expandable, extendable or layered to permit labeling of small Containers.
8. Use of the Word “Candy” and/or “Candies” Prohibited.
  - a. Licensees shall not use the word(s) “candy” and/or “candies” on the label of any Container holding Regulated Marijuana, or of any Marketing Layer.
  - b. Notwithstanding the requirements of this subparagraph, a Regulated Marijuana Business whose identity statement contains the word(s) “candy” and/or “candies” may place its Identity Statement on the label of the Container holding Regulated Marijuana, or of any Marketing Layer.
9. Child Resistant Certificate(s). A Licensee shall maintain a copy of the certificate showing that each Child-Resistant Container into which the Licensee places Regulated Marijuana is Child-Resistant and complies with the requirements of 16

C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995) in accordance with the requirements of Rule 3-905(A).

- a. Note that this Rule does not include any later amendments or editions to the Code of Federal Regulations. The Division has maintained a copy of 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995), which is available to the public for inspection and copying during the Division's regular business hours.

10. Containers and Marketing Layers. The Container and any Marketing Layer shall have a label with all information required by these 3-1000 Series Rules. Any intermediary packaging between the Container and the Marketing Layer is not required to be labeled in accordance with these rules.

11. Exit Packages.

- a. Exit Packages Permitted for Child-Resistant Containers. A Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store may but is not required to place a Child-Resistant Container into an Opaque Exit Package at the point of Transfer to the patient or consumer.
- b. Exit Packages Required for Regulated Marijuana Flower ~~,and Trim,~~ and ~~Seeds.~~ Any Regulated Marijuana flower, or trim, ~~or seeds~~ in a Container that is not Child-Resistant shall be placed into a Child-Resistant Exit Package at the point of Transfer to a patient or consumer. The Exit Package is not required to be labeled but may include the Medical Marijuana Store's, Retail Marijuana Store's, or Accelerator Store's Identity Statement and/or Standardized Graphic Symbol.

- C. Packaging and Labeling of Regulated Marijuana Flower and Trim, and Regulated Marijuana Concentrate Prior to Transfer to a Patient or Consumer. A Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana flower and trim, Retail Marijuana flower and trim, Medical Marijuana Concentrate, or Retail Marijuana Concentrate to a patient or consumer:

1. Packaging of Regulated Marijuana Flower and Trim. Prior to Transfer to a patient or a consumer, Regulated Marijuana flower and trim shall be in a Container that does not exceed the sales limit in Rules 5-115(C) and 6-110(C). The Container may but is not required to be Child-Resistant. Any Regulated Marijuana flower and trim in a Container that is not Child-Resistant shall be placed into a Child-Resistant Exit Package at the point of Transfer to a patient or consumer.
2. Packaging of Regulated Marijuana Concentrate. Prior to Transfer to a patient or consumer, Regulated Marijuana Concentrate shall be in a Child-Resistant Container that does not exceed the sales limit in Rules 5-115(C) and 6-110(C).
  - a. A Pressurized Metered Dose Inhaler, Vaporizer Delivery Device, or syringe-type device that is within an intended use that is listed in Rule 3-1015(B) and is not an Alternative Use Product need not itself be Child-



Resistant but must be placed into a Child-Resistant Container prior to Transfer to a patient or consumer.

- b. A Pressurized Metered Dose Inhaler, Vaporizer Delivery Device, or syringe-type device with an intended use that is listed in Rule 3-1015(B) and that is not an Alternative Use Product must be labeled with at least the Universal Symbol, but is not required to include **“Contains Marijuana. Keep away from children.”**, prior to Transfer to a patient or consumer. The Universal Symbol shall be legible and no smaller than ¼ of an inch by ¼ of an inch.
  - c. A Marketing Layer or Container for a Pressurized Metered Dose Inhaler or Vaporizer Delivery Device must be affixed with a label that states **“Not approved by the FDA.”**
  - d. Nothing in this Rule authorizes the use of a syringe for any type of injection involving a needle piercing the skin.
3. Labeling of Regulated Marijuana Flower and Trim, and Regulated Marijuana Concentrate. Prior to Transfer to a patient or consumer, every Container of Regulated Marijuana flower and trim, or Regulated Marijuana Concentrate and any Marketing Layer shall be affixed with a label that includes at least the following information:
- a. Required License Number(s). The license number for each of the following:
    - i. The Regulated Marijuana Cultivation Facility where the Regulated Marijuana was grown;
    - ii. If applicable, the Regulated Marijuana Cultivation Facility(ies) where the Physical Separation-Based Medical Marijuana Concentrate or Physical Separation-Based Retail Marijuana Concentrate was produced;
    - iii. If applicable, the Regulated Marijuana Products Manufacturer where the Medical Marijuana Concentrate or Retail Marijuana Concentrate was produced; and
    - iv. The Regulated Marijuana Store that sold the Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, or Retail Marijuana Concentrate to the patient or consumer, except the Regulated Marijuana Store may affix its license number to the Container or Marketing Layer.
    - v. Retail Marijuana that was designated as Medical Marijuana pursuant to Rule 5-235, 6-230, 6-730 must be labeled with the license number of the Retail Marijuana Cultivation Facility.
    - vi. Retail Marijuana Concentrate that was designated as Medical Marijuana Concentrate pursuant to Rule 5-335, 6-335, 6-830 must

be labeled with the license number of the Retail Marijuana Products Manufacturer.

- b. Batch Numbers. The Harvest Batch Number(s) assigned to the Regulated Marijuana or the Production Batch Number(s) assigned to the Regulated Marijuana Concentrate.
- c. Statement of Net Contents. The statement of net contents must identify the net weight of the Regulated Marijuana or net weight or volume of Regulated Marijuana Concentrate prior to its placement in the Container, using a standard of measure compatible with the Inventory Tracking System.
- d. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than  $\frac{1}{2}$  of an inch by  $\frac{1}{2}$  of an inch, with the following statement directly below the Universal Symbol:  
**"Contains Marijuana. Keep away from children."**
- e. Required Potency Statement.
  - i. The potency of Regulated Marijuana flower or trim shall be expressed as: (1) the percentage of total THC and CBD from the test results for that Harvest Batch, or (2) if the Harvest Batch is not required to be tested, either as: (i) a range of percentages of total THC and CBD that extends from the lowest percentage to the highest percentage for each **e**Cannabinoid listed, from every test conducted on that strain of Regulated Marijuana cultivated by the same Regulated Marijuana Cultivation Facility during the preceding six months or (ii) an average for each **e**Cannabinoid listed, from every test conducted on that strain of Regulated Marijuana cultivated by the Regulated Marijuana Cultivation Facility during the preceding six months. If CBD is not detected in Harvest Batch, then Total CBD potency is not required.
  - ii. The potency of Medical Marijuana Concentrate's or Retail Marijuana Concentrate's Total THC and CBD shall be expressed as a percentage. If CBD is not detected in the Production Batch, then Total CBD potency is not required. The potency of Regulated Marijuana, Medical Marijuana Concentrate, and Retail Marijuana Concentrate shall be displayed either: (i) In a font that is bold, and enclosed within an outlined shape such as a circle or square; or (ii) Highlighted with a bright color such as yellow.
- f. Date of Sale. The Regulated Marijuana Store shall affix the date of sale to the patient or consumer to the Container or Marketing Layer.
- g. Patient Number. The Medical Marijuana Store shall affix the patient's registration number to the Container or Marking Layer at the time of Transfer to the patient.

- h. Solvent List. A list of any solvent(s) used to produce any Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate.
  - i. Ingredient List Including Major Allergens. If applicable, a list of all Ingredients used to manufacture the Regulated Marijuana Concentrate including identification of any major allergens contained in the Regulated Marijuana Concentrate in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010). The Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010) requires disclosure of the following major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.
    - i. Note that this Rule does not include any later amendments or editions to the United States Code. The Division maintains a copy of 21 U.S.C. § 343 (2010), which is available to the public for inspection and copying during the Division's regular business hours.
  - j. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:
    - i. **"This product was produced without regulatory oversight for health, safety, or efficacy."**
    - ii. **"There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery."**
  - k. Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers.
    - i. Ingredient List. A list of all Ingredients, including Additives, used to manufacture the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.
    - ii. Expiration Date. Effective July 1, 2022, a Marijuana Products Manufacturer that produces a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler shall include an expiration date pursuant to Rule 3-335(M).
    - iii. Storage Conditions. Effective July 1, 2022, a Marijuana Products Manufacturer that produces a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler shall include ideal storage conditions for the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler pursuant to Rule 3-335(M).
- D. Packaging and Labeling of Regulated Marijuana Product, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, and Audited Product. A Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Accelerator Manufacturer, Medical Marijuana

Store, Retail Marijuana Store, and an Accelerator Store shall comply with the following minimum packaging and labeling requirements prior to Transferring Regulated Marijuana Product:

1. Packaging of Regulated Marijuana Product. Every Regulated Marijuana Product shall be in a Child-Resistant Container at the time of Transfer to a Medical Marijuana Store or Retail Marijuana Store in accordance with the following packaging limits:
  - a. Regulated Marijuana Product Other than Edible Medical Marijuana Product or Edible Retail Marijuana Product. Medical Marijuana Product that is not Edible Medical Marijuana Product and Retail Marijuana Product that is not Edible Retail Marijuana Product shall be placed into a Child-Resistant Container that does not exceed the sales limit in Rule 5-115(C) and 6-110(C). A Pressurized Metered Dose Inhaler, Vaporizer Delivery Device, or syringe-type device that is within the intended use that is listed in Rule 3-1015(B) and is not an Alternative Use Product need not itself be Child-Resistant but must be placed into a Child-Resistant Container prior to Transfer to a patient or consumer. A Pressurized Metered Dose Inhaler, Vaporizer Delivery Device, or syringe-type device within an intended use that is listed in Rule 3-1015(B) and that is not an Alternative Use Product must be labeled with at least the Universal Symbol, but is not required to include **“Contains Marijuana. Keep away from children.”**, prior to Transfer to a patient or consumer. The Universal Symbol shall be legible and no smaller than  $\frac{1}{4}$  of an inch by  $\frac{1}{4}$  of an inch. Nothing in this Rule authorizes the use of a syringe for any type of injection involving a needle piercing the skin.
  - b. Edible Medical Marijuana Product. Every Edible Medical Marijuana Product including Liquid Edible Medical Marijuana Product shall be in a Child-Resistant Container. If the Edible Medical Marijuana Product contains multiple portions then it shall be placed into a Child-Resistant Container that is Resealable.
  - c. Edible Retail Marijuana Product. Edible Retail Marijuana Product shall be in a Child-Resistant Container as follows:
    - i. Single-Serving Edible Retail Marijuana Product. Every Single-Serving Edible Retail Marijuana Product must be placed into a Child-Resistant Container.
    - ii. Bundled Single-Serving Edible Retail Marijuana Product. Single-Serving Edible Retail Marijuana Products that are placed into a Child-Resistant Container may be bundled into a larger Marketing Layer so long as the total amount of active THC per Marketing Layer does not exceed 100 milligrams.
    - iii. Multiple-Serving Edible Retail Marijuana Product. Every Multiple-Serving Edible Retail Marijuana Product shall be placed into a

Child-Resistant Container that is Resealable and shall not exceed 100 milligrams of active THC per Container.

- d. Liquid Edible Medical Marijuana Product and Liquid Edible Retail Marijuana Product. Liquid Edible Medical Marijuana Product and Single-Serving Liquid Edible Retail Marijuana Product shall be packaged in a Child-Resistant Container:
  - i. Repealed.
  - ii. Multiple-Serving Liquid Edible Retail Marijuana Product. Each Liquid Edible Retail Marijuana Product that is a Multiple-Serving Edible Retail Marijuana Product shall be:
    - Aa. Packaged in a structure that uses a single mechanism to achieve both Child-Resistant properties and accurate pouring measurement of each liquid serving in increments equal to or less than 10 milligrams of active THC per serving, with no more than 100 milligrams of active THC total per Container; and
    - Bb. The measurement component is within the Child-Resistant cap or closure of the bottle and is not a separate component.
  - iii. Multiple-Serving Liquid Edible Medical Marijuana Product. Each Liquid Edible Medical Marijuana Product that is a Multiple-Serving Edible Medical Marijuana Product shall be:
    - Aa. Packaged in a structure that uses a single mechanism to achieve both Child-Resistant properties and accurate pouring measurement of each liquid serving; and
    - Bb. The measurement component is within the Child-Resistant cap or closure of the bottle, and is not a separate component.
- e. Audited Product. The Container containing Audited Product for administration by: (i) metered dose nasal spray or (ii) vaginal administration must be Child Resistant and labeled. A Container holding Audited Product for rectal administration need not be Child-Resistant but must be placed into a Child-Resistant Container prior to Transfer to a patient or consumer.
  - i. A metered dose nasal spray must be affixed with a label that states: **“Not approved by FDA.”**
  - ii. The Container holding Audited Product for vaginal administration and rectal administration must be affixed with a label that states: **“Not approved by FDA.”**

- iii. For example and not by means of limitation, labels may be affixed using the following methods: accordion, expandable, extendable, layered, tags, or stickers.
2. Labeling of Regulated Marijuana Product. Prior to Transfer to a Regulated Marijuana Store and a patient or consumer, every Container of Regulated Marijuana Product and any Marketing Layer shall be affixed with a label that includes at least the following information:
- a. Required License Number(s). The license number for each of the following:
    - i. ~~Repealed. The Regulated Marijuana Cultivation Facility where the Medical Marijuana or Retail Marijuana was grown;~~
    - ii. The Regulated Marijuana Products Manufacturer where the Medical Marijuana Product or Retail Marijuana Product was produced; and
    - iii. The Regulated Marijuana Store that sold the Medical Marijuana Product to a patient or consumer, except the Regulated Marijuana Store may affix its license number to the Container or Marketing Layer.
  - b. Batch Numbers. The Production Batch Number(s) assigned to the Regulated Marijuana Product.
  - c. Statement of Net Contents. The statement of net contents must identify the net weight, volume, or number of Regulated Marijuana Products prior to its placement in the Container, using a standard of measure compatible with the Inventory Tracking System.
  - d. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol:  
**“Contains Marijuana. Keep away from children.”**
  - e. Ingredient List Including Major Allergens. A list of all Ingredients used to manufacture the Regulated Marijuana Product including identification of any major allergens contained in the Regulated Marijuana Product in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010). The Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010) requires disclosure of the following major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.
    - i. Note that this Rule does not include any later amendments or editions to the United States Code. The Division maintains a copy of 21 U.S.C. § 343 (2010), which is available to the public for inspection and copying during the Division’s regular business hours.

- f. Required Potency Statement. The Target Potency or potency value determined from testing by a Regulated Marijuana Testing Facility of the Regulated Marijuana Product's active THC and CBD expressed in milligrams. If the Regulated Marijuana Product's Target Potency or potency value of THC or CBD is less than 1 milligram, the potency may be expressed as "<1 mg." If CBD is not detected in the Regulated Marijuana Product, then active CBD potency is not required. The Target Potency or potency value, shall be displayed either:
    - i. In a font that is bold, and enclosed within an outlined shape such as a circle or square; or
    - ii. Highlighted with a bright color such as yellow.
  - g. Solvent List. A list of any solvent(s) used to produce any Solvent-Based Medical Marijuana Concentrate used as a production input in any Medical Marijuana Product, or Solvent-Based Retail Marijuana Concentrate used as a production input in any Retail Marijuana Product.
  - h. Date of Sale. The Regulated Marijuana Store shall affix the date of sale to the Container or Marketing Layer at the time of Transfer to the patient or consumer.
  - i. Patient Number. The Medical Marijuana Store shall affix the patient's registration number to the Container or Marking Layer at the time of Transfer to the patient.
  - j. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:
    - i. **"This product was produced without regulatory oversight for health, safety, or efficacy."**
    - ii. **"There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery."**
- 3. Labeling of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana. Prior to Transfer to a Regulated Marijuana Store and to a patient or consumer, every Container of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana and any Marketing Layer shall be affixed with a label that includes at least the following information:
  - a. Required License Number(s). The license number for each of the following:
    - i. The Regulated Marijuana Cultivation Facility where the Medical Marijuana or Retail Marijuana was grown;

- ii. The license number of the Regulated Marijuana Business where the Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana was produced, if different than in subparagraph (3)(a)(i); and
  - iii. The Regulated Marijuana Store that sold the Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana to a patient or consumer, except the Regulated Marijuana Store may affix its license number to the Container or Marketing Layer.
- b. Batch Numbers. The Production Batch Number(s) assigned to the Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana.
- c. Statement of Net Contents. The statement of net contents must identify the net weight (excluding the paper, wrapper, filter and/or equivalent) of each Pre-Rolled Marijuana joint or Infused Pre-Rolled Marijuana joint prior to its placement in the Container and the number of joints in each Container of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana, using a standard of measure compatible with the Inventory Tracking System.
- d. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol:  
**“Contains Marijuana. Keep away from children.”**
- e. Solvent List. If applicable, a list of any solvent(s) used to produce any Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate used in the creation of Infused Pre-Rolled Marijuana.
- f. Required Potency Statement. The potency of Pre-Rolled Marijuana shall be expressed as: (1) the percentage of total THC and CBD from the test results of each Production Batch, or (2) if each Production Batch is not required to be tested, either as: (i) a range of percentages of total THC and CBD that extends from the lowest percentage to the highest percentage for each **e**Cannabinoid listed, from every test conducted for a particular type of Pre-Rolled Marijuana produced by the same Regulated Marijuana Business during the preceding six months or (ii) an average for each **e**Cannabinoid listed, from every test conducted for a particular type of Pre-Rolled Marijuana produced by the same Regulated Marijuana Business during the preceding six months. If CBD is not detected in the Production Batch, then Total CBD potency is not required. The potency of Infused Pre-Rolled Marijuana shall be expressed as the percentages of total THC and CBD from the test results of each Production Batch. If CBD is not detected in the Production Batch, then Total CBD potency is not required. The potency of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana shall be displayed either:
  - i. In a font that is bold, and enclosed within an outlined shape such as a circle or square; or



- ii. Highlighted with a bright color such as yellow.
  - g. Date of Sale. The Regulated Marijuana Store shall affix the date of sale to the Container or Marketing Layer at the time of Transfer to the patient or consumer.
  - h. Patient Number. The Medical Marijuana Store shall affix the patient's registration number to the Container or Marking Layer at the time of Transfer to the patient.
  - i. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:
    - i. **"This product was produced without regulatory oversight for health, safety, or efficacy."**
    - ii. **"There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery."**
- E. Packaging and Labeling of Seeds and Immature Plants Prior to Transfer to a Patient or Consumer. A Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store shall comply with the following minimum packaging and labeling requirements prior to Transferring seeds or Immature plants to a patient or consumer:
  - 1. Packaging of Regulated Marijuana Seeds. Prior to Transfer to a patient or consumer, Regulated Marijuana seeds shall be in a Container. ~~The Container may but is not required to be Child-Resistant. Any Regulated Marijuana seeds in a Container that is not Child-Resistant shall be placed into a Child-Resistant Exit Package at the point of Transfer to a patient or consumer.~~
  - 2. Packaging of Immature Plants. Prior to Transfer to a patient or consumer, Immature Pplants shall be placed into a receptacle. ~~The receptacle may but is not required to be Child-Resistant.~~
  - 3. Labeling of Seeds and Immature Plants. Prior to Transfer to a patient or consumer, every Container holding Regulated Marijuana seeds and any receptacle containing an Immature Pplant must be affixed with a label that includes at least the following information:
    - a. Required License Number(s). The license number for each of the following:
      - i. The Medical Marijuana Cultivation Facility where the Medical Marijuana that produced the seeds or Immature Pplant was grown, the Retail Marijuana Cultivation Facility where the Retail Marijuana that produced the seeds or the Immature Pplant was grown, or the Accelerator Cultivator where the Retail Marijuana that produced the seeds or the Immature Pplant was grown; and

- ii. The Medical Marijuana Store that sold the seeds or Immature Pplant to the patient, the Retail Marijuana Store that sold the seeds or Immature Pplant to the consumer, or the Accelerator Store that sold the seeds or Immature Pplant to the consumer.
- b. Universal Symbol. The Universal Symbol on the front of the Container holding seeds and the receptacle containing each Immature Pplant, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol: **“Contains Marijuana. Keep away from children.”**
- c. Statement of Net Contents for Seeds. A statement of net contents identifying the number of seeds in the Container.
- d. Date of Sale. The Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store shall affix the date of sale to the patient or consumer to the Container or receptacle.
- e. Patient Number. The Medical Marijuana Store shall affix the patient’s registration number to the Container or receptacle at the time of Transfer to the patient.
- f. Required Warning Statements:
  - i. **“This product was produced without regulatory oversight for health, safety, or efficacy.”**
  - ii. **“There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery.”**

F. Permissive Information.

- 1. Identity Statement. A label affixed to a Container of Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product or any Marketing Layer may include, but is not required to include, the Identity Statement and/or Standardized Graphic Symbol for:
  - a. The Regulated Marijuana Cultivation Facility(ies) where the Medical Marijuana or Retail Marijuana was grown;
  - b. The Regulated Marijuana Products Manufacturer that manufactured the Regulated Marijuana Product or Regulated Marijuana Concentrate; and/or
  - c. The Regulated Marijuana Store that sold the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product.

2. Nutritional Fact Panel. Label(s) may include, but are not required to include, a nutritional fact panel or dietary supplement fact panel in substantial conformance with 21 CFR 101.9 (2016) or 21 C.F.R. 101.36 (2016) as follows:
  - a. For Edible Medical Marijuana Products or Edible Retail Marijuana Products other than pills, capsules, and tinctures and Food-Based ~~Medical-Regulated~~ Marijuana Concentrate ~~or Food-Based Retail Marijuana Concentrate~~ the nutritional fact panel shall be in substantial conformance with the requirements of 21 C.F.R. 101.9(C) (2016) which provides the FDA's nutritional labeling requirements for food;
  - b. For pills, capsules, and tinctures, the dietary supplement fact panel shall be in substantial conformance with the requirements of 21 C.F.R. 101.36 (2016) which provides the FDA's nutritional labeling requirements for dietary supplements.
    - i. Note that this Rule does not include any later amendments or editions to the Code of Federal Regulations. The Division maintains copies of 21 C.F.R. 101.9(C) (2016) and 21 C.F.R. 101.36 (2016), which are available to the public for inspection and copying during the Division's regular business hours.
3. Other Permissive Information. The labeling requirements in the 3-1000 Series Rules provide only the minimum labeling requirements. Licensees may include additional information on the label(s) so long as such information is consistent with the requirements of these Rules.

### **Basis and Purpose – 3-1015**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(d)(IV)(A)-(C), 44-10-203(2)(f), 44-10-203(2)(w), 44-10-203(1)(a), 44-10-601(2)(a), 44-10-603(4)(a), and 44-10-603(8), C.R.S. The purpose of this rule is to define additional labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and/or Regulated Marijuana Product (except Regulated Marijuana ~~seeds and Immature Plants~~ Genetic Material) based on its intended use. These labeling requirements are in addition to, not in lieu of, the labeling requirements in Rule 3-1010. This Rule 3-1015 was previously Rules M and R 1003-1, 1 CCR 212-1 and 1 CCR 212-2. The Division and State Licensing Authority intend to monitor data regarding Regulated Marijuana use-by dates following implementation of these rules, and will make any necessary changes, including but not limited to, reducing the nine months use-by date if Licensees choose not to conduct stabilization studies.

### **3-1015 – Additional Labeling Requirements Prior to Transfer to a Patient or Consumer**

- A. Applicability. This Rule establishes additional labeling requirements for Regulated Marijuana (except ~~Genetic Material~~ ~~seeds and Immature Plants~~), Regulated Marijuana Concentrate, and Regulated Marijuana Product prior to Transfer to a patient or consumer. The labeling requirements in this Rule apply to all Containers immediately containing Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated

Marijuana Product. These labeling requirements based on intended use are in addition to, not in lieu of, the requirements in Rule 3-1010.

1. Exemption for Transfers to Consumers by a Retail Marijuana Hospitality and Sales Business. Unless otherwise provided by these rules, a Retail Marijuana Hospitality and Sales Business Transferring Retail Marijuana to consumers in compliance with the packaging and labeling requirements of Rule 3-1020 is exempt from the requirements of this Rule.
- B. Additional Information Required on Every Container (Except ~~Seeds and Immature Plants~~Genetic Material) Prior to Transfer to a Patient or Consumer. Prior to Transfer to a patient or consumer, every Container of Regulated Marijuana (except ~~seeds and Immature Plants~~Genetic Material), Regulated Marijuana Concentrate, or Regulated Marijuana Product and any Marketing Layer must have a label that includes at least the following additional information.
  1. Statement of Intended Use. The Container and any Marketing Layer shall identify one or more intended use(s) for Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, and Retail Marijuana Product from the following exclusive list:
    - a. Inhaled Product:
      - i. Flower, shake, or trim;
      - ii. Pre-Rolled Marijuana and Infused-Pre-Rolled Marijuana;
      - iii. Solvent-Based Medical Marijuana Concentrate;
      - iv. Solvent-Based Retail Marijuana Concentrate;
      - v. Physical Separation-Based Medical Marijuana Concentrate;
      - vi. Physical Separation-Based Retail Marijuana Concentrate;
      - vii. Heat/Pressure-Based Medical Marijuana Concentrate;
      - viii. Heat/Pressure-Based Retail Marijuana Concentrate;
      - ix. Vaporizer Delivery Device;
      - x. Pressurized Metered Dose Inhaler.
    - b. For Oral Consumption:
      - i. Food or drink infused with Regulated Marijuana;
      - ii. Regulated Marijuana Concentrate intended to be consumed orally;
      - iii. Pills and capsules;
      - iv. Tinctures.
    - c. Skin and Body Products:
      - i. Topical;

- ii. Transdermal.
  - d. Audited Product:
    - i. Metered Dose Nasal Spray;
    - ii. Vaginal Administration;
    - iii. Rectal Administration.
- 2. Inhaled Product. The “Inhaled Product” intended use may be used only for products intended for consumption by smoking or Vaporizer Delivery Device where the product is heated or burned prior to consumption, or through use of a Pressurized Metered Dose Inhaler. The label(s) on all inhaled product intended use shall also include:
  - a. The potency statement required by Rule 3-1010 for: (1) flower, shake, or trim, (2) Pre-Rolled Marijuana, (3) Infused-Pre-Rolled Marijuana, (4) Solvent-Based Medical Marijuana Concentrate, (5) Solvent-Based Retail Marijuana Concentrate, (6) Physical Separation-Based Medical Marijuana Concentrate, (7) Physical Separation-Based Retail Marijuana Concentrate, (8) Heat/Pressure-Based Medical Marijuana Concentrate, (9) Heat/Pressure-Based Retail Marijuana Concentrate shall be stated as the percentage of Total THC and CBD. If CBD is not detected, then total CBD potency is not required.
  - a.5. Use-By Date for Inhaled Products Other Than Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers. Effective January 1, 2024, a product use-by date, upon which the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product will no longer be fit for consumption, or upon which the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product will no longer be optimally fresh. Once a label with a use-by date has been affixed to a Container containing Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product and any Marketing Layer, a Licensee shall not alter that use-by date or affix a new label with a later use-by date. The use-by date shall not be longer than nine months from the harvest or production date, unless shelf stability testing, including but not limited to potency, microbial, and water activity testing, supports a longer shelf life. All use-by dates must be entered into the Inventory Tracking System prior to Transfer. Prior to Transfer to a patient or consumer, a Regulated Marijuana Store or Accelerator Store must inform the patient or consumer if the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product is past its use-by date.
  - a.6. Expiration Date for Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers. Licensees must identify an expiration date upon which the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler will no longer be fit for consumption in accordance with Rule 3-335(M). Once a label with an expiration date has been affixed to a Container containing a

Vaporizer Delivery Device or Pressurized Metered Dose Inhaler and any Marketing Layer, a Licensee shall not alter that expiration date or affix a new label with a later expiration date. All expiration dates must be entered into the Inventory Tracking System prior to Transfer.

- b. The potency statement required by Rule 3-1010 for Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers shall be stated as either the percentage of Total THC and CBD, or the number of milligrams of Total THC and CBD, per cartridge, pen, or inhaler. If the potency value for Total THC or CBD of the Vaporizer Delivery Devices or Pressurized Metered Dose Inhalers is less than one milligram, the potency may be expressed as "<1 mg." If CBD is not detected in the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler, then total CBD potency is not required.
- c. Additional Labeling Requirement for Regulated Marijuana Concentrate to Promote Consumer Health and Awareness: Effective January 1, 2023, if a Regulated Marijuana Concentrate that is an Inhaled Product cannot easily be measured or separable to the recommended serving size established under Rule 3-335(D)(3)(d) and (4)(f), the Regulated Marijuana Manufacturer that manufactures the Regulated Marijuana Concentrate must:
  - i. Affix the Container of Regulated Marijuana Concentrate with a measuring device that permits the patient or consumer to measure each serving in a manner consistent with the recommended serving established under Rule 3-335(D); or
  - ii. Include a label on the Container of Regulated Marijuana Concentrate that provides instructions to allow the patient or consumer to measure each recommended serving pursuant to Rule 3-335(D).
- 3. For Oral Consumption. The label(s) on all Edible Medical Marijuana Products and Edible Retail Marijuana Products, including but not limited to confections, liquids, pills, capsules and tinctures, shall also include:
  - a. Potency Statement. The potency statement required by Rule 3-1010 shall be stated as: (1) milligrams of active THC and CBD per serving and (2) milligrams of active THC and CBD per Container where the Container contains more than one serving. The Target Potency may be used to fulfill the requirement of this Rule. If CBD is not detected, then active CBD potency is not required.
    - i. If the Edible Medical Marijuana Product's or Edible Retail Marijuana Product's Target Potency or potency value of active THC or CBD is less than one milligram per serving, the potency may be expressed as "<1 mg." If "<1 mg" was used to display the active THC or CBD per serving, then a corresponding statement regarding the total THC or CBD content for the entire Container

shall be included on the Container. For example, if there are five servings in the Container, "<5 mg" should be displayed for the active THC or CBD statement that was represented as "<1 mg" per serving.

- b. Additional Warning Statement Required. The following additional warning statement shall be included on the label on the Container or Marketing Layer for all Edible Medical Marijuana Product and Edible Retail Marijuana Product: **"The intoxicating effects of this product may be delayed by up to 4 hours."**
  - c. Expiration/Use-By Date. A product expiration date, upon which the Edible ~~Medical~~Regulated Marijuana Product ~~or Edible Retail Marijuana Product~~ will no longer be fit for consumption, or a use-by-date, upon which the Edible Medical Marijuana Product or Edible Retail Marijuana Product will no longer be optimally fresh. Once a label with an expiration or use-by date has been affixed to a Container containing an Edible ~~Regulated~~Medical Marijuana Product ~~or Edible Retail Marijuana Product~~ and any Marketing Layer, a Licensee shall not alter that expiration or use-by date or affix a new label with a later expiration or use-by date. All expiration or use-by dates must be entered into the Inventory Tracking System prior to Transfer.
    - i.        Prior to Transfer to a patient or consumer, a Regulated Marijuana Store or Accelerator Store must inform the patient or consumer if the Edible ~~Medical~~Regulated Marijuana Product ~~or Edible Retail Marijuana Product~~ is past its ~~expiration or~~ use-by date.
    - ii.        If an Edible Regulated Marijuana Product is labeled with an expiration date, a Regulated Marijuana Store shall not Transfer the product to a patient or consumer.
  - d. Production Date. The date on which the Edible ~~Medical~~Regulated Marijuana Product ~~or Edible Retail Marijuana Product~~ was produced which may be included in the Batch Number required by Rule 3-1010.
  - e. Statement Regarding Refrigeration. If an Edible ~~Medical~~Regulated Marijuana Product ~~or Edible Retail Marijuana Product~~ is perishable, a statement that the product must be refrigerated.
4. Skin and Body Products (Topical and Transdermal). The "Skin and Body Products" intended use may be used only for products intended for consumption by topical or transdermal application, and must be intended for external use only. The label(s) on all skin and body products shall also include:
- a. Topical Product Potency Statement. For topical product the potency statement required by Rule 3-1010 shall be stated as the number of milligrams of active THC and CBD per Container. The Target Potency may be used to fulfill the requirement of this Rule. If CBD is not detected, then active CBD potency is not required. If the THC or CBD comprises



less than one percent of the total ~~e~~Cannabinoids, the potency may be expressed as less than one percent of the total ~~e~~Cannabinoids.

- b. Transdermal Product Potency Statement. For transdermal product, the potency statement required by Rule 3-1010 shall be stated as the number of milligrams of active THC and CBD per transdermal product, and the total number of milligrams of active THC and CBD per Container. The Target Potency may be used to fulfill the requirement of this Rule. If CBD is not detected, then active CBD potency is not required.

- i. If the transdermal product's Target Potency or potency value of active THC or CBD is less than one milligram per transdermal product, the potency may be expressed as "<1 mg." If "<1 mg" was used to display the active THC or CBD per transdermal product, then a corresponding statement regarding the total THC or CBD content for the entire Container shall be included on the Container. For example, if there are five servings in the Container, "<5 mg" should be displayed for the active THC or CBD statement that was represented as "<1 mg" per serving.

- c. Expiration/Use-By Date. A product ~~expiration-or~~ use-by date, after which the skin and body product will no longer be fit for use. Once a label with an ~~expiration-or~~ use-by date has been affixed to any Container holding a skin and body product and any Marketing Layer, a Licensee shall not alter that ~~expiration-or~~ use-by date or affix a new label with a later ~~expiration-or~~ use-by date. All ~~expiration-or~~ use-by dates must be entered into the Inventory Tracking System prior to Transfer. Prior to Transfer to a patient or consumer, a Regulated Marijuana Store or Accelerator Store must inform the patient or consumer if the skin and body product is past its ~~expiration-or~~ use-by date.

- d. ~~Repealed Production Date. The date on which the skin and body product was produced which may be included in the Batch Number required by Rule 3-1010.~~

5. Audited Product. Packaging and labeling for all Audited Products: (i) metered dose nasal spray, (ii) vaginal administration, or (iii) rectal administration shall include:

- a. All packaging and labeling requirements required by this 3-1000 Series for Regulated Marijuana Products; except Rules 5-325 and 6-325 control where the context otherwise clearly requires.
- b. Audited Product shall be packaged and labeled for Transfer to a patient or consumer prior to Transfer from a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer.
- c. Expiration/Use-By Date. A product expiration date that is appropriate for the Audited Product when stored at room temperature as verified by testing required by Rules 5-325 and 6-325. Once a label with an



expiration date has been affixed to a Container containing an Audited Product, a Licensee shall not alter that expiration date, or affix a new label with a later expiration date. All expiration ~~or use-by~~ dates must be entered into the Inventory Tracking System prior to Transfer. ~~Prior to Transfer to a patient or consumer, a Regulated Marijuana Store or Accelerator Store must inform the patient or consumer if the Audited Product is past its expiration or use-by date.~~

- d. ~~Repealed. Production Date. The date on which the Audited Product was produced, which may be included in the Batch Number required by Rule 3-1010.~~

C. No Other Intended Use Permitted. No intended use other than those identified in this Rule shall be identified on any label, except as permitted by an Alternative Use Designation approved by the State Licensing Authority pursuant to Rules 5-325 and 6-325. Licensees shall accurately identify all intended use(s) from the exclusive list of intended uses in this Rule, or as required by the Alternative Use Designation, on the label.

1. Alternative Use Product. No Regulated Marijuana Business shall Transfer or accept an Alternative Use Product unless the Alternative Use Product received an Alternative Use Designation in accordance with Rules 5-325 and 6-325 and complied with all the requirements of Rules 5-325, 6-325, and 3-1005 through 3-1015, and with any additional packaging and labeling requirements identified in the Alternative Use Designation. At a minimum the label(s) on all Alternative Use Products shall include:

- a. All packaging and labeling requirements applicable to the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer by these 3-1000 Series Rules unless inconsistent with the Alternative Use Designation in which case the Alternative Use Designation shall control.
- b. Expiration/Use-By Date. A product expiration date that is appropriate for the Alternative Use Product when stored at room temperature as verified by a Regulated Marijuana Testing Facility. Once a label with an expiration date has been affixed to a Container containing Alternative Use Product, a Licensee shall not alter that expiration date, or affix a new label with a later expiration date.
- c. ~~Repealed. Production Date. The date on which the Alternative Use Product was produced, which may be included in the Batch Number required by Rule 3-1010.~~
- d. All other requirements identified by the Alternative Use Designation.

D. Multiple Intended Uses. Any Regulated Marijuana having more than one intended use shall identify every intended use on the label and shall comply with all labeling requirements for each intended use. If there is any conflict between the labeling requirements for multiple intended uses, the most restrictive labeling requirements shall

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be followed. Licensees shall not counsel or advise any patient or consumer to use Regulated Marijuana other than in accordance with the intended use(s) identified on the label.

- E. ~~Repealed. Decontaminated Product. Effective July 1, 2025, if a Licensee chooses to Decontaminate Regulated Marijuana following a failed test result, the Licensee must have the Division established label on every Container of the Decontaminated Regulated Marijuana flower, shake, trim, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana.~~

**Basis and Purpose – 3-1020**

The statutory authority for this rule includes but is not limited to 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to define minimum packaging and labeling requirements for Retail Marijuana Hospitality and Sales Businesses.

**3-1020 – Packaging and Labeling: Requirements for Transfers to a Consumer at a Retail Marijuana Hospitality and Sales Business**

- A. Applicability. This Rule establishes minimum requirements for packaging and labeling Retail Marijuana Transferred to a consumer at a Retail Marijuana Hospitality and Sales Business.
- B. Packaging and Labeling Exemptions and Minimum Requirements. A Retail Marijuana Hospitality and Sales Business may Transfer Retail Marijuana to a consumer without packaging and labeling under the following conditions:
1. The consumer intends to consume the Retail Marijuana on the Licensed Premises of the Retail Marijuana Hospitality and Sales Business;
  2. At the time of Transfer to a consumer, the Retail Marijuana Hospitality and Sales Business provides the consumer with a written statement of the potency of the Retail Marijuana's active THC and CBD, which shall be expressed as a percentage for Retail Marijuana and Retail Marijuana Concentrate, and expressed in milligrams for Retail Marijuana Product. If CBD is not detected in the Retail Marijuana, then active CBD potency is not required;
  3. The Retail Marijuana Hospitality and Sales Business maintains within the Restricted Access Area of the Licensed Premises—and makes available to the consumer upon request—written or electronic documentation reflecting all relevant information required in Rules 3-1010 and 3-1015; and
  4. For Multiple-Serving Edible Retail Marijuana Product or Multiple-Serving Liquid Edible Retail Marijuana Product, the Retail Marijuana Hospitality and Sales Business shall at the time of Transfer to the consumer provide a measurement device necessary for the consumer to achieve accurate measurements of each serving in increments equal to or less than 10 milligrams of active THC per serving.

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- C. Packaging and Labeling Required Before Retail Marijuana is Removed from the Licensed Premises. Prior to a consumer removing any unconsumed Retail Marijuana from the Licensed Premises, the Retail Marijuana Hospitality and Sales Business shall:
1. Provide the consumer with written or electronic documentation reflecting all relevant information required in Rules 3-1010 and 3-1015; and
  2. Place the unconsumed Retail Marijuana into a Child-Resistant Container, or if the Container is not Child-Resistant, a Child-Resistant Exit Package. The Container must be affixed with a label that includes at least the following:
    - a. Universal Symbol. The Universal Symbol on the Container, no smaller than ½ inch by ½ inch, with the following statement directly below the Universal Symbol: “**Contains Marijuana. Keep away from children.**”; and
    - b. Required Potency Statement. A written statement of the potency of the Retail Marijuana’s total THC and CBD expressed as a percentage. A written statement of the potency of the Retail Marijuana Product’s active THC and CBD expressed in milligrams. If the potency of the Regulated Marijuana Product’s active THC or CBD is less than 1 milligram, the potency may be expressed as “<1 mg.” If CBD is not detected in the Retail Marijuana, then active CBD potency is not required.
    - c. For Multiple-Serving Edible Retail Marijuana Product or Multiple-Serving Liquid Edible Retail Marijuana Product, the Retail Marijuana Hospitality and Sales Business shall provide a measurement device necessary for the consumer to achieve accurate measurements of each serving in increments equal to or less than 10 milligrams of active THC per serving.
- D. Additional Packaging and Labeling Requirements for Retail Marijuana Hospitality and Sales Businesses.
1. Font Size. Required labeling text on the Container must be no smaller than 1/16 of an inch.
  2. Labels Shall Not Be Designed to Appeal to Children. A Retail Marijuana Hospitality and Sales Business shall not place any content on a Container that reasonably appears to target individuals under the age of 21, including but not limited to, cartoon characters or similar images.
  3. False or Misleading Statements. Label(s) on a Container shall not include any false or misleading statements.
  4. Trademark Infringement Prohibited. No Container shall be intentionally or knowingly labeled so as to cause a reasonable consumer confusion as to whether the Retail Marijuana is a trademarked product or labeled in a manner that violates any federal trademark law or regulation.
  5. Health and Benefit Claims. The label(s) on the Container shall not make any claims regarding health or physical benefits to the consumer.

6. Use of English Language. Labeling text on the Container must be clearly written or printed and in the English language. In addition to the required English label, Licensees may include an additional, accurate foreign language translation on the label that otherwise complies with these rules.
7. Unobstructed and Conspicuous. Labeling text on the Container must be unobstructed and conspicuous. A Licensee may affix multiple labels to the Container, provided that none of the information required by these rules is obstructed. For example and not by means of limitation, labels may be accordion, expandable, extendable or layered to permit labeling of small Containers.
8. Use of the Word “Candy” and/or “Candies” Prohibited. Licensees shall not use the word(s) “candy” and/or “candies” on the label of any Container.
9. Child Resistant Certificate(s). A Licensee shall maintain a copy of the certificate showing that each Child-Resistant Container into which the Licensee places Retail Marijuana is Child-Resistant and complies with the requirements of 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995) in accordance with the requirements of Rule 3-905(A). Note that this Rule does not include any later amendments or editions to the Code of Federal Regulations. The Division has maintained a copy of 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995), which is available to the public for inspection and copying during the Division’s regular business hours.

### **Basis and Purpose – 3-1025**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(f), 44-10-203(1)(k), 44-10-203(3)(a)-(b) The purpose of this rule is to define minimum packaging and labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product Transferred to a Regulated Marijuana Testing Facility. The labeling requirements in this rule apply to all Containers immediately containing Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product being Transferred to a Regulated Marijuana Testing Facility.

### **3-1025 – Packaging and Labeling: Minimum Requirements for Test Batch Transfers to a Regulated Marijuana Testing Facility**

- A. Applicability. This Rule establishes minimum requirements for packaging and labeling of Regulated Marijuana Test Batches prior to Transfer to a Regulated Marijuana Testing Facility. The labeling requirements in this Rule apply to all Containers immediately containing Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, and Retail Marijuana Product.
- B. Packaging and Labeling of Test Batches of Regulated Marijuana Flower, Trim, Wet Whole Plant, and Regulated Marijuana Concentrate, Prior to Transfer to a Regulated Marijuana Testing Facility. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Test Batches of Medical Marijuana flower, trim, wet whole plant, or Medical Marijuana Concentrate to a Medical Marijuana Testing Facility, and prior to Transferring Test

Batches of Retail Marijuana flower, trim, wet whole plant, or Retail Marijuana Concentrate to a Retail Marijuana Testing Facility:

1. Packaging of Test Batches of Regulated Marijuana Flower, Trim, Wet Whole Plant and Regulated Marijuana Concentrate.
  - a. A Licensee shall submit Test Batches of Regulated Marijuana flower, trim, wet whole plant, or Regulated Marijuana Concentrate in a transparent Container to allow for the Sample Increments of the Test Batch to be photo documented.
  - b. Each Container containing a Test Batch of Regulated Marijuana flower, trim, or wet whole plant shall have at least 20% empty space. Test Batch Containers shall not be completely full so that individual Sample Increments of the Test Batch can be photo documented.
  - c. Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers. Test Batches from Production Batches of Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers must be packaged in the hardware or inhaler, respectively, that allows for the consumption.
2. Labeling of Test Batches of Regulated Marijuana Flower, Trim, Wet Whole Plant and Regulated Marijuana Concentrate. Prior to Transfer to a Regulated Marijuana Testing Facility, every Container containing a Test Batch of Regulated Marijuana flower, trim, wet whole plant, or Regulated Marijuana Concentrate shall be affixed with a label that includes at least the following information, some of which may be included on the Inventory Tracking System Inventory Tracking System-Tag:
  - a. For Test Batches from Harvest Batches, the license number of the Medical Marijuana Cultivation Facility where the Medical Marijuana was grown, or the Retail Marijuana Cultivation Facility where the Retail Marijuana was grown;
  - b. For Test Batches of Concentrates from Production Batches, the license number of the Medical Marijuana Products Manufacturer(s) where the Medical Concentrate was produced, or the Retail Marijuana Products Manufacturer(s) where the Retail Marijuana Concentrate was produced; and
  - c. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Regulated Marijuana or Regulated Marijuana Concentrate prior to its placement in the Container.
- C. Packaging and Labeling of Test Batches of Regulated Marijuana Product Prior to Transfer to a Regulated Marijuana Testing Facility. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Test Batches of Regulated Marijuana Product to a Regulated Marijuana Testing Facility:
  1. Packaging Test Batches of Regulated Marijuana Product.

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- a. Prior to any Transfer of a Test Batch to a Regulated Marijuana Testing Facility, the Test Batch of Regulated Marijuana Product subject to testing shall be placed into the Container(s) in which the rest of the Production Batch will be sold. The Container may but is not required to be Child-Resistant.
  2. Labeling of Test Batches of Regulated Marijuana Product. Prior to Transfer to a Regulated Marijuana Testing Facility, every Container containing a Test Batch of Regulated Marijuana Product shall be affixed with a label, which can be noted on the Inventory Tracking System Inventory Tracking System Tag, that includes at least the following information:
    - a. The license number of the Medical Marijuana Products Manufacturer or the Retail Marijuana Products Manufacturer that produced the Regulated Marijuana Product;
    - b. The Production Batch Number(s) assigned to the Regulated Marijuana Product;
    - c. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Regulated Marijuana Product prior to its placement in the Container; and
    - d. The serving size, number of serving per package, and the Target Potency as required for a Regulated Marijuana Testing Facility to assess potency variance.
- D. Packaging and Labeling of Test Batches of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana. Prior to Transfer to a Regulated Marijuana Testing Facility. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Test Batches of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana to a Medical Marijuana Testing Facility, and prior to Transferring Test Batches of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana to a Retail Marijuana Testing Facility:
1. Packaging of Test Batches of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana.
    - a. Prior to any Transfer of a Test Batch to a Regulated Marijuana Testing Facility, the Test Batch of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana subject to testing shall be placed into the Container(s) in which the rest of the Production Batch will be sold. The Container may but is not required to be Child-Resistant.
  2. Labeling of Test Batches of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana. Prior to Transfer to a Regulated Marijuana Testing Facility, every Container containing a Test Batch of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana shall be affixed with a label that includes at least the following information, some of which may be included on the Inventory Tracking System Inventory Tracking System Tag:

- a. For Test Batches from Harvest Batches, the license number of the Medical Marijuana Cultivation Facility where the Medical Marijuana was grown, or the Retail Marijuana Cultivation Facility where the Retail Marijuana was grown which was used to create Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana;
- b. For Test Batches of Concentrates from Production Batches, the license number of the Medical Marijuana Products Manufacturer(s) where the Medical Concentrate was produced, or the Retail Marijuana Products Manufacturer(s) where the Retail Marijuana Concentrate was produced which was used to create Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana;
- c. The Production Batch Number(s) assigned to the Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana; and
- d. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Regulated Marijuana or Regulated Marijuana Concentrate prior to its placement in the Container.

### **3-1100 Series – Accelerator Program Operations**

#### **Basis and Purpose – 3-1105**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(aa), 44-10-310(2), and 44-10-311(2), C.R.S. The purpose of this rule is to establish requirements for Accelerator-Endorsed Licensees and Accelerator Licensees participating in the accelerator program. The Accelerator Program permits different structures. The first option is for the Accelerator-Endorsed Licensee and the Accelerator Licensee to have a mentor/apprentice relationship at the same premises pursuant to Rules 3-1105 and 3-1110. The second option is for the Accelerator-Endorsed Licensee and the Accelerator Licensee to have a separate premises relationship pursuant to Rules 3-1105 and 3-1115.

#### **3-1105 – Accelerator Program Participation and Privileges**

- A. Licensed Premises. An Accelerator Licensee may share a Licensed Premises or operate at a separate premises of a Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, or Retail Marijuana Store that is an Accelerator-Endorsed Licensee.
  1. Shared Premises. An Accelerator Licensee may share the Licensed Premises of a Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, or Retail Marijuana Store pursuant to this Rule 3-1105 and Rule 3-1110. The Accelerator Licensee may share the Licensed Premises with a Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, or Retail Marijuana Store that is the Accelerator-Endorsed Licensee and is co-located with a Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Medical Marijuana Store, respectively.
  2. Separate Premises. An Accelerator Licensee participating in the accelerator program may operate at a separate premises of a Retail Marijuana Cultivation

Facility, Retail Marijuana Products Manufacturer, or Retail Marijuana Store pursuant to this Rule 3-1105 and Rule 3-1115.

B. Number of Licenses held by an Accelerator Licensee.

1. An Accelerator Licensee may initially apply to be an Accelerator Cultivator, Accelerator Manufacturer or Accelerator Store and hold a single license.
2. After 180 days of demonstrated operations, an Accelerator Licensee may apply for additional accelerator licenses, which may include different accelerator license types. An Accelerator Licensee may not apply for more than one accelerator license until at least 180 days of demonstrated operations.
3. A Controlling Beneficial Owner who holds an accelerator license shall not have an Owner's Interest in more than three of the same accelerator license type. No Controlling Beneficial Owner shall have an Owner's Interest in more than nine total accelerator licenses.

C. Accelerator-Endorsed Licensee Required Equity Assistance Proposal.

1. An Accelerator-Endorsed Licensee must disclose its equity assistance proposal to the Division and to any prospective Social Equity Licensee pursuant to Rule 2-285 and these 3-1100 Series Rules prior to entering any contractual agreements with an Accelerator Licensee.
2. Required Information. An equity assistance proposal must detail the technical, compliance, and/or capital assistance the Accelerator-Endorsed Licensee intends to provide an Accelerator Licensee. All equity assistance proposals must, at a minimum, including the following:
  - a. The types of assistance the Accelerator-Endorsed Licensee intends to provide, which may include but is not limited to, the following types of assistance:
    - i. Accounting;
    - ii. Business services (e.g. sales and marketing);
    - iii. Financial or capital support;
    - iv. Information technology support;
    - v. Access to legal services from an attorney licensed in the state of Colorado; or
    - vi. Regulatory compliance support.
  - b. Whether the Accelerator-Endorsed Licensee intends to subcontract with any third parties to provide technical or compliance assistance, and the identity of the prospective third parties, if known;
  - c. Any applicable timelines associated with the provisions of the assistance the Accelerator-Endorsed Licensee intends to provide;



- d. Whether the Accelerator-Endorsed Licensee intends to charge rent for a prospective Accelerator Licensee's use of the premises, and the amount of rent and required deposits, if applicable;
    - e. How the Accelerator-Endorsed Licensee plans to protect or minimize disruptions on a prospective Accelerator Licensee in the event of a change of Controlling Beneficial Owner of the Accelerator-Endorsed Licensee's license; and
    - f. Whether the Accelerator-Endorsed Licensee has been subject to any administrative action by the State Licensing Authority or the Local Jurisdiction within the preceding two years and, if so, whether there are any restrictions on the Licensee as a result of such administrative action.
  - 3. Voluntary Information. An equity assistance proposal may, but is not required to, include additional information about the Accelerator-Endorsed Licensee, including but not limited to the following:
    - a. The Accelerator-Endorsed Licensee's business objectives and organizational values;
    - b. A description of the Accelerator-Endorsed Licensee's work environment;
    - c. Information regarding the Accelerator-Endorsed Licensee's business profile, including company size, revenue, and distribution capabilities;
    - d. Any educational or training assistance provided to the Accelerator Licensee in navigating human resources matters; and
    - e. Any other information that may be useful to informing prospective Accelerator Licensees and determining compatibility between an Accelerator-Endorsed Licensee and Accelerator Licensee.
  - 4. Modification of Equity Assistance Proposal. Nothing in these rules shall preclude an Accelerator-Endorsed Licensee from amending or modifying its equity assistance proposal. The Accelerator-Endorsed Licensee shall submit the updated equity assistance proposal to the Division within 30 days of finalizing any such amendments or modifications.
  - 5. The Accelerator-Endorsed Licensee may request that a prospective Social Equity Licensee enter into a non-disclosure agreement prior to providing the prospective Social Equity Licensee a copy of the Accelerator-Endorsed Licensee's equity assistance proposal in order to ensure the information remains confidential.
- D. Equity Partnership Agreement – General Requirements. Prior to hosting or offering technical and/or capital support to an Accelerator Licensee, an Accelerator-Endorsed Licensee must first enter into an equity partnership agreement with the Accelerator Licensee. In addition to any other requirements in Rules 3-1110 and 3-1115, an equity partnership agreement must include the following minimum requirements:
- 1. The equity partnership agreement must be executed by both the Accelerator-Endorsed Licensee and the Accelerator Licensee.

2. The executed equity partnership agreement must represent the full legal and business relationship between the Accelerator-Endorsed Licensee and Accelerator Licensee unless additional agreements are permitted or required pursuant to Rules 3-1110 or Rule 3-1115.
  3. The executed equity partnership agreement shall at a minimum, include the following:
    - a. A description of the types of technical, compliance, and/or capital assistance the Accelerator-Endorsed Licensee is providing to the Accelerator Licensee;
    - b. The timeline associated with the assistance the Accelerator-Endorsed Licensee is providing;
    - c. If the Accelerator-Endorsed Licensee is charging rent for the Accelerator Licensee's use of the Licensed Premises, the rent amount, any required deposits, and length of lease;
    - d. How the Accelerator-Endorsed Licensee will protect or minimize disruptions to the Accelerator Licensee in the event of a change of owner of the Accelerator-Endorsed Licensee's license;
    - e. Conditions for amendments to the equity partnership agreement; and
    - f. Conditions for dissolution of the equity partnership agreement.
  4. An Accelerator-Endorsed Licensee must provide technical, compliance, and/or capital assistance to an Accelerator Licensee pursuant to its equity partnership agreement with an Accelerator Licensee. An Accelerator-Endorsed Licensee may provide technical and/or compliance assistance to an Accelerator Licensee through third parties. However, an equity partnership agreement cannot require an Accelerator Licensee to receive such assistance from a specific provider unless permitted pursuant to Rule 3-1115.
- E. There shall not be any agreement(s) or contracts between the Accelerator-Endorsed Licensee and the Accelerator Licensee that are not disclosed to the Division.
- F. Dissolution of Business Relationship. If the business relationship between the Accelerator-Endorsed Licensee and Accelerator Licensee dissolves, both parties must notify the Division within 10 days. The notification of dissolution must include the reasons for the dissolution of the business relationship between the Accelerator-Endorsed Licensee and Accelerator Licensee.
1. The Accelerator Licensee will have until renewal of the Accelerator License to identify a new Accelerator-Endorsed Licensee or apply for a new Regulated Marijuana Business license unless this deadline is extended by the Division. The Division may waive or reduce the application and/or licensing fees affiliated with the application. However, the Accelerator Licensee cannot operate without a Licensed Premises or an executed and valid equity partnership agreement with an Accelerator-Endorsed Licensee.

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2. Upon notification of dissolution of the accelerator business relationship, the Division will determine whether the Accelerator-Endorsed Licensee retains the social equity leader designation for that calendar year.
- G. Additional Privileges for Accelerator-Endorsed Licensees.
1. Social Equity Leader Designation. A Retail Marijuana Store, Retail Marijuana Cultivation Facility, or Retail Marijuana Products Manufacturer that is an Accelerator-Endorsed Licensee and that is operating under an equity partnership agreement with an Accelerator Licensee may be designated by the Division as a social equity leader for each year the Accelerator-Endorsed Licensee hosts an Accelerator Licensee on its premises. A social equity leader may use a logo or symbol created or approved by the Division to indicate its leadership status. The Accelerator-Endorsed Licensee may only use the social equity leader logo or symbol while the designation remains valid.
  2. Mitigation. The Division and the State Licensing Authority may consider a social equity leader designation as a mitigating factor when determining the initiation of administrative action or assessment of penalties.
  3. Compliance Assistance and Education Engagement. For an Accelerator-Endorsed Licensee operating under an equity partnership agreement with an Accelerator Licensee, the Division will conduct an on-site compliance assistance and education engagement with the Accelerator-Endorsed Licensee for purposes of supporting the Licensee's activities as an Accelerator-Endorsed Licensee.
  4. Application and License Fee Exemptions. An Accelerator-Endorsed Licensee may submit a request to the State Licensing Authority for an exemption from application and license fees for a change of Controlling Beneficial Owner, or change of location, ~~or modification of premises~~ that is directly related to its participation in the accelerator program.
    - a. The request for an exemption may be included with the submission of the application for which it is requesting an exemption from fees. The request for exemption must include any information demonstrating the application is related to its participation in the accelerator program, including but not limited to, the positive impact to the Accelerator Licensee.
    - b. If a request for an exemption is denied, the Applicant shall submit required fees within 10 days from notice that the fee exemption request was denied. Failure to submit required fees may result in denial of the application.

**Basis and Purpose – 3-1110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(aa), 44-10-310(2), and 44-10-311(2), C.R.S. The purpose of this rule is to establish requirements for Accelerator-Endorsed Licensees and Social Equity Licensees to participate in the accelerator program. This option is for the Accelerator-Endorsed Licensee and the Social Equity Licensee to have a mentor/apprentice type relationship pursuant to Rules 3-1105 and 3-1110.

**3-1110 – Accelerator Shared Premises**

- A. Equity Assistance Plan – Additional Requirements. In addition to all equity assistance proposal requirements outlined in Rule 3-1105(C)(1), an Accelerator-Endorsed Licensee intending to share its Licensed Premises with an Accelerator Licensee must also include the following in its equity assistance proposal:
1. How the Accelerator-Endorsed Licensee will protect or minimize disruptions to a prospective Accelerator Licensee in the event of a change of location of the Accelerator-Endorsed Licensee's Licensed Premises;
  2. The extent to which the Accelerator-Endorsed Licensee will provide equipment, ingredients, or other resources to an Accelerator Licensee pursuant to an equity partnership agreement.
- B. Equity Partnership Agreement – Additional Requirements. An Accelerator-Endorsed Licensee's equity assistance proposal that includes the information required by Rule 3-1105 and this Rule 3-1110 may also serve as the equity partnership agreement.
1. How the Accelerator-Endorsed Licensee will protect or minimize disruptions to the Accelerator Licensee in the event of a change of location of the Accelerator-Endorsed Licensee's Licensed Premises;
  2. Any intellectual property protections or restrictions;
  3. Any agreements about operational control of any shared equipment, premises, or shared personnel;
  4. Any agreements related to division of liability pursuant this Rule; and
  5. Any non-disclosure agreements.
- C. Division of Liability.
1. Shared Equipment. An Accelerator-Endorsed Licensee and Accelerator Licensee may share equipment in the same Licensed Premises if they have Standard Operating Procedures addressing the following:
    - a. Rotational/time schedule for utilizing equipment;
    - b. Changes to the schedule; and
    - c. Sanitizing equipment.
  2. Shared Ingredients and/or Co-Mingling of Inventory. An Accelerator-Endorsed Licensee and Accelerator Licensee may share non-marijuana ingredients such as soil, growing medium, fertilizers, sugar, flour, etc. If the Accelerator-Endorsed Licensee and the Accelerator Licensee share non-marijuana ingredients, they must have Standard Operating Procedures for the protection, use, and maintenance of such products.
  3. Inventory Tracking and Record Keeping. Both the Accelerator-Endorsed Licensee and the Accelerator Licensee are each required to comply with the Inventory Tracking Requirements in the 3-800 Series Rules and all business

records requirements in the 3-900 Series Rules. Nothing in this Rule prohibits an Accelerator-Endorsed Licensee from providing the Accelerator Licensee financial support to comply with these requirements such as purchasing Inventory Tracking System tags for use by the Accelerator Licensee.

4. Security and Surveillance. Both the Accelerator-Endorsed Licensee and the Accelerator Licensee are each required to comply with security and surveillance requirements in the 3-220 Series Rules. Nothing in this Rule prohibits an Accelerator-Endorsed Licensee from providing the Accelerator Licensee financial support to comply with these requirements.
  5. Other. Both the Accelerator-Endorsed Licensee and the Accelerator Licensee will be jointly liable for any violations related to the Licensed Premises, security requirements, video surveillance requirements, health and safety requirements, possession limits, and waste rules, unless the Licensees have expressly established severed liability in the equity partnership agreement. It may be considered mitigation if the Accelerator-Endorsed Licensee demonstrated the Accelerator Licensee failed to comply with the Standard Operating Procedures.
- D. Accelerator License Operational Control. The Accelerator-Endorsed Licensee and the Accelerator Licensee may define the division of operational control of equipment in the shared premises.
- E. Intellectual Property Protections. The Accelerator-Endorsed Licensee and the Accelerator Licensee shall maintain control over their individual intellectual property unless expressly agreed to in the equity partnership agreement.

### **Basis and Purpose – 3-1115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(aa), 44-10-310(2), and 44-10-311(2), C.R.S. The purpose of this rule is to establish requirements for Accelerator-Endorsed Licensees and Social Equity Licensees participating in the accelerator program. This option allows the Accelerator-Endorsed Licensee and the Social Equity Licensee to have a separate premises relationship pursuant to Rules 3-1105 and 3-1115.

### **3-1115 – Accelerator Separate Premises**

- A. Equity Assistance Proposal – Additional Requirements. In addition to all equity assistance proposal requirements outlined in Rule 3-1105(C)(1), an Accelerator-Endorsed Licensee intending to share a separate premises in its possession or control with an Accelerator Licensee must also include the following in its equity assistance proposal:
1. Estimate of the Accelerator Licensee's initial investment, if any;
  2. Estimate of the Accelerator-Endorsed Licensee's initial investment;
  3. Any anticipated application and/or licensing fees for which the Accelerator Licensee will be responsible;

4. Restrictions on the Accelerator Licensee's business (including any restrictions on sources of products or required vendors);
  5. Assistance provided by the Accelerator-Endorsed Licensee to the Accelerator Licensee (including assistance in installing required security; hiring and training employees; providing necessary equipment; establishing prices; establishing administrative, bookkeeping, accounting, and inventory control procedures; etc.);
  6. Advertising that will benefit the Accelerator Licensee;
  7. Use of the Accelerator-Endorsed Licensee's brand, trade name, or trademarks;
  8. Total number of licenses and locations of businesses the Accelerator-Endorsed Licensee owns, operates, or is affiliated with;
  9. Anticipated terms of the financing agreement, including leases and installment contracts offered directly or indirectly to the Accelerator Licensee;
  10. Terms of renewal, termination, transfer, and dispute resolution procedures;
  11. All proposed agreements, including any property or equipment leases;
  12. The Accelerator-Endorsed Licensee's total annual revenue and fair financial projections of the Accelerator Licensee; and
  13. The anticipated annual fee or percentage of profits the Accelerator Licensee will be required to pay the Accelerator-Endorsed Licensee for use of the Accelerator-Endorsed Licensee's brand, trade name, or trademarks.
- B. Equity Partnership Agreement – Additional Requirements. In addition to all equity partnership agreement requirements outlined in Rule 3-1105, an equity partnership agreement between an Accelerator-Endorsed Licensee and Accelerator Licensee who is operating on a separate premises from the Accelerator-Endorsed Licensee must include the following:
1. Initial Investment.
    - a. The Accelerator Licensee's initial business investment, if any; and
    - b. The Accelerator-Endorsed Licensee's initial business investment.
  2. Fees. The fees, if any, the Accelerator Licensee and the Accelerator-Endorsed Licensee will be responsible for, which may include, but need not be limited to:
    - a. Application and license fees;
    - b. Assistance with legal fees, if any; and
    - c. The annual fee or percentage of profits the Accelerator Licensee will be required to pay the Accelerator-Endorsed Licensee for use of the Accelerator-Endorsed Licensee's brand, trade name, or trademarks.

3. Restrictions on Accelerator Licensee Business Operations. Any restrictions placed on the Accelerator Licensee's business operations, which may include, but are not limited to:
    - a. Ingredients, formulas, and processes the Accelerator Licensee is required to use;
    - b. Sources of products;
    - c. Advertising; and
    - d. Third party vendors the Accelerator-Endorsed Licensee contracted with that the Accelerator Licensee will also be required to utilize;
  4. Accelerator-Endorsed Licensee Obligations. All assistance the Accelerator-Endorsed Licensee will provide which may include, but is not limited to:
    - a. Assistance in hiring and training of employees;
    - b. Establishing prices;
    - c. Establishing administrative, bookkeeping, accounting, and inventory control procedures;
    - d. Resolving operating problems; and
    - e. Licensed Premises and equipment buildout.
  5. Accelerator Licensee Obligations. If the Accelerator Licensee will be required to:
    - a. Comply with branding;
    - b. Utilize only the intellectual property of the Accelerator-Endorsed Licensee;
    - c. Use of identified third-party vendors; and
    - d. Selling product to specific purchasers.
  6. Terms of Renewal, Termination, and Dispute Resolution. Any terms regarding renewal of the business relationship, termination of the business relationship, and dispute resolution. Any dispute resolution terms may not require Division or State Licensing Authority involvement.
  7. Advertising. Any terms regarding advertising including the amount and methods of advertising, the distribution of costs for advertising, whether the Accelerator Licensee may do its own advertising, and how the costs of advertising will be distributed.
  8. Agreements. All agreements between the Accelerator-Endorsed Licensee and Accelerator Licensee, including leases for property or equipment and any nondisclosure agreements.
- C. Division of Liability.

1. Equipment. The Accelerator-Endorsed Licensee and the Accelerator Licensee are individually and separately responsible for their own equipment.
2. Ingredients. The Accelerator-Endorsed Licensee and the Accelerator Licensee are individually and separately responsible for their own ingredients, unless otherwise expressly agreed to in the equity partnership agreement.
3. Inventory Tracking and Record Keeping. Both the Accelerator-Endorsed Licensee and the Accelerator Licensee are each required to comply with the Inventory Tracking Requirements in the 3-800 Series Rules and the Business Records in the 3-900 Series Rules. Nothing in this Rule prohibits an Accelerator-Endorsed Licensee from providing the Accelerator Licensee financial support to comply with these requirements such as purchasing Inventory Tracking System tags for use by the Accelerator Licensee.
4. Security and Surveillance. The Accelerator-Endorsed Licensee and the Accelerator Licensee are individually and separately required to comply with security and surveillance requirements in the 3-200 Series Rules. Nothing in this Rule prohibits an Accelerator-Endorsed Licensee from providing the Accelerator Licensee financial support to comply with these requirements.
5. Other.
  - a. Accelerator Licensee Liability. An Accelerator Licensee is solely liable and responsible for all conduct and any violations that occur on the Accelerator Licensee's Licensed Premises.
  - b. Accelerator-Endorsed Licensee Liability. An Accelerator-Endorsed Licensee that makes available a separate premises in the Accelerator-Endorsed Licensee's possession to an Accelerator Licensee and who is in compliance with the Marijuana Code and these Rules will only be liable and responsible for conduct and any violations that occur on the Accelerator-Endorsed Licensee's Licensed Premises.
- D. Operational Control. The Accelerator-Endorsed Licensee and the Accelerator Licensee are each responsible for the operational control at their separate Licensed Premises.
- E. Intellectual Property. An Accelerator-Endorsed Licensee must permit and require the Accelerator Licensee to use the Accelerator-Endorsed Licensee's intellectual property. The Accelerator-Endorsed Licensee will maintain ownership and control of its intellectual property. The Accelerator Licensee shall maintain ownership and control of intellectual property it creates.

## Part 4 – Regulated Marijuana Testing Program

### 4-100 Series - Repealed

#### **Basis and Purpose—4-105**

~~The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b),~~



~~44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the mandatory testing portion of the Division's Regulated Marijuana sampling and testing program. This Rule 4-105 was previously Rules M and R-1502, 1 CCR 212-1 and 1 CCR 212-2.~~

#### **4-105 – Regulated Marijuana Testing Program: Mandatory Testing**

~~A. Required Test Batch Submission. A Regulated Marijuana Business may be required by the Division to submit a Test Batch(es) of Regulated Marijuana it possesses to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility at any time regardless of whether it has achieved a Reduced Testing Allowance and without notice.~~

- ~~1. Test Batches collected pursuant to this Rule may be tested for potency or contaminants which may include, but is not be limited to, Pesticide, microbials, mycotoxin, molds, elemental impurities, residual solvents, biological contaminants, and chemical contaminants.~~
- ~~2. When a Test Batch(es) is required to be submitted for testing, the Regulated Marijuana Business may not Transfer or process into a Medical Marijuana Concentrate or Medical Marijuana Product any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product, or Transfer or process into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product, from the Inventory Tracking System package, Harvest Batch or Production Batch from which the Test Batch was taken, until it passes all required testing.~~

~~B. Methods for Determining Required Testing.~~

- ~~1. Random Testing. The Division may require Test Batches to be submitted for testing through any one or more of the following processes: random process, risk-based process, or other internally developed process, regardless of whether a Regulated Marijuana Business has achieved a Reduced Testing Allowance.~~
- ~~2. Inspection or Enforcement Tests. In addition, the Division may require a Regulated Marijuana Business to submit a Sample for testing if the Division has reasonable grounds to believe that:~~
  - ~~a. Regulated Marijuana is contaminated or mislabeled;~~
  - ~~b. A Regulated Marijuana Business is in violation of any product safety, health or sanitary statute, rule or regulation; or~~
  - ~~c. The results of a test would further an investigation by the Division into a violation of any statute, rule, or regulation.~~
- ~~3. Beta Testing. The Division may require a Regulated Marijuana Business to submit Test Batches from certain randomly selected Harvest Batches or Production Batches for potency or contaminant testing prior to implementing mandatory testing.~~

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- ~~C. Minimum Testing Standards. The testing requirements contained in this 4-100 Series are the minimum required testing standards. Regulated Marijuana Businesses are responsible for ensuring adequate testing on any Regulated Marijuana they produce or Transfer to ensure safety for human consumption.~~
- ~~D. Additional Test Batch Types. The Division may also require a Regulated Marijuana Business to submit Test Batches comprised of items other than Regulated Marijuana to be tested for contaminants which may include, but may not be limited to, Pesticide, microbial, molds, elemental impurities, residual solvents, biological contaminants, and chemical contaminants. The following is a non-exhaustive list of the types of Test Batches that may be required to be submitted for contaminant testing:~~
- ~~1. Specific Regulated Marijuana plant(s) or any portion of a Regulated Marijuana plant(s);~~
  - ~~2. Any growing medium, water, or other substance used in the cultivation process;~~
  - ~~3. Any water, solvent, or other substance used in the processing of a Regulated Marijuana Concentrate;~~
  - ~~4. Any Ingredient or substance used in the manufacturing of a Regulated Marijuana Product; or~~
  - ~~5. Swab of any equipment or surface.~~
- ~~E. R&D Testing.~~
- ~~1. R&D Tests. A Regulated Marijuana Business may submit Test Batches from a Harvest Batch (including a Manicure Batch) or Production Batch for R&D testing. R&D testing may be performed for any test required by these 4-100 Series Rules or any other test.~~
    - ~~a. Harvest Batches or Production Batches that are Designated in the Inventory Tracking System as an R&D batch.~~
      - ~~i. The Regulated Marijuana from these batches shall not be Transferred to other Regulated Marijuana Businesses except for Regulated Marijuana Testing Facilities.~~
      - ~~ii. Failing R&D test results do not require compliance with failed test procedures and are not considered a failing result for the purposes of achieving or maintaining Reduced Testing Allowance.~~
    - ~~b. Harvest Batches or Production Batches that are Intended to be Transferred to other Regulated Marijuana Businesses.~~
      - ~~i. Passing R&D Test Results. If a Harvest or Production Batch passes an R&D test it shall not constitute a pass for the purposes of compliance with required contaminant or potency testing. If a Harvest or Production Batch passes an R&D test it shall not constitute a pass for purposes of achieving or maintaining a Reduced Testing Allowance. See Rules 4-120 and 4-125.~~

- ii. ~~Failed R&D Test Results.~~ If a Harvest or Production Batch fails an R&D test:
  - A. ~~It does not require compliance with failed test procedures. See Rule 4-135.~~
  - B. ~~If a Test Batch fails an R&D test that is a test type required by these Rules, the Licensee must submit a Test Batch from the same Harvest or Production Batch for compliance testing and obtain passing results for that test type prior to Transferring that Harvest or Production Batch to a Regulated Marijuana Business.~~
  - C. ~~If the Test Batch submitted pursuant to paragraph (1)(b) fails testing, compliance with the failed test procedures in Rule 4-135 is required.~~
  - D. ~~Licensees shall not Transfer Regulated Marijuana that they have reason to believe would not pass testing required by Rule 4-120 and 4-125, unless otherwise authorized in these rules.~~
- c. ~~Repealed.~~
- F. ~~Violation Affecting Public Safety.~~ Failure to comply with this Rule may constitute a license violation affecting public safety.

### **Basis and Purpose — 4-110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing sampling procedures and rules for the Division's Regulated Marijuana sampling and testing program. This Rule 4-110 was previously Rules M and R 1504, 1 CCR 212-1 and 1 CCR 212-2.

### **4-110 — Regulated Marijuana Testing Program: Sampling Procedures**

- A. ~~Collection of Test Batches.~~
  - 1. ~~Sample Increment Collection.~~ All Test Batches submitted for testing pursuant to this Rule must be collected by Division representatives or in accordance with the Division's sampling policy reflected in the marijuana laboratory testing reference library available at the Colorado Department of Public Health and Environment's website. This reference library may be continuously updated as new materials become available in accordance with section 25-1.5-106(3.5)(d), C.R.S.
  - 2. ~~Sample Increment Selection.~~ The Division may elect, at its sole direction, to assign Division representatives to collect Sample Increments, or may otherwise direct Sample Increment selection, including, but not limited to, through Division

~~designation of a Harvest Batch or Production Batch in the Inventory Tracking System from which a Regulated Marijuana Business shall select Test Batches for testing. A Regulated Marijuana Business, its Controlling Beneficial Owners, Passive Beneficial Owners, and employees shall not attempt to influence the Sample Increments selected by Division representatives. If the Division does not select the Harvest Batch or Production Batch to be tested, a Regulated Marijuana Business must collect and submit Sample Increments that are representative of the Harvest Batch or Production Batch being tested.~~

- ~~3. Adulteration or Alteration Prohibited. Pursuant to section 44-10-701(3)(b) and (9), C.R.S., it is unlawful for a Licensee or its agent to knowingly adulterate or alter, or attempt to adulterate or alter, any Sample Increments or Test Batches of Regulated Marijuana. The Sample Increments collected and submitted for testing must be representative of the Harvest Batch or Production Batch being tested. A violation of this sub-paragraph (A)(3) shall be considered a license violation affecting public safety and the person who commits adulteration or alteration of Sample Increments or Test Batches commits a class 2 misdemeanor and may be punished as provided in section 18-1.3-501, C.R.S.~~
- ~~4. Timing of Sample Increments for Harvest Batches and Production Batches. A Licensee shall not collect Sample Increments or submit Test Batches for testing until the Test Batch has completed all required steps and is in its final form as outlined in the standard operating procedures of the Licensee submitting the Test Batch, with the exception of packaging and labeling requirements which shall comply with Rule 3-1025.~~
  - ~~a. The following examples illustrate various methods, which are not limited to those listed herein, that a Licensee's standard operating procedures may include to verify a Test Batch completed all required steps and is in its final form pursuant to this Rule:~~
    - ~~i. The Licensee's standard operating procedures may include procedures that ensure the addition of all Ingredients or Additives has occurred and that the Harvest Batch or Production Batch associated with the Test Batch is completely ready to be packaged pending results of testing required by these Rules. This also includes creating Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana;~~
    - ~~ii. For a Production Batch of Concentrate, the Licensee's standard operating procedure may include procedures that ensure the entire Production Batch associated with the Test Batch has completed all sifting, extracting, purging, winterizing, and steps to remove plant pigments and ensuring the addition of all Ingredients and Additives has occurred.~~
    - ~~iii. For a Production Batch of Regulated Marijuana Product, the Licensee's standard operating procedure may include procedures that ensure the addition of all Ingredients and Additives has occurred and the Production Batch associated with the Test Batch~~

~~is completely ready to be packaged pending results of testing required by these Rules.~~

~~b. A Test Batch from a Harvest Batch or Production Batch shall be packaged and labeled according to Series 3-1025 prior to Transfer to a Regulated Marijuana Testing Facility.~~

~~c. This Rule 4-110(A)(4) does not apply for the submission of Test Batches submitted for R&D testing.~~

~~5. Vaporizer Delivery Device. This subsection (A)(5) is effective January 1, 2022. Retail Marijuana Concentrate that has been placed into a Vaporizer Delivery Device must be sampled and tested using a methodology that allows the laboratory to analyze the emission of the contents of the Vaporizer Delivery Device.~~

~~B. Designated Test Batch Collector Training, Documentation, and Designation.~~

~~1. Required Sample Increment Collection Training. To become a Designated Test Batch Collector an Owner Licensee or Employee Licensee involved in the Sample Increment Collection of Regulated Marijuana must be designated by a manager or Owner Licensee as such and must also complete either in-house training provided by the Regulated Marijuana Business or training from a third-party vendor including all of the topics set forth in subparagraph (2) of this Rule. Nothing in this rule requires a Designated Test Batch Collector to be employed by the Regulated Marijuana Business making the designation.~~

~~2. Designated Test Batch Collection Training Required Topics. The training required to become a Designated Test Batch Collector must include at least the following topics:~~

~~a. Part 4-100 Series Rules—Regulated Marijuana Testing Program;~~

~~b. The Marijuana Business's standard operating procedures on creating a Sampling Plan and Test Batches, and the CDPHE's Sampling Procedures.~~

~~c. "Guidance on Marijuana Sampling Procedures" Training Video or an equivalent training covering the following subjects:~~

~~i. Introduction to Sample Increment Collection:~~

~~A. Cross contamination as it relates to Sample Increment Collection;~~

~~B. Sample Increment Collection and how it works;~~

~~C. Sample Increment Collection documentation and record keeping requirements;~~

~~D. Penalties for Sample Increment or Test Batch adulteration or alteration;~~

~~E. Use of and disinfection of the Designated Test Batch Collection Area; and~~

~~F. Use of the Sample Plan.~~

~~3. Documentation of Designated Test Batch Collector Training. Any individual receiving the Designated Test Batch Collector training must sign and date a document which shall be maintained by the Regulated Marijuana Business as a business record pursuant to Rule 3-905. The document must acknowledge the following:~~

- ~~a. The identity of the Person that created the training, such as the Regulated Marijuana Business or a third-party vendor; and~~
- ~~b. That all required topics of the training identified in this Rule have been reviewed and understood by the Owner Licensee or Employee Licensee.~~

~~C. Test Batch Collection Requirements.~~

~~1. Required Minimum of Two Test Batch Collectors. At a minimum, two Designated Test Batch Collectors shall be involved in the collection of Sample Increments such that at least one Designated Test Batch Collector is responsible for collecting the Sample Increments and another Designated Test Batch Collector is responsible for reviewing documentation associated with the collection of Sample Increments in a timely manner and prior to any Transfer of the Production Batch or Harvest Batch from which Sample Increments were collected. This review can be completed in person or may be completed remotely by reviewing image(s) of the Test Batch and associated documentation. All Designated Test Batch Collectors must be identified as such in the Inventory Tracking System account associated with the Regulated Marijuana Business.~~

~~2. Sample Plan Required. A Designated Test Batch Collector must establish a Sample Plan consistent with the Regulated Marijuana Business's Standard Operating Procedure for Sample Increment Collection. At a minimum, a Sample Plan must include the following:~~

- ~~a. The date, amount or weight, and specific location for each Sample Increment collected;~~
- ~~b. Identification of and acknowledgements from all Designated Test Batch Collectors involved in the Sample Increment Collection; and~~
- ~~c. If applicable, the strain name(s) for each Harvest Batch from which Sample Increments are collected.~~

~~D. Minimum Number of Sample Increments Per Test Batch Submission. These sampling rules shall apply until such time as the State Licensing Authority revises these rules to implement a statistical sampling model. Unless a greater amount is required to comply with these rules or is required by a Regulated Marijuana Testing Facility to perform all requested testing, each Test Batch of Regulated Marijuana must contain at least the number of Sample Increments prescribed by this Section.~~

- ~~1. A Test Batch of Regulated Marijuana must be packaged and labeled according to Rule 3-1025.~~
- ~~2. The minimum number of Sample Increments required to be collected for each Test Batch from a Harvest Batch of Retail Marijuana or Medical Marijuana shall be determined by Table 4-110.D.2.T.~~
- ~~3. The minimum number of Sample Increments required to be collected for each Test Batch from a Production Batch of Regulated Marijuana Product, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Audited Product and Alternative Use Product shall be determined by Table 4-110.D.2.T.~~
  - ~~a. The Retail Marijuana Products Manufacturer or Medical Marijuana Products Manufacturer shall determine what constitutes a "Serving" and thus how many Servings are contained in a Production Batch of Regulated Marijuana Product, except that no serving of Edible Retail Marijuana Product can contain more than 10mg of active THC~~
  - ~~b. Because all Test Batches of Regulated Marijuana Product, Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana are required to be submitted for testing in their final form, in the event the required number of Sample Increments does not match up within a finished package, the manufacturer must increase the number of Sample Increments collected for the Test Batch such that only finished packages of Regulated Marijuana Products, Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana are submitted for testing. For example, if a Production Batch of 4000 chocolate bars is manufactured, with each bar containing 100 mg THC and 10 servings per bar, the Production Batch would contain 40,000 Sample Increments which would require collection of at least 33 Sample Increments per Test Batch. But in this case, the manufacturer would have to collect 40 Sample Increments for testing (4 complete chocolate bars in final form).~~
  - ~~c. No matter how small the Production Batch of Regulated Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana a minimum of two finished packages in final form must be submitted for a Test Batch.~~
- ~~4. The minimum number of Sample Increments required to be collected for each Test Batch from a Production Batch of Retail Marijuana Concentrate or Medical Marijuana Concentrate shall be determined by Table 4-110.D.2.T.~~
  - ~~a. Because all Test Batches of Retail Marijuana Concentrate and Medical Marijuana Concentrate are required to be submitted for testing in their final form, in the event the required number of Sample Increments does not match up with the number of Sample Increments in a finished package, the manufacturer must increase the number of Sample Increments collected for the Test Batch such that only finished packages of Marijuana Concentrate are submitted for testing. For example, if a Production Batch of 4,000 Vaporizer Delivery Devices is manufactured,~~



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~~with each Vaporizer Delivery Device containing 500 milligrams of Marijuana Concentrate, the Production Batch would contain 2,000 grams of Marijuana Concentrate, which would require collection of at least 15 Sample Increments per Test Batch. But in this case, the manufacturer would have to collect 16 Sample Increments for testing (8 vaporizer Delivery Devices in final form).~~

- ~~b. No matter how small the Production Batch of Retail Marijuana Concentrate or Medical Marijuana Concentrate, a minimum of two finished packages must be submitted for a Test Batch.~~

**Table 4-110.D.2.T**

Minimum Number of Sample Increments Required to be Collected per Test Batch	Regulated Marijuana (Sample Increment = 0.5 grams)		
	Total Weight of Harvest Batch (lbs)	Total Weight of Harvest Batch (grams)	Minimum Weight of Test Batch (grams)
<b>5</b>	<del>0.000 – 0.999</del>	<del>0.0 – 453.5</del>	<b>2.50</b>
<b>8</b>	<del>1.00 – 9.999</del>	<del>453.6 – 4535.9</del>	<b>4.00</b>
<b>15</b>	<del>10.000 – 19.999</del>	<del>4536.0 – 9071.8</del>	<b>7.50</b>
<b>22</b>	<del>20.000 – 39.999</del>	<del>9071.9 – 18143.6</del>	<b>11.00</b>
<b>33</b>	<del>40.000 – 99.999</del>	<del>18143.7 – 45359.2</del>	<b>16.50</b>
<b>43</b>	<del>100.000 – 199.999</del>	<del>45359.3 – 90718.4</del>	<b>21.50</b>
<b>53</b>	<del>200.000 – 499.999</del>	<del>90718.5 – 226796.1</del>	<b>26.50</b>
<b>80</b>	<del>500 or more</del>	<del>226796.2 or more</del>	<b>40.00</b>

Minimum Number of Sample Increments Required to be Collected per Test Batch	Regulated Marijuana Concentrate (Sample Increment = 0.25 g)		
	Total Weight of Production Batch (lbs)	Total Weight of Production Batch (grams)	Minimum Weight of Test Batch (grams)
<b>5</b>	<del>0.000 – 0.999</del>	<del>0.0 – 453.5</del>	<b>1.25</b>
<b>8</b>	<del>1.00 – 1.999</del>	<del>453.6 – 907.1</del>	<b>2.00</b>
<b>15</b>	<del>2.00 – 4.999</del>	<del>907.2 – 2267.9</del>	<b>3.75</b>
<b>22</b>	<del>5.000 – 14.999</del>	<del>2268.0 – 6803.8</del>	<b>5.50</b>
<b>33</b>	<del>15.000 – 49.999</del>	<del>6803.9 – 22679.6</del>	<b>8.25</b>



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<b>43</b>	<del>50.000—99.999</del>	<del>22679.7-45359.2</del>	<b>10.75</b>
<b>53</b>	<del>100.000—249.999</del>	<del>45359.3-113398.0</del>	<b>13.25</b>
<b>80</b>	<del>250 or more</del>	<del>113398.1 or more</del>	<b>20.00</b>

Minimum Number of Sample Increments Required to be Collected per Test Batch	Regulated Marijuana Products (Sample Increment = 1 Serving)				
	Number of Servings within Production Batch	Minimum Number of Units for a Test Batch for a 5-Serving Unit*	Minimum Number of Units for a Test Batch for a 10-Serving Unit*	Minimum Number of Units for a Test Batch for a 20-Serving Unit*	Minimum Number of Units for a Test Batch for a 100-Serving Unit*
<b>5</b>	<del>0—99</del>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>
<b>8</b>	<del>100—999</del>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>
<b>15</b>	<del>1000—4999</del>	<b>3</b>	<b>2</b>	<b>2</b>	<b>2</b>
<b>22</b>	<del>5000—9999</del>	<b>5</b>	<b>3</b>	<b>2</b>	<b>2</b>
<b>33</b>	<del>10000—49999</del>	<b>7</b>	<b>4</b>	<b>2</b>	<b>2</b>
<b>43</b>	<del>50000—99999</del>	<b>9</b>	<b>5</b>	<b>3</b>	<b>3</b>
<b>53</b>	<del>100000—249999</del>	<b>11</b>	<b>6</b>	<b>3</b>	<b>3</b>
<b>80</b>	<del>250000 or more</del>	<b>16</b>	<b>8</b>	<b>4</b>	<b>4</b>

\*Other serving amounts per unit are acceptable. These are provided as examples.

Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana		
Minimum Number of	Number of Pre-Rolls	Minimum Number of Pre-Rolls for a Test Batch when each Pre-Roll is

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<b>Sample Increments Required to be Collected per Test Batch</b>	<b>within the Production Batch</b>	<b>&lt; or = 0.39 g</b>	<b>0.40g to 0.50g</b>	<b>0.51g to 0.75g</b>	<b>0.76g– 1.00g</b>	<b>1.01g– 2.00g</b>	<b>2.01g– 3.00g</b>	<b>3.01g +</b>
5	0–99	5	4	3	2	2	2	2
8	100–999	8	5	4	3	2	2	2
15	1000–4999	15	10	8	5	4	2	2
22	5000–9999	22	14	11	8	6	3	2
33	10000–49999	33	21	17	11	9	5	3
43	50000–99999	43	27	22	15	11	6	4
53	100000– 249999	53	34	26	18	14	7	5
80	250000 or more	80	50	40	27	20	10	7

~~E. — Regulated Marijuana Testing Facility Selection. Unless otherwise restricted or prohibited by these rules or ordered by the State Licensing Authority, a Regulated Marijuana Business may select which Medical Marijuana Testing Facility or Retail Marijuana Testing Facility will test a Test Batch made up of Sample Increments collected pursuant to this Rule. However, the Division may elect, at its sole discretion, to assign a Regulated Marijuana Testing Facility to which a Regulated Marijuana Business must submit for testing any Test Batch made up of Sample Increments collected pursuant to this Rule.~~

~~F. — Hemp Product Sampling Procedures. Absent sampling and testing standards established by the Colorado Department of Public Health and Environment for the sampling and testing of Hemp Product, a Person Transferring a Hemp Product to a Licensee pursuant to the Marijuana Code and these Rules shall comply with the sampling and testing standards set forth in these 4-100 Series Rules — Regulated Marijuana Testing Program and as required by these Rules.~~

~~G. — Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

### **Basis and Purpose — 4-115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2); C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish the portion of the Division's mandatory testing and sampling program that is applicable to Regulated Marijuana Businesses, and specifically Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities. While

~~the Marijuana Code requires the State Licensing Authority to establish acceptable limits of potential contaminants, it also requires the State Licensing Authority to enact a plus or minus 15 percent potency variance, which is also included in this rule. This Rule 4-115 was previously Rules M and R 712, 1 CCR 212-1 and 1 CCR 212-2.~~

#### **4-115 – Regulated Marijuana Testing Program: Sampling and Testing Program**

~~A. Division Authority. The Division may require that a Test Batch be submitted to a specific Regulated Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.~~

- ~~1. Independent Third Party Review. The Division may require Regulated Marijuana to undergo an independent third party review to verify that the Regulated Marijuana does not pose a threat to public health and safety when the Division, in consultation with the Colorado Department of Public Health and Environment, has objective and reasonable grounds to believe and finds, upon a full investigation, one of the following:~~
  - ~~a. The Regulated Marijuana contains one or more substances known to cause harm; or~~
  - ~~b. The Regulated Marijuana contains one or more substances that could be toxic as consumed or applied in accordance with the intended use.~~
- ~~2. The fact that Regulated Marijuana contains marijuana shall not constitute grounds to require an independent third party review. Ingredients Generally Recognized as Safe by the U.S. Food & Drug Administration or that are regulated by the U.S. Food & Drug Administration under the Dietary Supplement Health and Education Act of 1994 that are included in Edible Medical Marijuana Product or Edible Retail Marijuana Product shall not constitute grounds to require an independent third party review.~~
- ~~3. Quarantine. In addition to any other remedies provided by law, the Division may immediately quarantine Regulated Marijuana pursuant to Rule 4-135(A) in any one of the following circumstances:~~
  - ~~a. The Division has objective and reasonable grounds to believe and finds, upon a full investigation, that a Regulated Marijuana Business has been guilty of deliberate and willful violations of these rules;~~
  - ~~b. The Regulated Marijuana or Alternative Use Product poses a potential threat to public health and safety;~~
  - ~~c. The Division has received one or more reports of an adverse event related to Regulated Marijuana or Alternative Use Product. For purpose of this Rule, adverse event means any untoward medical occurrence associated with the use of Regulated Marijuana or Alternative Use Product—this could include any unfavorable and unintended sign (including hospitalization, emergency department visit, doctor's visit, abnormal laboratory finding), symptom, or disease temporally associated with the use of a Regulated Marijuana or Alternative Use Product;~~

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- ~~d. The Division determines the independent third-party audit submitted pursuant to Rules 5-325(B) or 6-325(B) does not meet the requirements of Rules 5-325 or 6-325; or~~
    - ~~e. The Regulated Marijuana Products Manufacturer has violated or is not in compliance with all of the requirements in Rules 5-325 or 6-325.~~
  - ~~4. Any quarantine pursuant to subparagraph (A)(3) above shall remain in effect unless the Regulated Marijuana undergoes an independent third-party review to verify the Regulated Marijuana does not pose a risk to public health and safety.~~
  - ~~5. For the purpose of this Rule, full investigation means a reasonable ascertainment of the underlying facts on which the agency action is based.~~
- ~~B. Standard Minimum Weight of Test Batches and Photo Documentation.~~
  - ~~1. Standard Minimum Weight of Test Batches.~~
    - ~~a. Regulated Marijuana and Regulated Marijuana Concentrate. A Medical Marijuana Testing Facility must establish a standard minimum weight of Medical Marijuana and Medical Marijuana Concentrate, and a Retail Marijuana Testing Facility must establish a standard minimum weight of Retail Marijuana and Retail Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.~~
    - ~~b. Regulated Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana. Regulated Marijuana Testing Facilities must establish a standard number of Sample Increments required to be included in each Test Batch of Regulated Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana for every type of test that it conducts. See Rule 4-110—Regulated Marijuana Testing Program—Sampling Procedures.~~
  - ~~2. Photo Documentation of Test Batches.~~
    - ~~a. A Regulated Marijuana Testing Facility shall digitally photograph each Test Batch it receives to document the Sample Increments collected, condition of the Test Batch, and compliance with these rules.~~
    - ~~b. The Regulated Marijuana Testing Facility must maintain the digital photographs of each Test Batch as business records. See Rule 3-905—Required Business Records.~~
    - ~~c. Upon request by the Division, a Regulated Marijuana Testing Facility must provide copies of the digital photographs of Test Batches within seven days of the request unless a different deadline is agreed to.~~
- ~~C. Rejection of Test Batches.~~
  - ~~1. A Regulated Marijuana Testing Facility shall not accept a Test Batch that is smaller than its standard minimum amount.~~

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2. ~~A Regulated Marijuana Testing Facility shall not accept a Test Batch that does not contain the minimum number and weight of Sample Increments, or the Regulated Marijuana Testing Facility has reason to believe it was not collected in accordance with Test Batch collection requirements in Rule 4-110.~~
3. ~~Effective July 1, 2023, if a Regulated Marijuana Testing Facility suspects or has reason to suspect a Sample Increment or Test Batch has been adulterated, the Regulated Marijuana Testing Facility must:~~
- a. ~~Notify the Division; and~~
  - b. ~~Quarantine the Sample Increment or Test Batch for a minimum of 48 hours from the time of notification to the Division before proceeding with any testing.~~
- D. ~~Permissible Levels of Contaminants. If Regulated Marijuana is found to have a contaminant in levels exceeding those established as permissible under this Rule, then it shall be considered to have failed contaminant testing. Notwithstanding the permissible levels established in this Rule, the Division reserves the right to determine, upon good cause and reasonable grounds, that a particular Test Batch presents a risk to the public health or safety and therefore shall be considered to have failed a contaminant test.~~
1. ~~Microbials (Bacteria, Fungus)~~

<u>Substance</u>	<u>Acceptable Limits</u>	<u>Product to be Tested</u>
<del>Shiga toxin-producing <i>Escherichia coli</i> (STEC)* Bacteria</del>	<del>Absent in 1 g</del>	<ul style="list-style-type: none"> <li>● <del>Regulated Marijuana flower, shake, and trim (other than wet whole plant allocated for extraction);</del></li> </ul>
<del><i>Salmonella</i> species*— Bacteria</del>	<del>Absent in 1 g</del>	<ul style="list-style-type: none"> <li>● <del>Regulated Marijuana Products (other than Audited Product);</del></li> </ul>
<del><i>Aspergillus</i> (<i>A. fumigatus</i>, <i>A. flavus</i>, <i>A. niger</i>, <i>A. terreus</i>)</del>	<del>Absent in 1 g</del>	<ul style="list-style-type: none"> <li>● <del>Pre-Rolled Marijuana;</del></li> </ul>
<del>Total Yeast and Mold</del>	<del><math>\leq 1.0 \times 10^4</math> Colony Forming Unit (CFU) per 1 ml or 1 g</del>	<ul style="list-style-type: none"> <li>● <del>Infused Pre-Rolled Marijuana;</del></li> <li>● <del>Physical Separation-Based, Heat/Pressure-Based, and Food-Based Medical Marijuana Concentrate;</del></li> <li>● <del>Physical Separation-Based, Heat/Pressure-Based, and Food-Based Retail Marijuana Concentrate;</del></li> <li>● <del>Hemp Products;</del></li> </ul>

		<ul style="list-style-type: none"> <li>• <del>Pressurized Metered Dose Inhalers;</del></li> <li>• <del>Vaporizer Delivery Device;</del></li> <li>• <del>Solvent Based Medical Marijuana Concentrate produced through Remediation;</del></li> <li>• <del>Solvent Based Retail Marijuana Concentrate produced through Remediation;</del></li> <li>• <del>Solvent Based Medical Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials;</del></li> <li>• <del>Solvent Based Retail Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials;</del></li> <li>• <del>Re-testing of Regulated Marijuana flower, shake, and trim that has undergone Decontamination.</del></li> </ul>
	<del><math>\leq 1.0 \times 10^1</math> CFU/ml or <math>\leq 1.0 \times 10^1</math> CFU/g</del>	<del>Audited Product: administration by metered dose nasal spray or vaginal administration</del>
	<del><math>\leq 1.0 \times 10^2</math> CFU/ml or <math>\leq 1.0 \times 10^2</math> CFU/g</del>	<del>Audited Product: rectal administration</del>
Total aerobic microbial count	<del><math>\leq 1.0 \times 10^2</math> CFU/ml or <math>\leq 1.0 \times 10^2</math> CFU/g</del>	<del>Audited Product: administration by metered dose nasal spray or vaginal administration</del>
	<del><math>\leq 1.0 \times 10^3</math> CFU/ml or <math>\leq 1.0 \times 10^3</math> CFU/g</del>	<del>Audited Product: rectal administration</del>

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<i>Staphylococcus aureus</i>	Absent in 1 ml or 1 g	Audited Product: administration by metered dose nasal spray or vaginal administration
<i>Pseudomonas aeruginosa</i>	Absent in 1 ml or 1 g	Audited Product: administration by metered dose nasal spray or vaginal administration
Bile tolerant gram-negative bacteria	Absent in 1 ml or 1 g	Audited Product: administration by metered dose nasal spray
<i>Candida albicans</i>	Absent in 1 ml or 1 g	Audited Product: vaginal administration

\*The Regulated Marijuana Testing Facility shall contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits.

\*\* Regulated Marijuana Products with intended use for oral consumption or skin and body products are exempt from required aspergillus testing.

## 1.5 — Water Activity

<u>Substance</u>	<u>Acceptable Limits</u>	<u>Product to be Tested</u>
Water Activity	0.65 aW	<ul style="list-style-type: none"> <li>Regulated Marijuana flower shake, and trim (other than wet whole plant);</li> <li>Retesting of Regulated Marijuana flower, shake, and trim that has undergone Decontamination;</li> <li>Pre-Rolled Marijuana;</li> <li>Infused Pre-Rolled Marijuana.</li> </ul>

## 2. — Mycotoxins

<u>Substance</u>	<u>Acceptable Limits</u>	<u>Product to be Tested</u>
Aflatoxins (B1, B2, G1, and G2)	< 20 Parts Per Billion (PPB) (total of B1 + B2 + G1 + G2)	<ul style="list-style-type: none"> <li>Solvent-Based Medical Marijuana Concentrate manufactured from Medical Marijuana flower or trim that failed microbial testing;</li> <li>Solvent-Based Retail Marijuana Concentrate manufactured from Retail</li> </ul>
Ochratoxin A	< 20 PPB	

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		<p>Marijuana flower or trim that failed microbial testing;</p> <ul style="list-style-type: none"> <li>• Solvent Based Medical Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials;</li> <li>• Solvent Based Retail Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials;</li> <li>• Regulated Marijuana flower, shake, and trim that has undergone Decontamination.</li> </ul>
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3. Residual Solvents

<u>Substance</u>	<u>Acceptable Limits</u>	<u>Product to be Tested</u>
Acetone	< 1,000 Parts Per Million (PPM)	<ul style="list-style-type: none"> <li>• Solvent Based Medical Marijuana Concentrate;</li> <li>• Solvent Based Retail Marijuana Concentrate;</li> <li>• Hemp Product (if a solvent was used)</li> </ul>
Butanes	< 1,000 PPM	
Ethanol***	< 1,000 PPM	
Heptanes	< 1,000 PPM	
Isopropyl Alcohol	< 1,000 PPM	
Propane	< 1,000 PPM	
Benzene**	< 2 PPM	
Toluene**	< 180 PPM	
Pentane	< 1,000 PPM	
Hexane**	< 60 PPM	
Total Xylenes (m,p,o-xylenes)**	< 430 PPM	



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Methanol**	< 600 PPM	
Ethyl Acetate	< 1000 PPM	
Any other solvent not permitted for use pursuant to Rules 5-315 and 6-315.	None Detected	

\*\* Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use per Rule 6-315, limits have been listed here accordingly.

\*\*\*Note: Solvent Based Medical Marijuana Concentrate and Solvent Based Retail Marijuana Concentrate that exceeds the acceptable limit for ethanol may only be used in Medical Marijuana Concentrate or Medical Marijuana Product, or Retail Marijuana Concentrate or Retail Marijuana Product, which intended use is oral consumption, skin and body products, a vaporizer delivery device, pressurized metered dose inhaler, or Audited Product.

#### 4. Elemental Impurities

<u>Substance</u>	<u>Acceptable Limits Based on Intended Use</u>	<u>Product to be Tested</u>
Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)	<b>Inhaled Product or Audited Product: administration by metered dose nasal spray</b>  Lead — Max Limit: < .5 PPM Arsenic — Max Limit: < 0.2 PPM Cadmium — Max Limit: < 0.2 PPM Mercury — Max Limit: < 0.1 PPM	<ul style="list-style-type: none"> <li>Regulated Marijuana flower, shake, trim, and wet whole plant;</li> <li>Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate;</li> <li>Physical Separation-Based, Food-Based, Heat/Pressure-Based and Solvent-Based Retail Marijuana Concentrate;</li> </ul>
	<b>Topical and/or Transdermal</b>  Lead — Max Limit: < 10 PPM Arsenic — Max Limit: < 3 PPM Cadmium — Max Limit: < 3 PPM Mercury — Max Limit: < 1 PPM	

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	<p><del>Oral Consumption or Audited Product: rectal or vaginal administration</del></p> <p><del>Lead — Max Limit: &lt; 1 PPM</del></p> <p><del>Arsenic — Max Limit: &lt; 1.5 PPM</del></p> <p><del>Cadmium — Max Limit: &lt; 0.5 PPM</del></p> <p><del>Mercury — Max Limit: &lt; 1.5 PPM</del></p>	<ul style="list-style-type: none"> <li><del>• Regulated Marijuana Product;</del></li> <li><del>• Pre-Rolled Marijuana;</del></li> <li><del>• Infused Pre-Rolled Marijuana;</del></li> <li><del>• Pressurized Metered Dose Inhaler;</del></li> <li><del>• Vaporizer Delivery Device;</del></li> <li><del>• Audited Product;</del></li> <li><del>• Hemp Product</del></li> </ul>
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5. ~~Pesticides~~

- a. ~~Effective January 1, 2023, the following pesticides are currently subject to required testing, at the associated action limits:~~

<u>Substance</u>	<u>Action Limit</u>	<u>Product to be Tested</u>
Abamectin (Avermectins: B1a & B1b)	< 0.1 PPM	<ul style="list-style-type: none"> <li><del>• Regulated Marijuana flower, shake, trim, and wet whole plant;</del></li> <li><del>• Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate;</del></li> <li><del>• Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Retail Marijuana Concentrate;</del></li> <li><del>• Pre-Rolled Marijuana;</del></li> <li><del>• Infused Pre-Rolled Marijuana.</del></li> <li><del>• Hemp Product</del></li> </ul>
Azoxystrobin	< 0.02 PPM	
Bifenazate	< 0.02 PPM	
Etexazole	< 0.02 PPM	
Imazalil	< 0.05 PPM	
Imidacloprid	< 0.02 PPM	
Malathion	< 0.02 PPM	
Myclobutanil	< 0.02 PPM	
Permethrin (mix of isomers)	< 0.5 PPM	
Spinosad (Mixture of A and D)	< 0.1 PPM	
Spiromesifen	< 3.0 PPM	

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Spirotetramat	<0.02 PPM	
Tebuconazole	<0.05 PPM	

b. ~~Effective July 1, 2023, the following pesticides will be subject to required testing, at the associated action limits:~~

<u>Substance</u>	<u>Action Limit</u>	<u>Product To Be Tested</u>
Abamectin (Avermectins B1a & B1b)	<0.1 PPM	<ul style="list-style-type: none"> <li><del>Regulated Marijuana flower, shake, trim, and wet whole plant;</del></li> <li><del>Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate;</del></li> <li><del>Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Retail Marijuana Concentrate;</del></li> <li><del>Pre-Rolled Marijuana;</del></li> <li><del>Infused Pre-Rolled Marijuana.</del></li> <li><del>Hemp Product</del></li> </ul>
Azoxystrobin	<0.02 PPM	
Bifenthrin	<1.0 PPM	
Bifenazate	<0.02 PPM	
Boscalid	<0.02 PPM	
Carbaryl	<0.05 PPM	
Chlorpyrifos	<0.04 PPM	
Clothianidin	<0.05 PPM	
Cyhalothrin-lambda	<0.25 PPM	
Dichlorvos	<0.1 PPM	
Dimethoate	<0.02 PPM	
Dinotefuran	<0.1 PPM	
Diuron	<0.125 PPM	
Etexazole	<0.02 PPM	
Imazalil	<0.05 PPM	
Imidacloprid	<0.02 PPM	
Malathion	<0.02 PPM	

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Metalaxyl	<0.02 PPM	
Myclobutanil	<0.02 PPM	
Permethrins	<0.5 PPM	
Propiconazole	<0.1 PPM	
Pyriproxyfen	<0.01 PPM	
Spinosad	<0.1 PPM	
Spiromesifen	<3.0 PPM	
Spirotetramat	<0.02 PPM	
Tebuconazole	<0.05 PPM	
Thiabendazole	<0.02 PPM	
Thiamethoxam	<0.02 PPM	

c. ~~Effective July 1, 2024, the following pesticides will be subject to required testing, at the associated action limits:~~

<u>Substance</u>	<u>Action Limit</u>	<u>Product To Be Tested</u>
Abamectin (Avermectins B1a & B1b)	<0.1 PPM	<ul style="list-style-type: none"> <li><del>Regulated Marijuana flower, shake, trim, and wet whole plant;</del></li> <li><del>Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate;</del></li> <li><del>Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Retail Marijuana Concentrate;</del></li> </ul>
Acephate	<0.02 PPM	
Acequinocyl	<0.03 PPM	
Acetamiprid	<0.1 PPM	
Aldicarb	<1.0 PPM	
Allethrin	<0.2 PPM	
Atrazine	<0.025 PPM	
Azoxystrobin	<0.02 PPM	

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Benzovindiflupyr	< 0.02 PPM	<ul style="list-style-type: none"> <li>Pre-Rolled Marijuana;</li> <li>Infused Pre-Rolled Marijuana;</li> <li>Hemp Product</li> </ul>
Bifenazate	< 0.02 PPM	
Bifenthrin	< 1.0 PPM	
Boscalid	< 0.02 PPM	
Buprofezin	< 0.02 PPM	
Carbaryl	< 0.05 PPM	
Carbofuran	< 0.02 PPM	
Chlorantraniliprole	< 0.02 PPM	
Chlorphenapyr	< 0.05 PPM	
Chlorpyrifos	< 0.04 PPM	
Clofentezine	< 0.02 PPM	
Clothianidin	< 0.05 PPM	
Coumaphos	< 0.02 PPM	
Cyantraniliprole	< 0.02 PPM	
Cyfluthrin	< 0.2 PPM	
Cyhalothrin-lambda	< 0.25 PPM	
Cypermethrin	< 0.3 PPM	
Cyprodinil	< 0.25 PPM	
Daminozide	< 0.1 PPM	
Deltamethrin	< 0.5 PPM	
Diazinon	< 0.02 PPM	
Dichlorvos	< 0.1 PPM	
Dimethoate	< 0.02 PPM	

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Dimethomorph	<0.05 PPM	
Dinotefuran	<0.1 PPM	
Diuron	<0.125 PPM	
Dedemorph	<0.05 PPM	
Endosulfan-sulfate	<0.05 PPM	
Endosulfan-alpha	<0.2 PPM	
Endosulfan-beta	<0.05 PPM	
Ethoprophos	<0.02 PPM	
Etofenprox	<0.05 PPM	
Etoxazole	<0.02 PPM	
Etridiazole	<0.03 PPM	
Fenhexamid	<0.125 PPM	
Fenoxycarb	<0.02 PPM	
Fenpyroximate	<0.02 PPM	
Fensulfothion	<0.02 PPM	
Fenthion	<0.02 PPM	
Fenvalerate	<0.1 PPM	
Fipronil	<0.06 PPM	
Flonicamid	<0.05 PPM	
Fludioxonil	<0.02 PPM	
Fluopyram	<0.02 PPM	
Hexythiazox	<0.01 PPM	
Imazalil	<0.05 PPM	

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Imidacloprid	< 0.02 PPM
Iprodione	< 1.0 PPM
Kinoprene	< 0.5 PPM
Kresoxim-methyl	< 0.02 PPM
Malathion	< 0.02 PPM
Metaxyl	< 0.02 PPM
Methiocarb	< 0.02 PPM
Methomyl	< 0.05 PPM
Methoprene	< 2.0 PPM
Mevinphos	< 0.05 PPM
MGK-264	< 0.05 PPM
Myclobutanil	< 0.02 PPM
Naled	< 0.1 PPM
Novaluron	< 0.05 PPM
Oxamyl	< 3.0 PPM
Paclobutrazol	< 0.02 PPM
Parathion-methyl	< 0.05 PPM
Permethrins	< 0.5 PPM
Phenothrin	< 0.05 PPM
Phosmet	< 0.02 PPM
Pirimicarb	< 0.02 PPM
Prallethrin	< 0.05 PPM
Propiconazole	< 0.1 PPM

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Propoxur	<0.02 PPM	
Pyraclostrobin	<0.02 PPM	
Pyridaben	<0.05 PPM	
Pyriproxyfen	<0.01 PPM	
Quintozene	<0.02 PPM	
Resmethrin	<0.1 PPM	
Spinetoram	<0.02 PPM	
Spinosad	<0.1 PPM	
Spirodiclofen	<0.25 PPM	
Spiromesifen	<3.0 PPM	
Spirotetramat	<0.02 PPM	
Spiroxamine	<0.1 PPM	
Tebuconazole	<0.05 PPM	
Tebuenozone	<0.02 PPM	
Teflubenzuron	<0.05 PPM	
Tetrachlorvinphos	<0.02 PPM	
Tetramethrin	<0.1 PPM	
Thiabendazole	<0.02 PPM	
Thiacloprid	<0.02 PPM	
Thiamethoxam	<0.02 PPM	
Thiophanate-methyl	<0.05 PPM	
Trifloxystrobin	<0.02 PPM	



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- ~~6. Other Contaminants. If any Test Batch is found to contain levels of any microorganism, chemical, elemental impurity, or pesticides that could be toxic if consumed or present, then the Regulated Marijuana Testing Facility must notify the Regulated Marijuana Business and the Division, in accordance with subparagraph (7) of this Rule, and initiate corrective actions with all parties.~~
- ~~7. Division Notification. A Regulated Marijuana Testing Facility must notify the Division by timely input in the Inventory Tracking System if a Test Batch is found to contain levels of a contaminant not listed within this Rule that could be injurious to human health if consumed. See Rule 3-825.~~

~~E. Potency Testing.~~

- ~~1. Cannabinoids Potency Profiles. A Regulated Marijuana Testing Facility may test and report results for any Cannabinoid provided the test is conducted in accordance with the Regulated Marijuana Testing Facility's standard operating procedure.~~
- ~~2. Reporting of Results.~~
  - ~~a. For potency tests on Regulated Marijuana, Regulated Marijuana Concentrate, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana, results must be reported by listing a single percentage concentration for each Cannabinoid that represents an average of all Sample Increments within the Test Batch. This includes reporting the Total THC in addition to each Cannabinoid required in Rule 4-125.~~
  - ~~b. For potency tests conducted on Regulated Marijuana Product, whether conducted on each individual Production Batch or via a Reduced Testing Allowance per Rule 4-125, results must be reported by listing the total number of milligrams contained within a single Regulated Marijuana Product unit for sale for each Cannabinoid and stating whether the THC content is homogenous as defined in Paragraphs 3 and 4 of this subparagraph E.~~
  - ~~c. Effective Date for Reporting D8-THC, D10-THC, and Exo-THC. Requirements for reporting potency test results for D8-THC, D10-THC, and Exo-THC shall take effect on July 1, 2022.~~
- ~~3. Failed Potency Tests for Medical Marijuana Product.~~
  - ~~a. If the Cannabinoid content of Medical Marijuana Product is determined not to be homogeneous, then it shall be considered to have failed potency testing. A Production Batch of Medical Marijuana Product shall be considered homogeneous if a minimum of a total of four servings from two packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label. A Production Batch of Medical Marijuana Product shall be considered homogenous if a minimum of a total of four servings from four individual single serve packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label.~~

- ~~i. The four servings must also test within the allowed potency variance set forth in subparagraph E(5) of this Rule 4-115.~~
    - ~~ii. Any Cannabinoid that makes up less than 10 percent of the total amount of Cannabinoids in the Medical Marijuana Product shall not be subject to the requirements set forth in this subparagraph (E)(3).~~
  - ~~b. If an individually packaged Edible Medical Marijuana Product is determined to have more than the total milligrams of THC stated on the Container, or less than the total milligrams of THC stated on the Container, then the Test Batch shall be considered to have failed potency testing. Except that the potency variance provided for in subparagraph (E)(5) of this Rule 4-115 shall apply to potency testing.~~
- ~~4. Failed Potency Tests for Retail Marijuana Product.~~
- ~~a. If the Cannabinoid content of Retail Marijuana Product is determined not to be homogeneous, then it shall be considered to have failed potency testing. A Production Batch of Retail Marijuana Product shall be considered homogeneous if a minimum of a total of four servings from two packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label. A Production Batch of Retail Marijuana Product shall be considered homogenous if a minimum of a total of four servings from four individual single serve packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label.~~
    - ~~i. The four servings must also test within the allowed potency variance set forth in subparagraph E(5) of this Rule 4-115.~~
    - ~~ii. Any Cannabinoid that makes up less than 10 percent of the total amount of Cannabinoids in the Retail Marijuana Product shall not be subject to the requirements set forth in this subparagraph (E)(4).~~
  - ~~b. If an individually packaged Edible Retail Marijuana Product is determined to have more than 100 milligrams of THC within it, then the Test Batch shall be considered to have failed potency testing. If an individually packaged Edible Retail Marijuana Product is determined to have more than the total milligrams of THC stated on the Container, or less than the total milligrams of THC stated on the Container, then the Test Batch shall be considered to have failed potency testing. If a single serving in an individually packaged Edible Retail Marijuana Product is determined to have more than 10 milligrams of THC then the Test Batch shall be considered to have failed potency testing. Except that the potency variance provided for in subparagraph (E)(5) of this Rule 4-115 shall apply to potency testing.~~

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- ~~5. — Potency Variance. Regulated Marijuana Product provided to the Regulated Marijuana Testing Facility must comply with the following potency variance:~~
- ~~a. — For Regulated Marijuana Product with a Target Potency or making a potency claim for any cannabinoid of more than 2.5 milligrams per serving the potency variance shall differ no more than plus or minus 15 percent.~~
- ~~b. — For Regulated Marijuana Product with a Target Potency or making a potency claim for any cannabinoid of 2.5 milligrams or less per serving the potency variance shall differ no more than the greater of plus or minus 0.5 mg or 40 percent per serving.~~
- ~~F. — Testing Regulated Marijuana Ready for Transfer. All tests must occur at the time the Regulated Marijuana is ready for Transfer to another Regulated Marijuana Business, according to the required steps outlined in the standard operating procedures of the Licensee submitting the Test Batch.~~
- ~~F.5. — Licensees shall not Transfer Regulated Marijuana that they have reason to believe would not pass testing required by Rules 4-120 and 4-125, unless otherwise permitted in these rules.~~
- ~~G. — Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose — 4-120**

The statutory authority for this rule includes but is not limited to sections ~~44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S.~~ Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the contaminant testing and related Reduced Testing Allowance portion of the Division's Regulated Marijuana sampling and testing program. This Rule 4-120 was previously Rules M and R 1501, 1 CCR 212-1 and 1 CCR 212-2.

**4-120 — Regulated Marijuana Testing Program: Contaminant Testing**

- ~~A. — Contaminant Testing Required.~~
- ~~1. — A Regulated Marijuana Business shall not Transfer or process Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Regulated Marijuana Concentrate or Regulated Marijuana Product unless Test Batches from each Harvest Batch or Production Batch from which that Regulated Marijuana was derived has been tested by a Regulated Marijuana Testing Facility for contaminants and passed all contaminant tests required by this Rule, except as permitted in Rule 5-205(C), 6-205(C), or the cultivation or production process has achieved a Reduced Testing Allowance under this Rule.~~
- ~~B. — Reduced Testing Allowance and Ongoing Testing — Contaminant Testing.~~

- ~~1. Regulated Marijuana. A Regulated Marijuana Cultivation Facility's cultivation process may achieve a Reduced Testing Allowance for contaminant testing if every Harvest Batch that it produced during at least a six-week period (minimum 42 days) but no longer than a 12-week period (maximum 84 days) passed all contaminant tests required by Paragraph (C) of this Rule. This must include at least six Test Batches. The period begins from the date of the creation of the first Harvest Batch that passed reduced testing allowance testing. A Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator can achieve a Reduced Testing Allowance for all contaminants listed in paragraph (C) of this Rule at the same time or separately for each contaminant. A Regulated Marijuana Cultivation Facility must cultivate and process all Harvest Batches the same way, including the same growing media, lighting, pesticides, and drying, trimming, and packaging procedures to be eligible to obtain and maintain a Reduced Testing Allowance.~~
  - ~~a. Visual Microbial Growth. If a Regulated Marijuana Cultivation Facility is aware that a Harvest Batch contains visual microbial contamination, the Regulated Marijuana Cultivation Facility shall subject the Harvest Batch to microbial contaminant testing pursuant to Rule 4-120(C)(1). If the Test Batch fails testing, then the Harvest Batch shall be subject to the requirements in Rule 4-135(C). The Licensees must also follow Rule 4-120(F)(2).~~
  - ~~b. Effective July 1, 2024, a Regulated Marijuana Cultivation Facility may achieve a Reduced Testing Allowance for microbial contaminant testing pursuant to this Rule 4-120 if the Licensee has a Hazard Analysis and Critical Control Point (HACCP) System containing elements defined in ASTM D8250-19: "Standard Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products" that addresses each product type to receive Reduced Testing Allowance for microbial contaminant testing. The materials incorporated by reference shall be those effective as of January 8, 2024. This Rule does not include any later amendments or editions to this ASTM Standard. The Division maintains a copy of ASTM D8250-19 at 1697 Cole Boulevard, Suite 200, Lakewood, Colorado, 80401, which is available to the public for inspection during the Division's regular business hours. The pre-requisite programs requirements by the standard will be considered to have been met if the Regulated Marijuana Cultivation Facility includes documentation on how the sanitary and health requirements from Rules 3-310 and 3-330 are implemented to ensure the hygienic and safe processing of consumable marijuana. This HACCP System must address biological hazards at a minimum, and may also address additional hazards such as chemical hazards and physical hazards.~~
    - ~~i. If a Critical Control Point (CCP) is found to be outside of the Critical Limits (CLs) established in the HACCP plan during the production of a Harvest Batch(es) then this Harvest Batch(es) shall be submitted for microbial contaminant testing. For purposes~~

~~of this Rule, Critical Control Point (CCP) means a step in the processing of Regulated Marijuana at which control can be applied and is essential to prevent or eliminate a safety hazard or reduce it to an acceptable level and shall have the same meaning as defined and used in ASTM Standard D8250-19, which the Division has maintained a copy and is available to the public for inspection.~~

~~A. If the Harvest Batch passes microbial contaminant testing, then there is no effect on the Reduced Testing Allowance and the Harvest Batch may be Transferred.~~

~~B. If the Harvest Batch fails microbial contaminant testing, then the Licensee shall follow Rule 4-120(F)(2) to reauthorize the Reduced Testing Allowance for microbial contaminants.~~

~~ii. The HACCP System shall be documented as per ASTM D8250-19.6.1.12. The following records must be kept during the time that a Regulated Marijuana Cultivation Facility qualifies for and maintains a Reduced Testing Allowance for microbial contaminants and for one year after the Reduced Testing Allowance expires for any reason:~~

~~A. List of the HACCP team, including relevant experience;~~

~~B. Product description and intended use for each product type receiving a Reduced Testing Allowance for microbial contaminants;~~

~~C. Verified Process Flow Diagram, including Critical Control Points (CCPs);~~

~~D. Hazard Analysis;~~

~~E. List of CCPs and reasoning as to how they were identified;~~

~~F. List of Critical Limits (CLs) and reasoning as to how they were selected;~~

~~G. List of Monitoring Procedures for CCPs;~~

~~H. List of pre-planned Corrective Actions in case of deviations;~~

~~I. List of verification procedures;~~

~~J. HACCP system summary page that includes:~~

~~1. CCPs;~~

~~2. Critical Limits (CLs);~~

~~3. Monitoring Procedures;~~

- ~~4. Corrective Actions related to specific CCPs;~~
  - ~~5. Verification procedures; and~~
  - ~~6. Record Titles associated with the CCP activities (i.e. The Water Activity Monitoring Logbook, etc.);~~
  - ~~K. Support documentation of the CCP validation (i.e. microbial contaminants testing results for Reduced Testing Allowance qualification and maintenance periods); and~~
  - ~~L. Documents generated during operational activities related to the HACCP system, including at minimum: Verified Monitoring Logs for CCPs, Corrective and Preventive Actions documentation related to CCPs, and Material Changes related to HACCP system.~~
- ~~c. Effective July 1, 2024, to achieve a Reduced Testing Allowance for microbial contaminants, a Regulated Marijuana Cultivation Facility must conduct an internal audit to assess that they are in substantial compliance with the requirements of Rules 3-310, 3-330, 3-336, 4-110, 4-120, 6-210(D), and 6-210(E) by achieving a passing score. This internal audit will be performed and scored per the rubric listed in Rule 4-120(B)(1)(b)(i). A copy of this internal audit shall be retained as business records for one year. Internal Audit Scoring Rubric. The internal audit will be scored as follows:~~
  - ~~i. Scoring System: 0% – 100%~~
  - ~~ii. Passing Score: 80% – 100%~~
  - ~~iii. Non-Conformance Finding Deductions:~~
    - ~~A. Minor: 1%~~
    - ~~B. Major: 5%~~
    - ~~C. Critical: 100%~~
  - ~~iv. Definition of Non-Conformances:~~
    - ~~A. Minor: A deficiency in the compliance to Rule that reasonably could lead to a risk in product safety.~~
    - ~~B. Major: A deficiency in compliance to Rule that carries a highly likely to definite risk to product safety.~~
    - ~~C. Critical: A clear deficiency in compliance to Rule that could lead to serious injury or death; or if any falsification of records is found.~~
- ~~d. Effective July 1, 2024, Attestation of Substantial Compliance with Rules. To achieve a Reduced Testing Allowance for Microbial Contaminants, an authorized representative of the Regulated Marijuana Cultivation Facility~~

must sign an attestation that they are, to the best of their knowledge, in substantial compliance with Rules 3-330 and 4-120 by achieving a passing score. A copy of this Attestation shall be retained as business records for one year.

- ~~2. Regulated Marijuana Concentrate, Regulated Marijuana Product, Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana. A Regulated Marijuana Business's production process may achieve a Reduced Testing Allowance for contaminant testing if for a particular type of Regulated Marijuana Concentrate, Regulated Marijuana Product, or Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana every Production Batch that it produced during at least a four-week period (minimum 28 days) but no longer than an eight-week period (maximum 56 days) passed all contaminant tests required by Paragraph (C) of this Rule. This must include Test Batches from at least four Production Batches. This period begins from the date of the creation of the first Production Batch that passed reduced testing allowance testing. If a Regulated Marijuana Concentrate or Regulated Marijuana Product is manufactured using a different extraction process or infusion process or using any different Additives or Botanically Derived Compounds, it will be considered a different type of Regulated Marijuana Concentrate or Regulated Marijuana Product and therefore must separately achieve a Reduced Testing Allowance. If Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana is produced using different input materials, such as a different marijuana category (e.g. flower or trim), different wrapper materials, different processes, or different equipment, they must achieve separate Reduced Testing Allowances.~~
- ~~3. Reduced Testing Allowances are Effective for One Year. Once a Regulated Marijuana Business has successfully achieved a Reduced Testing Allowance for each of the contaminants listed in paragraph (C) of this Rule, the Reduced Testing Allowance is effective for one year (365 days inclusive, or 366 days inclusive during a leap year) from the date of the first passing harvest date or production date required to satisfy the Reduced Testing Allowance requirements.~~
- ~~4. Regulated Marijuana Ongoing Contaminant Testing. After successfully achieving a Reduced Testing Allowance, a Regulated Marijuana Business shall subject at least one Harvest Batch to all contaminant testing required by Paragraph (C) of this Rule once every 30-day period following the test submission date of the last Test Batch used to achieve the Reduced Testing Allowance. If during any 30-day period the Regulated Marijuana Business does not possess a Harvest Batch that is ready for testing, The Regulated Marijuana Business must subject its first Harvest Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Regulated Marijuana. If a Harvest Batch subject to ongoing contaminant testing fails contaminant testing, the Regulated Marijuana Business shall follow the procedure in Paragraph (F)(2) of this Rule. Ongoing contaminant testing pursuant to this Rule 4-120 shall be subject to the requirements in Rule 4-110. See Rule 4-110(A) — Collection of Test Batches.~~

  - ~~a. The Division may reduce the frequency of ongoing contaminant testing required if the Division has reasonable grounds to believe Medical~~



~~Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.~~

b. ~~If the Licensee fails to comply with paragraph (B)(4) of this Rule, the Regulated Marijuana Business is no longer authorized a Reduced Testing Allowance.~~

5. ~~Regulated Marijuana Concentrate, Regulated Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana Ongoing Contaminant Testing. After successfully achieving a Reduced Testing Allowance, once every 30 days the Regulated Marijuana Business shall subject at least one Production Batch of each particular type of Regulated Marijuana Concentrate, Regulated Marijuana Product, Pre-Rolled Marijuana, or Infused Pre-Rolled Marijuana for which it has achieved a Reduced Testing Allowance to all contaminant testing required by Paragraph (C) of this Rule. If during any 30-day period the Regulated Marijuana Business does not possess a Production Batch that is ready for testing, the Regulated Marijuana Business must subject its first Production Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Regulated Marijuana. If a Production Batch submitted for ongoing contaminant testing fails contaminant testing, the Regulated Marijuana Business shall follow the procedure in Paragraph (F)(2) of this Rule.~~

a. ~~The Division may reduce the frequency of ongoing contaminant testing required if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.~~

b. ~~If the Licensee fails to comply with paragraph (B)(5) of this Rule, the Regulated Marijuana Business is no longer authorized under a Reduced Testing Allowance.~~

6. ~~Reduced Testing Allowance Certification Fee. Effective January 8, 2024, a Licensee seeking to obtain Reduced Testing Allowance must first pay the fee in Rule 2-205.~~

a. ~~A Licensee who chooses to pay the Reduced Testing Allowance fee must also submit an attestation form that at a minimum requires the Licensee attest they understand these testing Rules and requirements.~~

b. ~~Upon the Division's receipt of payment of the fee and submission of the attestation form, a Licensee may exercise the privileges of Reduced Testing Allowance for a 12-month period.~~



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c. ~~If a Licensee is required, under these Rules, to reauthorize the Reduced Testing Allowance within the 12-month period, the Licensee is not required to pay a new fee.~~

d. ~~Reduced Testing Allowance Certification can be renewed annually.~~

G. ~~Required Contaminant Tests:~~

1. ~~Microbial Contaminant Testing. Harvest Batches of Regulated Marijuana, flower, shake, and trim, re-testing of Regulated Marijuana flower, shake, and/or trim that has undergone Decontamination, Production Batches of Physical Separation, Heat/Pressure, or Food-Based Medical Marijuana Concentrate, Production Batches of Physical Separation, Heat/Pressure, or Food-Based Retail Marijuana Concentrate, Solvent-Based Medical Marijuana Concentrate produced through Remediation, Solvent-Based Retail Marijuana Concentrate produced through Remediation, Regulated Marijuana Product, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Hemp Products, Pressurized Metered Dose Inhalers, Vaporizer Delivery Devices, and Audited Product must be tested for microbial contamination by a Regulated Marijuana Testing Facility at the frequency established by Paragraphs (A) and (B) of this Rule. The microbial contamination test must include, but need not be limited to, testing to determine the presence of and/or amounts present of microbial contaminants listed in Rule 4-115(D)(1): Shiga-toxin producing Escherichia coli (STEC)\*—Bacteria, Aspergillus (A. fumigatus, A. flavus, A. niger, A. terreus), Salmonella species\*—Bacteria, Total Yeast and Mold, Total aerobic microbial count, Staphylococcus Aureus, Pseudomonas aeruginosa, Bile tolerant gram negative bacteria and Candida albicans.~~

a. ~~Effective Date for Required Aspergillus Testing. Requirements for Aspergillus testing pursuant to this rule shall take effect on July 1, 2022.~~

1.5 ~~Water Activity Testing. Harvest Batches of Regulated Marijuana, flower, shake, and trim (other than wet whole plant), re-testing of Regulated Marijuana flower, shake, and/or trim that has undergone Decontamination, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana at the frequency established by Paragraphs (A) and (B) of this Rule.~~

2. ~~Residual Solvent Contaminant Testing. Production Batches of Solvent-Based Medical Marijuana Concentrate, Solvent-Based Retail Marijuana Concentrate, and Audited Product that contains any Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate produced by a Regulated Marijuana Products Manufacturer must be tested by a Regulated Marijuana Testing Facility for residual solvent contamination at the frequency established by Paragraphs (A) and (B) of this Rule. The residual solvent contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of acetone, butane, ethanol, heptanes, isopropyl alcohol, propane, benzene\*, toluene\*, pentane, hexane\*, methanol\*, ethyl acetate, and total xylenes\* (m, p, o—xylenes).~~

~~\* Note: These solvents are not approved for use. Testing is required for these solvents due to their possible presence in the solvents approved for use per Rule 5-315 and 6-315.~~

- ~~3. Mycotoxin Contaminant Testing. As part of Remediation, each Production Batch of Solvent-Based Medical Marijuana Concentrate produced by a Medical Marijuana Products Manufacturer or Solvent-Based Retail Marijuana Concentrate produced by a Regulated Marijuana Products Manufacturer from Regulated Marijuana that failed microbial contaminant testing produced must be tested by a Regulated Marijuana Testing Facility for mycotoxin contamination. Each failed Harvest Batch of Regulated Marijuana flower, shake, and/or trim and each failed Production Batch of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana that has undergone Decontamination must be tested by a Regulated Marijuana Testing Facility for mycotoxin contamination. Each Production Batch of Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contamination must be tested for mycotoxin contamination. The mycotoxin contaminant test must include, but need not be limited to, testing to determine the presence of, and amounts present of, aflatoxins (B1, B2, G1, and G2) and ochratoxin A. This is in addition to all other contaminant testing required by this Paragraph (C). This contaminant test cannot be exempt from testing by a Reduced Testing Allowance in accordance with subparagraph (B)(2) of this Rule, except Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contamination pursuant to Rule 4-121.~~
- ~~4. Pesticide Contaminant Testing. Harvest Batches of Regulated Marijuana, Production Batches of Regulated Marijuana Concentrate, Production Batches of Pre-Rolled Marijuana, and Production Batches of Infused Pre-Rolled Marijuana must be tested for Pesticide contamination by a Regulated Marijuana Testing Facility at the frequency established by this Rule 4-120(A) and (B). The Pesticide contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, the Pesticides listed in Rule 4-115(D)(5).~~
  - ~~a. Effective Date for Required Pesticide Contaminant Testing for Production Batches of Regulated Marijuana Concentrate. Requirements for Pesticide contaminant testing for Production Batches of Regulated Marijuana Concentrate pursuant to this rule shall take effect on July 1, 2021.~~
- ~~5. Elemental Impurities Testing.~~
  - ~~a. Each Harvest Batch and Production Batch of Regulated Marijuana must be tested for elemental impurities by a Regulated Marijuana Testing Facility at the frequency established in paragraphs (A) and (B) of this Rule. The elemental impurities test must include, but need not be limited to, testing to determine the presence of, and amounts present of, arsenic, cadmium, lead, and mercury.~~

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- ~~b. Emissions Testing. This subsection (C)(5)(b) is effective January 1, 2022. Each Harvest Batch and Production Batch of Regulated Marijuana Concentrate in a Vaporized Delivery Device must be tested for elemental impurities via emissions testing by a Regulated Marijuana Testing Facility at the frequency established in subparagraphs (A) and (B) of this Rule. The elemental impurities test must include, but need not be limited to, testing to determine the presence and amounts of arsenic, cadmium, lead, and mercury.~~
- ~~D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to a Regulated Marijuana Cultivation Facility or Regulated Marijuana Products Manufacturer Transferring or processing any Regulated Marijuana from that Harvest Batch or Production into a Regulated Marijuana Concentrate or Regulated Marijuana Product. Additional tests may include, but need not be limited to, screening for Pesticides, chemical contaminants, biological contaminants, or other types of microbes, molds, elemental impurities, or residual solvents.~~
- ~~E. Exemptions.~~
  - ~~1. Medical Marijuana Concentrate.~~
    - ~~a. A Medical Marijuana Products Manufacturer who combines multiple Production Batches of Solvent-Based Medical Marijuana Concentrate into a Production Batch of Solvent-Based Medical Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule only if all original Production Batches passed residual solvent testing. This does not apply if a solvent, Additive, or any other Ingredient was introduced during the combination of the Production Batches.~~
    - ~~b. A Production Batch of Medical Marijuana Concentrate shall be considered exempt from contaminant testing requirements pursuant to this Rule if the Medical Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Medical Marijuana Product, except that a Solvent-Based Medical Marijuana Concentrate must still be submitted for residual solvent contaminant testing and Medical Marijuana Concentrate must still be submitted for pesticide contaminant testing. The manufactured Medical Marijuana Product shall be subject to mandatory testing under this Rule.~~
  - ~~2. Retail Marijuana Concentrate.~~
    - ~~a. A Retail Marijuana Products Manufacturer or Accelerator Manufacturer who combines multiple Production Batches of Solvent-Based Retail Marijuana Concentrate into a Production Batch of Solvent-Based Retail Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule only if all original Production Batches passed residual solvent testing. This does not apply if a solvent, Additive or any other Ingredient was introduced during the combination of the Production Batches.~~

- ~~b. — A Production Batch of Retail Marijuana Concentrate shall be considered exempt from contaminant testing requirements pursuant to this Rule if the Retail Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Retail Marijuana Product, except that a Solvent-Based Retail Marijuana Concentrate must still be submitted for residual solvent contaminant testing and Retail Marijuana Concentrate must still be submitted for pesticide contaminant testing. The manufactured Retail Marijuana Product shall be subject to testing under this Rule.~~
  - ~~3. — Regulated Marijuana Product. A Regulated Marijuana Business that produces Regulated Marijuana Products with intended use for oral consumption or skin and body products, is exempt from aspergillus testing as required by these 4-100 Series Rules.~~
- ~~F. — Events Requiring Re-Authorization for a Reduced Testing Allowance—Contaminants.~~
  - ~~1. — Material Change. If a Licensee makes a Material Change to its cultivation or production process or its standard operating procedures, then it must have the first five Harvest Batches or Production Batches produced using the new procedures tested for all of the contaminants required by Paragraph (C) of this Rule regardless of whether its process has previously achieved a Reduced Testing Allowance regarding contaminants. If any of those tests fail, then the Regulated Marijuana Business's process must achieve a new Reduced Testing Allowance.~~
    - ~~a. — Pesticide or other Agricultural Substances. It is a Material Change if a Regulated Marijuana Cultivation Facility begins using a new or different Pesticide or other agricultural substances (e.g. nutrients, fertilizers) during its cultivation process.~~
    - ~~b. — Solvents. It is a Material Change if a Regulated Marijuana Products Manufacturer begins using a new or different solvent or combination of solvents or changes any parameters for equipment related to the solvent purging process, including but not limited to, time, temperature, or pressure.~~
    - ~~c. — Cultivation. It is a Material Change if a Regulated Marijuana Cultivation Facility begins using a new or different method for any material part of the cultivation process, including, but not limited to, changing from one growing medium to another.~~
    - ~~d. — Environmental Conditions. It is a Material Change if a Regulated Marijuana Cultivation Facility changes parameters associated with environmental conditions, including temperature, humidity, or lighting.~~
    - ~~e. — Cleaning and Sanitation. It is a Material Change if a Regulated Marijuana Cultivation Facility makes changes to cleaning or sanitation processes.~~

- ~~f. Inputs and Contact Surfaces. It is a Material Change if a Regulated Marijuana Cultivation Facility changes materials that have direct contact with product components, including but not limited to, ingredients, additives, or hardware such as Vaporizer Delivery Devices.~~
    - ~~g. Testing Required Prior to Transfer or Processing. When a Harvest Batch or Production Batch is required to be submitted for testing pursuant to this Rule, the Licensee that produced it may not Transfer or process Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Regulated Marijuana Concentrate or Regulated Marijuana Product unless the Harvest Batch or Production Batch passes all required testing.~~
  - ~~2. Failed Contaminant Testing and Reduced Testing Allowance. Failed contaminant testing may constitute a violation of these rules.~~
    - ~~a. If a Test Batch is required to be tested by these Rules or required to be tested by the Division pursuant to Rule 4-120(A) and fails contaminant testing, the Licensee shall follow the procedures in Rule 4-135 for any Inventory Tracking System package, Harvest Batch, or Production Batch from which the failed Sample was taken.~~
    - ~~b. The Licensee shall also submit Test Batches from three new Harvest Batches or Production Batches of the Regulated Marijuana for contaminant testing by a Regulated Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails contaminant testing, the Licensee shall achieve a new Reduced Testing Allowance for contaminants.~~
  - ~~3. Failed Internal Audit or a Failed MED Inspection for Compliance with Rule 4-120(B)(1)(b). If a Regulated Marijuana Cultivation Facility fails an internal audit or a Division inspection evaluating compliance with the requirements referenced in Rule 4-120(B)(1)(b), then the Licensee must:~~
    - ~~a. Correct the identified deficiencies. These activities to correct such deficiencies must follow Corrective Action Preventive Action procedures listed in Rule 6-120(D).~~
    - ~~b. Complete a new internal audit to the Rules listed in Rule 4-120(B)(1)(b) and scored according to Rule 4-120(B)(1)(c).~~
    - ~~c. Complete a new attestation of substantial compliance to the Rules referenced in Rule 4-120(B)(1)(d) signed by an authorized representative of the Regulated Marijuana Cultivation Facility.~~
    - ~~d. Follow Re-Authorization procedures listed in paragraph (F)(2) of this Rule after paragraphs (a)–(c) have been addressed.~~

~~In addition, regardless of completion of the steps above, the Regulated Marijuana Cultivation Facility may be required to submit additional Sample(s) or Test~~

~~Batches pursuant to Rule 4-105 to address concerns from the failed internal audit or Division inspection.~~

- ~~G. — Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

#### **Basis and Purpose — 4-121**

~~The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish requirements and exemptions for contaminant testing for wet whole plant.~~

#### **4-121 — Regulated Marijuana Testing Program: Wet Whole Plant Contaminant Testing**

- ~~A. — Microbial Contaminant Testing. A Regulated Marijuana Cultivation Facility shall not Transfer wet whole plant or process wet whole plant into Regulated Marijuana Concentrate unless Test Batches from each Harvest Batch of Regulated Marijuana wet whole plant were tested for microbial contamination by a Regulated Marijuana Testing Facility and passed all microbial contaminant tests except as permitted in Rules 5-205(C), 6-205(C), or the cultivation process has achieved a Reduced Testing Allowance under this Rule. The microbial contamination test must include, but need not be limited to, testing to determine the presence of and/or amounts present of microbial contaminants listed in Rule 4-115(D)(1): Shiga toxin-producing Escherichia coli (STEC)\*-Bacteria, Aspergillus (A. fumigatus, A. flavus, A. niger, A. terreus), Salmonella species\*-Bacteria, Total Yeast and Mold.~~
- ~~B. — Reduced Testing Allowance and Ongoing Testing — Microbial Contaminant Testing. A Regulated Marijuana Cultivation Facility's cultivation process for wet whole plant shall be deemed acceptable for a Reduced Testing Allowance for microbial contaminant testing if every Harvest Batch of wet whole plant that it produced during at least a three-week (minimum 21 days) period but no longer than a 12-week (maximum 84 days) period passed all microbial contaminant tests required by this Rule. This must include at least six Test Batches. A Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator can achieve a Reduced Testing Allowance for contaminants listed in this Rule 4-121.~~
- ~~C. — Reduced Testing Allowances are Effective for One Year. Once a Regulated Marijuana Business has successfully achieved a Reduced Testing Allowance for a contaminant test, the Reduced Testing Allowance is effective for one year (365 days inclusive, or 366 days inclusive during a leap year) from the date of the first passing harvest date or required to satisfy the Reduced Testing Allowance requirements.~~
- ~~D. — Regulated Marijuana Ongoing Contaminant Testing. After successfully achieving a Reduced Testing Allowance, once every 30 days a Regulated Marijuana Cultivation Facility shall subject at least one Harvest Batch of wet whole plant to microbial contaminant testing. If during any 30-day period a Regulated Marijuana Cultivation Facility does not possess a Harvest Batch of wet whole plant that is ready for testing, the~~

~~Regulated Marijuana Cultivation Facility must subject its first Harvest Batch of wet whole plant that is ready for testing to a microbial contaminant testing prior to Transfer or processing of the Regulated Marijuana wet whole plant. If a Harvest Batch of wet whole plant subject to ongoing contaminant testing fails contaminant testing, the Regulated Marijuana Cultivation Facility shall follow the procedure in Paragraph (F)(2) of Rule 4-120. Ongoing contaminant testing pursuant to this Rule shall be subject to the requirements in Rule 4-110. See Rule 4-110(A)—Collection of Test Batches.~~

- ~~1. The Division may reduce the frequency of ongoing contaminant testing required if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.~~
- ~~2. If the Licensee fails to comply with Paragraph (D) of this Rule, the Regulated Marijuana Cultivation Facility is no longer authorized a Reduced Testing Allowance.~~

~~E. Testing Exemptions for Wet Whole Plant.~~

- ~~1. Harvest Batches of Regulated Marijuana wet whole plant are exempt from required water activity testing.~~
- ~~2. Harvest Batches of Regulated Marijuana wet whole plant is exempt from required microbial contaminant testing if a Regulated Marijuana Cultivation Facility Transfers the Regulated Marijuana wet whole plant for the purposes of extraction to a Regulated Marijuana Business with at least one identical Controlling Beneficial Owner and in accordance with this Rule. If a Regulated Marijuana wet whole plant Harvest Batch is not tested for microbial contamination, each resulting Regulated Marijuana Concentrate Production Batch shall be tested for microbial contamination pursuant to Rule 4-120.~~

~~F. Regulated Marijuana Concentrate Produced from Wet Whole Plant That Was Not Tested for Microbial Contaminants.~~

- ~~1. Required Testing. Each Production Batch of Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contaminants in accordance with the exemption in paragraph (E)(2) of this Rule must be tested for microbial contaminants and mycotoxins. In addition, the Regulated Marijuana Concentrate must be tested in accordance with Rule 4-120 for other contaminants, including pesticides, elemental impurities, and residual solvents if applicable.~~
- ~~2. Regulated Marijuana Concentrate Produced from Wet Whole Plant Not Tested for Microbial Contamination. A Regulated Marijuana Business that produces Regulated Marijuana Concentrate may achieve a Reduced Testing Allowance for a Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contamination, subject to the following requirements:~~



- a. ~~Qualification Form. The Regulated Marijuana Business that produces Regulated Marijuana Concentrate from wet whole plant not tested for microbial contamination shall obtain a completed qualification form from the Regulated Marijuana Business that cultivated the wet whole plant. The qualification form must detail the following information related to the cultivation of the wet whole plant:~~
  - i. ~~Implemented quality management systems;~~
  - ii. ~~Record keeping;~~
  - iii. ~~Notification of Material Change;~~
  - iv. ~~Notification of a wet whole plant microbial Test Batch failure;~~
  - v. ~~Cultivation and post harvest procedures;~~
  - vi. ~~Cleaning; and~~
  - vii. ~~Corrective action and preventative action.~~
- b. ~~Completion Required. The Regulated Marijuana Business that wishes to Transfer the wet whole plant that was not tested for microbial contamination must provide a completed qualification form detailing the information listed above.~~
- c. ~~Approval. The Regulated Marijuana Business that receives a Transfer of wet whole plant is responsible for ensuring it conforms with specified approval requirements, which shall include but is not limited to the following:~~
  - i. ~~The receiving Regulated Marijuana Business has confirmed it has not received notification by the Regulated Marijuana Cultivation Facility of a Material Change to its cultivation process;~~
  - ii. ~~The receiving Regulated Marijuana Business has inspected the wet whole plant Harvest Batch for visual microbial contamination. If visual microbial contamination is identified in the Harvest Batch of wet whole plant, the Licensee shall subject the Harvest Batch to microbial contaminant testing pursuant to Rule 4-121. If the Test Batch fails testing, then the Harvest Batch shall be subject to the requirements in Rule 4-135(C).; and~~
  - iii. ~~The receiving Regulated Marijuana Business has obtained evidence of compliance with testing requirements for the wet whole plant and proof of any Reduced Testing Allowances, if applicable.~~
- d. ~~Origin Verification. Verification of the Regulated Marijuana Business that cultivated the wet whole plant used to manufacture the Regulated Marijuana Concentrate.~~



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3. ~~Recordkeeping Requirements.~~ A Regulated Marijuana Business shall maintain copies of documents and other records evidencing compliance with this Rule as part of its business books and records. ~~See Rule 3-905 – Business Records Required.~~
- G. ~~Pesticide and Elemental Impurities Testing for Regulated Marijuana Wet Whole Plant.~~ Each Harvest Batch of Regulated Marijuana wet whole plant must be tested for Pesticide and Elemental Impurities testing in accordance with Rule 4-120.
- H. ~~Events Requiring Re-Authorization for a Reduced Testing Allowance.~~ A Regulated Marijuana Cultivation Facility must follow Rule 4-120 for any events that would require a Re-Authorization for a Reduced Testing Allowance. That may include a failed test or a Material Change described in Rule 4-120 (F). The Licensee must act in accordance with Rule 4-120 (F)(2) if either scenario occurs.
- I. ~~Violation Affecting Public Safety.~~ Failure to comply with this Rule may constitute a license violation affecting public safety.

**Basis and Purpose – 4-125**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the potency testing and related Reduced Testing Allowance portion of the Division's Regulated Marijuana sampling and testing program. This Rule 4-125 was previously Rules M and R 1503, 1 CCR 212-1 and 1 CCR 212-2.

**4-125 – Regulated Marijuana Testing Program: Potency Testing****A. ~~Potency Testing – General.~~**

1. ~~Test Batches.~~ A Test Batch submitted for potency testing may only be comprised of sample increments that are of the same strain of Medical Marijuana or Retail Marijuana or from the same Production Batch of Medical Marijuana Concentrate or Medical Marijuana Product, or from the same Production Batch of Retail Marijuana Concentrate or Retail Marijuana Product, or from the same Production Batch of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana.
2. ~~Cannabinoid Profile.~~ A potency test conducted pursuant to this Rule must at least determine the level of concentration of D8-THC, D9-THC, D-10-THC, Exo-THC, THCA, CBD, CBDA, and CBN.

**B. ~~Potency Testing for Regulated Marijuana.~~**

1. ~~Initial Potency Testing.~~ A Regulated Marijuana Cultivation Facility must have potency tests conducted by a Regulated Marijuana Testing Facility on four Harvest Batches, created a minimum of one week apart, for each strain of Regulated Marijuana that it cultivates. ~~See Rule 4-105(B).~~

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- ~~a. The first potency test must be conducted on each strain prior to the Regulated Marijuana Cultivation Facility Transferring or processing into a Medical Marijuana Concentrate any Medical Marijuana of that strain, or into a Retail Marijuana Concentrate any Retail Marijuana of that strain.~~
    - ~~b. All four potency tests must be conducted on each strain no later than December 1, 2014 or six months after the Regulated Marijuana Cultivation Facility begins cultivating that strain, whichever is later.~~
  - ~~2. Ongoing Potency Testing. After the initial four potency tests, a Regulated Marijuana Cultivation Facility shall have each strain of Regulated Marijuana that it cultivates tested for potency at least once per quarter.~~
    - ~~a. If the Licensee fails to comply with paragraph (B)(2) of this Rule, the Regulated Marijuana Cultivation Facility is no longer authorized for a Reduced Testing Allowance.~~
- ~~C. Potency Testing for Regulated Marijuana Concentrate except Kief.~~
  - ~~1. A Medical Marijuana Cultivation Facility or a Medical Marijuana Products Manufacturer must have a potency test conducted by a Medical Marijuana Testing Facility on every Production Batch of Medical Marijuana Concentrate that it produces prior to Transferring or processing into a Medical Marijuana Product any of the Medical Marijuana Concentrate from that Production Batch.~~
  - ~~2. A Retail Marijuana Cultivation Facility, Accelerator Cultivator, Retail Marijuana Products Manufacturer, or an Accelerator Manufacturer must have a potency test conducted by a Retail Marijuana Testing Facility on every Production Batch of Retail Marijuana Concentrate that it produces prior to Transferring or processing into a Retail Marijuana Product any of the Retail Marijuana Concentrate from that Production Batch.~~
- ~~D. Repealed.~~
- ~~E. Potency Testing for Regulated Marijuana Product.~~
  - ~~1. Potency Testing Required for Regulated Marijuana Product. A Regulated Marijuana Products Manufacturer shall have potency tests conducted by a Regulated Marijuana Testing Facility on every Production Batch of each type of Regulated Marijuana Product that it produces prior to Transferring any of the Regulated Marijuana Product from that Production Batch, unless the Regulated Marijuana Products Manufacturer has successfully achieved a Reduced Testing Allowance for potency and homogeneity for the particular type of Regulated Marijuana Product.~~
  - ~~2. Required Tests. Potency and homogeneity tests conducted on Regulated Marijuana Product must determine the level of concentration of the required Cannabinoids and whether or not THC is homogeneously distributed throughout the product.~~
  - ~~3. Partially Infused Regulated Marijuana Products. If only a portion of a Regulated Marijuana Product is infused with Regulated Marijuana, then the Regulated~~

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~~Marijuana Products Manufacturer must inform the Regulated Marijuana Testing Facility of exactly which portions of the Regulated Marijuana Product are infused and which portions are not infused.~~

~~E.1. Potency Testing Required for Pre-Rolled Marijuana.~~

- ~~1. A Regulated Marijuana Business shall have potency tests conducted by a Regulated Marijuana Testing Facility on every Production Batch of each type of Pre-Rolled Marijuana product that it produces prior to Transferring or selling any of the Pre-Rolled Marijuana from that Production Batch if the Regulated Marijuana Business is using multiple strains from different sources (e.g. self-grown source, wholesale source) and/or selecting only a part of the Harvest Batch(es) that is not representative of the entire Harvest Batch each time they produce a certain type of Pre-Rolled Marijuana (e.g. using only the shake/trim out of a Harvest Batch).~~
- ~~2. If each type of Pre-Rolled Marijuana is created using select parts of a single strain (e.g. flower only, shake/trim only) or a specific ratio of strains from specified sources (e.g. self-grown source, wholesale source) defined by the Regulated Marijuana Business' standard operating procedures, a Regulated Marijuana Business shall have potency tests conducted according to paragraph (E.1)(2)(a) and (b) of this Rule by a Regulated Marijuana Testing Facility for each type of Pre-Rolled Marijuana product that it produces prior to Transferring or selling any of the Pre-Rolled Marijuana from a Production Batch.~~
  - ~~a. Initial Potency Testing. Initial potency tests shall be conducted by a Regulated Marijuana Testing Facility on four Production Batches, created a minimum of one week apart, for each type of Pre-Rolled Marijuana that is created using a single strain or a specific ratio of strains defined by the Regulated Marijuana Business' standard operating procedures.~~
  - ~~b. Ongoing Potency Testing. After the initial four potency tests, ongoing potency tests shall be conducted by a Regulated Marijuana Testing Facility at least once per quarter for each type of Pre-Rolled Marijuana that is created using a single strain or a specific ratio of strains defined by the Regulated Marijuana Business' standard operating procedures.~~
- ~~3. A Regulated Marijuana Business shall be considered exempt from potency testing if the Pre-Rolled Marijuana Production Batch uses a single strain and uses all parts of the Harvest Batch that were included in the potency testing of the Harvest Batch prior to creating the Pre-Rolled Marijuana Production Batches. In this case, the potency test results of the Harvest Batch shall be used for the Pre-Rolled Marijuana Production Batch.~~
- ~~4. Production Batches of Pre-Rolled Marijuana are exempt from homogeneity testing.~~

~~E.2. Potency Testing Required for Infused Pre-Rolled Marijuana.~~

- ~~1. A Regulated Marijuana Business shall have potency tests conducted by a Regulated Marijuana Testing Facility on every Production Batch of Infused Pre-~~

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~~Rolled Marijuana product that it produces prior to Transferring any of the Infused Pre-Rolled Marijuana from that Production Batch.~~

- ~~2. Production Batches of Infused Pre-Rolled Marijuana are exempt from homogeneity testing.~~

~~F. Reduced Testing Allowance – Potency and Homogeneity.~~

- ~~1. A Retail Marijuana Products Manufacturer or Accelerator Manufacturer may achieve a Reduced Testing Allowance for potency and homogeneity for each type of Retail Marijuana Product it manufactures.~~
  - ~~a. For Edible Retail Marijuana Products a potency test result that is within 15 percent of the target potency will count towards a Reduced Testing Allowance.~~
    - ~~i. For Edible Retail Marijuana Products that contain 2.5 milligrams of THC or less per serving, a potency test result that is within the greater of plus or minus 0.5 milligrams or 40 percent per serving will count towards a Reduced Testing Allowance.~~
- ~~2. A Medical Marijuana Products Manufacturer may achieve a Reduced Testing Allowance for potency and homogeneity for each type of non-Edible Medical Marijuana Product and each type of Edible Medical Marijuana Product that it manufactures.~~
  - ~~a. For Edible Medical Marijuana Products that contain 100 milligrams of THC or less per Container, a potency test result that is within 15 percent of the target potency will count towards a Reduced Testing Allowance.~~
    - ~~i. For Edible Medical Marijuana Products that contain 2.5 milligrams of THC or less per serving and less than 100 milligrams of THC per Container, a potency test result that is within the greater of plus or minus 0.5 milligrams or 40 percent per serving will count towards a Reduced Testing Allowance.~~
  - ~~b. For Edible Medical Marijuana Products that contain between 101 and 500 milligrams of THC per Container, a potency test result that is within 10 percent of the target potency will count towards a Reduced Testing Allowance.~~
  - ~~c. For Edible Medical Marijuana Products that contain 501 milligrams of THC or more per Container, a potency test result that is within 5 percent of the target potency will count towards a Reduced Testing Allowance.~~
- ~~3. A Regulated Marijuana Products Manufacturer's production process for a particular type of Regulated Marijuana Product shall be deemed acceptable for a Reduced Testing Allowance for potency and homogeneity testing if every Production Batch that it produces for that particular type of Regulated Marijuana Product during at least a four-week period but no longer than an eight-week period passes all potency and homogeneity tests required by Rule 4-125. This must include at least four Test Batches.~~

- ~~4. Expiration of a Reduced Testing Allowance. A Regulated Marijuana Products Manufacturer is required to achieve a new Reduced Testing Allowance every 12 months from the date the Reduced Testing Allowance is achieved (365 days inclusive, or 366 days inclusive during a leap year from the date of the first Production Batch utilized to initiate establishing a Reduced Testing Allowance), after which point the Reduced Testing Allowance expires. When the Reduced Testing Allowance expires, the Regulated Marijuana Business shall comply with the requirements of this Rule.~~
- ~~5. Regulated Marijuana Product Ongoing Potency and Homogeneity Testing. After successfully achieving a Reduced Testing Allowance, once per quarter a Regulated Marijuana Products Manufacturer shall subject at least one Production Batch of each type of Medical Marijuana Product or Retail Marijuana Product that it produces to potency and homogeneity testing required by Paragraph (D) of this Rule. If during any quarter the Regulated Marijuana Products Manufacturer does not possess a Production Batch that is ready for testing, the Licensee must subject its first Production Batch that is ready for testing to the required potency and homogeneity testing prior to Transfer or processing of the Regulated Marijuana. If a Test Batch submitted for ongoing potency and homogeneity testing fails potency and homogeneity testing, the Licensee shall follow the procedure in Paragraph (H) of this Rule. Ongoing potency and homogeneity testing pursuant to this Rule 4-125 shall be subject to the requirements in Rule 4-110. See Rule 4-110(A) – Collection of Test Batches.~~
  - ~~a. The Division may reduce the frequency of ongoing potency and homogeneity testing required if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing potency and homogeneity testing to the Licensee's last electronic mailing address provided to the Division.~~
  - ~~b. If the Licensee fails to comply with paragraph (F)(5) of this Rule, the Regulated Marijuana Cultivation Facility is no longer authorized for a Reduced Testing Allowance.~~
- ~~G. Exemption. Any Regulated Marijuana that will be allocated for extraction in the Inventory Tracking System shall be considered exempt from potency testing pursuant to this Rule.~~
- ~~H. Events Requiring Re-Authorization for a Reduced Testing Allowance – Potency and Homogeneity – Regulated Marijuana Product.~~
  - ~~1. Material Change. If a Regulated Marijuana Products Manufacturer elects to achieve a Reduced Testing Allowance for any Regulated Marijuana Products for potency and homogeneity and it makes a Material Change to its production process for that particular type of Regulated Marijuana Product, then the Regulated Marijuana Products Manufacturer shall achieve a new Reduced Testing Allowance.~~

- a. ~~New Equipment.~~ It is a Material Change if the Regulated Marijuana Products Manufacturer begins using new or different equipment for any material part of the production process.
  - b. ~~Repealed.~~
  - c. ~~Testing Required Prior to Transfer.~~ When a Production Batch is required to be submitted for testing pursuant to this Rule, the Regulated Marijuana Products Manufacturer that produced it may not Transfer Regulated Marijuana Product from that Production Batch unless it obtains a passing test.
2. ~~Failed Potency Testing.~~ Failed potency testing may constitute a violation of these rules.
- a. ~~If a Test Batch is required to be tested by these Rules or required to be tested by the Division pursuant to Rule 4-115(A) and fails potency testing, the Regulated Marijuana Products Manufacturer shall follow the procedures in Rule 4-135(C) for any Inventory Tracking System package or Production Batch associated with the failed Sample.~~
  - b. ~~The Regulated Marijuana Products Manufacturer shall also submit Test Batches from three new Production Batches of the Regulated Marijuana Product t for potency testing by a Regulated Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails potency testing, the Regulated Marijuana Products Manufacturer shall achieve a new Reduced Testing Allowance.~~
- I. ~~Violation Affecting Public Safety.~~ Failure to comply with this Rule may constitute a license violation affecting public safety.

**Basis and Purpose—4-130**

~~The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing rules requiring Regulated Marijuana Businesses to cover certain costs associated with the Division's Regulated Marijuana Sampling and Testing Program. This Rule 4-130 was previously Rules M and R-1506, 1 CCR 212-1 and 1 CCR 212-2.~~

**4-130—Regulated Marijuana Testing Program: Costs**

~~The cost for all sampling and tests conducted pursuant to these rules shall be the financial responsibility of the Regulated Marijuana Business that is required to submit the Sample for testing.~~

**Basis and Purpose—4-135**

~~The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f),~~

~~44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing rules governing the quarantining of potentially contaminated product and the destruction of product that failed contaminant or potency testing for Division's Regulated Marijuana Sampling and Testing Program. This Rule 4-135 was previously Rules M and R 1507, 1 CCR 212-1 and 1 CCR 212-2.~~

#### **~~4-135 — Regulated Marijuana Testing Program: Contaminated Product and Failed Test Results and Procedures~~**

##### **~~A. — Quarantining of Product.~~**

- ~~1. — If the Division has reasonable grounds to believe that a particular Harvest Batch, Production Batch, or Inventory Tracking System package of Regulated Marijuana is contaminated or presents a risk to public safety, then the Division may require a Regulated Marijuana Business to quarantine it until the completion of the Division's investigation, which may include, but is not limited to, the receipt of any test results.~~
- ~~2. — If a Regulated Marijuana Business is notified by any local or state agency, or by a Regulated Marijuana Testing Facility that a Test Batch failed a contaminant or potency testing, then the Regulated Marijuana Business shall quarantine any Regulated Marijuana from any Inventory Tracking System package, Harvest Batch or Production Batch associated with that failed Test Batch and must follow the procedures established pursuant to this Rule.~~
- ~~3. — Except as provided by this Rule, Regulated Marijuana that has been quarantined pursuant to this Rule must be physically separated from all other inventory and the Licensee may not Transfer or further process the Regulated Marijuana.~~
- ~~4. — In addition to any other method authorized by law, the Division may implement the quarantine through the Inventory Tracking System by (a) indicating failed test results and (b) limiting the Licensee's ability to Transfer the quarantined Regulated Marijuana unless otherwise permitted by these rules.~~

~~B. — Failed Contaminant Testing: All Contaminant Testing Except Microbial and Water Activity Testing of Regulated Marijuana Flower, Wet Whole Plant, Trim, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Pesticide Testing, and Elemental Impurities Testing of Regulated Marijuana Flower or Trim. If a Regulated Marijuana Business is notified by the Division or a Regulated Marijuana Testing Facility that a Test Batch failed contaminant testing (except microbial and water activity testing of Regulated Marijuana flower or trim, Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana, Pesticide testing, and elemental impurities testing of Regulated Marijuana flower or trim), then for each Inventory Tracking System package, Harvest Batch, or Production Batch associated With that failed Test Batch the Regulated Marijuana Business must either:~~



- ~~1. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch or Production Batch pursuant to Rule 3-230—Waste Disposal;~~
- ~~2. Decontaminate the Inventory Tracking System package, Harvest Batch, or Production Batch, and create two new Test Batches, each containing the requisite number of Sample Increments, and have those Test Batches tested for the required contaminant test that failed. Such testing must comport with the sampling procedures under Rule 4-110.~~
  - ~~a. A Licensee must either (1) submit both new Test Batches to the same Regulated Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities;~~
  - ~~b. If both new Test Batches pass the required contaminant testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch of Regulated Marijuana or Regulated Marijuana Product associated with each Test Batch may be Transferred or processed into a Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, or Retail Marijuana Product;~~
  - ~~c. If one or both of the Test Batches do not pass contaminant testing, then the Regulated Marijuana Business must destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch included in that Test Batch pursuant to Rule 3-230—Waste Disposal.~~
- ~~3. The Regulated Marijuana Business may Transfer the Inventory Tracking System package, Harvest Batch, or Production Batch that failed contaminant testing to another Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, or an Accelerator Manufacturer for Decontamination, and create two new Test Batches after Decontamination has occurred, each containing the requisite number of Sample Increments, and have those Test Batches tested for the required contaminant test that failed. Such testing must comport with the sampling procedures under Rule 4-110.~~
  - ~~a. A Licensee must either (1) submit both new Test Batches to the same Regulated Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities;~~
  - ~~b. If both new Test Batches pass the required contaminant testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch of Regulated Marijuana or Regulated Marijuana Product associated with each Test Batch may be Transferred or processed into a Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, or Retail Marijuana Product;~~



~~c. If one or both of the Test Batches do not pass contaminant testing, then the Regulated Marijuana Business must destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch included in that Test Batch pursuant to Rule 3-230—Waste Disposal.~~

~~C. Failed Contaminant Testing: Microbial Testing of Regulated Marijuana Flower, Wet Whole Plant, Trim, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana. If a Regulated Marijuana Business is notified by the Division or a Regulated Marijuana Testing Facility that a Test Batch of Regulated Marijuana flower, wet whole plant, trim, Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana failed microbial testing, then for each Inventory Tracking System package, Harvest Batch, or Production Batch associated with that failed Test Batch the Regulated Marijuana Business must either:~~

- ~~1. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 2-230—Waste Disposal;~~
- ~~2. Decontaminate the Inventory Tracking System package, Harvest Batch, or Production Batch, and create two new Test Batches, each containing the requisite number of Sample Increments, and submit those Test Batches for microbial contaminant testing. Such testing must comply with the sampling procedures under Rule 4-110. If the Inventory Tracking System package, Harvest Batch, or Production Batch has undergone Decontamination, then it must also pass a mycotoxin and water activity test prior to Transfer. The mycotoxin and water activity testing must occur after the final Decontamination attempt but is not required to occur until after the Inventory Tracking System package, Harvest Batch, or Production Batch has passed microbial testing. If a Test Batch fails mycotoxin or water activity testing the Regulated Marijuana Business must follow the failed contaminant testing procedures pursuant to Paragraphs (B) and (C.5.) of this Rule. Pursuant to Rule 4-120(C), wet whole plant is exempt from water activity testing.~~

~~a. A Licensee must either (1) submit both new Test Batches to the same Regulated Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Regulated Marijuana Testing Facilities.~~

~~b. If both Test Batches pass the required microbial testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch associated with each Test Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.~~

~~c. If one or both of the Test Batches do not pass microbial testing, then the Regulated Marijuana Business must:~~

- ~~i. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 3-230 – Waste Disposal;~~
  - ~~ii. Decontaminate and re-test in accordance with this Paragraph (C)(2); or~~
  - ~~iii. Transfer the Inventory Tracking System package, Harvest Batch, or Production Batch for Decontamination or Remediation pursuant to Paragraph (C)(3)(b) below.~~
- ~~3. In lieu of Decontamination pursuant to Paragraph (C)(2) above, the Regulated Marijuana Business may Transfer all Regulated Marijuana from the Inventory Tracking System packages, Harvest Batches, and Production Batches associated with that failed Test Batch to a Regulated Marijuana Cultivation Facility for Decontamination, or may Transfer such Regulated Marijuana to a Regulated Marijuana Products Manufacturer for Decontamination and/or Remediation. If the Regulated Marijuana Business receiving the Regulated Marijuana for Decontamination will Transfer the Regulated Marijuana back to the originating Regulated Marijuana Business following the Decontamination procedures, then the originating Regulated Marijuana Business is responsible for all required testing. If the Regulated Marijuana Business receiving the Regulated Marijuana for Decontamination will Transfer the Regulated Marijuana to a different Regulated Marijuana Business or further processes the Regulated Marijuana following Decontamination, then the receiving Regulated Marijuana Business that performed the Decontamination is responsible for all required testing.~~
  - ~~a. Decontamination. The Regulated Marijuana Business may Decontaminate the Inventory Tracking System package, Harvest Batch, or Production Batch, and create two new Test Batches, each containing the requisite number of Sample Increments, and submit those Test Batches for microbial contaminant testing. Such testing must comply with the sampling procedures under Rule 4-110. If the Inventory Tracking System package, Harvest Batch, or Production Batch has undergone Decontamination, then it must also pass a mycotoxin and water activity test prior to Transfer. The mycotoxin and water activity testing must occur after the final Decontamination attempt but is not required to occur until after the Inventory Tracking System package, Harvest Batch, or Production Batch has passed microbial testing. If a Test Batch fails mycotoxin or water activity testing the Regulated Marijuana Business must follow the failed contaminant testing procedures pursuant to Paragraphs (B) and (C.5.) of this Rule. Pursuant to Rule 4-120(C), wet whole plant is exempt from water activity testing.~~
    - ~~i. A Licensee must either (1) submit both new Test Batches to the same Regulated Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two~~

~~different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities~~

- ~~ii. If both Test Batches pass the required microbial testing, then the Inventory Tracking System packages, Harvest Batch, or Production Batch associated with each Test Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.~~
- ~~iii. If one or both of the Test Batches that were created from Harvest Batches or Production Batches pursuant to Paragraph (C)(3)(a) do not pass microbial testing, the Regulated Marijuana Business must either:~~
  - ~~A. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 3-230 Waste Disposal;~~
  - ~~B. Decontaminate and re-test in accordance with this paragraph;~~
  - ~~C. Attempt Remediation pursuant to Paragraph (C)(3)(b), except for Production Batches of Infused Pre-Rolled Marijuana; or~~
  - ~~D. Transfer the Inventory Tracking System package, Harvest Batch, or Production Batch of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana for Decontamination or Transfer the Inventory Tracking System package, Harvest Batch, or Production Batch of Pre-Rolled Marijuana for Remediation pursuant to Paragraph (C)(3)(b).~~
- ~~b. Remediation. The Regulated Marijuana Products Manufacturer may Remediate the Inventory Tracking System package, Harvest Batch, or Production Batch of Pre-Rolled Marijuana, if possible, and create two new Test Batches, each containing the requisite number of Sample Increments. The new Test Batches are required to be re-tested for Microbial, Mycotoxin, and Water Activity contaminant testing. Such testing must comport with sampling procedures under Rule 4-110.~~
  - ~~i. For Remediation, the Regulated Marijuana Business shall process the Inventory Tracking System package, Harvest Batch, or Production Batch of Pre-Rolled Marijuana associated with the failed Test Batch into a Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate.~~
  - ~~ii. The Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate that was manufactured pursuant to Paragraph (C)(3)(b) shall undergo all required~~

~~contaminant testing pursuant to Rule 4-120(C)—Regulated Marijuana Testing Program—Contaminant Testing, potency testing pursuant to Rule 4-125—Regulated Marijuana Testing Program—Potency Testing, and any other testing required or allowed by the Marijuana Code or these rules, including but not limited to microbial and mycotoxins contamination. Such testing must comport with the sampling procedures under Rule 4-110.~~

- ~~iii.—If the Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate that was manufactured pursuant to Paragraph (C)(3)(b) fails contaminant testing, the Regulated Marijuana Business shall destroy and document the destruction of the Inventory Tracking System package(s) or Production Batch(es) of Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate pursuant to Rule 3-230—Waste Disposal.~~

- ~~4.—Nothing in this Rule removes or alters the responsibility of the Retail Marijuana Business Transferring the Retail Marijuana that failed microbial testing from complying with the requirement to pay excise tax pursuant to article 28.8 of title 39, C.R.S.~~

~~C.5.—Failed Contaminant Testing: Water Activity Testing. If a Regulated Marijuana Business is notified by the Division or a Regulated Marijuana Testing Facility that a Test Batch of Regulated Marijuana flower, trim, Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana failed water activity testing, then for each Inventory Tracking System package, Harvest Batch, or Production Batch associated with that failed Test Batch the Regulated Marijuana Business must either:~~

- ~~1.—Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 2-230—Waste Disposal; or~~
- ~~2.—Decontaminate the Inventory Tracking System package, Harvest Batch, or Production Batch, and create two new Test Batches, each containing the requisite number of Sample Increments, and submit those Test Batches for water activity testing. Such testing must comply with the sampling procedures under Rule 4-110. If the Inventory Tracking System package, Harvest Batch, or Production Batch has undergone Decontamination, then it must also pass a microbial contaminant test prior to Transfer. The microbial contaminant test is not required to occur until after the Inventory Tracking System package, Harvest Batch, or Production Batch has passed water activity testing. If a Test Batch fails microbial contaminant testing the Regulated Marijuana Business must follow the failed contaminant testing procedures pursuant to Paragraph (C) above. Pursuant to Rule 4-120(E), wet whole plant is exempt from water activity testing.~~
  - ~~a.—A Licensee must either (1) submit both new Test Batches to the same Regulated Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Regulated Marijuana Testing Facilities.~~

- ~~b. If both Test Batches pass the required water activity testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch associated with each Test Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.~~
    - ~~c. If one or both of the Test Batches do not pass water activity testing, then the Regulated Marijuana Business must:
      - ~~i. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 3-230—Waste Disposal;~~
      - ~~ii. Decontaminate and re-test in accordance with this Paragraph (C.5)(2); or~~
      - ~~iii. Transfer the Inventory Tracking System package, Harvest Batch, or Production Batch for Decontamination or Remediation pursuant to Paragraph (C)(3)(b) below.~~~~
  - ~~3. In lieu of Decontamination pursuant to Paragraph (C.5)(2) above, the Regulated Marijuana Business may Transfer all Regulated Marijuana from the Inventory Tracking System packages, Harvest Batches, or Production Batches associated with that failed Test Batch to a Regulated Marijuana Cultivation Facility for Decontamination, or may Transfer such Regulated Marijuana to a Regulated Marijuana Products Manufacturer for Decontamination and/or Remediation. If the Regulated Marijuana Business receiving the Regulated Marijuana for Decontamination will Transfer the Regulated Marijuana back to the originating Regulated Marijuana Business following the Decontamination procedures, then the originating Regulated Marijuana Business is responsible for all required testing. If the Regulated Marijuana Business receiving the Regulated Marijuana for Decontamination will Transfer the Regulated Marijuana to a different Regulated Marijuana Business or further process the Regulated Marijuana following Decontamination, then the receiving Regulated Marijuana Business that performed the Decontamination is responsible for all required testing.~~
    - ~~a. Decontamination. The Regulated Marijuana Business may Decontaminate the Inventory Tracking System package, Harvest Batch, or Production Batch, and create two new Test Batches, each containing the requisite number of Sample Increments, and submit those Test Batches for water activity testing. Such testing must comply with the sampling procedures under Rule 4-110. If the Inventory Tracking System package, Harvest Batch, or Production Batch has undergone Decontamination, then it must also pass a microbial contaminant test prior to Transfer. The microbial contaminant testing is not required to occur until after the Inventory Tracking System package, Harvest Batch, or Production Batch has passed water activity testing. If a Test Batch fails microbial contaminant testing the Regulated Marijuana Business must follow the failed contaminant testing procedures pursuant to Paragraph (C) above. Pursuant to Rule 4-120(C), wet whole plant is exempt from water activity testing.~~

- ~~i. A Licensee must either (1) submit both new Test Batches to the same Regulated Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities~~
- ~~ii. If both Test Batches pass the required testing, then the Inventory Tracking System packages, Harvest Batch, or Production Batch associated with each Test Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.~~
- ~~iii. If one or both of the Test Batches that were created from Harvest Batches or Production Batches pursuant to Paragraph (C.5)(3)(a) do not pass water activity testing, the Regulated Marijuana Business must either:~~
  - ~~A. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 3-230 Waste Disposal;~~
  - ~~B. Decontaminate and re-test in accordance with this paragraph;~~
  - ~~C. Attempt Remediation pursuant to Paragraph (C.5)(3)(b), except for Production Batches of Infused Pre-Rolled Marijuana; or~~
  - ~~D. Transfer the Inventory Tracking System package, Harvest Batch, or Production Batch of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana for Decontamination or Transfer the Inventory Tracking System package, Harvest Batch, or Production Batch of Pre-Rolled Marijuana for Remediation pursuant to Paragraph (C.5)(3)(b).~~
- ~~b. Remediation. The Regulated Marijuana Products Manufacturer may Remediate the Inventory Tracking System package, Harvest Batch, or Production Batch of Pre-Rolled Marijuana, if possible, and create two new Test Batches, each containing the requisite number of Sample Increments. The new Test Batches are required to be re-tested for Microbial, Mycotoxin, and Water Activity contaminant testing. Such testing must comport with sampling procedures under Rule 4-110.~~
  - ~~i. For Remediation, the Regulated Marijuana Business shall process the Inventory Tracking System package, Harvest Batch, or Production Batch of Pre-Rolled Marijuana associated with the failed Test Batch into a Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate.~~
  - ~~ii. The Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate that was manufactured~~

~~pursuant to Paragraph (C)(3)(b) shall undergo all required contaminant testing pursuant to Rule 4-120(C) — Regulated Marijuana Testing Program — Contaminant Testing, potency testing pursuant to Rule 4-125 — Regulated Marijuana Testing Program — Potency Testing, and any other testing required or allowed by the Marijuana Code or these rules, including but not limited to microbial and mycotoxins contamination. Such testing must comport with the sampling procedures under Rule 4-110.~~

~~iii. — If the Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate that was manufactured pursuant to Paragraph (C.5)(3)(b) fails contaminant testing, the Regulated Marijuana Business shall destroy and document the destruction of the Inventory Tracking System package(s) or Production Batch(es) of Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate pursuant to Rule 3-230 — Waste Disposal.~~

~~4. — Nothing in this Rule removes or alters the responsibility of the Retail Marijuana Business Transferring the Retail Marijuana that failed microbial testing from complying with the requirement to pay excise tax pursuant to article 28.8 of title 39, C.R.S.~~

~~D. — Failed Contaminant Testing: Pesticide Testing. If a Regulated Marijuana Business is notified by the Division or a Regulated Marijuana Testing Facility that a Test Batch failed Pesticide testing, then for each Inventory Tracking System package, Harvest Batch, or Production Batch associated with that failed Test Batch the Regulated Marijuana Business must either:~~

~~1. — Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 3-230 — Waste Disposal; or~~

~~2. — Request that the Regulated Marijuana Testing Facility that reported the original fail conduct two additional analyses of the original Test Batch submitted in accordance with Rule 4-110.~~

~~a. — If both retesting analyses pass the required Pesticide testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch of Regulated Marijuana, Regulated Marijuana Concentrate, Regulated Marijuana Product, Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.~~

~~b. — If one or both of the retesting analyses do not pass Pesticide testing, then the Regulated Marijuana Business must destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 3-230 — Waste Disposal.~~



~~D.1. Failed Contaminant Testing: Elemental Impurities Testing of Regulated Marijuana Flower, Wet Whole Plant, and Trim. If a Regulated Marijuana Business is notified by the Division or a Testing Facility that a Test Batch of Regulated Marijuana flower, wet whole plant, or trim failed elemental impurities testing, then for each Inventory Tracking System package or Harvest Batch associated with that failed Test Batch the Regulated Marijuana Business must either:~~

- ~~1. Destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule 3-230 Waste Disposal.~~
- ~~2. Request that the Regulated Marijuana Testing Facility that reported the original fail conduct two additional analyses of the original Test Batch submitted in accordance with Rule 4-110.~~
  - ~~a. If both retesting analyses pass the required elemental impurities testing, then the Inventory Tracking System package or Harvest Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.~~
  - ~~b. If one or both of the retesting analyses do not pass elemental impurities testing, then the Regulated Marijuana Business must either destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule 3-230 Waste Disposal or Remediate the Inventory Tracking System package or Harvest Batch pursuant to Paragraph (3).~~
- ~~3. If the failed Test Batch is not deemed hazardous waste per the Resource Conservation and Recovery Act or other applicable federal, state, or local regulations, then the Regulated Marijuana Business may Transfer all Regulated Marijuana from the Inventory Tracking System packages or Harvest Batch associated with that failed Test Batch to a Regulated Marijuana Products Manufacturer for Remediation.~~
  - ~~a. The Regulated Marijuana Business that Transfers the Retail Marijuana that failed elemental impurities testing must comply with the requirement to pay excise tax pursuant to article 28.8 of title 39, C.R.S.~~
  - ~~b. The Regulated Marijuana Products Manufacturer may Remediate the Inventory Tracking System package or Harvest Batch associated with the failed Test Batch by processing it into a Regulated Marijuana Concentrate. The Regulated Marijuana Products Manufacturer is prohibited from adding any other Regulated Marijuana to the Regulated Marijuana Concentrate it manufactures pursuant to this Rule.~~
  - ~~c. In addition to all applicable regulations, the Regulated Marijuana Products Manufacturer must comply with 3-230 (C)(1), 5-315(D)(9), and 6-315 (D)(9).~~
  - ~~d. The Regulated Marijuana Concentrate that was manufactured pursuant to Paragraph (D.1)(3)(b) shall undergo all required contaminant testing pursuant to Rule 4-120(C) Regulated Marijuana Testing Program~~



~~Contaminant Testing, potency testing pursuant to Rule 4-125—Regulated Marijuana Testing Program—Potency Testing, and any other testing required or allowed by the Marijuana Code or these rules, including but not limited to elemental impurities testing. Such testing must comport with the sampling procedures under Rule 4-110.~~

~~e. For elemental impurities testing, the Regulated Marijuana Business must create two new Test Batches from the Remediated Production Batch, each containing the requisite number of Sample Increments, and have those Test Batches tested. Such testing must comport with the sampling procedures under Rule 4-110.~~

~~i. A Licensee must either (1) submit both new Test Batches to the same Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Marijuana Testing Facilities.~~

~~ii. If both Test Batches pass the required elemental impurities testing, then the Inventory Tracking System package or Harvest Batch associated with each Test Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.~~

~~iii. If one or both of the Test Batches do not pass elemental impurities testing, then the Regulated Marijuana Business must destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule 3-230—Waste Disposal.~~

~~f. All Production Batches undergoing Remediation for elemental impurities must be tested and are not eligible for a Reduced Testing Allowance or otherwise exempt from required testing.~~

~~4. Nothing in this Rule eliminates or alters the responsibility of the Retail Marijuana Business Transferring the Retail Marijuana that failed elemental impurities testing from complying with the requirement to pay excise tax pursuant to article 28.8 of Title 39, C.R.S.~~

~~E. Failed Potency Testing. If a Regulated Marijuana Business is notified by the Division or a Regulated Marijuana Testing Facility that a Test Batch of Regulated Marijuana Product failed potency testing, then for each Inventory Tracking System package or Production Batch associated with that failed Test Batch the Regulated Marijuana Business must either:~~

~~1. Destroy and document the destruction of the Inventory Tracking System package or Production Batch pursuant to Rule 3-230—Waste Disposal; or~~

~~2. Attempt corrective measures, if possible, and create two new Test Batches each containing the requisite number of Sample Increments, and have those Test Batches tested for the required potency test that failed. Such testing must comport with the sampling procedures under Rule 4-110.~~

- ~~a. A Licensee must either (1) submit both new Test Batches to the same Regulated Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Regulated Marijuana Testing Facilities.~~
- ~~b. If both new Test Batches pass potency testing, then the Inventory Tracking System package or Production Batch associated with each Test Batch may be Transferred.~~
- ~~c. If one or both of the Test Batches do not pass potency testing, then the Regulated Marijuana Products Manufacturer must destroy and document the destruction of Inventory Tracking System package or Production Batch pursuant to Rule 3-230 Waste Disposal.~~

~~F. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

#### **4-200 Series - Testing Program Requirements**

##### **Basis and Purpose – 4-205**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the mandatory testing portion of the Division's Regulated Marijuana sampling and testing program. This Rule 4-205 was previously Rules 4-105, 4-115, and 4-130, 1 CCR 212-3, and Rules M and R 1502, 1 CCR 212-1 and 1 CCR 212-2.

##### **4-205 – Regulated Marijuana Testing Program: Mandatory Testing**

- A. Required Test Batch Submission. The Division may require a Regulated Marijuana Business to submit a Test Batch(es) of Regulated Marijuana it possesses to a Regulated Marijuana Testing Facility at any time regardless of whether it has achieved a Reduced Testing Allowance and without notice.
  - 1. Test Batches collected pursuant to this Rule may be tested for potency or contaminants which may include, but are not limited to, Pesticides, microbials, mycotoxin, molds, elemental impurities, residual solvents, biological contaminants, and chemical contaminants.
  - 2. When a Test Batch(es) is required to be submitted for testing, the Regulated Marijuana Business may not Transfer or process into a Medical Marijuana Concentrate or Medical Marijuana Product any Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product, or Transfer or process into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product, from the Inventory Tracking System package, Harvest Batch or Production Batch from which the Test Batch was taken, until it passes all required testing.

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B. Methods for Determining Required Testing.

1. Random Testing. The Division may require Test Batches to be submitted for testing through any one or more of the following processes: random process, risk-based process, or other internally developed process, regardless of whether a Regulated Marijuana Business has achieved a Reduced Testing Allowance.
2. Inspection or Enforcement Tests. In addition, the Division may require a Regulated Marijuana Business to submit a Test Batch for testing if the Division has reasonable grounds to believe that:
  - a. Regulated Marijuana is contaminated or mislabeled;
  - b. A Regulated Marijuana Business is in violation of any product safety, health or sanitary statute, rule, or regulation; or
  - c. The results of a test would further an investigation by the Division into a violation of any statute, rule, or regulation.
3. Additional Division-Directed Testing. The Division may require a Regulated Marijuana Business to submit Test Batches from certain randomly selected Harvest Batches or Production Batches for potency or contaminant testing prior to implementing mandatory testing.

C. Minimum Testing Standards. The testing requirements contained in this 4-200 Series are the minimum required testing standards. Regulated Marijuana Businesses are responsible for ensuring adequate testing on any Regulated Marijuana they produce or Transfer to ensure safety for human consumption.D. Additional Test Batch Types. The Division may also require a Regulated Marijuana Business to submit Test Batches comprised of items other than Regulated Marijuana to be tested for contaminants which may include, but may not be limited to, Pesticides, microbials, molds, elemental impurities, residual solvents, biological contaminants, and chemical contaminants. The following is a non-exhaustive list of the types of Test Batches that may be required to be submitted for contaminant testing:

1. Specific Regulated Marijuana plant(s) or any portion of a Regulated Marijuana plant(s);
2. Any growing medium, water, or other substance used in the cultivation process;
3. Any water, solvent, or other substance used in the processing of a Regulated Marijuana Concentrate;
4. Any Ingredient or substance used in the manufacturing of a Regulated Marijuana Product; or
5. Swab of any equipment or surface.

E. Division Authority. The Division may require that a Test Batch be submitted to a specific Regulated Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.

1. Independent Third-Party Review. The Division may require Regulated Marijuana to undergo an independent third-party review to verify that the Regulated Marijuana does not pose a threat to public health and safety when the Division, in consultation with the Colorado Department of Public Health and Environment, has objective and reasonable grounds to believe and finds, upon a full investigation, one of the following:
    - a. The Regulated Marijuana contains one or more substances known to cause harm; or
    - b. The Regulated Marijuana contains one or more substances that could be toxic as consumed or applied in accordance with the intended use.
  2. The fact that Regulated Marijuana contains marijuana shall not constitute grounds to require an independent third-party review. Ingredients Generally Recognized as Safe by the U.S. Food & Drug Administration or that are regulated by the U.S. Food & Drug Administration under the Dietary Supplement Health and Education Act of 1994 that are included in Edible Medical Marijuana Product or Edible Retail Marijuana Product shall not constitute grounds to require an independent third-party review.
  3. Quarantine. In addition to any other remedies provided by law, the Division may immediately quarantine Regulated Marijuana pursuant to Rule 4-240(A) in any one of the following circumstances:
    - a. The Division has objective and reasonable grounds to believe and finds, upon a full investigation, that a Regulated Marijuana Business has been guilty of deliberate and willful violations of these rules;
    - b. The Regulated Marijuana or Alternative Use Product poses a potential threat to public health and safety;
    - c. The Division has received one or more reports of an Adverse Health Event related to Regulated Marijuana or Alternative Use Product;
    - d. The Division determines the independent third-party audit submitted pursuant to Rules 5-325(B) or 6-325(B) does not meet the requirements of Rules 5-325 or 6-325; or
    - e. The Regulated Marijuana Products Manufacturer has violated or is not in compliance with all of the requirements in Rules 5-325 or 6-325.
  4. Any quarantine pursuant to subparagraph (E)(3) above shall remain in effect unless the Regulated Marijuana undergoes an independent third-party review to verify the Regulated Marijuana does not pose a risk to public health and safety.
  5. For the purpose of this Rule, full investigation means a reasonable ascertainment of the underlying facts on which the agency action is based.
- F. The cost for all sampling and tests conducted pursuant to these rules shall be the financial responsibility of the Regulated Marijuana Business that is required to submit the Test Batch for testing.

G. Testing Regulated Marijuana Ready for Transfer.

1. All tests must occur at the time the Regulated Marijuana is ready for Transfer to another Regulated Marijuana Business, according to the required steps outlined in the Standard Operating Procedures of the Licensee submitting the Test Batch.
2. Licensees shall not Transfer Regulated Marijuana that they have reason to believe would not pass testing required by Rules 4-210 and 4-215, unless otherwise permitted in these Rules.

**Basis and Purpose – 4-210**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing potency testing procedures and rules for the Division's Regulated Marijuana sampling and testing program. This Rule 4-210 was previously Rules 4-115 and 4-125, 1 CCR 212-3, Rules M and R 1504, 1 CCR 212-1 and 1 CCR 212-2.

**4-210 – Regulated Marijuana Testing Program: Potency Testing**A. Potency Testing.

1. Cannabinoids Potency Profiles. A Regulated Marijuana Testing Facility may test and report results for any Cannabinoid provided the test is conducted in accordance with the Regulated Marijuana Testing Facility's Standard Operating Procedure.
2. Reporting of Results.
  - a. For potency tests on Regulated Marijuana, Regulated Marijuana Concentrate, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana, results must be reported by listing a single percentage concentration for each Cannabinoid that represents an average of all Sample Increments within the Test Batch. This includes reporting the Total THC in addition to each Cannabinoid required in Rule 4-210.
  - b. For potency tests conducted on Regulated Marijuana Product, whether conducted on each individual Production Batch or via a Reduced Testing Allowance per Rule 4-210, results must be reported by listing the total number of milligrams contained within a single Regulated Marijuana Product unit for sale for each Cannabinoid and stating whether the THC content is homogenous as defined in Paragraph 4 of this subparagraph (E).

B. Potency Testing – Cannabinoid Profile. A potency test conducted pursuant to this Rule must at least determine the level of concentration of D8-THC, D9-THC, D-10 THC, Exo-THC, THCA, CBD, CBDA, and CBN.

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C. Potency Testing for Regulated Marijuana.

1. Initial Potency Testing. A Regulated Marijuana Cultivation Facility must have potency tests conducted by a Regulated Marijuana Testing Facility on four Harvest Batches, created a minimum of one week apart, for each strain of Regulated Marijuana that it cultivates.
  - a. The first potency test must be conducted on each strain prior to the Regulated Marijuana Cultivation Facility Transferring or processing into a Medical Marijuana Concentrate any Medical Marijuana of that strain, or into a Retail Marijuana Concentrate any Retail Marijuana of that strain.
  - b. All four potency tests must be conducted on each strain six months after the Regulated Marijuana Cultivation Facility begins cultivating that strain.
2. Ongoing Potency Testing. After the initial four potency tests, a Regulated Marijuana Cultivation Facility shall have each strain of Regulated Marijuana that it cultivates tested for potency at least once per quarter.
  - a. If the Licensee that has completed testing required by subparagraph (C)(1) of this Rule fails to comply with subparagraph (C)(2) of this Rule, the Regulated Marijuana Cultivation Facility must test every Harvest Batch that they produce or comply with the testing requirements in subparagraph (C)(1) of this Rule.
3. Kief Potency Testing. Kief potency testing may follow Potency Testing for Regulated Marijuana if Kief is produced from the same strain of Regulated Marijuana. If Kief is produced from multiple strains, must comply with paragraph (D) of Rule 4-210.

D. Potency Testing for Regulated Marijuana Concentrate.

1. A Medical Marijuana Cultivation Facility or a Medical Marijuana Products Manufacturer must have a potency test conducted by a Medical Marijuana Testing Facility on every Production Batch of Medical Marijuana Concentrate that it produces prior to Transferring or processing into a Medical Marijuana Product any of the Medical Marijuana Concentrate from that Production Batch.
2. A Retail Marijuana Cultivation Facility, Accelerator Cultivator, Retail Marijuana Products Manufacturer, or an Accelerator Manufacturer must have a potency test conducted by a Retail Marijuana Testing Facility on every Production Batch of Retail Marijuana Concentrate that it produces prior to Transferring or processing into a Retail Marijuana Product any of the Retail Marijuana Concentrate from that Production Batch.

E. Potency Testing for Regulated Marijuana Product.

1. Potency Testing Required for Regulated Marijuana Product. A Regulated Marijuana Products Manufacturer shall have potency tests conducted by a Regulated Marijuana Testing Facility on every Production Batch of each type of Regulated Marijuana Product that it produces prior to Transferring any of the Regulated Marijuana Product from that Production Batch, unless the Regulated

Marijuana Products Manufacturer has successfully achieved a Reduced Testing Allowance for potency and homogeneity for the particular type of Regulated Marijuana Product.

2. Required Tests. Potency and homogeneity tests conducted on Regulated Marijuana Product must determine the level of concentration of the required Cannabinoids and whether or not THC is homogeneously distributed throughout the product.
3. Partially Infused Regulated Marijuana Products. If only a portion of a Regulated Marijuana Product is infused with Regulated Marijuana, then the Regulated Marijuana Products Manufacturer must inform the Regulated Marijuana Testing Facility of exactly which portions of the Regulated Marijuana Product are infused and which portions are not infused.
4. Failed Potency Tests for Regulated Marijuana Product.
  - a. If the Cannabinoid content of Regulated Marijuana Product is determined not to be homogeneous, then it shall be considered to have failed potency testing. A Production Batch of Regulated Marijuana Product shall be considered homogeneous if a minimum of four servings from two packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label. A Production Batch of Regulated Marijuana Product shall be considered homogenous if a minimum of four servings from four individual single serve packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label.
    - i. The potency for each of the four servings must be within the allowed potency variance set forth in subparagraph (E)(5) of this Rule 4-210. Any Cannabinoid that makes up less than 10 percent of the total amount of Cannabinoids in the Regulated Marijuana Product shall not be subject to the requirements set forth in this subparagraph (E)(4).
  - b. If an individually packaged Edible Medical Marijuana Product is determined to have more than the total milligrams of THC stated on the Container, or less than the total milligrams of THC stated on the Container, then the Test Batch shall be considered to have failed potency testing. Except that the potency variance provided for in subparagraph (E)(5) of this Rule 4-210 shall apply to potency testing.
  - c. If an individually packaged Edible Retail Marijuana Product is determined to have more than 100 milligrams of THC within it, then the Test Batch shall be considered to have failed potency testing. If an individually packaged Edible Retail Marijuana Product is determined to have more than the total milligrams of THC stated on the Container, or less than the total milligrams of THC stated on the Container, then the Test Batch shall be considered to have failed potency testing. If a single serving in an individually packaged Edible Retail Marijuana Product is determined to



have more than 10 milligrams of THC then the Test Batch shall be considered to have failed potency testing. Except that the potency variance provided for in subparagraph (E)(5) of this Rule 4-210 shall apply to potency testing.

5. Potency Variance. Regulated Marijuana Product provided to the Regulated Marijuana Testing Facility must comply with the following potency variance:

- a. For Regulated Marijuana Product with a Target Potency or making a potency claim for any Cannabinoid of more than 2.5 milligrams per serving the potency variance shall differ no more than plus or minus 15 percent.
- b. For Regulated Marijuana Product with a Target Potency or making a potency claim for any Cannabinoid of 2.5 milligrams or less per serving the potency variance shall differ no more than the greater of plus or minus 0.5 mg or 40 percent per serving.

F. Potency Testing Required for Pre-Rolled Marijuana.

- 1. A Regulated Marijuana Business shall have potency tests conducted by a Regulated Marijuana Testing Facility on every Production Batch of each type of Pre-Rolled Marijuana product that it produces prior to Transferring or selling any of the Pre-Rolled Marijuana from that Production Batch if the Regulated Marijuana Business is using multiple strains from different sources (e.g. self-grown source, wholesale source) and/or selecting only a part of the Harvest Batch(es) that is not representative of the entire Harvest Batch each time they produce a certain type of Pre-Rolled Marijuana (e.g. using only the shake/trim out of a Harvest Batch).
- 2. If each type of Pre-Rolled Marijuana is created using select parts of a single strain (e.g. flower only, shake/trim only) or a specific ratio of strains from specified sources (e.g. self-grown source, wholesale source) defined by the Regulated Marijuana Business' Standard Operating Procedures, a Regulated Marijuana Business shall have potency tests conducted according to paragraph (F)(2)(a) and (b) of this Rule by a Regulated Marijuana Testing Facility for each type of Pre-Rolled Marijuana product that it produces prior to Transferring or selling any of the Pre-Rolled Marijuana from a Production Batch.
  - a. Initial Potency Testing. Initial potency tests shall be conducted by a Regulated Marijuana Testing Facility on four Production Batches, created a minimum of one week apart, for each type of Pre-Rolled Marijuana that is created using a single strain or a specific ratio of strains defined by the Regulated Marijuana Business' Standard Operating Procedures.
  - b. Ongoing Potency Testing. After the initial four potency tests, ongoing potency tests shall be conducted by a Regulated Marijuana Testing Facility at least once per quarter for each type of Pre-Rolled Marijuana that is created using a single strain or a specific ratio of strains defined by the Regulated Marijuana Business' Standard Operating Procedures.



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G. Potency Testing Required for Infused Pre-Rolled Marijuana. A Regulated Marijuana Business shall have potency tests conducted by a Regulated Marijuana Testing Facility on every Production Batch of Infused Pre-Rolled Marijuana product that it produces prior to Transferring any of the Infused Pre-Rolled Marijuana from that Production Batch.

**Basis and Purpose – 4-215**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing contaminant testing procedures and rules for the Division's Regulated Marijuana sampling and testing program. This Rule 4-215 was previously Rules 4-115, 4-120, and 4-121, 1 CCR 212-3, Rules M and R 1504, 1 CCR 212-1 and 1 CCR 212-2.

**4-215 – Regulated Marijuana Testing Program: Contaminant Testing**

A. Contaminant Testing Required.

1. A Regulated Marijuana Business shall not Transfer or process Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Regulated Marijuana Concentrate or Regulated Marijuana Product unless Test Batches from each Harvest Batch or Production Batch from which that Regulated Marijuana was derived has been tested by a Regulated Marijuana Testing Facility for contaminants and passed all contaminant tests required by this Rule, except as permitted in Rule 5-205(C), 6-205(C), or the cultivation or production process has achieved a Reduced Testing Allowance under this Rule.

B. Regulated Marijuana Contaminant Testing.

1. The following table provides required tests for Regulated Marijuana flower.

**4-215(B)(1) 1**

	<u>Flower, shake, &amp; trim</u>	<u>Prerolls</u>	<u>Wet Whole Plant Allocated for Extraction</u>
<u>Water Activity</u>	<u>Yes</u>	<u>Yes</u>	<u>No</u>
<u>Mycotoxins</u>	<u>No</u>	<u>No</u>	<u>No</u>
<u>Residual Solvents</u>	<u>No</u>	<u>No</u>	<u>No</u>

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	<u>Flower, shake, &amp; trim</u>	<u>Prerolls</u>	<u>Wet Whole Plant Allocated for Extraction</u>
<u>Elemental Impurities</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>
<u>Pesticides</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>
<u>Microbials</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes*</u>

\* Note: Some exemptions may apply.

2. The following table provides required tests for post-Decontamination retesting.

**4-215(B)(2) 1**

	<u>Flower, shake, &amp; trim, &amp; Prerolls</u>
<u>Water Activity</u>	<u>Yes</u>
<u>Mycotoxins</u>	<u>Yes</u>
<u>Residual Solvents</u>	<u>No</u>
<u>Elemental Impurities</u>	<u>No</u>
<u>Pesticides</u>	<u>No</u>
<u>Microbials</u>	<u>Yes</u>

C. Regulated Marijuana Concentrate Testing.

**4-215(C) 1**

	<u><b>Solvent-Based Concentrate</b></u> <i>(Processed from Flower that did not have a failed test result)</i>	<u><b>Solvent-Based Concentrate</b></u> <i>(Processed from remediated flower or untested Wet Whole Plant)</i>	<u><b>Water, Heat, or Pressure Based Concentrate</b></u>	<u><b>Infused Pre-Rolled Marijuana</b></u>	<u><b>Vaporizer Delivery Devices</b></u> <i>(If Regulated Marijuana Concentrate is made into a Vaporizer Delivery Device, additional tests as indicated)</i>
<u>Water Activity</u>	<u>No</u>	<u>No</u>	<u>No</u>	<u>Yes</u>	<u>No</u>
<u>Mycotoxins</u>	<u>No</u>	<u>Yes</u>	<u>Yes</u>	<u>No</u>	<u>No</u>
<u>Residual Solvents</u>	<u>Yes</u>	<u>Yes</u>	<u>No</u>	<u>No</u>	<u>No</u>
<u>Elemental Impurities</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>
<u>Pesticides</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>	<u>No</u>
<u>Microbials</u>	<u>No</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>

\* Note: Some exemptions may apply.

D. Regulated Marijuana Products, Audited Products, and Hemp Products Testing.

**4-215(D) 1**

	<b><u>Regulated Marijuana Products</u></b> <i>(Edible Regulated Marijuana Products, Topicals, and Transdermal Products)</i>	<b><u>Audited Products</u></b>	<b><u>Hemp Products</u></b>
<u>Water Activity</u>	<u>No</u>	<u>No</u>	<u>No</u>
<u>Mycotoxins</u>	<u>No</u>	<u>No</u>	<u>No</u>
<u>Residual Solvents</u>	<u>No</u>	<u>No</u>	<u>If solvents were used</u>
<u>Elemental Impurities</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>
<u>Pesticides</u>	<u>No</u>	<u>No</u>	<u>Yes</u>
<u>Microbials</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>

**E. Required Contaminant Tests.**

1. Microbial Contaminant Testing. Harvest Batches of Regulated Marijuana, flower, shake, and trim, re-testing of Regulated Marijuana flower, shake, and/or trim that has undergone Decontamination, Production Batches of Physical Separation-, Heat/Pressure-, or Food-Based Medical Marijuana Concentrate, Production Batches of Physical Separation-, Heat/Pressure-, or Food-Based Retail Marijuana Concentrate, Solvent-Based Regulated Marijuana Concentrate produced through Remediation, Regulated Marijuana Product, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Hemp Products, Pressurized Metered Dose Inhalers, Vaporizer Delivery Devices, and Audited Product must be tested for microbial contamination by a Regulated Marijuana Testing Facility at the frequency established by Rules 4-215(A) and 4-230(B). The microbial contamination test must include, but need not be limited to, testing to determine the presence of and/or amounts present of microbial contaminants listed in Rule 4-215(J)(3): Shiga-toxin producing Escherichia coli (STEC)\*- Bacteria, Aspergillus (A. fumigatus, A. flavus, A. niger, A. terreus), Salmonella species\* – Bacteria, Total Yeast and Mold, Total aerobic microbial count, Staphylococcus Aureus, Pseudomonas aeruginosa, Bile tolerant gram negative bacteria and Candida albicans.

2. Water Activity Testing. Harvest Batches of Regulated Marijuana, flower, shake, and trim (other than wet whole plant), re-testing of Regulated Marijuana flower, shake, and/or trim that has undergone Decontamination, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana at the frequency established by Rules 4-215(A) and 4-230(B) of this Rule.
3. Residual Solvent Contaminant Testing. Production Batches of Solvent-Based Regulated Marijuana Concentrate and Audited Product that contains any Solvent-Based Regulated Marijuana Concentrate produced by a Regulated Marijuana Products Manufacturer must be tested by a Regulated Marijuana Testing Facility for residual solvent contamination at the frequency established by Rules 4-215(A) and 4-230(B). The residual solvent contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of acetone, butane, ethanol, heptanes, isopropyl alcohol, propane, benzene\*, toluene\*, pentane, hexane\*, methanol\*, ethyl acetate, and total xylenes\* (m, p, o – xylenes).

\* Note: These solvents are not approved for use. Testing is required for these solvents due to their possible presence in the solvents approved for use per Rule 5-315 and 6-315.
4. Mycotoxin Contaminant Testing. As part of Remediation, each Production Batch of Solvent-Based Regulated Marijuana Concentrate produced by a Regulated Marijuana Products Manufacturer from Regulated Marijuana that failed microbial contaminant testing produced must be tested by a Regulated Marijuana Testing Facility for mycotoxin contamination. Each Harvest Batch of Regulated Marijuana flower, shake, and/or trim and each Production Batch of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana that has failed required microbial contaminant testing and has undergone Decontamination must be tested by a Regulated Marijuana Testing Facility for mycotoxin contamination. Each Production Batch of Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contamination must be tested for mycotoxin contamination. The mycotoxin contaminant test must include, but need not be limited to, testing to determine the presence of, and amounts present of, aflatoxins (B1, B2, G1, and G2) and ochratoxin A. This is in addition to all other contaminant testing required by this Paragraph (E). This contaminant test cannot be exempt from testing by a Reduced Testing Allowance in accordance with Rule 4-230(B)(2), except Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contamination pursuant to Rule 4-245.
5. Pesticide Contaminant Testing. Harvest Batches of Regulated Marijuana, Production Batches of Regulated Marijuana Concentrate, Production Batches of Pre-Rolled Marijuana, and Production Batches of Infused Pre-Rolled Marijuana must be tested for Pesticide contamination by a Regulated Marijuana Testing Facility at the frequency established by this Rule 4-215(A) and Rule 4-230(B). The Pesticide contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, the Pesticides listed in Rule 4-215(J)(8).

6. Elemental Impurities Testing.
- a. Each Harvest Batch and Production Batch of Regulated Marijuana must be tested for elemental impurities by a Regulated Marijuana Testing Facility at the frequency established in subparagraph (A) of this Rule and Rule 4-230(A) - (B). The elemental impurities test must include, but need not be limited to, testing to determine the presence of, and amounts present of, arsenic, cadmium, lead, and mercury.
  - b. Emissions Testing. Each Harvest Batch and Production Batch of Regulated Marijuana Concentrate in a Vaporized Delivery Device must be tested for elemental impurities via emissions testing by a Regulated Marijuana Testing Facility at the frequency established in subparagraph (A) of this Rule and Rule 4-230(A) - (B). The elemental impurities test must include, but need not be limited to, testing to determine the presence and amounts of arsenic, cadmium, lead, and mercury.
- F. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to a Regulated Marijuana Cultivation Facility or Regulated Marijuana Products Manufacturer Transferring or processing any Regulated Marijuana from that Harvest Batch or Production into a Regulated Marijuana Concentrate or Regulated Marijuana Product. Additional tests may include, but need not be limited to, screening for Pesticides, chemical contaminants, biological contaminants, or other types of microbes, molds, elemental impurities, or residual solvents.
- G. Microbial Contaminant Testing. A Regulated Marijuana Cultivation Facility shall not Transfer wet whole plant or process wet whole plant into Regulated Marijuana Concentrate unless Test Batches from each Harvest Batch of Regulated Marijuana wet whole plant were tested for microbial contamination by a Regulated Marijuana Testing Facility and passed all microbial contaminant tests except as permitted in Rules 5-205(C), 6-205(C), or the cultivation process has achieved a Reduced Testing Allowance under this Rule. The microbial contamination test must include, but need not be limited to, testing to determine the presence of and/or amounts present of microbial contaminants listed in Rule 4-215(J)(3): Shiga-toxin producing *Escherichia coli* (STEC)\*-Bacteria, *Aspergillus* (*A. fumigatus*, *A. flavus*, *A. niger*, *A. terreus*), *Salmonella* species\* – Bacteria, Total Yeast and Mold.
- H. Regulated Marijuana Concentrate Produced from Wet Whole Plant That Was Not Tested for Microbial Contaminants.
- 1. Required Testing. Each Production Batch of Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contaminants in accordance with the exemption in Rule 4-245(B)(2) must be tested for microbial contaminants and mycotoxins. In addition, the Regulated Marijuana Concentrate must be tested in accordance with Rule 4-215 for other contaminants, including pesticides, elemental impurities, and residual solvents if applicable.
- I. Pesticide and Elemental Impurities Testing for Regulated Marijuana Wet Whole Plant. Each Harvest Batch of Regulated Marijuana wet whole plant must be tested for Pesticide

and Elemental Impurities testing in accordance with Rule 4-215. A Regulated Marijuana Cultivation Facility may receive a Reduced Testing Allowance for these contaminants.

J. Permissible Levels of Contaminants. If Regulated Marijuana is found to have a contaminant in levels exceeding those established as permissible under this Rule, then it shall be considered to have failed contaminant testing. Notwithstanding the permissible levels established in this Rule, the Division reserves the right to determine, upon good cause and reasonable grounds, that a particular Test Batch presents a risk to the public health or safety and therefore shall be considered to have failed a contaminant test.

1. Other Contaminants. If any Test Batch is found to contain levels of any microorganism, chemical, elemental impurity, or pesticides that could be toxic if consumed or present, then the Regulated Marijuana Testing Facility must notify the Regulated Marijuana Business and the Division, in accordance with subparagraph (J)(2) of this Rule, and initiate corrective actions with all parties.

2. Division Notification. A Regulated Marijuana Testing Facility must notify the Division by timely input in the Inventory Tracking System if a Test Batch is found to contain levels of a contaminant not listed within this Rule that could be injurious to human health if consumed. See Rule 3-825.

3. Microbials Testing (Bacteria, Fungus).

a. The following table represents permissible levels of contaminants for the identified substances tested in the following products:

i. Regulated Marijuana flower, shake, and trim (other than wet whole plant allocated for extraction that is transferred for the purposes of extraction to a Regulated Marijuana business with at least one identical Controlling Beneficial Owner);

ii. Regulated Marijuana Products (other than Audited Product);

iii. Pre-Rolled Marijuana;

iv. Infused Pre-Rolled Marijuana;

v. Physical Separation-Based, Heat/Pressure-Based, and Food-Based Medical Marijuana Concentrate;

vi. Physical Separation-Based, Heat/Pressure-Based, and Food-Based Retail Marijuana Concentrate;

vii. Hemp Products;

viii. Pressurized Metered Dose Inhalers;

ix. Vaporizer Delivery Device

x. Solvent-Based Regulated Marijuana Concentrate produced through Remediation;

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- xi. Solvent-Based Regulated Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials; and
- xii. Re-testing of Regulated Marijuana flower, shake, and trim that has undergone Decontamination.

**4-215(J)(3)(a) 1**

<u>Substance</u>	<u>Acceptable Limits</u>
<u>–Shiga-toxin producing <i>Escherichia coli</i> (STEC)*- Bacteria</u>	<u>Absent in 1 g</u>
<u><i>Salmonella</i> species* – Bacteria</u>	<u>Absent in 1 g</u>
<u><i>Aspergillus</i> (<i>A. fumigatus</i>, <i>A. flavus</i>, <i>A. niger</i>, <i>A. terreus</i>)</u>	<u>Absent in 1 g</u>
<u>Total Yeast and Mold</u>	<u>&lt; 1.0 x 10<sup>4</sup> Colony Forming Unit (CFU) per 1 ml or 1 g</u>

\*The Regulated Marijuana Testing Facility shall contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits.

\*\* Regulated Marijuana Products with intended use for oral consumption or skin and body products are exempt from required aspergillus testing.

- b. The following table represents permissible levels of contaminants for the identified substances tested in certain products:

**4-215(J)(3)(b) 1**

<u>Substance</u>	<u>Acceptable Limits</u>	<u>Product to be Tested</u>
<u>Total Yeast and Mold</u>	<u>≤ 1.0 x 10<sup>1</sup> CFU/ml or ≤ 1.0 x 10<sup>1</sup> CFU/g</u>	<u>Audited Product: administration by metered dose nasal spray or vaginal administration</u>
<u>Total Yeast and Mold</u>	<u>≤ 1.0 x 10<sup>2</sup> CFU/ml or ≤ 1.0 x 10<sup>2</sup> CFU/g</u>	<u>Audited Product: rectal administration</u>
<u>Total aerobic microbial count</u>	<u>≤ 1.0 x 10<sup>2</sup> CFU/ml or ≤ 1.0 x 10<sup>2</sup> CFU/g</u>	<u>Audited Product: administration by metered dose nasal spray or vaginal administration</u>



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<u>Substance</u>	<u>Acceptable Limits</u>	<u>Product to be Tested</u>
<u>Total aerobic microbial count</u>	<u><math>\leq 1.0 \times 10^3</math> CFU/ml or <math>\leq 1.0 \times 10^3</math> CFU/g</u>	<u>Audited Product: rectal administration</u>
<u>Staphylococcus aureus</u>	<u>Absent in 1 ml or 1 g</u>	<u>Audited Product: administration by metered dose nasal spray or vaginal administration</u>
<u>Pseudomonas aeruginosa</u>	<u>Absent in 1 ml or 1 g</u>	<u>Audited Product: administration by metered dose nasal spray or vaginal administration</u>
<u>Bile tolerant gram negative bacteria</u>	<u>Absent in 1 ml or 1 g</u>	<u>Audited Product: administration by metered dose nasal spray</u>
<u>Candida albicans</u>	<u>Absent in 1 ml or 1 g</u>	<u>Audited Product: vaginal administration</u>

4. Water Activity.

a. The following table represents permissible levels of contaminants for the identified substances tested in the following products:

- i. Regulated Marijuana flower shake, and trim (other than wet whole plant);
- ii. Retesting of Regulated Marijuana flower, shake, and trim that has undergone Decontamination;
- iii. Pre-Rolled Marijuana; and
- iv. Infused Pre-Rolled Marijuana.

## 4-215(J)(4) 1

<u>Substance</u>	<u>Acceptable Limits</u>
<u>Water Activity</u>	<u>0.65 aW</u>

5. Mycotoxins.

a. The following table represents permissible levels of contaminants for the identified substances tested in the following products:

- i. Solvent-Based Regulated Marijuana Concentrate manufactured from Regulated Marijuana flower or trim that failed microbial testing;
- ii. Regulated Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials; and

- iii. Regulated Marijuana flower, shake, and trim that has undergone Decontamination.

**4-215(J)(5) 1**

<u>Substance</u>	<u>Acceptable Limits</u>
<u>Aflatoxins (B1, B2, G1, and G2)</u>	<u>&lt; 20 Parts Per Billion (PPB)</u> <u>(total of B1 + B2 + G1 + G2)</u>
<u>Ochratoxin A</u>	<u>&lt; 20 PPB</u>

6. Residual Solvents.

- a. The following table represents permissible levels of contaminants for the identified substances tested in the following products:

- i. Solvent-Based Regulated Marijuana Concentrate; and  
 ii. Hemp Product (if a solvent was used).

**4-215(J)(6)(a) 1**

<u>Substance</u>	<u>Acceptable Limits</u>
<u>Acetone</u>	<u>&lt; 1,000 Parts Per Million (PPM)</u>
<u>Butanes</u>	<u>&lt; 1,000 PPM</u>
<u>Ethanol***</u>	<u>&lt; 1,000 PPM</u>
<u>Heptanes</u>	<u>&lt; 1,000 PPM</u>
<u>Isopropyl Alcohol</u>	<u>&lt; 1,000 PPM</u>
<u>Propane</u>	<u>&lt; 1,000 PPM</u>
<u>Benzene**</u>	<u>&lt; 2 PPM</u>
<u>Toluene**</u>	<u>&lt; 180 PPM</u>
<u>Pentane</u>	<u>&lt; 1,000 PPM</u>
<u>Hexane**</u>	<u>&lt; 60 PPM</u>
<u>Total Xylenes (m,p, o-xylenes)**</u>	<u>&lt; 430 PPM</u>

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<u>Substance</u>	<u>Acceptable Limits</u>
<u>Methanol**</u>	<u>&lt; 600 PPM</u>
<u>Ethyl Acetate</u>	<u>&lt; 1000 PPM</u>
<u>Any other solvent not permitted for use pursuant to Rules 5-315 and 6-315.</u>	<u>None Detected</u>

\*\* Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use per Rule 6-315, limits have been listed here accordingly.

\*\*\* Note: Solvent-Based Medical Marijuana Concentrate and Solvent-Based Retail Marijuana Concentrate that exceeds the acceptable limit for ethanol may only be used in Medical Marijuana Concentrate or Medical Marijuana Product, or Retail Marijuana Concentrate or Retail Marijuana Product, which intended use is oral consumption, skin and body products, a vaporizer delivery device, pressurized metered dose inhaler, or Audited Product.

### 7. Elemental Impurities.

a. The following table represents permissible levels of contaminants for the identified substances tested in the following products:

- i. Regulated Marijuana flower, shake, trim, and wet whole plant;
- ii. Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate;
- iii. Physical Separation-Based, Food-Based, Heat/Pressure-Based and Solvent Based Retail Marijuana Concentrate;
- iv. Regulated Marijuana Product;
- v. Pre-Rolled Marijuana;
- vi. Infused Pre-Rolled Marijuana;
- vii. Pressurized Metered Dose Inhaler;
- viii. Vaporizer Delivery Device;
- ix. Audited Product; and
- x. Hemp Product.

### 4-215(J)(7)(a) 1

<u>Substance</u>	<u>Acceptable Limits Based on Intended Use</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Inhaled Product or Audited Product: administration by metered dose nasal spray</u>

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<u>Substance</u>	<u>Acceptable Limits Based on Intended Use</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Lead – Max Limit: &lt; .5 PPM</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Arsenic – Max Limit: &lt; 0.2 PPM</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Cadmium – Max Limit: &lt; 0.2 PPM</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Mercury – Max Limit: &lt; 0.1 PPM</u>

b. The following table represents permissible levels of contaminants for the identified substances tested in the following products:

- i. Regulated Marijuana flower, shake, trim, and wet whole plant;
- ii. Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate;
- iii. Physical Separation-Based, Food-Based, Heat/Pressure-Based and Solvent Based Retail Marijuana Concentrate;
- iv. Regulated Marijuana Product;
- v. Pre-Rolled Marijuana;
- vi. Infused Pre-Rolled Marijuana;
- vii. Pressurized Metered Dose Inhaler;
- viii. Vaporizer Delivery Device;
- ix. Audited Product; and
- x. Hemp Product.

**4-215(J)(7)(b) 1**

<u>Substance</u>	<u>Acceptable Limits Based on Intended Use</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Topical and/or Transdermal</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Lead – Max Limit: &lt; 10 PPM</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Arsenic – Max Limit: &lt; 3 PPM</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Cadmium – Max Limit: &lt; 3 PPM</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Mercury – Max Limit: &lt; 1 PPM</u>

c. The following table represents permissible levels of contaminants for the identified substances tested in the following products:

- i. Regulated Marijuana flower, shake, trim, and wet whole plant;
- ii. Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate;
- iii. Physical Separation-Based, Food-Based, Heat/Pressure-Based and Solvent Based Retail Marijuana Concentrate;
- iv. Regulated Marijuana Product;
- v. Pre-Rolled Marijuana;
- vi. Infused Pre-Rolled Marijuana;
- vii. Pressurized Metered Dose Inhaler;
- viii. Vaporizer Delivery Device;
- ix. Audited Product; and
- x. Hemp Product.

**4-215(J)(7)(c) 1**

<u>Substance</u>	<u>Acceptable Limits Based on Intended Use</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Oral Consumption or Audited Product: rectal or vaginal administration</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Lead – Max Limit: &lt; 1 PPM</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Arsenic – Max Limit: &lt; 1.5 PPM</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Cadmium – Max Limit: &lt; 0.5 PPM</u>
<u>Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)</u>	<u>Mercury – Max Limit: &lt; 1.5 PPM</u>

**8. Pesticides.**

a. The following pesticides are subject to required testing, at the associated action limits, in the following products:

- i. Regulated Marijuana flower, shake, trim, and wet whole plant;
- ii. Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate;
- iii. Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Retail Marijuana Concentrate;
- iv. Pre-Rolled Marijuana;
- v. Infused Pre-Rolled Marijuana; and
- vi. Hemp Product.

**4-215(J)(8)(a) 1**

<u>Substance</u>	<u>Action Limit</u>
<u>Abamectin</u> (Avermectins: B1a & B1b)	<u>&lt; 0.1 PPM</u>
<u>Acephate</u>	<u>&lt; 0.02 PPM</u>
<u>Acequinocyl</u>	<u>&lt; 0.03 PPM</u>
<u>Acetamiprid</u>	<u>&lt; 0.1 PPM</u>
<u>Aldicarb</u>	<u>&lt; 1.0 PPM</u>
<u>Allethrin</u>	<u>&lt; 0.2 PPM</u>
<u>Atrazine</u>	<u>&lt; 0.025 PPM</u>
<u>Azoxystrobin</u>	<u>&lt; 0.02 PPM</u>
<u>Benzovindiflupyr</u>	<u>&lt; 0.02 PPM</u>
<u>Bifenazate</u>	<u>&lt; 0.02 PPM</u>
<u>Bifenthrin</u>	<u>&lt; 1.0 PPM</u>
<u>Boscalid</u>	<u>&lt; 0.02 PPM</u>
<u>Buprofezin</u>	<u>&lt; 0.02 PPM</u>
<u>Carbaryl</u>	<u>&lt; 0.05 PPM</u>
<u>Carbofuran</u>	<u>&lt; 0.02 PPM</u>
<u>Chlorantraniliprole</u>	<u>&lt; 0.02 PPM</u>
<u>Chlorfenapyr</u>	<u>&lt; 0.05 PPM</u>
<u>Chlorpyrifos</u>	<u>&lt; 0.04 PPM</u>
<u>Clofentezine</u>	<u>&lt; 0.02 PPM</u>
<u>Clothianidin</u>	<u>&lt; 0.05 PPM</u>
<u>Coumaphos</u>	<u>&lt; 0.02 PPM</u>
<u>Cyantraniliprole</u>	<u>&lt; 0.02 PPM</u>
<u>Cyfluthrin</u>	<u>&lt; 0.2 PPM</u>
<u>Cyhalothrin-lambda</u>	<u>&lt; 0.25 PPM</u>

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<u>Substance</u>	<u>Action Limit</u>
<u>Cypermethrin</u>	<u>&lt; 0.3 PPM</u>
<u>Cyprodinil</u>	<u>&lt; 0.25 PPM</u>
<u>Daminozide</u>	<u>&lt; 0.1 PPM</u>
<u>Deltamethrin</u>	<u>&lt; 0.5 PPM</u>
<u>Diazinon</u>	<u>&lt; 0.02 PPM</u>
<u>Dichlorvos</u>	<u>&lt; 0.1 PPM</u>
<u>Dimethoate</u>	<u>&lt; 0.02 PPM</u>
<u>Dimethomorph</u>	<u>&lt; 0.05 PPM</u>
<u>Dinotefuran</u>	<u>&lt; 0.1 PPM</u>
<u>Diuron</u>	<u>&lt; 0.125 PPM</u>
<u>Dodemorph</u>	<u>&lt; 0.05 PPM</u>
<u>Endosulfan sulfate</u>	<u>&lt; 0.05 PPM</u>
<u>Endosulfan-alpha</u>	<u>&lt; 0.2 PPM</u>
<u>Endosulfan-beta</u>	<u>&lt; 0.05 PPM</u>
<u>Ethoprophos</u>	<u>&lt; 0.02 PPM</u>
<u>Etofenprox</u>	<u>&lt; 0.05 PPM</u>
<u>Etoxazole</u>	<u>&lt; 0.02 PPM</u>
<u>Etridiazole</u>	<u>&lt; 0.03 PPM</u>
<u>Fenhexamid</u>	<u>&lt; 0.125 PPM</u>
<u>Fenoxycarb</u>	<u>&lt; 0.02 PPM</u>
<u>Fenpyroximate</u>	<u>&lt; 0.02 PPM</u>
<u>Fensulfothion</u>	<u>&lt; 0.02 PPM</u>
<u>Fenthion</u>	<u>&lt; 0.02 PPM</u>
<u>Fenvalerate</u>	<u>&lt; 0.1 PPM</u>
<u>Fipronil</u>	<u>&lt; 0.06 PPM</u>
<u>Flonicamid</u>	<u>&lt; 0.05 PPM</u>
<u>Fludioxonil</u>	<u>&lt; 0.02 PPM</u>



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<u>Substance</u>	<u>Action Limit</u>
<u>Fluopyram</u>	<u>&lt; 0.02 PPM</u>
<u>Hexythiazox</u>	<u>&lt; 0.01 PPM</u>
<u>Imazalil</u>	<u>&lt; 0.05 PPM</u>
<u>Imidacloprid</u>	<u>&lt; 0.02 PPM</u>
<u>Iprodione</u>	<u>&lt; 1.0 PPM</u>
<u>Kinoprene</u>	<u>&lt; 0.5 PPM</u>
<u>Kresoxim-methyl</u>	<u>&lt; 0.02 PPM</u>
<u>Lambda-Cyhalothrin</u>	<u>&lt; 0.25 PPM</u>
<u>Malathion</u>	<u>&lt; 0.02 PPM</u>
<u>Metalaxyl</u>	<u>&lt; 0.02 PPM</u>
<u>Methiocarb</u>	<u>&lt; 0.02 PPM</u>
<u>Methomyl</u>	<u>&lt; 0.05 PPM</u>
<u>Methoprene</u>	<u>&lt; 2.0 PPM</u>
<u>Mevinphos</u>	<u>&lt; 0.05 PPM</u>
<u>MGK-264</u>	<u>&lt; 0.05 PPM</u>
<u>Myclobutanil</u>	<u>&lt; 0.02 PPM</u>
<u>Naled</u>	<u>&lt; 0.1 PPM</u>
<u>Novaluron</u>	<u>&lt; 0.05 PPM</u>
<u>Oxamyl</u>	<u>&lt; 3.0 PPM</u>
<u>Paclobutrazol</u>	<u>&lt; 0.02 PPM</u>
<u>Parathion-methyl</u>	<u>&lt; 0.05 PPM</u>
<u>Permethrin (Mixture of Isomers)</u>	<u>&lt; 0.5 PPM</u>
<u>Phenothrin</u>	<u>&lt; 0.05 PPM</u>
<u>Phosmet</u>	<u>&lt; 0.02 PPM</u>
<u>Pirimicarb</u>	<u>&lt; 0.02 PPM</u>
<u>Prallethrin</u>	<u>&lt; 0.05 PPM</u>

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<b><u>Substance</u></b>	<b><u>Action Limit</u></b>
<u>Propiconazole</u>	<u>&lt; 0.1 PPM</u>
<u>Propoxur</u>	<u>&lt; 0.02 PPM</u>
<u>Pyraclostrobin</u>	<u>&lt; 0.02 PPM</u>
<u>Pyridaben</u>	<u>&lt; 0.05 PPM</u>
<u>Pyriproxyfen</u>	<u>&lt; 0.01 PPM</u>
<u>Quintozene</u>	<u>&lt; 0.02 PPM</u>
<u>Resmethrin</u>	<u>&lt; 0.1 PPM</u>
<u>Spinetoram</u>	<u>&lt; 0.02 PPM</u>
<u>Spinosad (Mixture of A and D)</u>	<u>&lt; 0.1 PPM</u>
<u>Spirodiclofen</u>	<u>&lt; 0.25 PPM</u>
<u>Spiromesifen</u>	<u>&lt; 3.0 PPM</u>
<u>Spirotetramat</u>	<u>&lt; 0.02 PPM</u>
<u>Spiroxamine</u>	<u>&lt; 0.1 PPM</u>
<u>Tebuconazole</u>	<u>&lt; 0.05 PPM</u>
<u>Tebufenozide</u>	<u>&lt; 0.02 PPM</u>
<u>Teflubenzuron</u>	<u>&lt; 0.05 PPM</u>
<u>Tetrachlorvinphos</u>	<u>&lt; 0.02 PPM</u>
<u>Tetramethrin</u>	<u>&lt; 0.1 PPM</u>
<u>Thiabendazole</u>	<u>&lt; 0.02 PPM</u>
<u>Thiacloprid</u>	<u>&lt; 0.02 PPM</u>
<u>Thiamethoxam</u>	<u>&lt; 0.02 PPM</u>
<u>Thiophanate-methyl</u>	<u>&lt; 0.05 PPM</u>
<u>Trifloxystrobin</u>	<u>&lt; 0.02 PPM</u>

**Basis and Purpose – 4-220**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2).

C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing R&D testing procedures and rules for the Division's Regulated Marijuana sampling and testing program. This Rule 4-220 was previously Rules 4-105, 1 CCR 212-3, Rules M and R 1504, 1 CCR 212-1 and 1 CCR 212-2.

#### **4-220 – Regulated Marijuana Testing Program: R&D Testing**

A. R&D Testing. A Regulated Marijuana Business may submit Test Batches from a Harvest Batch (including a Manicure Batch) or Production Batch for R&D testing. R&D testing may be performed for any test required by these 4-200 Series Rules or any other test.

1. Harvest Batches or Production Batches that are Designated in the Inventory Tracking System as an R&D batch.

a. The Regulated Marijuana from these batches shall not be Transferred to other Regulated Marijuana Businesses except for Regulated Marijuana Testing Facilities.

b. Failing R&D test results do not require compliance with failed test procedures and are not considered a failing result for the purposes of achieving or maintaining Reduced Testing Allowance.

2. Harvest Batches or Production Batches that are Intended to be Transferred to other Regulated Marijuana Businesses.

a. Passing R&D Test Results. If a Harvest or Production Batch passes an R&D test it shall not constitute a pass for the purposes of compliance with required contaminant or potency testing. If a Harvest or Production Batch passes an R&D test it shall not constitute a pass for purposes of achieving or maintaining a Reduced Testing Allowance. See Rules 4-210 and 4-230.

b. Failed R&D Test Results. If a Harvest or Production Batch fails an R&D test:

i. It does not require compliance with failed test procedures. See Rule 4-240.

ii. If a Test Batch fails an R&D test that is a test type required by these Rules, the Licensee must submit a Test Batch from the same Harvest or Production Batch for compliance testing and obtain passing results for that test type prior to Transferring that Harvest or Production Batch to a Regulated Marijuana Business.

iii. If the Test Batch submitted pursuant to paragraph (1)(b)(ii)(B) fails testing, compliance with the failed test procedures in Rule 4-240 is required.

iv. Licensees shall not Transfer Regulated Marijuana that they have reason to believe would not pass testing required by Rule 4-210 and 4-215, unless otherwise authorized in these rules.

**Basis and Purpose – 4-225**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing sampling procedures and rules for the Division's Regulated Marijuana sampling and testing program. This Rule 4-225 was previously Rules 4-110 and 4-125, 1 CCR 212-3, Rules M and R 1504, 1 CCR 212-1 and 1 CCR 212-2.

**4-225 – Regulated Marijuana Testing Program: Sampling Procedures****A. Collection of Test Batches.**

1. Sample Increment Collection. All Test Batches submitted for testing pursuant to this Rule must be collected by Division representatives or in accordance with the Division's sampling policy reflected in the marijuana laboratory testing reference library available at the Colorado Department of Public Health and Environment's website. This reference library may be continuously updated as new materials become available in accordance with section 25-1.5-106(3.5)(d), C.R.S.
2. Sample Increment Selection. The Division may elect, at its sole direction, to assign Division representatives to collect Sample Increments, or may otherwise direct Sample Increment selection, including, but not limited to, through Division designation of a Harvest Batch or Production Batch in the Inventory Tracking System from which a Regulated Marijuana Business shall select Test Batches for testing. A Regulated Marijuana Business, its Controlling Beneficial Owners, Passive Beneficial Owners, and employees shall not attempt to influence the Sample Increments selected by Division representatives. If the Division does not select the Harvest Batch or Production Batch to be tested, a Regulated Marijuana Business must collect and submit Sample Increments that are representative of the Harvest Batch or Production Batch being tested.
3. Adulteration or Alteration Prohibited. Pursuant to section 44-10-701(3)(b) and (9), C.R.S., it is unlawful for a Licensee or its agent to knowingly adulterate or alter, or attempt to adulterate or alter, any Sample Increments or Test Batches of Regulated Marijuana. The Sample Increments collected and submitted for testing must be representative of the Harvest Batch or Production Batch being tested. A person who commits adulteration or alteration of Sample Increments or Test Batches commits a class 2 misdemeanor and may be punished as provided in section 18-1.3-501, C.R.S.

- B. Timing of Sample Increments for Harvest Batches and Production Batches. A Licensee shall not collect Sample Increments or submit Test Batches for testing until the Harvest or Production Batch that is represented by the Test Batch has completed all required steps and is in its final form as outlined in the Standard Operating Procedures of the Licensee submitting the Test Batch, with the exception of packaging and labeling requirements which shall comply with Rule 3-1025.

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1. The following examples illustrate various methods, which are not limited to those listed herein, that a Licensee's Standard Operating Procedures may include to verify a Test Batch completed all required steps and is in its final form pursuant to this Rule:
  - a. The Licensee's Standard Operating Procedures may include procedures that ensure the addition of all Ingredients or Additives has occurred and that the Harvest Batch or Production Batch associated with the Test Batch is completely ready to be packaged pending results of testing required by these Rules. This also includes creating Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana;
  - b. For a Production Batch of Concentrate, the Licensee's Standard Operating Procedure may include procedures that ensure the entire Production Batch associated with the Test Batch has completed all sifting, extracting, purging, winterizing, and steps to remove plant pigments and ensuring the addition of all Ingredients and Additives has occurred.
  - c. For a Production Batch of Regulated Marijuana Product, the Licensee's Standard Operating Procedure may include procedures that ensure the addition of all Ingredients and Additives has occurred and the Production Batch associated with the Test Batch is completely ready to be packaged pending results of testing required by these Rules.
2. A Test Batch from a Harvest Batch or Production Batch shall be packaged and labeled according to Series 3-1025 prior to Transfer to a Regulated Marijuana Testing Facility.
3. This Rule 4-225(B) does not apply for the submission of Test Batches submitted for R&D testing.
4. Vaporizer Delivery Device. Retail Marijuana Concentrate that has been placed into a Vaporizer Delivery Device must be sampled and tested using a methodology that allows the laboratory to analyze the emission of the contents of the Vaporizer Delivery Device.

**C. Potency Testing – General.**

1. Test Batches. A Test Batch submitted for potency testing may only be comprised of Sample Increments that are of the same strain of Medical Marijuana or Retail Marijuana or from the same Production Batch of Medical Marijuana Concentrate or Medical Marijuana Product, or from the same Production Batch of Retail Marijuana Concentrate or Retail Marijuana Product, or from the same Production Batch of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana.

**D. Designated Test Batch Collector Training, Documentation, and Designation.**

1. Required Sample Increment Collection Training. To become a Designated Test Batch Collector an Owner Licensee or Employee Licensee involved in the Sample Increment Collection of Regulated Marijuana must be designated by a manager or Owner Licensee as such and must also complete either in-house

training provided by the Regulated Marijuana Business or training from a third-party vendor including all of the topics set forth in subparagraph (2) of this Rule. Nothing in this rule requires a Designated Test Batch Collector to be employed by the Regulated Marijuana Business making the designation.

2. Designated Test Batch Collection Training Required Topics. The training required to become a Designated Test Batch Collector must include at least the following topics:

a. Part 4–200 Series Rules - Regulated Marijuana Testing Program;

b. The Regulated Marijuana Business's Standard Operating Procedures on creating a Sampling Plan and Test Batches, and the CDPHE's Sampling Procedures.

c. “Guidance on Marijuana Sampling Procedures” Training Video or an equivalent training covering the following subjects:

i. Introduction to Sample Increment Collection:

A. Cross contamination as it relates to Sample Increment Collection;

B. Sample Increment Collection and how it works;

C. Sample Increment Collection documentation and record keeping requirements;

D. Penalties for Sample Increment or Test Batch adulteration or alteration;

E. Use of and disinfection of the Designated Test Batch Collection Area; and

F. Use of the Sample Plan.

3. Documentation of Designated Test Batch Collector Training. Any individual receiving the Designated Test Batch Collector training must sign and date a document which shall be maintained by the Regulated Marijuana Business as a business record pursuant to Rule 3-905. The document must acknowledge the following:

a. The identity of the Person that created the training, such as the Regulated Marijuana Business or a third-party vendor; and

b. That all required topics of the training identified in this Rule have been reviewed and understood by the Owner Licensee or Employee Licensee.

E. Test Batch Collection Requirements.

1. Required Minimum of Two Test Batch Collectors. At a minimum, two Designated Test Batch Collectors shall be involved in the collection of Sample Increments such that at least one Designated Test Batch Collector is responsible for collecting the Sample Increments and another Designated Test Batch Collector is

responsible for reviewing documentation associated with the collection of Sample Increments in a timely manner and prior to any Transfer of the Production Batch or Harvest Batch from which Sample Increments were collected. This review can be completed in person or may be completed remotely by reviewing image(s) of the Test Batch and associated documentation. All Designated Test Batch Collectors must be identified as such in the Inventory Tracking System account associated with the Regulated Marijuana Business.

2. Sample Plan Required. A Designated Test Batch Collector must establish a Sample Plan consistent with the Regulated Marijuana Business's Standard Operating Procedure for Sample Increment Collection. At a minimum, a Sample Plan must include the following:

- a. The date, amount or weight, and specific location for each Sample Increment collected;
- b. Identification of and acknowledgements from all Designated Test Batch Collectors involved in the Sample Increment Collection; and
- c. If applicable, the strain name(s) for each Harvest Batch from which Sample Increments are collected.

F. Minimum Number of Sample Increments Per Test Batch Submission. These sampling rules shall apply until such time as the State Licensing Authority revises these rules to implement a statistical sampling model. Unless a greater amount is required to comply with these rules or is required by a Regulated Marijuana Testing Facility to perform all requested testing, each Test Batch of Regulated Marijuana must contain at least the number of Sample Increments prescribed by this Section.

- 1. A Test Batch of Regulated Marijuana must be packaged and labeled according to Rule 3-1025.
- 2. The minimum number of Sample Increments required to be collected for each Test Batch from a Harvest Batch of Retail Marijuana or Medical Marijuana shall be determined as directed in subparagraphs (F)(4)(c)(i) – (iv) of this Rule.
- 3. The minimum number of Sample Increments required to be collected for each Test Batch from a Production Batch of Regulated Marijuana Product, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Audited Product and Alternative Use Product shall be determined as directed in subparagraphs (F)(4)(c)(i) – (iv) of this Rule.
  - a. The Retail Marijuana Products Manufacturer or Medical Marijuana Products Manufacturer shall determine what constitutes a "Serving" and thus how many Servings are contained in a Production Batch of Regulated Marijuana Product, except that no serving of Edible Retail Marijuana Product can contain more than 10mg of active THC
  - b. Because all Test Batches of Regulated Marijuana Product, Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana are required to be submitted for testing in their final form, in the event the required number of Sample

Increments does not match up within a finished package, the manufacturer must increase the number of Sample Increments collected for the Test Batch such that only finished packages of Regulated Marijuana Products, Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana are submitted for testing. For example, if a Production Batch of 4000 chocolate bars is manufactured, with each bar containing 100 mg THC and 10 servings per bar, the Production Batch would contain 40,000 Sample Increments which would require collection of at least 33 Sample Increments per Test Batch. But in this case, the manufacturer would have to collect 40 Sample Increments for testing (4 complete chocolate bars in final form).

c. No matter how small the Production Batch of Regulated Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana a minimum of two finished packages in final form must be submitted for a Test Batch.

4. The minimum number of Sample Increments required to be collected for each Test Batch from a Production Batch of Retail Marijuana Concentrate or Medical Marijuana Concentrate shall be determined as directed in subparagraphs (F)(4)(c)(i) – (iv) of this Rule.

a. Because all Test Batches of Retail Marijuana Concentrate and Medical Marijuana Concentrate are required to be submitted for testing in their final form, in the event the required number of Sample Increments does not match up with the number of Sample Increments in a finished package, the manufacturer must increase the number of Sample Increments collected for the Test Batch such that only finished packages of Marijuana Concentrate are submitted for testing. For example, if a Production Batch of 4,000 Vaporizer Delivery Devices is manufactured, with each Vaporizer Delivery Device containing 500 milligrams of Marijuana Concentrate, the Production Batch would contain 2,000 grams of Marijuana Concentrate, which would require collection of at least 15 Sample Increments per Test Batch. But in this case, the manufacturer would have to collect 16 Sample Increments for testing (8 vaporizer Delivery Devices in final form).

b. No matter how small the Production Batch of Retail Marijuana Concentrate or Medical Marijuana Concentrate, a minimum of two finished packages must be submitted for a Test Batch.

c. Determining minimum number of Sample Increments.

i. The following table represents Regulated Marijuana Sample Increments of 0.5 grams:



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**4-225(F)(4)(c)(i) 1**

<u>Minimum Number of Sample Increments Required to be Collected per Test Batch</u>	<u>Total Weight of Harvest Batch (lbs)</u>	<u>Total Weight of Harvest Batch (grams)</u>	<u>Minimum Weight of Test Batch (grams)</u>
<u>5</u>	<u>0.000 -0.999</u>	<u>0.0 -453.5</u>	<u>2.50</u>
<u>8</u>	<u>1.00 -9.999</u>	<u>453.6 -4535.9</u>	<u>4.00</u>
<u>15</u>	<u>10.000 -19.999</u>	<u>4536.0 - 9071.8</u>	<u>7.50</u>
<u>22</u>	<u>20.000 -39.999</u>	<u>9071.9 - 18143.6</u>	<u>11.00</u>
<u>33</u>	<u>40.000 -99.999</u>	<u>18143.7 - 45359.2</u>	<u>16.50</u>
<u>43</u>	<u>100.000 - 199.999</u>	<u>45359.3 - 90718.4</u>	<u>21.50</u>
<u>53</u>	<u>200.000 - 499.999</u>	<u>90718.5 - 226796.1</u>	<u>26.50</u>
<u>80</u>	<u>500 or more</u>	<u>226796.2 or more</u>	<u>40.00</u>

ii. The following table represents Regulated Marijuana Concentrate Sample Increments of 0.25 grams:

**4-225(F)(4)(c)(ii) 1**

<u>Minimum Number of Sample Increments Required to be Collected per Test Batch</u>	<u>Total Weight of Production Batch (lbs)</u>	<u>Total Weight of Production Batch (grams)</u>	<u>Minimum Weight of Test Batch (grams)</u>
<u>5</u>	<u>0.000 -0.999</u>	<u>0.0-453.5</u>	<u>1.25</u>
<u>8</u>	<u>1.00 - 1.999</u>	<u>453.6-907.1</u>	<u>2.00</u>
<u>15</u>	<u>2.00 - 4.999</u>	<u>907.2-2267.9</u>	<u>3.75</u>
<u>22</u>	<u>5.000 - 14.999</u>	<u>2268.0-6803.8</u>	<u>5.50</u>
<u>33</u>	<u>15.000 – 49.999</u>	<u>6803.9-22679.6</u>	<u>8.25</u>
<u>43</u>	<u>50.000 – 99.999</u>	<u>22679.7-45359.2</u>	<u>10.75</u>
<u>53</u>	<u>100.000 – 249.999</u>	<u>45359.3- 113398.0</u>	<u>13.25</u>
<u>80</u>	<u>250 or more</u>	<u>113398.1 or more</u>	<u>20.00</u>

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iii. The following table represents Regulated Marijuana Products Sample Increments of 1 Serving:

## 4-225(F)(4)(c)(iii) 1

<u>Minimum Number of Sample Increments Required to be Collected per Test Batch</u>	<u>Number of Servings within Production Batch</u>	<u>Minimum Number of Units for a Test Batch for a 5-Serving Unit*</u>	<u>Minimum Number of Units for a Test Batch for a 10-Serving Unit*</u>	<u>Minimum Number of Units for a Test Batch for a 20-Serving Unit*</u>	<u>Minimum Number of Units for a Test Batch for a 100-Serving Unit*</u>
<u>5</u>	<u>0 - 99</u>	<u>2</u>	<u>2</u>	<u>2</u>	<u>2</u>
<u>8</u>	<u>100 - 999</u>	<u>2</u>	<u>2</u>	<u>2</u>	<u>2</u>
<u>15</u>	<u>1000 - 4999</u>	<u>3</u>	<u>2</u>	<u>2</u>	<u>2</u>
<u>22</u>	<u>5000 - 9999</u>	<u>5</u>	<u>3</u>	<u>2</u>	<u>2</u>
<u>33</u>	<u>10000 - 49999</u>	<u>7</u>	<u>4</u>	<u>2</u>	<u>2</u>
<u>43</u>	<u>50000 - 99999</u>	<u>9</u>	<u>5</u>	<u>3</u>	<u>3</u>
<u>53</u>	<u>100000 - 249999</u>	<u>11</u>	<u>6</u>	<u>3</u>	<u>3</u>
<u>80</u>	<u>250000 or more</u>	<u>16</u>	<u>8</u>	<u>4</u>	<u>4</u>

\*Other serving amounts per unit are acceptable. These are provided as examples.

iv. Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana. The following table represents the minimum number of Pre-Rolls for a Test Batch based on the minimum number of Sample Increments required to be collected per Test Batch, the number of Pre-Rolls within the Production Batch, and the weight of each Pre-Roll.

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4-225(F)(4)(c)(iv) 1

		<u>Pre-Roll Weight</u> : <u>&lt; or = 0.39 g</u>	<u>Pre-Roll Weight</u> : <u>0.40g to 0.50g</u>	<u>Pre-Roll Weight</u> : <u>0.51g to 0.75g</u>	<u>Pre-Roll Weight</u> : <u>0.76g to 1.00g</u>	<u>Pre-Roll Weight</u> : <u>1.01g to 2.00g</u>	<u>Pre-Roll Weight</u> : <u>2.01g to 3.00g</u>	<u>Pre-Roll Weight</u> : <u>3.01g +</u>
<u>Minimum Number of Sample Increments Required to be Collected per Test Batch</u>	<u>Number of Pre-Rolls within the Production Batch</u>	<u>Minimum Number of Pre-Rolls for a Test Batch</u>	<u>Minimum Number of Pre-Rolls for a Test Batch</u>	<u>Minimum Number of Pre-Rolls for a Test Batch</u>	<u>Minimum Number of Pre-Rolls for a Test Batch</u>	<u>Minimum Number of Pre-Rolls for a Test Batch</u>	<u>Minimum Number of Pre-Rolls for a Test Batch</u>	<u>Minimum Number of Pre-Rolls for a Test Batch</u>
<u>5</u>	<u>0 - 99</u>	<u>5</u>	<u>4</u>	<u>3</u>	<u>2</u>	<u>2</u>	<u>2</u>	<u>2</u>
<u>8</u>	<u>100 - 999</u>	<u>8</u>	<u>5</u>	<u>4</u>	<u>3</u>	<u>2</u>	<u>2</u>	<u>2</u>
<u>15</u>	<u>1000 - 4999</u>	<u>15</u>	<u>10</u>	<u>8</u>	<u>5</u>	<u>4</u>	<u>2</u>	<u>2</u>
<u>22</u>	<u>5000 - 9999</u>	<u>22</u>	<u>14</u>	<u>11</u>	<u>8</u>	<u>6</u>	<u>3</u>	<u>2</u>
<u>33</u>	<u>10000 - 49999</u>	<u>33</u>	<u>21</u>	<u>17</u>	<u>11</u>	<u>9</u>	<u>5</u>	<u>3</u>
<u>43</u>	<u>50000 - 99999</u>	<u>43</u>	<u>27</u>	<u>22</u>	<u>15</u>	<u>11</u>	<u>6</u>	<u>4</u>
<u>53</u>	<u>100000 - 249999</u>	<u>53</u>	<u>34</u>	<u>26</u>	<u>18</u>	<u>14</u>	<u>7</u>	<u>5</u>
<u>80</u>	<u>250000 or more</u>	<u>80</u>	<u>50</u>	<u>40</u>	<u>27</u>	<u>20</u>	<u>10</u>	<u>7</u>

G. Regulated Marijuana Testing Facility Selection. Unless otherwise restricted or prohibited by these Rules or ordered by the State Licensing Authority, a Regulated Marijuana

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Business may select which Medical Marijuana Testing Facility or Retail Marijuana Testing Facility will test a Test Batch made up of Sample Increments collected pursuant to this Rule. However, the Division may elect, at its sole discretion, to assign a Regulated Marijuana Testing Facility to which a Regulated Marijuana Business must submit for testing any Test Batch made up of Sample Increments collected pursuant to this Rule.

- H. Hemp Product Sampling Procedures. Absent sampling and testing standards established by the Colorado Department of Public Health and Environment for the sampling and testing of Hemp Product, a Person Transferring a Hemp Product to a Licensee pursuant to the Marijuana Code and these Rules shall comply with the sampling and testing standards set forth in these 4-200 Series Rules – Regulated Marijuana Testing Program and as required by these Rules.

**Basis and Purpose – 4-230**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing contaminant testing and related Reduced Testing Allowance procedures and rules for the Division's Regulated Marijuana sampling and testing program. This Rule 4-230 was previously Rules 4-120, 4-121, and 4-125, 1 CCR 212-3, Rules M and R 1504, 1 CCR 212-1 and 1 CCR 212-2.

**4-230 – Regulated Marijuana Testing Program: Reduced Testing Allowance Procedures**

- A. Achieving a Reduced Testing Allowance.

**4-230(A) 1**

<u>Product Class</u>	<u>Minimum time for testing all batches of product to qualify for RTA</u>	<u>Maximum time for testing all batches of product to qualify for RTA</u>	<u>Minimum number of Test Batches for product to qualify for RTA</u>	<u>Scope of products that must be tested to qualify for RTA</u>	<u>Test Types eligible for RTA (Note: All Test Types are individual RTAs)</u>
<u>Regulated Marijuana</u>	<u>6 weeks (42 days)</u>	<u>12 weeks (84 days)</u>	<u>6 Test Batches</u>	<u>All Regulated Marijuana produced in a given Cultivation Facility</u>	<u>Pesticides, Elemental Impurities, Microbial Contaminants</u>

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<u>Product Class</u>	<u>Minimum time for testing all batches of product to qualify for RTA</u>	<u>Maximum time for testing all batches of product to qualify for RTA</u>	<u>Minimum number of Test Batches for product to qualify for RTA</u>	<u>Scope of products that must be tested to qualify for RTA</u>	<u>Test Types eligible for RTA (Note: All Test Types are individual RTAs)</u>
<u>Regulated Marijuana Product</u>	<u>4 weeks (28 days)</u>	<u>8 weeks (56 days)</u>	<u>4 Test Batches</u>	<u>A specific type of Regulated Marijuana Product (Rule 4-230(B)(2))</u>	<u>Pesticides, Elemental Impurities, Microbial Contaminants, Residual Solvents Potency, Homogeneity</u>
<u>Wet Whole Plant</u>	<u>3 weeks (21 days)</u>	<u>12 weeks (84 days)</u>	<u>6 Test Batches</u>	<u>All Wet Whole Plant produced in a given Cultivation Facility</u>	<u>Microbial Contaminants</u>

B. Reduced Testing Allowance and Ongoing Testing – Contaminant Testing.

1. Regulated Marijuana. A Regulated Marijuana Cultivation Facility's cultivation process may achieve a Reduced Testing Allowance for contaminant testing if every Harvest Batch that it produced during at least a six-week period (minimum 42 days) but no longer than a 12-week period (maximum 84 days) passed all contaminant tests required by Rule 4-215(E). This must include at least six Test Batches. The period begins from the date of the creation of the first Harvest Batch that passed Reduced Testing Allowance testing. A Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator can achieve a Reduced Testing Allowance for all contaminants listed in Rule 4-215(E) at the same time or separately for each contaminant. A Regulated Marijuana Cultivation Facility must cultivate and process all Harvest Batches the same way, including the same growing media, lighting, pesticides, and drying, trimming, and packaging procedures to be eligible to obtain and maintain a Reduced Testing Allowance.
2. Regulated Marijuana Concentrate, Regulated Marijuana Product, Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana. A Regulated Marijuana Business's production process may achieve a Reduced Testing Allowance for contaminant testing if for a particular type of Regulated Marijuana Concentrate, Regulated Marijuana Product, or Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana every Production Batch that it produced during at least a four-week period (minimum 28 days) but no longer than an eight-week period (maximum 56 days)

passed all contaminant tests required by Rule 4-215(E). This must include Test Batches from at least four Production Batches. This period begins from the date of the creation of the first Production Batch that passed Reduced Testing Allowance testing. If a Regulated Marijuana Concentrate or Regulated Marijuana Product is manufactured using a different extraction process or infusion process or using any different Additives or Botanically Derived Compounds, it will be considered a different type of Regulated Marijuana Concentrate or Regulated Marijuana Product and therefore must separately achieve a Reduced Testing Allowance. If Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana is produced using different input materials, such as a different marijuana category (e.g. flower or trim), different wrapper materials, different processes, or different equipment, they must achieve separate Reduced Testing Allowances.

C. Wet Whole Plant. A Regulated Marijuana Cultivation Facility's cultivation process for wet whole plant shall be deemed acceptable for a Reduced Testing Allowance for microbial contaminant testing if every Harvest Batch of wet whole plant that it produced during at least a three-week (minimum 21 days) period but no longer than a 12-week (maximum 84 days) period passed all microbial contaminant tests required by this Rule. This must include at least six Test Batches. A Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator can achieve a Reduced Testing Allowance for contaminants listed in this Rule 4-230.

D. Reduced Testing Allowance - Potency and Homogeneity.

1. A Retail Marijuana Products Manufacturer or Accelerator Manufacturer may achieve a Reduced Testing Allowance for potency and homogeneity for each type of Retail Marijuana Product it manufactures.

a. For Edible Retail Marijuana Products a potency test result that is within 15 percent of the target potency will count towards a Reduced Testing Allowance.

i. For Edible Retail Marijuana Products that contain 2.5 milligrams of THC or less per serving, a potency test result that is within the greater of plus or minus 0.5 milligrams or 40 percent per serving will count towards a Reduced Testing Allowance.

2. A Medical Marijuana Products Manufacturer may achieve a Reduced Testing Allowance for potency and homogeneity for each type of non-Edible Medical Marijuana Product and each type of Edible Medical Marijuana Product that it manufactures.

a. For Edible Medical Marijuana Products that contain 100 milligrams of THC or less per Container, a potency test result that is within 15 percent of the target potency will count towards a Reduced Testing Allowance.

i. For Edible Medical Marijuana Products that contain 2.5 milligrams of THC or less per serving and 100 milligrams of THC or less per Container, a potency test result that is within the greater of plus or

minus 0.5 milligrams or 40 percent per serving will count towards a Reduced Testing Allowance.

b. For Edible Medical Marijuana Products that contain between 101 and 500 milligrams of THC per Container, a potency test result that is within 10 percent of the target potency will count towards a Reduced Testing Allowance.

c. For Edible Medical Marijuana Products that contain 501 milligrams of THC or more per Container, a potency test result that is within 5 percent of the target potency will count towards a Reduced Testing Allowance.

3. A Regulated Marijuana Products Manufacturer's production process for a particular type of Regulated Marijuana Product shall be deemed acceptable for a Reduced Testing Allowance for potency and homogeneity testing if every Production Batch that it produces for that particular type of Regulated Marijuana Product during at least a four-week period but no longer than an eight-week period passes all potency and homogeneity tests required by Rule 4-210. This must include at least four Test Batches.

E. Expiration of a Reduced Testing Allowance. Once a Regulated Marijuana Business has successfully achieved Reduced Testing Allowance for any contaminants listed in Rule 4-215 or Potency as required by 4-210(E), Reduced Testing Allowance is effective for one year from the date of the first passing Harvest Batch or Production Batch. One year is equal to 365 days inclusive, or 366 days inclusive during a leap year. When the Reduced Testing Allowance expires, the Regulated Marijuana Business shall achieve new Reduced Testing Allowance or Perform all testing Required by 4-210 and 4-215.

F. Reduced Testing Allowance Certification Fee. A Licensee seeking to obtain Reduced Testing Allowance must first pay the fee in Rule 2-140(A).

1. A Licensee who chooses to pay the Reduced Testing Allowance fee must also submit an attestation form that at a minimum requires the Licensee attest they understand these testing Rules and requirements.

2. Upon the Division's receipt of payment of the fee and submission of the attestation form, a Licensee may exercise the privileges of Reduced Testing Allowance for a 12-month period.

3. If a Licensee is required, under these Rules, to reauthorize the Reduced Testing Allowance within the 12-month period, the Licensee is not required to pay a new fee.

4. Reduced Testing Allowance Certification can be renewed annually.

G. Maintaining a Reduced Testing Allowance.

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<u>Product Class</u>	<u>Frequency for Submitting Required Ongoing Contaminant Tests for Maintaining RTA</u>	<u>Frequency for Submitting Required Ongoing Potency &amp; Homogeneity Tests for Maintaining RTA</u>
<u>Regulated Marijuana, Regulated Marijuana Concentrate, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana</u>	<u>1 Test Batch every 30 days</u>	<u>N/A</u>
<u>Wet Whole Plant</u>	<u>1 Test Batch every 30 days (Microbial Only)</u>	<u>N/A</u>
<u>Regulated Marijuana Product</u>	<u>1 Test Batch every 30 days</u>	<u>1 Test Batch every quarter (90) days</u>

Note: If during any period of ongoing testing specified in the table above the Regulated Marijuana Business does not possess a Harvest Batch or Production Batch that is ready for testing, the Regulated Marijuana Business must subject its first Harvest Batch or Production Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Regulated Marijuana, Regulated Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana.

H. Regulated Marijuana Ongoing Contaminant Testing. After successfully achieving a Reduced Testing Allowance, a Regulated Marijuana Business shall subject at least one Harvest Batch to all contaminant testing required by Rule 4-215(E) once every 30-day period following the test submission date of the last Test Batch used to achieve the Reduced Testing Allowance. If during any 30-day period the Regulated Marijuana Business does not possess a Harvest Batch that is ready for testing, the Regulated Marijuana Business must subject its first Harvest Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Regulated Marijuana. If a Harvest Batch subject to ongoing contaminant testing fails contaminant testing, the Regulated Marijuana Business shall follow the procedure in subparagraph (K)(2) of this Rule. Ongoing contaminant testing pursuant to this Rule 4-230 shall be subject to the requirements in Rule 4-225. See Rule 4-225(A) – Collection of Test Batches.

1. The Division may reduce the frequency of ongoing contaminant testing required if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.
2. If the Licensee fails to comply with subparagraph (H) of this Rule, the Regulated Marijuana Business is no longer authorized a Reduced Testing Allowance.



3. Visual Microbial Growth - Regulated Marijuana. If a Regulated Marijuana Cultivation Facility is aware that a Harvest Batch contains visual microbial contamination, the Regulated Marijuana Cultivation Facility shall subject the Harvest Batch to microbial contaminant testing pursuant to Rule 4-215(E). If the Test Batch fails testing, then the Harvest Batch shall be subject to the requirements in Rule 4-240(C). The Licensees must also follow subparagraph (K)(2) of this Rule.
- I. Regulated Marijuana Ongoing Contaminant Testing – Wet Whole Plant. After successfully achieving a Reduced Testing Allowance, once every 30 days a Regulated Marijuana Cultivation Facility shall subject at least one Harvest Batch of wet whole plant to microbial contaminant testing. If during any 30-day period a Regulated Marijuana Cultivation Facility does not possess a Harvest Batch of wet whole plant that is ready for testing, the Regulated Marijuana Cultivation Facility must subject its first Harvest Batch of wet whole plant that is ready for testing to microbial contaminant testing prior to Transfer or processing of the Regulated Marijuana wet whole plant. If a Harvest Batch of wet whole plant subject to ongoing contaminant testing fails contaminant testing, the Regulated Marijuana Cultivation Facility shall follow the procedure in subparagraph (K)(2) of this Rule. Ongoing contaminant testing pursuant to this Rule shall be subject to the requirements in Rule 4-225. See Rule 4-225(A) – Collection of Test Batches.
    1. The Division may reduce the frequency of ongoing contaminant testing required if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.
    2. If the Licensee fails to comply with Paragraph (H) of this Rule, the Regulated Marijuana Cultivation Facility is no longer authorized a Reduced Testing Allowance.
  - J. Regulated Marijuana Product Ongoing Potency and Homogeneity Testing. After successfully achieving a Reduced Testing Allowance, once per quarter a Regulated Marijuana Products Manufacturer shall subject at least one Production Batch of each type of Medical Marijuana Product or Retail Marijuana Product that it produces to potency and homogeneity testing required by subparagraph (D) of this Rule. If during any quarter the Regulated Marijuana Products Manufacturer does not possess a Production Batch that is ready for testing, the Licensee must subject its first Production Batch that is ready for testing to the required potency and homogeneity testing prior to Transfer or processing of the Regulated Marijuana. If a Test Batch submitted for ongoing potency and homogeneity testing fails potency and homogeneity testing, the Licensee shall follow the procedure in subparagraph (K) of this Rule. Ongoing potency and homogeneity testing pursuant to this Rule 4-210 shall be subject to the requirements in Rule 4-225. See Rule 4-225(A) – Collection of Test Batches.
    1. The Division may reduce the frequency of ongoing potency and homogeneity testing required if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached

maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing potency and homogeneity testing to the Licensee's last electronic mailing address provided to the Division.

2. If the Licensee fails to comply with subparagraph (J) of this Rule, the Regulated Marijuana Cultivation Facility is no longer authorized for a Reduced Testing Allowance.

K. Events Requiring Reauthorization for a Reduced Testing Allowance. A Regulated Marijuana Cultivation Facility must follow subparagraph (L) of this Rule for any events that would require a reauthorization for a Reduced Testing Allowance. That may include a failed test or a Material Change described in subparagraph (K)(1) of this Rule. The Licensee must act in accordance with Rule 4-230(K)(2) if either scenario occurs.

1. Material Change. If a Licensee makes a Material Change to its cultivation or production process or its Standard Operating Procedures, then it shall follow Reduced Testing Allowance Reauthorization Procedures in Rule 4-230(L).
  - a. New Equipment. It is a Material Change if the Regulated Marijuana Products Manufacturer begins using new or different equipment for any material part of the production process.
  - b. Pesticide or other Agricultural Substances. It is a Material Change if a Regulated Marijuana Cultivation Facility begins using a new or different Pesticide or other agricultural substances (e.g. nutrients, fertilizers) during its cultivation process.
  - c. Solvents. It is a Material Change if a Regulated Marijuana Products Manufacturer begins using a new or different solvent or combination of solvents or changes any parameters for equipment related to the solvent purging process, including but not limited to, time, temperature, or pressure.
  - d. Cultivation. It is a Material Change if a Regulated Marijuana Cultivation Facility begins using a new or different method for any material part of the cultivation process, including, but not limited to, changing from one growing medium to another.
  - e. Environmental Conditions. It is a Material Change if a Regulated Marijuana Cultivation Facility changes parameters associated with environmental conditions, including temperature, humidity, or lighting.
  - f. Cleaning and Sanitation. It is a Material Change if a Regulated Marijuana Cultivation Facility makes changes to cleaning or sanitation processes.
  - g. Inputs and Contact Surfaces. It is a Material Change if a Regulated Marijuana Products Manufacturer changes materials that have direct contact with product components, including but not limited to, ingredients, additives, or hardware such as a Vaporizer Delivery Devices.

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- h. Testing Required Prior to Transfer or Processing. When a Harvest Batch or Production Batch is required to be submitted for testing pursuant to this Rule, the Licensee that produced it may not Transfer or process Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product unless the Harvest Batch or Production Batch passes all required testing.
2. Failed Required Testing and Reduced Testing Allowance. Failed required testing may constitute a violation of these rules.
- a. If a Test Batch is required to be tested by these Rules or required to be tested by the Division pursuant to Rule 4-215(A) and fails contaminant testing, the Licensee shall follow the procedures in Rule 4-240 for any Inventory Tracking System package, Harvest Batch, or Production Batch from which the failed Test Batch was taken.
- b. The Licensee will not be considered qualified for a Reduced Testing Allowance for the required test type(s) that failed required testing. To qualify for the Reduced Testing Allowance again, the Licensee shall follow subparagraph (L) of this Rule.
3. Failed Internal Audit or a Failed Division Inspection for Compliance with Rule 4-230(M)(1).
- a. If a Regulated Marijuana Cultivation Facility fails an internal audit or a Division inspection evaluating compliance with the requirements referenced in subparagraph (M)(1) of this Rule, then the Licensee must:
- i. Correct the identified deficiencies. These activities to correct such deficiencies must follow Corrective Action Preventive Action procedures listed in Rules 5-210(D) and 6-210(D).
- ii. Complete a new internal audit to the Rules listed in subparagraph (M)(1) of this Rule and scored according to Rule 4-230(M)(2)(a) - (d).
- iii. Complete a new attestation of substantial compliance to the Rules referenced in subparagraph (M)(3) of this Rule, signed by an authorized representative of the Regulated Marijuana Cultivation Facility.
- iv. Follow re-authorization procedures listed in subparagraph (N) of this Rule after subparagraphs (K)(3)(a)(i) – (iii) of this Rule have been addressed.
- b. In addition, regardless of completion of the steps above, the Regulated Marijuana Cultivation Facility may be required to submit additional Test Batches pursuant to Rule 4-205 to address concerns from the failed internal audit or Division inspection.
- L. Reauthorization of a Reduced Testing Allowance.

1. Material Change. If a Licensee is required by these Rules to reauthorize a Reduced Testing Allowance for a Material Change pursuant to Rule 4-230(K)(1), the Licensee shall submit Test Batches pursuant to Rule 4-225(B) from the next five (5) Harvest Batches or Production Batches of the same product type for all required testing.
  2. Failed Required Testing. If a Licensee is required by these Rules to reauthorize a Reduced Testing Allowance for a failed test pursuant to Rule 4-230(K)(2) the Licensee shall submit Test Batches pursuant to Rule 4-225(B) for the test type that failed from the next five (5) Harvest Batches or Production Batches of the same product type.
  3. Failed Internal Audit or a Failed Division Inspection for Compliance. If a Licensee is required by these Rules to reauthorize a Reduced Testing Allowance pursuant to Rule 4-230(K)(3), the Licensee shall submit Test Batches pursuant to Rule 4-225(B) for microbial contaminant testing from the next five (5) Harvest Batches it produces.
  4. If all five (5) of the Test Batches pass required testing pursuant to Rule 4-230(L)(1) – (3), the Licensee will have reauthorized the Reduced Testing Allowance for the required test. The reauthorization tests will satisfy ongoing testing requirements for the Reduced Testing Allowance during the 30-day period that reauthorization testes were submitted.
  5. If any of the five (5) submitted Test Batches fails testing pursuant to Rule 4-230(L)(1) – (3), the Licensee will no longer have a Reduced Testing Allowance for the required test type(s), and the Licensee must follow the procedures in this Rule 4-230(A).
- M. Special Cases Pertaining to Reduced Testing Allowance. The following are specific additional considerations for Reduced Testing Allowance requirements.
1. A Regulated Marijuana Cultivation Facility may achieve a Reduced Testing Allowance for microbial contaminant testing pursuant to this Rule 4-230 if the Licensee has a Hazard Analysis and Critical Control Point (HACCP) System containing elements defined in ASTM D8250-19: “Standard Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products” that addresses each product type to receive Reduced Testing Allowance for microbial contaminant testing. The materials incorporated by reference shall be those effective as of January 8, 2024. This Rule does not include any later amendments or editions to this ASTM Standard. The Division maintains a copy of ASTM D8250-19 at 1697 Cole Boulevard, Suite 200, Lakewood, Colorado, 80401, which is available to the public for inspection during the Division’s regular business hours. The pre-requisite programs requirements by the standard will be considered to have been met if the Regulated Marijuana Cultivation Facility includes documentation on how the sanitary and health requirements from Rules 3-310 and 3-330 are implemented to ensure the hygienic and safe processing of consumable marijuana. This HACCP System must address biological hazards at a minimum, and may also address additional hazards such as chemical hazards and physical hazards.

- a. If a Critical Control Point (CCP) is found to be outside of the Critical Limits (CLs) established in the HACCP plan during the production of a Harvest Batch(es) then the Harvest Batch(es) shall be submitted for microbial contaminant testing. For purposes of this Rule, Critical Control Point (CCP) means a step in the processing of Regulated Marijuana at which control can be applied and is essential to prevent or eliminate a safety hazard or reduce it to an acceptable level and shall have the same meaning as defined and used in ASTM Standard D8250-19, which the Division has maintained a copy and is available to the public for inspection.
  - i. If the Harvest Batch passes microbial contaminant testing, then there is no effect on the Reduced Testing Allowance and the Harvest Batch may be Transferred.
  - ii. If the Harvest Batch fails microbial contaminant testing, then the Licensee shall follow subparagraph (K)(2) of this Rule to reauthorize the Reduced Testing Allowance for microbial contaminants.
- b. The HACCP System shall be documented as per ASTM D8250-19.6.1.12. The following records must be kept during the time that a Regulated Marijuana Cultivation Facility qualifies for and maintains a Reduced Testing Allowance for microbial contaminants and for one year after the Reduced Testing Allowance expires for any reason:
  - i. List of the HACCP team, including relevant experience;
  - ii. Product description and intended use for each product type receiving a Reduced Testing Allowance for microbial contaminants;
  - iii. Verified Process Flow Diagram, including Critical Control Points (CCPs);
  - iv. Hazard Analysis;
  - v. List of CCPs and reasoning as to how they were identified;
  - vi. List of Critical Limits (CLs) and reasoning as to how they were selected;
  - vii. List of Monitoring Procedures for CCPs;
  - viii. List of pre-planned Corrective Actions in case of deviations;
  - ix. List of verification procedures;
  - x. HACCP system summary page that includes:
    - A. CCPs;
    - B. Critical Limits (CLs);

- C. Monitoring Procedures;
    - D. Corrective Actions related to specific CCPs;
    - E. Verification procedures; and
    - F. Record Titles associated with the CCP activities (i.e. The Water Activity Monitoring Logbook, etc.);
  - xi. Support documentation of the CCP validation (i.e. microbial contaminants testing results for Reduced Testing Allowance qualification and maintenance periods); and
  - xii. Documents generated during operational activities related to the HACCP system, including at minimum: Verified Monitoring Logs for CCPs, Corrective and Preventive Actions documentation related to CCPs, and Material Changes related to HACCP system.
- 2. To achieve a Reduced Testing Allowance for microbial contaminants, a Regulated Marijuana Cultivation Facility must conduct an internal audit to assess that they are in substantial compliance with the requirements of Rules 3-310, 3-330, 3-336, 4-225, 4-230, 5-210(D), 5-210(E), 6-210(D), and 6-210(E) by achieving a passing score. This internal audit will be performed and scored per the rubric listed in Rule 4-230(M)(2)(a-d). A copy of this internal audit shall be retained as business records for one year. Internal Audit Scoring Rubric. The internal audit will be scored as follows:
  - a. Scoring System: 0% - 100%
  - b. Passing Score: 80% - 100%
  - c. Non-Conformance Finding Deductions:
    - i. Minor: -1%
    - ii. Major: -5%
    - iii. Critical: -100%
  - d. Definition of Non-Conformances:
    - i. Minor: A deficiency in the compliance to Rule that reasonably could lead to a risk in product safety.
    - ii. Major: A deficiency in compliance to Rule that carries a highly likely-to-definite risk to product safety.
    - iii. Critical: A clear deficiency in compliance to Rule that could lead to serious injury or death; or if any falsification of records is found.
- 3. Attestation of Substantial Compliance with Rules. To achieve a Reduced Testing Allowance for Microbial Contaminants, an authorized representative of the Regulated Marijuana Cultivation Facility must sign an attestation that they are, to the best of their knowledge, in substantial compliance with Rules 3-310, 3-330, 3-

336, 4-230, 5-210, and 6-210 by achieving a passing score. A copy of this attestation shall be retained as business records for one year.

N. Regulated Marijuana Concentrate Produced from Wet Whole Plant Not Tested for Microbial Contamination. A Regulated Marijuana Business that produces Regulated Marijuana Concentrate may achieve a Reduced Testing Allowance for a Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contamination, subject to the following requirements:

1. Qualification Form. The Regulated Marijuana Business that produces Regulated Marijuana Concentrate from wet whole plant not tested for microbial contamination shall obtain a completed qualification form from the Regulated Marijuana Business that cultivated the wet whole plant. The qualification form must detail the following information related to the cultivation of the wet whole plant:
  - a. Implemented quality management systems;
  - b. Record keeping;
  - c. Notification of Material Change;
  - d. Notification of a wet whole plant microbial Test Batch failure;
  - e. Cultivation and post-harvest procedures;
  - f. Cleaning; and
  - g. Corrective action and preventative action.
2. Completion Required. The Regulated Marijuana Business that wishes to Transfer the wet whole plant that was not tested for microbial contamination must provide a completed qualification form detailing the information listed above.
3. Approval. The Regulated Marijuana Business that receives a Transfer of wet whole plant is responsible for ensuring it conforms with specified approval requirements, which shall include, but is not limited to the following:
  - a. The receiving Regulated Marijuana Business has confirmed it has not received notification by the Regulated Marijuana Cultivation Facility of a Material Change to its cultivation process;
  - b. The receiving Regulated Marijuana Business has inspected the wet whole plant Harvest Batch for visual microbial contamination. If visual microbial contamination is identified in the Harvest Batch of wet whole plant, the Licensee shall subject the Harvest Batch to microbial contaminant testing pursuant to Rule 4-215. If the Test Batch fails testing, then the Harvest Batch shall be subject to the requirements in Rule 4-240(C); and
  - c. The receiving Regulated Marijuana Business has obtained evidence of compliance with testing requirements for the wet whole plant and proof of any Reduced Testing Allowances, if applicable.



4. Origin Verification. Verification of the Regulated Marijuana Business that cultivated the wet whole plant used to manufacture the Regulated Marijuana Concentrate.
- O. Recordkeeping Requirements. A Regulated Marijuana Business shall maintain copies of documents and other records evidencing compliance with this Rule as part of its business books and records. See Rule 3-905 – Business Records Required.

#### **Basis and Purpose – 4-235**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the potency testing and related Reduced Testing Allowance portion of the Division's Regulated Marijuana sampling and testing program. This Rule 4-235 was previously Rules 4-120, 4-121, 4-125, and 4-135, 1 CCR 212-3, Rules M and R 1503, 1 CCR 212-1 and 1 CCR 212-2.

#### **4-235– Regulated Marijuana Testing Program: Potency Test Fail Procedures**

- A. Failed Potency Testing. If a Regulated Marijuana Business is notified by the Division or a Regulated Marijuana Testing Facility that a Test Batch of Regulated Marijuana Product failed potency testing, then for each Inventory Tracking System package or Production Batch associated with that failed Test Batch the Regulated Marijuana Business must either:
1. Destroy and document the destruction of the Inventory Tracking System package or Production Batch pursuant to Rule 3-230 – Waste Disposal; or
  2. Attempt corrective measures, if possible, and create two new Test Batches each containing the requisite number of Sample Increments, and have those Test Batches tested for the required potency test that failed. Such testing must comport with the sampling procedures under Rule 4-225.
    - a. A Licensee must either (1) submit both new Test Batches to the same Regulated Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Regulated Marijuana Testing Facilities.
    - b. If both new Test Batches pass potency testing, then the Inventory Tracking System package or Production Batch associated with each Test Batch may be Transferred.
    - c. If one or both of the Test Batches do not pass potency testing, then the Regulated Marijuana Products Manufacturer must destroy and document the destruction of Inventory Tracking System package or Production Batch pursuant to Rule 3-230 – Waste Disposal.
- B. Failed Potency Testing and Reduced Testing Allowance. Failed potency testing may constitute a violation of these Rules.



1. If a Test Batch is required to be tested by these Rules or required to be tested by the Division pursuant to Rule 4-205(E) and fails potency testing, the Regulated Marijuana Products Manufacturer shall follow the procedures in subparagraph (B) of this Rule for any Inventory Tracking System package or Production Batch associated with the failed Test Batch.
2. If the Regulated Marijuana Products Manufacturer has achieved a Reduced Testing Allowance, they shall also submit Test Batches from three new Production Batches of the Regulated Marijuana Product for potency testing by a Regulated Marijuana Testing Facility within no more than 30 days from the Production Batch date. If any one of the three submitted Test Batches fails potency testing, the Regulated Marijuana Products Manufacturer shall achieve a new Reduced Testing Allowance.

### **Basis and Purpose – 4-240**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing rules governing the quarantining of potentially contaminated product and the destruction of product that failed contaminant or potency testing for Division's Regulated Marijuana Sampling and Testing Program. This Rule 4-240 was previously Rules 4-115, 4-125, and 4-135, 1 CCR 212-3, Rules M and R 1507, 1 CCR 212-1 and 1 CCR 212-2.

### **4-240 – Regulated Marijuana Testing Program: Contaminated Product and Failed Test Results and Procedures**

#### **A. Quarantining of Product.**

1. If the Division has reasonable grounds to believe that a particular Harvest Batch, Production Batch, or Inventory Tracking System package of Regulated Marijuana is contaminated or presents a risk to public safety, then the Division may require a Regulated Marijuana Business to quarantine it until the completion of the Division's investigation, which may include, but is not limited to, the receipt of any test results.
2. If a Regulated Marijuana Business is notified by any local or state agency, or by a Regulated Marijuana Testing Facility that a Test Batch failed a contaminant or potency testing, then the Regulated Marijuana Business shall quarantine any Regulated Marijuana from any Inventory Tracking System package, Harvest Batch or Production Batch associated with that failed Test Batch and must follow the procedures established pursuant to this Rule.
3. Except as provided by this Rule, Regulated Marijuana that has been quarantined pursuant to this Rule must be physically separated from all other inventory and the Licensee may not Transfer or further process the Regulated Marijuana.

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4. In addition to any other method authorized by law, the Division may implement the quarantine through the Inventory Tracking System by (a) indicating failed test results and (b) limiting the Licensee's ability to Transfer the quarantined Regulated Marijuana unless otherwise permitted by these rules
- B. Failed Pesticide Contaminant Testing and Failed Elemental Impurities Testing of Regulated Marijuana Flower, Wet Whole Plant, or Trim. If a Regulated Marijuana Business is notified by the Division or a Regulated Marijuana Testing Facility that a Test Batch failed Pesticide testing of any product type or elemental impurities testing of Regulated Marijuana flower, wet whole plant, or trim, then for each Inventory Tracking System package, Harvest Batch, or Production Batch associated with that failed Test Batch the Regulated Marijuana Business may request that the Regulated Marijuana Testing Facility that reported the original fail conduct two additional analyses of the original Test Batch submitted in accordance with Rule 4-225.
1. If both retesting analyses pass the required Pesticide testing, then the Inventory Tracking System package, Harvest Batch, or Production Batch of Regulated Marijuana, Regulated Marijuana Concentrate, Regulated Marijuana Product, Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.
2. If one or both of the retesting analyses do not pass testing, then the Regulated Marijuana Business must destroy and document the destruction of the Inventory Tracking System package, Harvest Batch, or Production Batch pursuant to Rule 3-230 – Waste Disposal.
- a. Solely for in the case of elemental impurities, if one or both of the retesting analyses do not pass testing, then the Licensee may remediate the batch following the rules in subparagraph (C)(3) outlined below.
- C. Failed Contaminant Testing. If a Regulated Marijuana Business is notified by the Division or a Regulated Marijuana Testing Facility that a Test Batch failed contaminant testing, then for each Inventory Tracking System package, Harvest Batch, or Production Batch associated with that failed Test Batch the Regulated Marijuana Business must destroy, Decontaminate or Remediate the Batch, as described by this Rule 4-240:
1. Destroy. Destroy and document the destruction of the Inventory Tracking System package, Harvest Batch or Production Batch pursuant to Rule 3-230 – Waste Disposal;
2. Decontamination. In some special circumstances outlined below, batches may be Decontaminated instead of being destroyed. In those circumstances, a Licensee may Decontaminate the batch themselves or may Transfer the Inventory Tracking System package, Harvest Batch, or Production Batch that failed contaminant testing to another Regulated Marijuana Products Manufacturer, Regulated Marijuana Cultivation Facility (except failed Solvent-Based Regulated Marijuana Concentrate, Heat/Pressure-Based Regulated Marijuana Concentrate, and Regulated Marijuana Product) or an Accelerator Manufacturer for Decontamination.

- a. For all types of Decontamination, after Decontamination has been performed on Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product, the Licensee must do the following: Create two new Test Batches, each containing the requisite number of Sample Increments, and have those Test Batches tested for the required contaminant test that failed. Such testing must comport with the sampling procedures under Rule 4-225. A Licensee shall (1) submit both new Test Batches to the same Regulated Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Medical Marijuana Testing Facilities or Retail Marijuana Testing Facilities.
  - i. If both retesting analyses pass the required contaminant testing, then the Inventory Tracking System package or Harvest Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product;
  - ii. If one or both of the retesting analyses do not pass contaminant testing, then the Regulated Marijuana Business must either destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule 3-230 – Waste Disposal, or Remediate the Inventory Tracking System package or Harvest Batch pursuant to Paragraph (3).
- b. Nothing in this Rule eliminates or alters the responsibility of the Regulated Marijuana Business Transferring the Regulated Marijuana that failed contaminant testing from complying with the requirement to pay excise tax pursuant to article 28.8 of Title 39, C.R.S.
- c. The types of contaminants and batches that may be decontaminated are outlined below along with any additional stipulations besides those in subparagraph (C)(2) of this Rule. If a contaminant and batch type are not listed below, then the batch may not be decontaminated.
  - i. Failed Microbial Testing of Physical Separation-Based, Heat/Pressure-Based, Food-Based Retail Marijuana Concentrate, Physical Separation-Based, Heat/Pressure-Based, Food-Based Medical Marijuana Concentrate, Vaporizer Delivery Device, and Regulated Marijuana Product.
  - ii. Failed Microbial Testing of Regulated Marijuana Flower, Wet Whole Plant, Trim, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana.
    - A. If the Inventory Tracking System package, Harvest Batch, or Production Batch has undergone Decontamination, then it must also pass a mycotoxin and water activity test prior to Transfer. The mycotoxin and water activity testing must occur after the final Decontamination attempt, but is not required to occur until after the Inventory Tracking System

package, Harvest Batch, or Production Batch has passed microbial testing. If a Test Batch fails mycotoxin or water activity testing the Regulated Marijuana Business must follow the failed contaminant testing procedures pursuant to subparagraphs (B) and (C) of this Rule. Pursuant to Rule 4-245(B), wet whole plant is exempt from water activity testing.

iii. Failed Water Activity Testing.

A. If the Inventory Tracking System package, Harvest Batch, or Production Batch has undergone Decontamination, then it must also pass a microbial contaminant test prior to Transfer. The microbial contaminant test is not required to occur until after the Inventory Tracking System package, Harvest Batch, or Production Batch has passed water activity testing. If a Test Batch fails microbial contaminant testing, the Regulated Marijuana Business must follow the failed contaminant testing procedures pursuant to subparagraph (C) above.

B. Pursuant to Rule 4-245(B), wet whole plant is exempt from water activity testing.

iv. Failed Residual Solvent Testing of Solvent-Based Regulated Marijuana Concentrate.

d. Third-Party Decontamination Testing Responsibility. If the Regulated Marijuana Business receiving the Regulated Marijuana for Decontamination will Transfer the Regulated Marijuana back to the originating Regulated Marijuana Business following the Decontamination procedures, then the originating Regulated Marijuana Business is responsible for all required testing. If the Regulated Marijuana Business receiving the Regulated Marijuana for Decontamination will Transfer the Regulated Marijuana to a different Regulated Marijuana Business or further processes the Regulated Marijuana following Decontamination, then the receiving Regulated Marijuana Business that performed the Decontamination is responsible for all required testing following the procedures in subparagraph (C)(2) of this Rule.

3. Remediation. In lieu of destroying or Decontaminating the Batch pursuant to Paragraph (C)(2) above, in the specific circumstances outlined below, the Regulated Marijuana Business may Remediate the batch themselves or Transfer all Regulated Marijuana from the Inventory Tracking System packages, Harvest Batches, and Production Batches associated with that failed Test Batch to a Regulated Marijuana Products Manufacturer for Remediation pursuant to the following types of Regulated Marijuana listed in subparagraph (3)(c) of this Rule.

a. For all types of permitted Remediation, after Remediation procedures for the failing contaminant have been completed, the Licensee must do the

following: Create two new Test Batches, each containing the requisite number of Sample Increments, and have those Test Batches tested for the required contaminant test that failed. Such testing must comport with the sampling procedures under Rule 4-225.

- i. If both retesting analyses pass the required contaminant testing, then the Inventory Tracking System package or Harvest Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.
  - ii. If one or both of the retesting analyses do not pass contaminant testing, then the Regulated Marijuana Business must either destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule 3-230 – Waste Disposal.
  - iii. If a batch that has undergone Remediation fails contaminant testing other than the tests performed pursuant to Rule 4-240(C)(3)(a)(i) and (ii), the Regulated Marijuana Business shall destroy and document the destruction of the Inventory Tracking System package(s) or Production Batch(es) of Regulated Marijuana Concentrate pursuant to Rule 3-230 – Waste Disposal or Decontaminate the Inventory Tracking System package(s) pursuant to this Rule 4-240.
- b. Nothing in this Rule eliminates or alters the responsibility of the Retail Marijuana Business Transferring the Retail Marijuana that failed contaminant testing from complying with the requirement to pay excise tax pursuant to article 28.8 of Title 39, C.R.S.
- c. The types of contaminants and batches that may be Remediated are outlined below along with any additional stipulations besides those in subparagraph (C)(3) of this Rule. If a contaminant and batch type are not listed below, then the batch may not be Remediated.
  - i. Failed Microbial Testing of Regulated Marijuana Flower, Wet Whole Plant, Trim, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana. The new Test Batches are required to be re-tested for microbial, mycotoxin, and water activity contaminant testing. Such testing must comport with sampling procedures under Rule 4-225.
  - ii. Failed Microbial Testing of Physical Separation-Based and Heat/Pressure-Based Retail Marijuana Concentrate, Physical Separation-Based and Heat/Pressure-Based Medical Marijuana Concentrate and Vaporizer Delivery Device. The new Test Batches are required to be re-tested for microbial and mycotoxin contaminant testing. Such testing must comport with sampling procedures under Rule 4-225.

- iii. Failed Water Activity Testing of Regulated Marijuana Flower, Wet Whole Plant, Trim, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana. The new Test Batches are required to be re-tested for microbial, mycotoxin, and water activity contaminant testing. Such testing must comport with sampling procedures under Rule 4-225.
- iv. Failed Contaminant Testing: Elemental Impurities Testing of Regulated Marijuana Flower, Wet Whole Plant, Physical Separation-Based and Heat/Pressure-Based Regulated Marijuana Concentrate, and Vaporizer Delivery Device.
  - A. If the failed Test Batch is not deemed hazardous waste per the Resource Conservation and Recovery Act or other applicable federal, state, or local regulations, then the Regulated Marijuana Business may Transfer all Regulated Marijuana from the Inventory Tracking System packages, Harvest Batch, or Production Batch associated with that failed Test Batch to a Regulated Marijuana Products Manufacturer for Remediation.
  - B. The Retail Marijuana Business that Transfers the Retail Marijuana that failed elemental impurities testing must comply with the requirement to pay excise tax pursuant to article 28.8 of Title 39, C.R.S.
  - C. The Regulated Marijuana Products Manufacturer may Remediate the Inventory Tracking System package or Harvest Batch associated with the failed Test Batch by processing it into a Regulated Marijuana Concentrate. The Regulated Marijuana Products Manufacturer is prohibited from adding any other Regulated Marijuana to the Regulated Marijuana Concentrate it manufactures until the Regulated Marijuana Concentrate Production Batch passes all required testing pursuant to this Rule.
  - D. In addition to all applicable regulations, the Regulated Marijuana Products Manufacturer must comply with 3-230(C)(1), 5-315(D)(9), and 6-315(D)(9).
  - E. The Regulated Marijuana Concentrate that was manufactured pursuant to subparagraph (C)(3)(c)(v)(C) of this Rule shall undergo all required contaminant testing pursuant to Rule 4-215 - Regulated Marijuana Testing Program: Contaminant Testing, potency testing pursuant to Rule 4-210 - Regulated Marijuana Testing Program: Potency Testing, and any other testing required or allowed by the Marijuana Code or these Rules, including but not limited to elemental impurities testing. Such testing must comport with the sampling procedures under Rule 4-225.

- F. For elemental impurities testing, the Regulated Marijuana Business must create two new Test Batches from the Remediated Production Batch, each containing the requisite number of Sample Increments, and have those Test Batches tested. Such testing must comport with the sampling procedures under Rule 4-225.
  - G. A Licensee must either (1) submit both new Test Batches to the same Marijuana Testing Facility that reported the original failed test result, or (2) submit the new Test Batches to two different Marijuana Testing Facilities.
  - H. If both Test Batches pass the required elemental impurities testing, then the Inventory Tracking System package or Harvest Batch associated with each Test Batch may be Transferred or processed into a Regulated Marijuana Concentrate or Regulated Marijuana Product.
  - I. If one or both of the Test Batches do not pass elemental impurities testing, then the Regulated Marijuana Business must destroy and document the destruction of the Inventory Tracking System package or Harvest Batch pursuant to Rule 3-230 - Waste Disposal.
  - J. All Production Batches undergoing Remediation for elemental impurities must be tested and are not eligible for a Reduced Testing Allowance or otherwise exempt from required testing.
- d. Third-Party Remediation Testing Responsibility. If the Regulated Marijuana Business receiving the Regulated Marijuana for Remediation will Transfer the Regulated Marijuana back to the originating Regulated Marijuana Business following the Remediation procedures, then the originating Regulated Marijuana Business is responsible for all required testing. If the Regulated Marijuana Business receiving the Regulated Marijuana for Remediation will Transfer the Regulated Marijuana to a different Regulated Marijuana Business or further processes the Regulated Marijuana following Remediation, then the receiving Regulated Marijuana Business that performed the Remediation is responsible for all required testing following the procedures in subparagraph (C)(3) of this Rule.

#### **Basis and Purpose – 4-245**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing



rules governing the quarantining of potentially contaminated product and the destruction of product that failed contaminant or potency testing for Division's Regulated Marijuana Sampling and Testing Program. This Rule 4-245 was previously Rule 4-115, 4-125, and 4-135, 1 CCR 212-3, Rules M and R 1507, 1 CCR 212-1 and 1 CCR 212-2.

#### **4-245 – Regulated Marijuana Testing Program: Exemptions**

##### **A. Exemptions.**

##### **1. Medical Marijuana Concentrate.**

- a. A Medical Marijuana Products Manufacturer who combines multiple Production Batches of Solvent-Based Medical Marijuana Concentrate into a Production Batch of Solvent-Based Medical Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule only if all original Production Batches passed residual solvent testing. This does not apply if a solvent, Additive, or any other Ingredient was introduced during the combination of the Production Batches.**
- b. A Production Batch of Medical Marijuana Concentrate shall be considered exempt from contaminant testing requirements pursuant to this Rule if the Medical Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Medical Marijuana Product, except that a Solvent-Based Medical Marijuana Concentrate must still be submitted for residual solvent contaminant testing and Medical Marijuana Concentrate must still be submitted for pesticide contaminant testing. The manufactured Medical Marijuana Product shall be subject to mandatory testing under this Rule.**

##### **2. Retail Marijuana Concentrate.**

- a. A Retail Marijuana Products Manufacturer or Accelerator Manufacturer who combines multiple Production Batches of Solvent-Based Retail Marijuana Concentrate into a Production Batch of Solvent-Based Retail Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule only if all original Production Batches passed residual solvent testing. This does not apply if a solvent, Additive or any other Ingredient was introduced during the combination of the Production Batches.**
- b. A Production Batch of Retail Marijuana Concentrate shall be considered exempt from contaminant testing requirements pursuant to this Rule if the Retail Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Retail Marijuana Product, except that a Solvent-Based Retail Marijuana Concentrate must still be submitted for residual solvent contaminant testing and Retail Marijuana Concentrate must still be submitted for pesticide contaminant testing. The**



manufactured Retail Marijuana Product shall be subject to testing under this Rule.

3. Regulated Marijuana Product. A Regulated Marijuana Business that produces Regulated Marijuana Products with intended use for oral consumption or skin and body products, is exempt from aspergillus testing as required by these 4-200 Series Rules.

B. Testing Exemptions for Wet Whole Plant.

1. Harvest Batches of Regulated Marijuana wet whole plant are exempt from required water activity testing.
2. Harvest Batches of Regulated Marijuana wet whole plant are exempt from required microbial contaminant testing if a Regulated Marijuana Cultivation Facility Transfers the Regulated Marijuana wet whole plant for the purposes of extraction to a Regulated Marijuana Business with at least one identical Controlling Beneficial Owner and in accordance with this Rule. If a Regulated Marijuana wet whole plant Harvest Batch is not tested for microbial contamination, each resulting Regulated Marijuana Concentrate Production Batch shall be tested for microbial contamination pursuant to Rule 4-215.

- C. Pre-Rolled Marijuana Potency Exemption. A Regulated Marijuana Business shall be considered exempt from potency testing if the Pre-Rolled Marijuana Production Batch uses a single strain and uses all parts of the Harvest Batch that were included in the potency testing of the Harvest Batch prior to creating the Pre-Rolled Marijuana Production Batches. In this case, the potency test results of the Harvest Batch shall be used for the Pre-Rolled Marijuana Production Batch.

- D. Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana Homogeneity Exemption. Production Batches of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana are exempt from homogeneity testing.

- E. Potency Testing Exemption for Marijuana Allocated for Extraction. Any Regulated Marijuana that will be allocated for extraction in the Inventory Tracking System shall be considered exempt from potency testing pursuant to this Rule.

## **Part 5 – Medical Marijuana Business License Types**

### **5-100 Series – Medical Marijuana Stores**

#### **Basis and Purpose – 5-105**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(d)(I)-(VI), 44-10-313(7), 44-10-313(4), 44-10-313(14), 44-10-401(2)(a)(I), 44-10-501, and 44-10-505, C.R.S. The purpose of this rule is to establish a Medical Marijuana Store's license privileges. This Rule 5-105 was previously Rule M 401, 1 CCR 212-1.

#### **5-105 – Medical Marijuana Store: License Privileges**

- A. Licensed Premises. To the extent authorized by Rule 3-215 – Medical Marijuana Business and Retail Marijuana Business – Shared Licensed Premises and Operational

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Separation, a Medical Marijuana Store may share a Licensed Premises with a commonly-owned Retail Marijuana Store. However, a separate license is required for each specific business or business entity, regardless of geographical location.

- B. Authorized Sources of Medical Marijuana. A Medical Marijuana Store may only Transfer Medical Marijuana that was obtained from a Medical Marijuana Business.
- C. Authorized Transfers. A Medical Marijuana Store may only Transfer Medical Marijuana to a patient, a primary caregiver, another Medical Marijuana Store, a Medical Marijuana Cultivation Facility, a Medical Marijuana Products Manufacturer, or a Medical Marijuana Testing Facility.
- D. Test Batches Provided for Testing. A Medical Marijuana Store may provide Test Batches of its products to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Store shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- E. Authorized On-Premises Storage. A Medical Marijuana Store is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules.
- F. Authorized Marijuana Transport. A Medical Marijuana Store is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana so long as the place where transportation orders are taken and delivered is a licensed Medical Marijuana Business. Nothing in this Rule prevents a Medical Marijuana Store from transporting its own Medical Marijuana.
- G. Performance-Based Incentives. A Medical Marijuana Store may compensate its employees using performance-based incentives, including sales-based performance-based incentives.
- H. Authorized Transfers of Hemp Products. A Medical Marijuana Store may Transfer Hemp Product to a patient only after it has verified:
  - 1. That the Hemp Product has passed all required testing pursuant to the ~~4-2004-100~~ Series Rules at a Medical Marijuana Testing Facility; and
  - 2. That the Person Transferring the Hemp Product to the Medical Marijuana Store is registered with the Colorado Department of Public Health and Environment as a Hemp Product Manufacturer pursuant to section 25-5-427~~6~~, C.R.S.
- I. Medical Marijuana Store Delivery Permit. A Medical Marijuana Store with a valid delivery permit may accept delivery orders and deliver Medical Marijuana to a patient who is 21 years of age or older, or the patient's parent or guardian who is also the patient's primary caregiver pursuant to Rule 3-615. A Medical Marijuana Store that does not possess a valid delivery permit cannot deliver Medical Marijuana to a patient, parent, or guardian.
- J. Automated Dispensing Machines. A Medical Marijuana Store may use an automated machine in the Restricted Access Area of its Licensed Premises to dispense Regulated Marijuana to patients without interaction with an Owner Licensee or Employee Licensee

if the automated machine is reasonably monitored and complies with all requirements of these rules including but not limited to:

1. Health and safety standards,
2. Testing,
3. Packaging and labeling requirements,
4. Inventory tracking,
5. Identification requirements, and
6. Transfer limits to patients.

K. Walk-up or Drive-Up Window. A Medical Marijuana Store may serve patients through a walk-up window or drive-up window pursuant to the requirements of this Rule.

1. ~~Repealed. Modification of Premises Required. Before accepting orders for sales of Medical Marijuana to a patient through either a walk-up window or a drive-up window, a Medical Marijuana Store shall apply for, and obtain approval of, an application for a modification of its Licensed Premises for the addition of a walk-up window or a drive-up window.~~
2. The area immediately outside the walk-up window or drive-up window must be under the Licensee's possession and control and cannot include any public property such as public streets, public sidewalks, or public parking lots.
3. Order and Identification Requirements.
  - a. Prior to accepting an order or Transferring Medical Marijuana to a patient, the Employee Licensee or Owner Licensee must physically view and inspect the patient's identification and the patient's registry identification card.
  - b. The Medical Marijuana Store may accept internet or telephone orders or may accept orders from the patient at the walk-up or drive-up window.
  - c. All orders received through a walk-up window or drive-up window must be placed by the patient from a menu. The Medical Marijuana Store may not display Medical Marijuana at the walk-up window or drive-up window.
4. Payment Requirements. Cash, credit, debit, cashless ATM, or other payment methods are permitted for payment for Medical Marijuana at the walk-up window or drive-up window.
5. Video Surveillance Requirements. For every Transfer of Regulated Marijuana through either a walk-up window or drive-up window, the Medical Marijuana Store's video surveillance must enable the recording of the patient's identity (and patient's vehicle in the event of drive-up window), and must enable the recording of the Licensee verifying the patient's identification, registry identification card, and completion of the transaction through the Transfer of Regulated Marijuana.

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6. Packaging and Labeling Requirements. A Medical Marijuana Store utilizing a walk-up or drive-up window must ensure that all Medical Marijuana is packaged and labeled in accordance with Rules 3-1010 and Rule 3-1015 prior to Transfer to the patient.
7. Local Restrictions. Transfers of Regulated Marijuana using a walk-up window or drive-up window are subject to requirements and restrictions imposed by the relevant Local Licensing Authority.
- L. Sales over the Internet. A Medical Marijuana Store may accept orders and payment for Medical Marijuana over the internet.
  1. Online Order Requirements.
    - a. Online orders must include the patient's or primary caregiver's name and date of birth.
    - b. Prior to accepting the order, the store must provide and the customer must acknowledge receipt of:
      - i. A digital copy of the pregnancy warning required in Rule 5-120; and
      - ii. If accepting an order for Medical Marijuana Concentrate, the Medical Marijuana Store must also provide the educational resource required in Rule 5-115(C.5).
    - c. Licensees must maintain Standard Operating Procedures documenting their compliance with the requirements of this subparagraph (L).
  2. Transfer of Medical Marijuana to the Patient.
    - a. The patient or primary caregiver must be physically present on the Licensed Premises to take possession of Medical Marijuana.
    - b. The Medical Marijuana Store must verify the patient's or primary caregiver's physical identification matches the name and date of birth the patient or primary caregiver provided at the time of the order.
  3. Delivery. A Medical Marijuana Store that holds a valid delivery permit may make sales of Medical Marijuana over the internet in accordance with Rule 3-615.
  4. Approved Sources of Payment. Medical Marijuana Stores may accept payment using any legal method of payment, gift card pre-payments, or pre-payment accounts established with a Medical Marijuana Store except that any payment with an Electronic Benefits Transfer Services Card is not permitted.
    - a. A Local Licensing Authority or Local Jurisdiction may further restrict legal methods of payment not expressly permitted by section 44-10-203(2)(dd)(XV), C.R.S.

**Basis and Purpose—5-110**

~~The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-313(7), 44-10-313(4), 44-10-401(2)(a)(I), and 44-10-501, C.R.S. The purpose of this rule is to establish the requirements and processes applicable to a Medical Marijuana Store registering patients for primary store purposes. This Rule 5-110 was previously Rule M 402, 1 CCR 212-1.~~

### **5-110 – Registration of a Primary Medical Marijuana Store – Repealed.**

- ~~A. — Patient Designation Required. A Medical Marijuana Store may possess in the aggregate, only the amount of Medical Marijuana permitted by Rule 5-115 for each patient who has designated the Medical Marijuana Store as being his or her primary store. A patient's designation of a Medical Marijuana Store as his or her primary Medical Marijuana Store in accordance with these Rules establishes the Medical Marijuana Store registration requirements set forth in section 25-1.5-106(8)(f), C.R.S.~~
- ~~B. — Change Only Allowed Every 30 Days. A Medical Marijuana Store shall not register a patient as being the patient's primary store if the patient has designated another Medical Marijuana Store as his or her primary store in the preceding 30 days. The Medical Marijuana Store and its employees must require a patient to sign in writing that he or she has not designated another Medical Marijuana Store as his or her primary store before including that patient's Medical Marijuana in its maximum allowed on-hand Medical Marijuana inventory calculation under Rule 5-115.~~
- ~~C. — Notification to Former Medical Marijuana Store. A Medical Marijuana Store must maintain a copy of a written or electronic notification that it provided to a patient's former primary Medical Marijuana Store advising that the Medical Marijuana Store has been designated as the patient's new primary Medical Marijuana Store.~~
- ~~D. — Documents Required. In addition to all records required to be maintained by Rule 3-905 — Business Records Required, the new primary Medical Marijuana Store shall maintain:~~
- ~~1. — Written authorization from the patient;~~
  - ~~2. — A hard or electronic copy of the patient's registry card;~~
  - ~~3. — A copy of the patient's proof of identification; and.~~
  - ~~4. — The physician certification and, if authorized for sales exceeding the statutory daily limits the patient's uniform certification form.~~
- ~~E. — Violation Affecting Public Safety. Notwithstanding the provisions in Rule 5-110(B), it may be considered a violation affecting public safety for a Medical Marijuana Store and its employees to become a patient's primary store when the patient already had designated one or more other Medical Marijuana Stores as his or her primary store.~~

### **Basis and Purpose – 5-115**

The statutory authority for this includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-313(7), 44-10-313(4), 44-10-401(2)(a)(I), 44-10-501, and 44-10-505, 44-10-501(10) C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 14(4). The purpose of this rule is to clarify those acts that are prohibited, or limited in some fashion, by a licensed Medical Marijuana Store.

The sales limitations provision reflects the sales limitation imposed by statute. Clarifying the limitations on sales provides Medical Marijuana Stores and their employees with necessary information to avoid being complicit in a patient acquiring more Medical Marijuana than is lawful under the Colorado Constitution pursuant to Article XVIII, Subsection 14(4).

This Rule 5-115 was previously Rule M 403, 1 CCR 212-1.

### **5-115 – Medical Marijuana Sales: General Limitations or Prohibited Acts**

- A. Possession Limits. A Medical Marijuana Store may only possess at its Licensed Premises the number of ounces of Medical Marijuana (excluding Medical Marijuana Products and Medical Marijuana Concentrate) that equals the greater of: 1) twice the total, aggregate ounces of Medical Marijuana all of its registered patients are allowed to possess, or 2) the total, aggregate ounces of Medical Marijuana that the Medical Marijuana Store Transferred to patients in the thirty (30) previous calendar days. Under no circumstance shall a Medical Marijuana Store possess more Medical Marijuana than permitted by this subparagraph.
- B. Medical Marijuana Products Manufacturers. A Medical Marijuana Store may also contract for the manufacture of Medical Marijuana Product with Medical Marijuana Products Manufacturer Licensees utilizing a contract as provided for in Rule 5-310 – Medical Marijuana Products Manufacturer: General Limitations or Prohibited Acts (Infused Product Contracts). Medical Marijuana distributed to a Medical Marijuana Products Manufacturer by a Medical Marijuana Store pursuant to such a contract for use solely in Medical Marijuana Product(s) that are returned to the contracting Medical Marijuana Store shall not be included for purposes of determining compliance with paragraph A.
- B.5 Standard Operating Procedures. A Medical Marijuana Store must establish written Standard Operating Procedures for the management and storage of Medical Marijuana inventory and the sale of Medical Marijuana to patients. A written copy of the Standard Operating Procedures must be maintained on the Licensed Premises.
1. A Medical Marijuana Store must provide adequate training to every Owner Licensee and Employee Licensee who performs a task or set of tasks that are referenced in the Standard Operating Procedures. Adequate training must include, but need not be limited to, providing a copy of the Standard Operating Procedures for that Licensed Premises detailing at least all of the topics required to be included in the Standard Operating Procedures.
- C. Patient Sales Requirements. A Medical Marijuana Store shall comply with the sales and Inventory Tracking requirements in Rule 5-125.
- C.5. Educational Resource. When completing a sale of Medical Marijuana Concentrate, a Medical Marijuana Store shall physically attach to the patient's receipt of sale, product container, or exit packaging~~provide the patient with~~ the tangible educational resource created by the State Licensing Authority regarding the use of Regulated Marijuana Concentrate.
- D. Repealed.

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- E. Transfer Restriction.
1. Sampling Units. A Medical Marijuana Store may not possess or Transfer Sampling Units.
  2. Research Transfers Prohibited. A Medical Marijuana Store shall not Transfer any Medical Marijuana to a Pesticide Manufacturer or a Marijuana Research and Development Facility.
- F. Licensees May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to Transfer Medical Marijuana to a patient.
- G. Delivery Outside Colorado Prohibited. A Medical Marijuana Store holding a valid delivery permit shall not deliver Medical Marijuana to an address that is outside the state of Colorado.
- H. Storage and Display Limitations. A Medical Marijuana Store shall not display Medical Marijuana outside of a designated Restricted Access Area or in a manner in which Medical Marijuana can be seen from outside the Licensed Premises. Storage of Medical Marijuana shall otherwise be maintained in Limited Access Areas or Restricted Access Area.
- I. Transfer of Expired Product Prohibited. A Medical Marijuana Store shall not Transfer any expired Edible Medical Marijuana Product, Vaporizer Delivery Device, Pressurized Metered Dose Inhaler, Audited Marijuana Product, or Alternative Use Product to a patient.
- J. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit.
1. The Transfer of Edible Medical Marijuana Product in the following shapes is prohibited:
    - a. The distinct shape of a human, animal, or fruit; or
    - b. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
  2. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Medical Marijuana Business. Nothing in this subparagraph (L)(2) alters or eliminates a Licensee's obligation to comply with the requirements of the 3-1000 Series Rules – Packaging, Labeling, and Product Safety.
  3. Edible Medical Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
  4. Edible Medical Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible.
- K. Adverse Health Event Reporting. A Medical Marijuana Store must report Adverse Health Events pursuant to Rule 3-920.



- L. Corrective and Preventive Action. ~~This paragraph L shall be effective January 1, 2021. A~~ Medical Marijuana Store shall establish and maintain written procedures for implementing Corrective Action and Preventive Action. The written procedures shall include the requirements listed below as determined by the Licensee. All activities required under this Rule, and their results, shall be documented and kept as business records. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:
1. What constitutes a Nonconformance in the Licensee's business operation;
  2. Analyzing processes, work operations, reports, records, service records, complaints, returned product, and/or other sources of data to identify existing and potential root causes of Nonconformances or other quality problems;
  3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
  4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
  5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
  6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
  7. Ensuring the information related to quality problems or Nonconformances is disseminated to those directly responsible for assuring the quality of products or the prevention of such problems; and
  8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.
- M. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

### **Basis and Purpose – 5-120**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(b), 44-10-203(1)(k), and 44-10-203(3)(h), C.R.S. The purpose of this rule is to establish that a Medical Marijuana Store must control and safeguard access to certain areas where Medical Marijuana will be sold, and to prevent diversion to non-patients. This Rule 5-120 was previously Rule M 404, 1 CCR 212-1.

### **5-120 – Point of Sale: Restricted Access Area**

- A. Identification of Restricted Access Area. All areas where Medical Marijuana is sold, possessed for sale, displayed, or dispensed for sale shall be identified as a Restricted Access Area and shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half



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inch in height, which shall state, “Restricted Access Area – Only Medical Marijuana Patients Allowed.”

- B. Patients in Restricted Access Area. The Restricted Access Area must be supervised by a Licensee at all times to ensure that only persons with a valid patient registry card, primary caregivers of minors with a valid patient registry card (which may include guardians or parents of minors), advising caregivers who accompany patients that hold a valid registry card and whom they are advising, or transporting caregivers permitted to deliver Medical Marijuana to homebound patients as permitted by section 25-1.5-106(9)(e), C.R.S., are present in the Restricted Access Area. When allowing a patient or caregiver access to a Restricted Access Area, Employee Licensees shall make reasonable efforts to limit the number of patients and caregivers in relation to the number of Employee Licensees in the Restricted Access Area at any time.
- C. Display of Medical Marijuana. The display of Medical Marijuana for sale is allowed only in Restricted Access Areas. Any product displays that are readily accessible to the patient must be supervised by the Employee Licensee at all times when patients are present.
- D. Pregnancy Warning. Medical Marijuana Stores must post, at all times and in a prominent place at every point-of-sale inside the Restricted Access Area, a warning that is at minimum three inches high and six inches wide that reads:

**WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.

**Basis and Purpose– 5-125**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(d)(I)-(VI), 44-10-313(7), 44-10-313(4), 44-10-401(2)(a)(I), 44-10-501, and 44-10-505, C.R.S. The purpose of this rule is to identify Medical Marijuana Store sales requirements including patient quantity limits, Inventory Tracking System requirements to identify discrepancies with daily authorized quantity limits and THC potency authorizations and to require that Medical Marijuana Stores provide an educational resource to patients regarding the use of Medical Marijuana Concentrate.

**5-125 – Patient Sale Requirements**

- A. Sales Limitations.
1. A Medical Marijuana Store and its employees shall not sell to a patient in a single business day, individually or in any combination, more than:
    - a. Two ounces of medical marijuana flower; or
    - b. Eight grams of Medical Marijuana Concentrate for a patient 21 years old of age or older, or two grams of Medical Marijuana Concentrate for a patient between 18 and 20 years old; or
    - c. Medical Marijuana Products containing a combined total of 20,000 mg.

2. A Medical Marijuana Store and its employees shall not sell more than:
  - a. Six Immature plants unless the patient has designated the Medical Marijuana Store as his or her primary store and supplied it with documentation from the patient's physician allowing the patient more than six plants;
  - b. One half of the patient's extended plant count to a patient who has designated the Medical Marijuana Store as his or her primary store and supplied it with documentation from the patient's physician allowing the patient more than six plants; or
  - c. Six Medical Marijuana plant seeds unless the patient has designated the Medical Marijuana Store as his or her primary store and supplied it with documentation from the patient's physician allowing the patient more than six Medical Marijuana seeds. One Medical Marijuana plant is equivalent to one Medical Marijuana seed.

#### 2.5 Registry of a Primary Medical Marijuana Store.

- a. Change Only Allowed Every 30 Days. A Medical Marijuana Store shall not register a patient as being the patient's primary store if the patient has designated another Medical Marijuana Store as his or her primary store in the preceding 30 days.
- b. A Medical Marijuana Store must notify and maintain a copy of a written or electronic notification that it provided to a patient's former primary Medical Marijuana Store advising that the Medical Marijuana Store has been designated as the patient's new primary Medical Marijuana Store.
- c. Documents Required. In addition to all records required to be maintained by Rule 3-905 – Business Records Required, the primary Medical Marijuana Store shall maintain:
  - i. Written authorization from the patient;
  - ii. A hard or electronic copy of the patient's registry card;
  - iii. A copy of the patient's proof of identification; and.
  - iv. The physician certification and, if authorized for sales exceeding the statutory daily limits, the patient's uniform certification form.

#### 3. Exemptions to Sales Limitations.

- a. A Medical Marijuana Store may sell Medical Marijuana or Medical Marijuana Product in an amount that exceeds the sales limitation in subparagraph (A)(1) of this Rule if:
  - i. The patient has received a physician recommendation for more than two ounces of Medical Marijuana flower and the patient has designated the Medical Marijuana Store as his or her primary store;

- ii. The patient has received a physician recommendation exempting the patient from the Medical Marijuana Product sales limitation and the patient has designated the Medical Marijuana Store as his or her primary store;
  - iii. The patient has designated the Medical Marijuana Store as his or her primary store and the patient has received a physician recommendation exempting the patient from the Medical Marijuana Concentrate sales limitation because:
    - A. Repealed;
    - B. The uniform certification form specifically states that the patient needs more than eight grams of Medical Marijuana Concentrate if a patient is 21 years of age or older, or two grams of Medical Marijuana Concentrate if the patient is between 18 and 20 years old;
    - C. It would be a significant Physical or Geographic Hardship for the patient to make a daily purchase; or
    - D. The patient had a registry identification card prior to 18 years of age; ~~or-~~
  - iv. If the patient is homebound, with a physician recommendation exempting the patient from the Medical Marijuana Concentrate sales limitation, the patient is not required to register with a Medical Marijuana Store.
- b. Significant Physical Hardship: A patient's physician who has a bona fide patient-physician relationship may provide an exemption to the patient's daily Medical Marijuana Concentrate sales limits based on the physician's determination that the patient has a significant physical hardship. The physician's determination of a significant physical hardship must be documented on the patient's uniform certification form which must be signed by the patient's physician. The circumstances that constitute a significant physical hardship are as follows:
- i. The patient has been diagnosed with a chronic or debilitating disease or disabling medical condition or limited physical condition that restricts the mobility of the patient;
  - ii. The patient does not have the ability to obtain a driver's license based on the patient's medical condition; or
  - iii. The patient cannot use, or it would be onerous for the patient to use, public transportation or another ride sharing service based on the patient's medical condition.
- c. Significant Geographic Hardship: A patient's physician who has a bona fide patient-physician relationship may provide an exemption to the patient's daily Medical Marijuana Concentrate sales limits based on the

physician's determination that the patient has a significant geographic hardship. The physician's determination of a significant geographic hardship must be documented on the patient's uniform certification form which must be signed by the patient's physician. The circumstances that constitute a significant geographic hardship are as follows:

- i. The patient does not reside in the following counties: Adams, Arapahoe, Boulder, Denver, Douglas, El Paso, Jefferson, Larimer, or Pueblo; and
  - ii. At least one of the following circumstances:
    - A. The patient resides in a county that does not permit the operation of Medical Marijuana Stores and that county is not listed above; or
    - B. The patient does not have a means of transportation and resides in an area without public transportation or Medical Marijuana Stores cannot be accessed by a patient using public transportation; or
    - C. The physician recommended a Medical Marijuana Concentrate that is not available from a Medical Marijuana Store located in the patient's county of residence.
- B. Multiple Transactions. For purposes of Rule 5-125(A), a single transaction to a patient includes multiple Transfers to the same patient during the same business day where the Medical Marijuana Store employee knows or reasonably should know that such Transfer would result in the patient possessing more than the quantities of Medical Marijuana set forth above. In determining the imposition of any penalty for violation of this Rule 5-125(A), the State Licensing Authority will consider any mitigating and aggravating factors set forth in Rule 8-235(C).
- C. Inventory Tracking Requirements.
1. Before Completing a Transfer of Medical Marijuana to a patient, a Medical Marijuana Store and its Employee Licensee shall access and retrieve real-time sales data based on the patient identification number to verify that a sale to the patient will not exceed the daily authorized sales limit. The Medical Marijuana Store and Employee Licensee shall decline to complete the Transfer of Medical Marijuana to the patient if it would exceed the patient's daily authorized purchase limit which may be determined by a user error message from the Inventory Tracking System.
  2. At the time of the sale to the patient the Medical Marijuana Store and its Employee Licensee shall record the sale in real time in the Inventory Tracking System. A Medical Marijuana Store may use a secondary software platform to transmit patient sale data to the Inventory Tracking system.
  3. Temporary Outage of Inventory Tracking System. A Medical Marijuana Store may rely on the uniform certification form and is not responsible for any unintentional

sale in excess of the authorized Medical Marijuana quantity limit that occurs during the outage, provided that the Medical Marijuana Store uploads its sales data into the Inventory Tracking System as soon as reasonably practicable after the end of the outage. A temporary outage is any event in which there is a technology-related inability to enter or retrieve real time sales data from the Inventory Tracking System.

- D. Educational Resource. When completing a sale of Medical Marijuana Concentrate, a Medical Marijuana Store shall physically attach to the patient's receipt of sale, product container, or exit packaging~~provide the patient with~~ the tangible educational resource created by the State Licensing Authority regarding the use of Regulated Marijuana Concentrate.
- E. Confidentiality. All data collected pursuant to Rule, including any personal identifying patient information, is subject to the confidentiality requirements of 44-10-204, C.R.S.
- F. ~~Repealed. Violation Affecting Public Safety. Violation of this Rule may be considered a license violation affecting public safety~~

## **5-200 Series – Medical Marijuana Cultivation Facilities**

### **Basis and Purpose – 5-205**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-401(2)(a)(II), 44-10-313, 44-10-502, and 44-10-503, C.R.S. The purpose of this rule is to establish a Medical Marijuana Cultivation Facility's license privileges in addition to the privileges outlined in these rules. This Rule 5-205 was previously Rule M 501, 1 CCR 212-1.

### **5-205 – Medical Marijuana Cultivation Facility: License Privileges**

- A. Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Business – Shared Licensed Premises and Operational Separation, a Medical Marijuana Cultivation Facility may share a Licensed Premises with a commonly owned Retail Marijuana Cultivation Facility. However, a separate license is required for each specific business entity regardless of geographical location. In addition, a Medical Marijuana Cultivation Facility may share and operate at the same Licensed Premises as a Marijuana Research and Development Facility so long as:
  - 1. Each business or business entity holds a separate license;
  - 2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;
  - 3. Both the Marijuana Research and Development Facility and the Medical Marijuana Cultivation Facility comply with all terms and conditions of the R&D Co-Location Permit; and
  - 4. Both the Marijuana Research and Development Facility and the Medical Marijuana Cultivation Facility comply with all applicable rules. See 5-700 Series Rules.

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- B. Cultivation of Medical Marijuana and Production of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Medical Marijuana Concentrate Authorized. A Medical Marijuana Cultivation Facility may propagate, cultivate, harvest, prepare, cure, package, store, and label Medical Marijuana and Physical Separation-Based Medical Marijuana Concentrate. A Medical Marijuana Cultivation Facility may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Medical Marijuana Concentrate.
- C. Authorized Transfers. A Medical Marijuana Cultivation Facility may Transfer Medical Marijuana and Physical Separation-Based Medical Marijuana Concentrate to another Medical Marijuana Cultivation Facility, a Medical Marijuana Store, a Medical Marijuana Products Manufacturer, a Medical Marijuana Testing Facility, a Marijuana Research and Development Facility, or a Pesticide Manufacturer.
1. A Medical Marijuana Cultivation Facility shall not Transfer Flowering plants. A Medical Marijuana Cultivation Facility may only Transfer Vegetative plants as authorized pursuant to Rule 3-605.
  2. A Medical Marijuana Cultivation Facility may Transfer Sampling Units of Medical Marijuana or Medical Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-502(5), C.R.S., and Rule 5-230.
  3. A Medical Marijuana Cultivation Facility may Transfer Medical Marijuana or Medical Marijuana Concentrate to another Medical Marijuana Cultivation Facility prior to testing required by these rules only if such Transfer is in accordance with one of the two options below.
    - a. The Medical Marijuana Cultivation Facility may Transfer Medical Marijuana ~~or~~ Medical Marijuana Concentrate, Pre-Rolled Marijuana, or Infused Pre-Rolled Marijuana to another Medical Marijuana Cultivation Facility prior to testing if such Transfer is to perform a Microbial Control Step and only after all other steps outlined in the Medical Marijuana Cultivation Facility's Sstandard Operating Procedures have been completed, including but not limited to drying, curing, and trimming; or
    - b. The Medical Marijuana Cultivation Facility may Transfer Medical Marijuana or Medical Marijuana Concentrate to another Medical Marijuana Cultivation Facility prior to testing, drying, curing, trimming, or completion of any other steps in the Medical Marijuana Cultivation Facility's Sstandard Operating Procedures, subject to the following additional requirements:
      - i. The Medical Marijuana Cultivation Facility receiving the Transfer is identified as a centralized processing hub in the Inventory Tracking System and must have identical Controlling Beneficial Owner(s) with the originating Medical Marijuana Cultivation Facility;

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- ii. An originating Medical Marijuana Cultivation Facility may only Transfer Medical Marijuana to one receiving Medical Marijuana Cultivation Facility that will be serving as a centralized processing hub.
  - iii. The Medical Marijuana or Medical Marijuana Concentrate is weighed prior to leaving the originating Medical Marijuana Cultivation Facility and immediately upon receipt at the receiving Medical Marijuana Cultivation Facility and in accordance with Rule 3-605;
  - iv. The Transfer, weighing and entry into the Inventory Tracking System are all completed within 24 hours from initiating the Transfer;
  - v. The receiving Medical Marijuana Cultivation Facility is responsible for compliance with all testing requirements regardless of any testing performed prior to Transfer. If the receiving Medical Marijuana Cultivation Facility is pursuing a Reduced Testing Allowance, a Reduced Testing Allowance must be achieved separately for Medical Marijuana received from each originating Medical Marijuana Cultivation Facility. A Medical Marijuana Cultivation Facility that has achieved a Reduced Testing Allowance must maintain and produce complete testing records that can verify that facility's compliance with testing and Reduced Testing Allowance requirements; and
  - vi. The Sstandard Operating Procedures for the originating Medical Marijuana Cultivation Facility and receiving Medical Marijuana Cultivation Facility clearly reflect the steps taken by each facility to Transfer, transport, receive, process, and test Harvest Batches.
- 4. A Medical Marijuana Cultivation Facility may Transfer Medical Marijuana to a Retail Marijuana Cultivation Facility or Accelerator Cultivator in accordance with Rules 5-235, 6-230, and 6-730.
- 5. A Medical Marijuana Cultivation Facility may sell, Transfer, or ship ~~Immature Plants, Medical Marijuana seeds, and~~ Genetic Material in accordance with section 44-10-502(7)(b), C.R.S. to a Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator. Transfers made under this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.
- D. Packaging Processed Medical Marijuana. Processed Medical Marijuana plants shall be packaged in units of ten pounds or less and labeled pursuant to the 3-1000 Series Rules – Labeling, Packaging, and Product Safety, and securely sealed in a tamper-evident manner.



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- E. Authorized Marijuana Transport. A Medical Marijuana Cultivation Facility is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana so long as the place where transportation orders are taken is a Medical Marijuana Business and the transportation order is delivered to a licensed Medical Marijuana Business or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana Cultivation Facility from transporting its own Medical Marijuana.
- F. Performance-Based Incentives. A Medical Marijuana Cultivation Facility may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Medical Marijuana Cultivation Facility may not compensate a Sampling Manager using Sampling Units. See Rule 5-230 – Sampling Unit Protocols.
- G. Authorized Sources of Medical Marijuana , ~~Seeds, Immature Plants,~~ and Genetic Material.
1. A Medical Marijuana Cultivation Facility may obtain Medical Marijuana ~~seeds or Immature Plants from its own Medical Marijuana, properly Transferred Retail Marijuana cultivated at a Retail Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or~~ properly Transferred from another Medical Marijuana Business pursuant to the inventory tracking requirements in the Rule 3-800 Series. A Medical Marijuana Cultivation Facility may also receive Transfers of Retail Marijuana from a Retail Marijuana Cultivation Facility or Accelerator Cultivator in compliance with Rules 5-235, 6-230, and 6-730. A Medical Marijuana Cultivation facility may not bring ~~seeds, Immature Plants, or other~~ marijuana that is not Regulated Marijuana onto the Licensed Premises at any time.
  2. A Medical Marijuana Cultivation Facility may obtain ~~Regulated Marijuana seeds, Immature Plants, and~~ Genetic Material in accordance with section 44-10-502(7)(a), C.R.S.:
    - a. ~~From another Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility;~~
    - b. ~~A Retail Marijuana Testing Facility;~~
    - c. ~~A marijuana cultivation or testing facility licensed or otherwise approved pursuant to a permit or registration issued by a government agency to operate in another state or territory of the United States;~~
    - d. ~~An individual licensed as an Employee Licensee in Colorado, or holding a permit, registration, or license to work in another state or territory of the United States that regulates marijuana; or~~
    - e. ~~Pursuant to any federal statute or regulation.~~
  3. Transfers made under subparagraph (G)(2) of this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.
- H. Centralized Distribution Permit. A Medical Marijuana Cultivation Facility may apply to the State Licensing Authority for a Centralized Distribution Permit for authorization to



temporarily store Medical Marijuana Concentrate and Medical Marijuana Product received from a Medical Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Medical Marijuana Stores.

1. For purposes of a Centralized Distribution Permit only, the term “commonly owned” means at least one natural person who is disclosed to the Division who has a minimum of five percent ownership in both the Medical Marijuana Cultivation Facility possessing a Centralized Distribution Permit and the Medical Marijuana Store to which the Medical Marijuana Concentrate and Medical Marijuana Product will be Transferred.
  2. To apply for a Centralized Distribution Permit, a Medical Marijuana Cultivation Facility may submit an addendum to its new or renewal application or a separate addendum prior to a renewal application on forms prepared by the Division to request a Centralized Distribution Permit. The Medical Marijuana Cultivation Facility shall send a copy of its Centralized Distribution Permit addendum to the Local Licensing Authority in the jurisdiction in which the Centralized Distribution Permit is proposed at the same time it submits the addendum to the State Licensing Authority.
  3. A Medical Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit and has obtained all required approvals from the local licensing jurisdiction where it is located, if any, may accept Transfers of Medical Marijuana Concentrate and Medical Marijuana Product from a Medical Marijuana Products Manufacturer for the sole purpose of temporary storage and Transfer to commonly owned Medical Marijuana Stores.
    - a. A Medical Marijuana Cultivation Facility may only accept Medical Marijuana Concentrate and Medical Marijuana Product that is packaged and labeled for sale to a patient pursuant to the 3-1000 Series Rules.
    - b. A Medical Marijuana Cultivation Facility storing Medical Marijuana Concentrate and Medical Marijuana Product pursuant to a Centralized Distribution Permit shall not store such Medical Marijuana Concentrate or Medical Marijuana Product on the Medical Marijuana Cultivation Facility's Licensed Premises for more than 90 days from the date of receipt.
    - c. All Transfers of Medical Marijuana Concentrate and Medical Marijuana Product by a Medical Marijuana Cultivation Facility shall be without consideration.
  4. All security and surveillance requirements that apply to a Medical Marijuana Cultivation Facility apply to activities conducted pursuant to the privileges of a Centralized Distribution Permit.
- I. Transition Permit. A Medical Marijuana Cultivation Facility may only operate at two geographical locations pursuant to Rule 2-255(D).

#### **Basis and Purpose – 5-220**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(d), 44-10-203(1)(k), 44-10-203(1)(c), 44-10-203(2)(d)(I)-(VI), and 44-10-401(2)(a)(II), C.R.S. The purpose of this rule is to establish the categories of Medical Marijuana Concentrate that may be produced at a Medical Marijuana Cultivation Facility and standards for the production of those concentrate. This Rule 5-220 was previously Rule M 506, 1 CCR 212-1.

### **5-220 – Medical Marijuana Cultivation Facility: Medical Marijuana Concentrate Production**

- A. Permitted Production of Certain Categories of Medical Marijuana Concentrate. A Medical Marijuana Cultivation Facility may only produce Physical Separation-Based Medical Marijuana Concentrate on its Licensed Premises and only in an area clearly designated as a Limited Access Area. See Rule 3-405- Business Records Required. No other method of production or extraction for Medical Marijuana Concentrate may be conducted within the Licensed Premises of a Medical Marijuana Cultivation Facility unless the Controlling Beneficial Owner(s) of the Medical Marijuana Cultivation Facility also has a valid Medical Marijuana Products Manufacturer license and the room in which Medical Marijuana Concentrate is to be produced is physically separated from all cultivation areas and has clear signage identifying the room.
- B. Safety and Sanitary Requirements for Concentrate Production. If a Medical Marijuana Cultivation Facility produces Physical Separation-Based Medical Marijuana Concentrate, then all areas in which those concentrates are produced and all Owner Licensees and Employees Licensees engaged in the production of those concentrate shall be subject to all of requirements imposed upon a Medical Marijuana Products Manufacturer that produces Medical Marijuana Concentrate, including general requirements. See 3-300 Series Rules – Health and Safety Regulations and Rule 5-315 Medical Marijuana Products Manufacturer: Medical Marijuana Concentrate Production.
- C. Possession of Other Categories of Medical Marijuana Concentrate.
1. It shall be considered a violation of this Rule if a Medical Marijuana Cultivation Facility possesses a Medical Marijuana Concentrate other than a Physical Separation-Based Medical Marijuana Concentrate on its Licensed Premises unless: the Controlling Beneficial Owner(s) of the Medical Marijuana Cultivation Facility also has a valid Medical Marijuana Products Manufacturer license, or the Medical Marijuana Cultivation Facility has been issued a Centralized Distribution Permit and is in possession of the Medical Marijuana Concentrate in compliance with Rule 5-205(H).
  2. Notwithstanding subparagraph (C)(1) of this Rule 5-220, a Medical Marijuana Cultivation Facility shall be permitted to possess Solvent-Based Medical Marijuana Concentrate only when the possession is due to the Transfer of Medical Marijuana flower or trim that failed microbial testing to a Medical Marijuana Products Manufacturing Facility for processing into a Solvent-Based Medical Marijuana Concentrate, and the Medical Marijuana Products Manufacturer Transfers the resultant Solvent-Based Medical Marijuana Concentrate back to the originating Medical Marijuana Cultivation Facility.
    - a. The Medical Marijuana Cultivation Facility shall comply with all requirements in Rule ~~4-240 4-135(C)~~ when having Solvent-Based Medical

Marijuana Concentrate manufactured out of Medical Marijuana flower or trim that failed microbial testing.

- b. The Medical Marijuana Cultivation Facility is responsible for submitting the Solvent-Based Medical Marijuana Concentrate for all required testing for contaminants pursuant to Rule ~~4-2154-120~~ – ~~Medical-Regulated~~ Marijuana Testing Program – Contaminant Testing, for potency pursuant to Rule ~~4-2104-125~~ – ~~RegulatedMedical~~ Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Marijuana Rules or Marijuana Code.

- D. Production of Alternative Use Product or Audited Product Prohibited. A Medical Marijuana Cultivation Facility shall not produce an Alternative Use Product or Audited Product.
- E. Possession of Alternative Use Product or Audited Product. A Medical Marijuana Cultivation Facility is authorized to possess or Transfer Alternative Use Product and/or Audited Product only if the Medical Marijuana Cultivation Facility received the Alternative Use Product and/or Audited Product pursuant to a Centralized Distribution Permit from a Medical Marijuana Products Manufacturer that is manufacturing and Transferring the Alternative Use Product or Audited Product in accordance with Rule 5-325.

### **Basis and Purpose – 5-225**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(5), 44-10-401(2)(a)(II), 44-10-502, C.R.S. The rule establishes a means by which to manage the overall production of Medical Marijuana. The intent of this rule is to encourage responsible production to meet demand for Medical Marijuana, while also avoiding overproduction or underproduction. The establishment of production management is necessary to ensure there is not significant under or over production, either of which will increase incentives to engage in diversion and facilitate the sale of illegal marijuana. This Rule 5-225 was previously Rule M 507, 1 CCR 212-1.

### **5-225 – Medical Marijuana Cultivation Facility: Production Management**

- A. One Medical Marijuana Cultivation Facility per Licensed Premises. Except as permitted by subparagraph (B)(1)(b), a Licensed Premises shall only have one Medical Marijuana Cultivation Facility ~~!L~~icense and each Licensed Premises must be located at a distinct address recognized by the local jurisdiction.
  - 1. Existing Medical Marijuana Cultivation Facilities that have Multiple Licenses at a single Licensed Premises.
    - a. Mandatory Collapse for Licenses with Identical Controlling Beneficial Owner Percentages.
      - i. Medical Marijuana Cultivation Facilities that have multiple licenses at a single Licensed Premises and that have identical Controlling Beneficial Owners holding identical ownership percentages are subject to mandatory collapse. Such Licensees shall notify the Division prior to June 30, 2019 which Medical Marijuana

Cultivation Facility license they desire to survive. The Medical Marijuana Cultivation Facility license identified as the surviving license will remain active after July 1, 2019; all other Medical Marijuana Cultivation Facility licenses shall be surrendered effective July 1, 2019.

- ii. The production management class for the surviving Medical Marijuana Cultivation Facility license will be calculated pursuant to subparagraph (B)(3) below using the aggregate average plants actually cultivated by all Medical Marijuana Cultivation Facility licenses that were located at the Licensed Premises during the period January 1, 2018 to December 31, 2018.
  - b. Optional Collapse for Licenses with Non-Identical Controlling Beneficial Owner Percentages. Medical Marijuana Cultivation Facilities that have multiple licenses at a single Licensed Premises and that do not have identical Controlling Beneficial Owners holding identical ownership percentages as of July 1, 2019, may continue operating all Medical Marijuana Cultivation Facility licenses that existed at that Licensed Premises prior to July 1, 2019. The maximum plant count for each such Medical Marijuana Cultivation Facility will be calculated pursuant to subparagraph (B)(3) below based on the number of average plants actually cultivated by that Medical Marijuana Cultivation Facility during the period January 1, 2018 to December 31, 2018.
    - i. Medical Marijuana Cultivation Facilities that are permitted to continue operating multiple licenses at a single Licensed Premises after July 1, 2019, may collapse through one or more approved change of ownership applications, or one or more voluntary license surrenders, establishing identical Controlling Beneficial Owners holding identical ownership percentages for all Medical Marijuana Cultivation Facilities at the single Licensed Premises.
    - ii. For any change of ownership application or voluntary license surrender seeking collapse after July 1, 2019, the Medical Marijuana Cultivation Facility shall identify the license that will survive. The Medical Marijuana Cultivation Facility license identified as the surviving license will remain after collapse; all other Medical Marijuana Cultivation Facility licenses will be surrendered at the time of collapse.
    - iii. The class for the surviving Medical Marijuana Cultivation Facility license will be determined according to subparagraph (B)(3) below based on the aggregate average number of Medical Marijuana plants actually cultivated by all Medical Marijuana Cultivation Facility Licensees that were located at the Licensed Premises during the 180 days prior to the collapse.
2. Collapse after July 1, 2019. After July 1, 2019, Medical Marijuana Cultivation Facility licenses shall be permitted to collapse at a single Licensed Premises

through an approved change of location application if all Medical Marijuana Cultivation Facility licenses for which collapse is sought meet the following requirements:

- a. All Medical Marijuana Cultivation Facility licenses sought to be collapsed have been consistently operating for at least 180 days prior to the proposed collapse;
- b. All Medical Marijuana Cultivation Facility licenses sought to be collapsed have identical Controlling Beneficial Owners holding identical ownership percentages;
- c. There is no pending administrative action regarding any of Medical Marijuana Cultivation Facility licenses sought to be collapsed;
- d. The class for the surviving Medical Marijuana Cultivation Facility license has not been decreased in the 180 days prior to the change of location application;
- e. All Medical Marijuana Cultivation Facility Licensees identify the desired surviving license and agree that all other Medical Marijuana Cultivation Facility licenses will be surrendered at the time of collapse; and
- f. Determining Class for Surviving License.
  - i. Surviving License Class Will Not Decrease. The class for the surviving license will not be decreased as a result of any approved change of location application.
  - ii. Surrendered License is Class 1, Class 2, or Class 3. For the surviving license to increase one class or one increment of 3,000 plants if already higher than class 3, during the 180 days prior to the change of location application, the surrendered license must have cultivated at least 50% of the maximum authorized plant count and Transferred at least 85% of the inventory it produced during that time.
  - iii. Surrendered License is Higher than Class 3. For the surviving license to increase by the maximum authorized plant count of the surrendered license, during the 180 days prior to the change of location application the surrendered license must have cultivated at least 50% of the maximum authorized plant count and Transferred at least 85% of the inventory it produced during that time. If during the 180 days prior to the change of location application, the surrendering license did not cultivate at least 50% of the maximum authorized plant count and Transfer at least 85% of the inventory it produced, the surviving license will only increase one class or one increment of 3,000 plants if already higher than class 3.

- iv. Division Determination of Class. If a collapse results in a maximum authorized plant count in the middle of a class, the surviving license's maximum authorized plant count will be rounded up to the top of that class.

B. Production Management.

1. Production Management Classes.

- a. Class 1: 1 – 500 plants
- b. Class 2: 501 – 1,500 plants
- c. Class 3: 1,501 – 3,000 plants
  - i. The maximum authorized plant count above 3,000 plants shall increase in one or two increments of 3,000 plants. A Medical Marijuana Cultivation Facility may be allowed to increase its maximum authorized plant count one or two increments of 3,000 plants at a time upon application and approval by the Division pursuant to the requirements of paragraph (E) of this Rule 5-225.

2. All initial Medical Marijuana Cultivation Facility licenses issued on or after July 1, 2019 will be issued as a Class 1 License.

3. Each Medical Marijuana Cultivation Facility with a license(s) granted before July 1, 2019, at a minimum, will be placed into the production management class that includes the average number of plants it cultivated during the period January 1, 2018 to December 31, 2018.

- a. Medical Marijuana Cultivation Facilities with less than 180 days of consistent cultivation history will be placed into the class 1 production management class.
- b. Any Medical Marijuana Cultivation Facility that artificially increases plant count or otherwise misrepresents any data in connection with its plant count will be placed into the class the Division determines it would have been placed into without the artificial increase or misrepresentation. ~~In addition, any such artificial increase of plant count or other misrepresentation is a public safety violation that may result in administrative action.~~

4. Immature Plants. For purposes of calculating the maximum number of authorized plants, Immature Plants are excluded but must be fully accounted for in the Inventory Tracking System.

5. Ground for Denial. The Division may deny an application for additional plants pursuant to paragraph E of this Rule if the Licensee exceeded the authorized plant count during the relevant time period for production.

6. ~~Repealed. Violation Affecting Public Safety. It may be considered a license violation affecting public safety for a Licensee to exceed the authorized plant count pursuant to these Rules.~~

C. Inventory Management.

1. Inventory Management for Medical Marijuana Cultivation Facilities that Have One or Two Harvest Seasons a Year. Beginning the 721<sup>st</sup> day from the commencement of its first cultivation activities, a Medical Marijuana Cultivation Facility that has one or two harvest seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Medical Marijuana flower and trim the Licensee reported as a package in the Inventory Tracking System~~produced~~ that was Transferred to another Medical Marijuana Business in the previous 720 days.
2. Inventory Management for Medical Marijuana Cultivation Facilities That Have More Than Two Harvest Seasons a Year. Beginning the 181<sup>st</sup> day from the commencement of its first cultivation activities, a Medical Marijuana Cultivation Facility that has more than two harvest seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Medical Marijuana flower and trim the Licensee reported as a package in the Inventory Tracking System~~produced~~ that was Transferred to another Medical Marijuana Business in the previous 180 days.

D. Class Decrease. For any Medical Marijuana Cultivation Facility that is authorized to cultivate more than 500 plants, the Division may review the purchases, Transfers, and cultivated plant count in connection with the license renewal process or after an investigation. Based on the Division's review, it may reduce the Licensee's maximum allowed plant count to a lower production management class identified in subparagraph (B)(1) of this Rule 5-225. When determining whether to reduce the maximum authorized plant count, the Division may consider the following non-exhaustive factors including but not limited to:

1. The Licensee Transferred less than 70% of the inventory it reported as packaged in the Inventory Tracking System during any 180 day review period;
2. On average during the previous 180 days, the Licensee actually cultivated less than 90% of the maximum number of plants authorized by the next lower production management class;
3. Whether the plants/inventory suffered a catastrophic event during the review period;
4. Existing inventory and inventory history;
5. Sales contracts;
6. Number of patients registered to any commonly owned Medical Marijuana Store; and
7. Any other factors relevant to ensuring responsible cultivation, production, and inventory management.

E. Application for Additional Plants.1. Medical Marijuana Cultivation Facilities That Have One or Two Harvest Seasons Per Year.

- a. After one harvest season during which the Medical Marijuana Cultivation Facility Transferred and consistently cultivated, the Licensee may apply to the Division for a production management class increase to be authorized to cultivate the number of plants in the next highest production management class. The Licensee must demonstrate:
  - i. That during the previous harvest season, prior to the class increase application, it consistently cultivated an average amount of plants that is at least 85% of its maximum authorized plant count;
  - ii. That the Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System in the previous 360 days to another Medical Marijuana Business;
  - iii. The Division may consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the previous 360 days, if the Licensee cultivated between 75% and 85% of its maximum authorized plant count; and
  - iv. Any other information requested to aid the Division in its evaluation of the production management class increase application.
- b. If the Division approves the production management class increase application, the Licensee shall pay the applicable Expanded Production Management Class Fee in Rule 2-125 prior to cultivating the additional authorized plants. ~~See Rule 2-205—Fees.~~
- c. For a Licensee with an authorized plant count in Classes 2 or 3 to continue producing at its expanded authorized plant count, the Licensee shall pay the requisite Medical Marijuana Cultivation Facility license fee and the applicable ~~e~~Expanded ~~p~~Production ~~m~~Management ~~e~~Class ~~f~~Fee in Rule 2-125 at license renewal. ~~See Rule 2-205—Fees.~~
- d. After one harvest season during which the Medical Marijuana Cultivation Facility Transferred and consistently cultivated the Licensee may apply to increase its authorized plant count by: (a) two production management classes, or (b) if already authorized to cultivate at a class 3, two increments of 3,000 plants (6,000 plants total), every 360 days. It is within the Division's discretion to determine whether or not to grant the requested two classes or two increments of 3,000 plant (6,000 plants total).
  - i. The Licensee must demonstrate:



- A. That the Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count, and
  - B. That the Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Medical Marijuana Business;
  - C. If the Medical Marijuana Cultivation Facility cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a package in the Inventory Tracking System during that time period and/or Transfers into the Medical Marijuana Cultivation Facility or related Medical Marijuana Store(s).
- ii. In making its determination, the Division may consider the following exclusive factors:
- A. The Medical Marijuana Cultivation Facility currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two classes or two increments of 3,000 plants;
  - B. The Medical Marijuana Cultivation Facility cultivated on average at least 90% of its authorized plant count and during the preceding 360 days the Medical Marijuana Cultivation Facility and/or one or more commonly owned Medical Marijuana Stores Transferred in Medical Marijuana from one or more unrelated Medical Marijuana Cultivation Facility(ies);
  - C. The Medical Marijuana Cultivation Facility has entered into written agreement(s) or contract(s) for the sale of Medical Marijuana in the next 360 days supporting the requested two production management class increase or two increments of 3,000 plants; or
  - D. An established history of responsible cultivation and Transfer by the Medical Marijuana Cultivation Facility;
  - E. Any history of noncompliance with the Medical Code, Marijuana Code, and/or Rules by the Medical Marijuana Cultivation Facility, or any commonly owned Medical Marijuana Business, and/or any investigation of, or administrative action against, the Medical Marijuana Cultivation Facility or any commonly owned Medical Marijuana Business; or

- F. Any other pertinent facts or circumstances regarding responsible production and inventory management.

2. Medical Marijuana Cultivation Facilities That Have More Than Two Harvest Seasons per Year.

- a. After a 180-day period during which the Medical Marijuana Cultivation Facility Transferred and consistently cultivated, the Licensee may apply to the Division for a production management class increase to be authorized to cultivate the number of plants in the next highest production management class. The Division may consider the following in determining whether to approve the production management class increase:
- i. That for the 180 days prior to the production management class increase application, the Licensee consistently cultivated an average amount of plants that is at least 85% of its maximum authorized plant count, and
  - ii. That the Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Medical Marijuana Business.
  - iii. The Division may also consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the 180-day time period, if the Licensee cultivated between 75% and 85% of its maximum authorized plant count.
  - iv. Any other information requested to aid the Division in its evaluation of the production management class increase application.
- b. If the Division approves the production management class increase application, the Licensee shall pay the applicable Expanded Production Management ~~e~~Class License Fee in Rule 2-125 prior to cultivating the additional authorized plants. ~~See Rule 2-205—Fees.~~
- c. For a Licensee with an authorized plant count in Class 2 or Class 3 to continue producing at its expanded authorized plant count, the Licensee shall pay the requisite Medical Marijuana Cultivation Facility license fee and the applicable ~~e~~Expanded ~~p~~P~~m~~Management ~~e~~Class ~~f~~Fee in Rule 2-125 at license renewal. ~~See Rule 2-205—Fees.~~
- d. After accruing 180 days during which the Medical Marijuana Cultivation Facility Transferred and consistently cultivated the Licensee may apply to increase its authorized plant count by: (a) two production management classes, or (b) if already authorized to cultivate at a class 3, two increments of 3,000 plants (6,000 plants total) every 180 days. It is within the Division's discretion to determine whether or not to grant the requested two classes or increments of 3,000 plants (6,000 plants total).

- i. The Licensee must demonstrate:
  - A. That the Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count; and
  - B. That the Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Medical Marijuana Business;
  - C. If the Medical Marijuana Cultivation Facility cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a packing in the Inventory Tracking System during that time period and/or Transfers into the Medical Marijuana Cultivation Facility or related Medical Marijuana Store(s).
- ii. In making its determination, the Division may consider the following exclusive factors:
  - A. The Medical Marijuana Cultivation Facility currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two classes or two increments of 3,000 plants;
  - B. The Medical Marijuana Cultivation Facility cultivated on average at least 90% of its authorized plant count and during the preceding 180 days the Medical Marijuana Cultivation Facility and/or one or more commonly owned Medical Marijuana Stores Transferred in Medical Marijuana from one or more unrelated Medical Marijuana Cultivation Facility(ies);
  - C. The Medical Marijuana Cultivation Facility has entered into a written agreement(s) or contract(s) for the sale of Medical Marijuana in the next 180 days supporting the requested two production management class increase or two increments of 3,000 plants;
  - D. An established history of responsible cultivation and Transfer by the Medical Marijuana Cultivation Facility;
  - E. Any history of noncompliance with the Medical Code, Marijuana Code, and/or Rules by the Medical Marijuana Cultivation Facility, or any commonly owned Medical Marijuana Business, and/or any investigation of, or administrative action against, the Medical Marijuana Cultivation Facility or any commonly owned Medical Marijuana Business; or

- F. Any other pertinent facts or circumstances regarding responsible production and inventory management.
- e. A Medical Marijuana Cultivation Facility that does not have 180 days of cultivating history may apply to increase its plant count to a Class 2 or Class 3 pursuant only to this subparagraph (E)(2)(e). A Medical Marijuana Cultivation Facility applying for a production management class increase request under this subparagraph (E)(2)(e) must demonstrate all of the following at the time of application:
    - i. The Medical Marijuana Cultivation Facility making the class increase request also owns at least three Medical Marijuana Stores with identical Controlling Beneficial Owners;
    - ii. The Controlling Beneficial Owners of the Medical Marijuana Cultivation Facility and three Medical Marijuana Stores used to support the class increase request have owned the aforementioned Medical Marijuana Store licenses for at least the preceding 180 days;
    - iii. The three Medical Marijuana Stores used to support the class increase request have consistently Transferred Regulated Marijuana to consumers in the preceding 180 days and have a history of wholesale purchases that justify the need for a class increase above a class 1;
    - iv. In the 180 days preceding the Licensee's class increase request pursuant to this subparagraph (e), the Medical Marijuana Cultivation Facility, three Medical Marijuana Stores, and identical Controlling Beneficial Owners have not been subject to administrative action by the State Licensing Authority;
    - v. The Medical Marijuana Cultivation Facility making the class increase request has an established history of responsible cultivation and Transfers of its Regulated Marijuana inventory; and
    - vi. The Medical Marijuana Cultivation Facility subject to the class increase request has not previously requested a class increase pursuant to this subparagraph (e).
- 3. Application for Class Increase. Applications for a class increase shall be submitted on Division forms, and shall be complete and accurate. Applications for a class increase that include any artificial increase of plant count, manipulation of Transfer history, or other misrepresentation will be denied. ~~In addition to denial, any artificial increase of plant count, manipulation of Transfer history, or other misrepresentation is a public safety violation that may result in administrative action.~~
- F. Maximum Allowed Medical Marijuana Cultivation Facility Licenses.

1. A Person that is a Controlling Beneficial Owner with an Interest in Three or More Medical Marijuana Cultivation Facility Licenses. For every multiple of three Medical Marijuana Cultivation Facility licenses in which a Person is a Controlling Beneficial Owner, the Person must also be a Controlling Beneficial Owner in at least one Medical Marijuana Store. For example: (1) a Person that is a Controlling Beneficial Owner in three, four, or five Medical Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least one Medical Marijuana Store; (2) a Person that is a Controlling Beneficial Owner in six, seven, or eight Medical Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least two Medical Marijuana Stores; (3) a Person that is a Controlling Beneficial Owner in nine, ten, or eleven Medical Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least three Medical Marijuana Stores; etcetera.
  2. A Person that is a Controlling Beneficial Owner in Less than Three Medical Marijuana Cultivation Facility Licenses. A Person that is a Controlling Beneficial Owner in less than three Medical Marijuana Cultivation Facility licenses shall not be required to be a Controlling Beneficial Owner in a Medical Marijuana Store.
- G. The State Licensing Authority, in his or her sole discretion, may adjust any of the plant limits described in this Rule 5-225 on an industry-wide aggregate basis for all Medical Marijuana Cultivation Facilities subject to that limitation.

**Basis and Purpose – 5-230**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-401(2)(a)(II), and 44-10-502(5), C.R.S. The purpose of this rule is to establish the circumstances under which a Medical Marijuana Cultivation Facility may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado's regulated Medical Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager may receive in a calendar month and imposes inventory tracking, reporting and recordkeeping requirements on a Medical Marijuana Cultivation Facility that Transfer Sampling Units. This Rule 5-230 was previously Rule M 508, 1 CCR 212-1.

**5-230 – Medical Marijuana Cultivation Facility: Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, a Medical Marijuana Cultivation Facility may designate no more than five Sampling Managers in the Inventory Tracking System.
1. Only management personnel of the Medical Marijuana Cultivation Facility who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  2. An individual designated as a Sampling Manager by a Medical Marijuana Cultivation Facility must possess a valid patient registry card.
  3. An individual may be designated as a Sampling Manager by more than one Regulated Marijuana Business.

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4. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.
  5. A Medical Marijuana Cultivation Facility that wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling Manager ~~S~~standard ~~O~~perating ~~P~~rocedures that explain the requirements of section 44-10-502(5), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 5-230. See *also* Rule 3-905 – Business Records Required. A Medical Marijuana Cultivation Facility shall maintain and update such ~~S~~standard ~~O~~perating ~~P~~rocedures as necessary to reflect accurately any changes in the relevant statutes and rules.
- B. Sampling Unit Limits. Only one Sampling Unit may be designated per Harvest Batch or Production Batch. A Sampling Unit shall not be designated until the Harvest Batch or Production Batch has satisfied the testing requirements in ~~4-2004-100~~ Series Rules – Regulated Marijuana Testing Program.
1. A Sampling Unit of Medical Marijuana flower or trim shall not exceed one gram.
  2. A Sampling Unit of Medical Marijuana Concentrate shall not exceed one-quarter of one gram; except that a Sampling Unit of Medical Marijuana Concentrate which has the intended use of being delivered in a vaporized form shall not exceed one-half of one gram.
- C. Transfer Restrictions.
1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
  2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Medical Marijuana Cultivation Facility as a Sampling Manager for the calendar month in which the Transfer occurs.
  3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than one ounce of Medical Marijuana or fifteen grams of Medical Marijuana Concentrate.
  4. The monthly limit established in subparagraph (C)(3) applies to each Sampling Manager, regardless of the number of Medical Marijuana Businesses with which the Sampling Manager is associated.
  5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (C)(3). Before Transferring any Sampling Units, a Medical Marijuana Cultivation Facility shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limits established in subparagraph (C)(3).

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6. A Sampling Manager shall not Transfer any Sampling unit to any other Person, including but not limited to any other Person designated as a Sampling Manager.
- D. Compensation Prohibited. A Medical Marijuana Cultivation Facility may not use Sampling Units to compensate a Sampling Manager.
- E. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.
- F. Acceptable Purposes. Sampling Units shall only be designated and Transferred for purposes of quality control and product development in accordance with section 44-10-502(5), C.R.S.
- G. Recordkeeping Requirements. A Medical Marijuana Cultivation Facility shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule 3-905 – Business Records Required. At a minimum, a Medical Marijuana Cultivation Facility shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of either quality control or product development. A Medical Marijuana Cultivation Facility shall also maintain copies of the Medical Marijuana Cultivation Facility's Standard Operating Procedures provided to Sampling Managers.
- H. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 5-235**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-401(2)(a)(II), 44-10-502(9)(a)-(c), 44-10-502(9.5), and 39-28.8-297, C.R.S. The purpose of this rule is to allow a Medical Marijuana Cultivation Facility to receive Transfers of Retail Marijuana from a Retail Marijuana Cultivation Facility in order to change its designation from “Retail” to “Medical.”

**5-235 – Medical Marijuana Cultivation Facility: Ability to Change Designation of Regulated Marijuana**

- A. Changing Designation from Retail Marijuana to Medical Marijuana. Beginning July 1, 2022, a Medical Marijuana Cultivation Facility may accept Retail Marijuana from a Retail Marijuana Cultivation Facility in order to change its designation from Retail Marijuana to Medical Marijuana pursuant to the following requirements:
1. The Medical Marijuana Cultivation Facility may only accept Retail Marijuana that has passed all required testing;
  2. The Medical Marijuana Cultivation Facility and the Retail Marijuana Cultivation Facility are co-located;
  3. The Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility have at least one identical Controlling Beneficial Owner;

4. The Medical Marijuana Cultivation Facility must receive the Transfer and designate the inventory as Medical Marijuana in the Inventory Tracking System the same day. The Medical Marijuana Cultivation Facility must assign and attach an Inventory Tracking System tag reflecting its Medical Marijuana license number to the Medical Marijuana following completion of the Transfer in the Inventory Tracking System;
  5. After the designation change, the Medical Marijuana cannot be Transferred to the originating or any other Retail Marijuana Business or otherwise treated as Retail Marijuana. The inventory is Medical Marijuana and is subject to all permissions and limitations in the 5-200 series rules;
  6. Both the Medical Marijuana Cultivation Facility and the Retail Marijuana Cultivation Facility must remain at, or under, its inventory limit before and after the Retail Marijuana changes its designation to Medical Marijuana; and
  7. The Transfer and change of designation does not create a right to a refund of any Retail Marijuana excise tax incurred or paid prior to the Transfer and change of designation.
- B. Changing Designation from Medical Marijuana to Retail Marijuana. Beginning January 1, 2023, a Medical Marijuana Cultivation Facility may Transfer Medical Marijuana to a Retail Marijuana Cultivation Facility or Accelerator Cultivator in order to change its designation from Medical Marijuana to Retail Marijuana pursuant to the following requirements:
1. The Medical Marijuana Cultivation Facility may only Transfer Medical Marijuana that has passed all required testing in accordance with the ~~4-2004-100~~ Series Rules – Regulated Marijuana Testing Program;
  2. The Medical Marijuana Cultivation Facility and the Retail Marijuana Cultivation Facility or Accelerator Cultivator share a Licensed Premises in accordance with Rule 3-215, unless:
    - a. The Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility or Accelerator Cultivator have at least one identical Controlling Beneficial Owner; and
    - b. The Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility or Accelerator Cultivator cannot share a Licensed Premises because the Local Licensing Authority or Local Jurisdiction prohibits the operation of either a Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility.
  3. The Medical Marijuana Cultivation Facility must report the Transfer in the Inventory Tracking System the same day that the change in designation from Medical Marijuana to Retail Marijuana occurs;
  4. After the designation change, the Retail Marijuana cannot be Transferred to the originating or any other Medical Marijuana Business or otherwise be treated as



Medical Marijuana. The inventory is Retail Marijuana and is subject to all permissions and limitations in the 6-200 Series Rules;

5. Both the Medical Marijuana Cultivation Facility and the Retail Marijuana Cultivation Facility or Accelerator Cultivator must remain at, or under, its respective inventory limit before and after the Medical Marijuana changes its designation to Retail Marijuana;
6. The Retail Marijuana Cultivation Facility or Accelerator Cultivator shall pay any Retail Marijuana excise tax that is imposed pursuant to section 39-28.8-302, C.R.S.;
7. The Retail Marijuana Cultivation Facility or Accelerator Cultivator shall notify the Local Licensing Authority or Local Jurisdiction where the Medical Marijuana Cultivation Facility and the Retail Marijuana Cultivation Facility or Accelerator Cultivator operate and pay any applicable excise tax on the Retail Marijuana in the manner determined by the Local Licensing Authority or Local Jurisdiction; and
8. Pursuant to the requirements of this subparagraph (B), a Medical Marijuana Cultivation Facility may make a virtual Transfer of Medical Marijuana that is reflected in the Inventory Tracking System even if the Medical Marijuana is not physically moved prior to the change of designation to Retail Marijuana.

#### **Basis and Purpose – 5-240**

The Statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(j.5), 44-10-203(1)(k), 44-10-401(2)(a)(II), and 44-10-502(10)(a)-(c). The purpose of this rule is to allow a Medical Marijuana Cultivation Facility Licensee that plans to cultivate Medical Marijuana outdoors to submit a contingency plan to the Division for approval in anticipation of an Adverse Weather Event.

#### **5-240 Medical Marijuana Cultivation Facility: Contingency Plan for Outdoor Cultivation**

##### **A. Submission of Contingency Plan.**

1. Beginning January 1, 2022, Medical Marijuana Cultivation Facility Licensees that plan to cultivate Medical Marijuana outdoors may submit a contingency plan to the Division for approval in anticipation of an Adverse Weather Event. The Medical Marijuana Cultivation Facility shall also submit a copy of the plan to the Local Licensing Authority in the local jurisdiction where the Licensee operates, and if Transferring Medical Marijuana to the Licensed Premises of a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or an off-premises storage facility outside of that jurisdiction, the Local Licensing Authority in that jurisdiction.
2. A Medical Marijuana Cultivation Facility may submit a contingency plan at any time, but it must be filed at least 7 days prior to taking action pursuant to the contingency plan and must be approved by the State Licensing Authority prior to taking action pursuant to the contingency plan.

3. After initial submission and approval of a contingency plan, a contingency plan must be submitted with the Medical Marijuana Cultivation Facility's license renewal application. Any material change to a contingency plan prior to a renewal application must be submitted for review and approval pursuant to sub~~paragraph~~section (A)(2) above prior to taking action pursuant to the revised contingency plan.
4. The Division shall notify the appropriate Local Licensing Authorities of the approval of the contingency plan.

B. Requirements for Outdoor Contingency Plans.

1. Identification of the type of Adverse Weather Event that the plan applies to, including any deviations based on the type of Adverse Weather Event.
2. Primary Contact. A primary contact for the Medical Marijuana Cultivation Facility must be identified on the contingency plan, including the: name, title, phone number, and email address of the primary contact. The Medical Marijuana Cultivation Facility shall notify the Division of any change to the primary contact or required contact information within 48 hours of the change.
3. Transport Manifest. If the contingency plan provides for the Transfer of Medical Marijuana, a Medical Marijuana Cultivation Facility shall submit a standing transport manifest that could be used by a Licensee upon approval during an Adverse Weather Event if creating a transport manifest through the Inventory Tracking System is impracticable. The standing transport manifest shall include: identification and address of the receiving Licensee.
4. Disclosure of Receiving Licensed Premises.
  - a. Medical Marijuana may only be Transferred to the Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and/or an off-premises storage facility.
  - b. If Medical Marijuana will be Transferred to the Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and/or off-premises storage facility pursuant to a contingency plan, that plan must include the name, ownership, and address of the receiving Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and/or off-premises storage facility, along with a diagram of the proposed receiving Licensed Premises.
  - c. The receiving Licensed Premises shall be an existing location that currently holds an approved state and local license or an off-premises storage facility permit. The receiving Licensee is not required to share any Controlling Beneficial Owners with the Transferring Medical Marijuana Cultivation Facility.
  - d. A Medical Marijuana Cultivation Facility that cultivates outdoors may identify and Transfer Medical Marijuana to no more than five receiving Licensed Premises' as part of a contingency plan.

5. Disclosure of Modifications to the Premises and Security and Surveillance. Proposed modifications to the Licensed Premises and any anticipated impacts to compliance with security and surveillance requirements pursuant to Rules 3-225 (C)(1), 3-225 (C)(5) and 3-225 (C)(6).
- C. License Requirements when Acting Pursuant to a Contingency Plan. To the extent that this sub~~paragraph~~section (C) conflicts with other rule sections, this sub~~paragraph~~section shall control during the time that a Licensee is acting pursuant to a contingency plan.
  1. Notification.
    - a. Notification of action pursuant to an approved contingency plan shall be made to the Division within 24 hours after initiating action pursuant to a contingency plan. A Medical Marijuana Cultivation Facility that cultivates outdoors must also notify the Local Licensing Authority in the local jurisdiction where the ~~L~~icensee operates, and if Transferring Medical Marijuana to the Licensed Premises of a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or an off-premises storage facility outside of that jurisdiction, the Local Licensing Authority in that jurisdiction.
    - b. Notification of ceasing action pursuant to the approved contingency plan shall be made to the Division within 24 hours of returning to normal business operations. If action will continue more than 7 days after initiating action pursuant to a contingency plan the ~~L~~icensee shall contact the Division and explain why they cannot return to normal business operations.
    - c. Any notification shall be made in writing and can be made by email to the Division.
  2. Production Management. Medical Marijuana Transferred to a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility pursuant to a contingency plan is not included in the receiving Licensed Premises' inventory limit until the Medical Marijuana Cultivation Facility acting pursuant to the contingency plan returns to normal business operations.
  3. Modification of Premises. ~~Notification for a modification of a Licensed Premises is not required as part of a contingency plan unless the modification of premises becomes a permanent modification. If that change becomes a permanent change, notification is required pursuant to Rule 2-260. An application for a modification of a Licensed Premises is not required as part of a contingency plan unless the modification or change in premises becomes a permanent modification. If that change becomes a permanent change, a modification of premises application must be submitted within 14 days.~~
  4. Security Requirements. All security and surveillance requirements that apply to a Medical Marijuana Cultivation Facility apply to activities conducted pursuant to the contingency plan. If the contingency plan does not require the Transfer of

Regulated Marijuana to another Licensed Premises, but requires plants to be covered or video surveillance to be otherwise temporarily obstructed, exemptions to the video surveillance requirements in Rules 3-225 (C)(1), 3-225 (C)(5) and 3-225 (C)(6) may be approved as part of the contingency plan.

5. Inventory Tracking Requirements. Licensees must use the Inventory Tracking System to ensure Medical Marijuana is identified and tracked during all times that action is being taken pursuant to a contingency plan. If a Medical Marijuana Cultivation Facility harvests, Transfers, or packages Medical Marijuana it must be fully reconciled in the Inventory Tracking System within 48 hours of initiating action pursuant to the contingency plan.
  - a. Harvest Requirements. If Medical Marijuana is harvested, the weight of Medical Marijuana can be captured on a per harvest level and equally applied to individual plants rather than requiring the initial wet weight of each plant. This initial harvest weight may be captured at a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility upon arrival at the Licensed Premises approved as part of the contingency plan. Harvest Batches and Inventory Tracking System packages must be reported by the Medical Marijuana Cultivation Facility acting pursuant to the contingency plan in the Inventory Tracking System.
  - b. Transport Manifest. The Medical Marijuana Cultivation Facility acting pursuant to the contingency plan must report all Medical Marijuana that is Transferred to a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility on a transport manifest.
    - i. A Licensee may use the approved standing transport manifest during an Adverse Weather Event only when using the Inventory Tracking System is not possible.
    - ii. The Licensee shall manually fill out the dates, times, and individual transporting Medical Marijuana on a copy of the standing transport manifest.
    - iii. The Licensee shall ensure the standing transport manifest and copy of the approved Contingency plan remain in the Licensee's possession during any transport of Medical Marijuana when it is not possible to use an Inventory Tracking System generated transportation manifest at the time of the Adverse Weather Event.
6. Transfers. If Medical Marijuana is Transferred to another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility it is exempted from the packaging and labeling requirements in Rule 3-1005(B).
7. Virtual and Physical Separation. If Medical Marijuana is Transferred to a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail

Marijuana Cultivation Facility and/or off-premises storage facility that inventory must be virtually separated by Harvest Batch and must also be virtually and physically separated from the receiving Licensee's inventory. Harvest Batches must also be clearly identified at the receiving Licensed Premises with the Harvest Batch name and date of harvest.

8. Finishing Product. After Transferring Medical Marijuana to another Licensed Premises, a Medical Marijuana Cultivation Facility may finish that harvest at the receiving Licensed Premises if all Medical Marijuana is accounted for in the Inventory Tracking System and the Licensed Premises is in compliance with all surveillance requirements.
9. Testing. The originating Licensee acting pursuant to a contingency plan is responsible for the submission of Test Batch(es).
  - a. Each Harvest Batch or Production Batch Transferred pursuant to a contingency plan must be submitted for all required tests and is not eligible for a Reduced Testing Allowance or otherwise exempt from required testing.
  - b. Any passing or failing tests of a Harvest Batch or Production Batch Transferred pursuant to a contingency plan will not count for or against a Licensee's Reduced Testing Allowance.

### **5-300 Series – Medical Marijuana Products Manufacturer Facilities**

#### **Basis and Purpose – 5-305**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(d)(I)-(VI), 44-10-313(14), and 44-10-503, C.R.S. The purpose of this rule is to establish a Medical Marijuana Products Manufacturer's license privileges. This Rule 5-305 was previously Rule M 601, 1 CCR 212-1.

#### **5-305 – Medical Marijuana Products Manufacturer: License Privileges**

- A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Products Manufacturer may share and operate at the same Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location. In addition, a Medical Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises as a Marijuana Research and Development Facility so long as:
  1. Each business or business entity holds a separate license;
  2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;

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3. Both the Marijuana Research and Development Facility and the Medical Marijuana Products Manufacturer comply with all terms and conditions of the R&D Co-Location Permit; and
  4. Both the Marijuana Research and Development Facility and the Medical Marijuana Products Manufacturer comply with all applicable rules. See 5-700 Series Rules.
- B. Authorized Transfers. A Medical Marijuana Products Manufacturer is authorized to Transfer Medical Marijuana as follows:
1. Medical Marijuana Concentrate and Medical Marijuana Product.
    - a. A Medical Marijuana Products Manufacturer may Transfer its own Medical Marijuana Product and Medical Marijuana Concentrate to Medical Marijuana Stores, other Medical Marijuana Products Manufacturers, Medical Marijuana Testing Facility, Marijuana Research and Development Facility and Pesticide Manufacturers.
    - b. A Medical Marijuana Products Manufacturer may Transfer Medical Marijuana Product and Medical Marijuana Concentrate to a Medical Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit.
      - i. Prior to any Transfer pursuant to this Rule 5-305(B)(1)(b), a Medical Marijuana Products Manufacturer shall verify Medical Marijuana Cultivation Facility possesses a valid Centralized Distribution Permit. See Rule 5-205 – Medical Marijuana Cultivation Facility: License Privileges.
      - ii. For any Transfer pursuant to this Rule 5-305(B)(1)(b), A Medical Marijuana Products Manufacturer shall only Transfer Medical Marijuana Product and Medical Marijuana Concentrate that is packaged and labeled for Transfer to a patient. See 3-1000 Series Rules.
  2. Medical Marijuana.
    - a. A Medical Marijuana Products Manufacturer may Transfer Medical Marijuana to another Medical Marijuana Products Manufacturer, a Medical Marijuana Store, a Marijuana Research and Development Facility or a Pesticide Manufacturer.
  3. Sampling Units. A Medical Marijuana Products Manufacturer may also Transfer Sampling Units of its own Medical Marijuana Products and Medical Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-503(10), C.R.S., and Rule 5-320.
  4. Decontaminated Medical Marijuana. A Medical Marijuana Products Manufacturer may Transfer Medical Marijuana back to the Medical Marijuana Cultivation Facility that Transferred the Medical Marijuana for Decontamination.

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- C. Manufacture of Medical Marijuana Concentrate, Medical Marijuana Product, Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana Authorized. A Medical Marijuana Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana Concentrate Medical Marijuana Product comprised of Medical Marijuana and other Ingredients intended for use or consumption, such as Edible Medical Marijuana Products, ointments, or tinctures. A Medical Marijuana Products Manufacturer may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana.
1. Hemp Product Authorized. A Medical Marijuana Products Manufacturer that uses Hemp Product as an Ingredient in the manufacture and preparation of Medical Marijuana Product must comply with this subparagraph (C)(1) of this Rule.
- a. Prior to accepting and taking possession of any Hemp Product for use as an Ingredient in a Medical Marijuana Product the Medical Marijuana Products Manufacturer shall verify the following:
- i. That the Hemp Product has passed all required testing pursuant to the ~~4-2004-100~~ Series Rules at a Medical Marijuana Testing Facility; and
- ii. That the Person Transferring the Hemp Product to the Medical Marijuana Products Manufacturer is registered with the Colorado Department of Public Health and Environment as a Hemp Product Manufacturer pursuant to section 25-5-42~~7~~6, C.R.S.
- D. Location Prohibited. A Medical Marijuana Products Manufacturer may not manufacture, prepare, package, store, or label Medical Marijuana Product in a location that is operating as a retail food establishment.
- E. Test Batches Provided for Testing.
1. A Medical Marijuana Products Manufacturer may provide Test Batches of its Medical Marijuana Concentrate or Medical Marijuana Product to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- F. Authorized Marijuana Transport. A Medical Marijuana Products Manufacturer is authorized to utilize a Medical Marijuana Transporter for transportation of its Medical Marijuana Product or Medical Marijuana Concentrate so long as the place where transportation orders are taken is a licensed Medical Marijuana Business and the transportation order is delivered to a Medical Marijuana Business, or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana Products Manufacturer from transporting its own Medical Marijuana or Medical Marijuana Concentrate.
- G. Performance-Based Incentives. A Medical Marijuana Products Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Medical Marijuana Products Manufacturer may not compensate a Sampling Manager using Sampling Units. See Rule 5-320 – Sampling Unit Protocols.

- H. Receipt of Retail Marijuana Concentrate. A Medical Marijuana Products Manufacturer may receive a Transfer of Retail Marijuana Concentrate in compliance with Rules 5-335, 6-335, and 6-730.

### **Basis and Purpose – 5-315**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(i), 44-10-401(2)(a)(III), and 44-10-503, C.R.S. The purpose of this rule is to establish the categories of Medical Marijuana Concentrate that may be produced at a Medical Marijuana Products Manufacturer and establish standards for the production of those concentrate. Nothing in this rule authorizes the unlicensed practice of engineering under Article 25 of Title 12, C.R.S. This Rule 5-315 was previously Rule M 605, 1 CCR 212-1.

### **5-315 – Medical Marijuana Products Manufacturer: Medical Marijuana Concentrate Production.**

- A. Permitted Categories of Medical Marijuana Concentrate Production.
1. A Medical Marijuana Products Manufacturer may produce Physical Separation-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate, and Heat/Pressure-Based Medical Marijuana Concentrate
  2. A Medical Marijuana Products Manufacturer may also produce Solvent-Based Medical Marijuana Concentrate using only the following solvents: butane, propane, CO<sub>2</sub>, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent is expressly prohibited unless it is approved by the Division.
  3. A Medical Marijuana Products Manufacturer may submit a request to the Division to consider the approval of solvents not permitted for use under this Rule during the next formal rulemaking.
- B. General Applicability. A Medical Marijuana Products Manufacturer that engages in the production of Medical Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:
1. Ensure that the space in which any Medical Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule 3-905 – Business Records Required.
  2. Ensure that all applicable sanitary rules are followed. See 3-300 Series Rules.
  3. Ensure that the Sstandard Operating Procedure for each method used to produce a Medical Marijuana Concentrate includes, but need not be limited to, step-by-step instructions on how to safely and appropriately:
    - a. Conduct all necessary safety checks prior to commencing production;
    - b. Prepare Medical Marijuana for processing;
    - c. Extract Cannabinoids and other essential components of Medical Marijuana;



- d. Purge any solvent or other unwanted components from a Medical Marijuana Concentrate,
  - e. Clean all equipment, counters and surfaces thoroughly; and
  - f. Dispose of any waste produced during the processing of Medical Marijuana in accordance with all applicable local, state and federal laws, rules and regulations. See Rule 3-230 – Waste Disposal.
- 4. Establish written and documentable quality control procedures designed to maximize safety for Owner Licensees and Employee Licensees and minimize potential product contamination.
- 5. Establish written emergency procedures to be followed by Owner Licensees or Employee Licensees in case of a fire, chemical spill or other emergency.
- 6. Have a comprehensive training manual that provides step-by-step instructions for each method used to produce a Medical Marijuana Concentrate. The training manual must include, but need not be limited to, the following topics:
  - a. All ~~S~~standard ~~O~~perating ~~P~~rocedures for each method of concentrate production used;
  - b. The Medical Marijuana Products Manufacturer's quality control procedures;
  - c. The emergency procedures;
  - d. The appropriate use of any necessary safety or sanitary equipment;
  - e. The hazards presented by all solvents used as described in the safety data sheet for each solvent;
  - f. Clear instructions on the safe use of all equipment involved in each process and in accordance with manufacturer's instructions, where applicable; and
  - g. Any additional periodic cleaning required to comply with all applicable sanitary rules.
- 7. Provide adequate training to every Owner Licensee or Employee Licensee prior to that individual undertaking any step in the process of producing a Medical Marijuana Concentrate.
  - a. Adequate training must include, but need not be limited to, providing a copy of the training manual for that Licensed Premises and live, in-person instruction detailing at least all of the topics required to be included in the training manual.
  - b. The individual training an Owner Licensee or Employee Licensee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner Licensee

or Employee Licensee can safely produce a Medical Marijuana Concentrate. See Rule 3-905 – Business Records Required.

- c. The Owner Licensee or Employee Licensee that received the training must sign and date a document attesting that he or she can safely implement all Sstandard Operating Procedures, quality control procedures, and emergency procedures, operate all closed-loop extraction systems, use all safety, sanitary and other equipment and understands all hazards presented by the solvents to be used within the Licensed Premises and any additional periodic cleaning required to maintain compliance with all applicable sanitary rules. See Rule 3-905 – Business Records Required.

8. Maintain clear and comprehensive records of the name, signature and Owner Licensee or Employee License number of every individual who engaged in any step related to the creation of a Production Batch of Medical Marijuana Concentrate and the step that individual performed. See Rule 3-905 – Business Records Required.

C. Physical Separation-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate, and Heat/Pressure-Based Medical Marijuana Concentrate.  
Medical Marijuana Products Manufacturer that engages in the production of a Medical Marijuana Concentrate must:

1. Ensure that all equipment, counters, and surfaces used in the production of a Medical Marijuana Concentrate is food-grade including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials, molds and fungi and can be easily cleaned.
2. Ensure that all equipment, counters, and surfaces used in the production of a Medical Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.
3. Ensure that any room in which dry ice is stored or used in processing Medical Marijuana into a Medical Marijuana Concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO<sub>2</sub>.
4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner Licensee or Employee Licensee engaged in the production of a Medical Marijuana Concentrate.
5. Ensure that only finished drinking water and ice made from finished drinking water is used in the production of a Physical Separation-Based Medical Marijuana Concentrate.
6. Ensure that if propylene glycol or glycerin is used in the production of a Food-Based Medical Marijuana Concentrate, then the propylene glycol or glycerin to be used is food-grade.

7. Follow all of the rules related to the production of a Solvent-Based Medical Marijuana Concentrate if a pressurized system is used in the production of a Medical Marijuana Concentrate.
- D. Solvent-Based Medical Marijuana Concentrate. A Medical Marijuana Products Manufacturer that engages in the production of Solvent-Based Medical Marijuana Concentrate must:
1. Obtain a report from an Industrial Hygienist or a Professional Engineer that certifies that the equipment, Licensed Premises and Standard Operating Procedures comply with these rules and all applicable local and state building codes, fire codes, electrical codes and other laws. If a local jurisdiction has not adopted a local building code or fire code or if local regulations do not address a specific issue, then the Industrial Hygienist or Professional Engineer shall certify compliance with the International Building Code of 2012 (<http://www.iccsafe.org>), the International Fire Code of 2012 (<http://www.iccsafe.org>) or the National Electric Code of 2014 (<http://www.nfpa.org>), as appropriate. Note that this Rule does not include any later amendments or editions to each Code. The Division has maintained a copy of each code, which are available to the public;
  - a. Flammable Solvent Determinations. If a Flammable Solvent is to be used in the processing of Medical Marijuana into a Medical Marijuana Concentrate, then the Industrial Hygienist or Professional Engineer must:
    - i. Establish a maximum amount of Flammable Solvents and other flammable materials that may be stored within that Licensed Premises in accordance with applicable laws, rules, and regulations.
    - ii. Determine what type of electrical equipment, which may include but need not be limited to outlets, lights, junction boxes, must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored in accordance with applicable laws, rules, and regulations.
    - iii. Determine whether a gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules, and regulations.
    - iv. Determine whether fire suppression system must be installed within the room in which Medical Marijuana Concentrate are to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules, and regulations.
  - b. CO<sub>2</sub> Solvent Determination. If CO<sub>2</sub> is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO<sub>2</sub> gas monitoring system must be installed within

the room in which Medical Marijuana Concentrate are to be produced or CO<sub>2</sub> is stored, and if required the system's specifications, in accordance with applicable laws, rules, and regulations.

- c. Exhaust System Determination. The Industrial Hygienist or Professional Engineer must determine whether a fume vent hood or exhaust system must be installed within the room in which Medical Marijuana Concentrate are to be produced, and if required the system's specifications, in accordance with applicable laws, rules, and regulations.
  - d. Material Change. If a Medical Marijuana Products Manufacturer makes a Material Change to its equipment or a concentrate production procedure, in addition to all other requirements, it must obtain a report from an Industrial Hygienist or Professional Engineer re-certifying its ~~S~~standard ~~O~~perating ~~P~~rocedures and, if changed, its equipment as well.
  - e. Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Medical Marijuana Products Manufacturer by the designer or manufacturer of any equipment used in the processing of Medical Marijuana into a Medical Marijuana Concentrate.
  - f. Records Retention. A Medical Marijuana Products Manufacturer must maintain copy of all reports received from an Industrial Hygienist and Professional Engineer on its Licensed Premises. Notwithstanding any other law, rule, or regulation, compliance with this Rule is not satisfied by storing these reports outside of the Licensed Premises. Instead the reports must be maintained on the Licensed Premises until the Licensee ceases production of Medical Marijuana Concentrate.
2. Ensure that all equipment, counters, and surfaces used in the production of a Solvent-Based Medical Marijuana Concentrate must be food-grade and must not react adversely with any of the solvents to be used in the Licensed Premises. Additionally, all counters and surface areas must be constructed in a manner that reduces the potential development of microbials, molds, and fungi and can be easily cleaned;
  3. Ensure that the room in which Solvent-Based Medical Marijuana Concentrate shall be produced must contain an emergency eye-wash station;
  4. Ensure that a professional grade, closed-loop extraction system capable of recovering the solvent is used to produce Solvent-Based Medical Marijuana Concentrate;
    - a. UL or ETL Listing.
      - i. If the system is UL or ETL listed, then a Medical Marijuana Products Manufacturer may use the system in accordance with the manufacturer's instructions.

- ii. If the system is UL or ETL listed but the Medical Marijuana Products Manufacturer intends to use a solvent in the system that is not listed in the manufacturer's instructions for use in the system, then, prior to using the unlisted solvent within the system, the Medical Marijuana Products Manufacturer must obtain written approval for use of the non-listed solvent in the system from either the system's manufacturer or a Professional Engineer after the Professional Engineer has conducted a peer review of the system. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
    - iii. If the system is not UL or ETL listed, then there must a designer of record. If the designer of record is not a Professional Engineer, then the system must be peer reviewed by a Professional Engineer. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
  - b. Ethanol or Isopropanol. A Medical Marijuana Products Manufacturer Facility need not use a professional grade, closed-loop system extraction system capable of recovering the solvent for the production of a Solvent-Based Medical Marijuana Concentrate if ethanol or isopropanol are the only solvents being used in the production process.
- 5. Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;
  - a. A Medical Marijuana Products Manufacturer must obtain a safety data sheet for each solvent used or stored on the Licensed Premises. A Medical Marijuana Products Manufacturer must maintain a current copy of the safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule 3-905 – Business Records Required.
  - b. A Medical Marijuana Products Manufacturer is prohibited from using denatured alcohol to produce a Medical Marijuana Concentrate, unless the denaturant is an approved solvent listed in Rule 5-315(A)(2) and the alcohol and the denaturant meet all other requirements set forth in this Rule.
- 6. Ensure that all Flammable Solvents or other flammable materials, chemicals and waste are stored in accordance with all applicable laws, rules and regulations. At no time may a Medical Marijuana Products Manufacturer store more Flammable Solvent on its Licensed Premises than the maximum amount established for that Licensed Premises by the Industrial Hygienist or Professional Engineer;
- 7. Ensure that the appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner

Licensee or Employee Licensee engaged in the production of a Solvent-Based Medical Marijuana Concentrate; and

8. Ensure that a trained Owner Licensee or Employee Licensee is present at all times during the production of a Solvent-Based Medical Marijuana Concentrate whenever an extraction process requires the use of pressurized equipment.
9. Medical Marijuana Products Manufacturers Engaged in the Remediation of Medical Marijuana for elemental impurities. Medical Marijuana Products Manufacturers engaged in the Remediation of Medical Marijuana for elemental impurities shall:
  - a. Implement effective cleaning procedures, additional testing plans, and other measures that will be performed to prevent cross contamination.
    - i. If potentially contaminated equipment, ingredients, or solvents used in the Remediation process are used for processing other 'non Remediated' material, the subsequent Production Batch made using the equipment, ingredients, or solvent must then be tested for elemental impurities, and the Production Batch made using that equipment, ingredients, or solvents is not eligible for testing exemptions through a Reduced Testing Allowance or otherwise exempt from required testing.
    - ii. Manufacturers must document the equipment and lots of ingredients/solvents used in Remediation to ensure this requirement is met.
  - b. Register as a hazardous waste generator, obtain a U.S. Environmental Protection Agency ID number for manifesting hazardous waste, and must have a disposal contract in place with a hazardous waste management company prior to attempting Remediation.
  - c. Have a staff member who has received basic training in hazardous waste identification, storage, and disposal procedures, or hire a consultant who satisfies this criteria.
  - d. Regardless of which type of analyte, if the Medical Marijuana flower, wet whole plant, or trim has failed elemental impurities testing, the Licensee must implement Standard Operating Procedures to ensure:
    - i. That contaminated material is stored in a labelled container identifying the material as potentially hazardous, and that the container seals in such a way to prevent the risk of cross contamination or inhalation of dusts.
    - ii. That when material is removed from the sealed container and handled in any fashion (preparation, the extraction or other Remediation process, wasting, etc.), any workers exposed to dusts or particulates generated from the material must wear appropriate personal protective equipment (PPE), including at

minimum: gloves, American National Standards Institute (ANSI) Z87.1 safety glasses, and a respirator rated to protect them from airborne dusts or particulates that may contain elemental impurities. Respirators should utilize National Institute for Occupational Safety and Health rated particulate filters of sufficient grade to prevent exposure to airborne dusts that could contain elemental impurities.

- A. Workers utilizing a respirator must comply with applicable Occupational Safety and Health Administration regulations regarding respirator use before handling contaminated material. This includes receiving respirator clearance from a qualified professional and passing a respirator fit test before using a respirator.
- e. Additional forms of environmental airborne particulate control, such as industrial air filtration systems, handling material inside of enclosures, etc. must be implemented by the Licensee to minimize the risk of exposure or cross contamination of contaminated dusts.
- f. These steps must be documented in the Licensee's respiratory protection program that all employees exposed to plant material or waste products contaminated with elemental impurities must be trained on.
- g. The Licensee must establish and train employees on ~~S~~standard ~~O~~perating ~~P~~rocedures designed to safely handle this contaminated material and prevent cross contamination.
- h. Mercury poses additional workplaces hazards since it is easily volatilized and since mercury vapor is highly toxic. Before attempting to remediate any Regulated Marijuana flower, wet whole plant, or trim that has failed elemental impurities testing and contains mercury, Licensees must additionally:
  - i. Work with a certified industrial hygienist to develop and implement some form of monitoring program that is capable of detecting mercury vapor concentrations in the areas where material contaminated with mercury will be processed and can be used to generate time weighted average exposures to mercury vapor. The monitoring system must be sufficient to ensure airborne concentrations of mercury do not exceed Occupational Safety and Health Administration Permissible Exposure Limits for Airborne Contaminants.
  - ii. Have a certified industrial hygienist approve the Licensee's air handling system for managing mercury vapors in a fashion that is compliant with the Occupational Safety and Health Administration, and other applicable federal, state, and local regulations.

- iii. Utilize a National Institute for Occupational Safety and Health rated half mask respirator with cartridges rated specifically for mercury vapor.
  - i. A Licensee must ensure their processes and safety practices comply with applicable federal, state, and local environmental health and safety regulations.
10. Medical Marijuana Products Manufacturer Engaged in the Remediation of Medical Marijuana for Microbial Contamination. Medical Marijuana Products Manufacturers engaged in the Remediation of Medical Marijuana for microbial contamination shall:
- a. Implement effective cleaning procedures, additional testing plans, and other measures that will be performed to prevent cross contamination.
  - b. Ensure that contaminated material is stored in a labeled container identifying the material as potentially hazardous, and that the container seals in such a way to prevent the risk of cross contamination or inhalation of dusts.
  - c. Ensure that when material is removed from the sealed container and handled in any fashion (preparation, the extraction or other Remediation process, wasting, etc.), any workers exposed to dusts or particulates generated from the material must wear appropriate personal protective equipment (PPE), including at minimum: gloves, American National Standards (ANSI) Z87.1 safety glasses, and a respirator rated to protect them from airborne dusts or particulates that may contain elemental impurities. Respirators should utilize National Institute for Occupational Safety and Health rated particulate filters of sufficient grade to prevent exposure to airborne dusts that could contain elemental impurities.
    - i. Workers utilizing a respirator must comply with applicable Occupational Safety and Health Administration regulations regarding respirator use before handling contaminated material. This includes receiving respirator clearance from a qualified professional and passing a respirator fit test before using a respirator.
  - d. Implement additional forms of environmental airborne particulate control, such as industrial air filtration systems, handling material inside of enclosures, etc. must be implemented by the Licensee to minimize the risk of exposure or cross contamination of contaminated dusts.
  - e. These steps must be documented in the Licensee's respiratory protection program that all employees exposed to plant material or waste products contaminated with elemental impurities must be trained on.
  - f. The Licensee must establish and train employees on Standard Operating Procedures designed to safely handle this contaminated material and prevent cross contamination.



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- g. The Licensee must ensure their processes and safety practices comply with applicable federal, state, and local environmental health and safety regulations.
- E. Ethanol and Isopropanol. If a Medical Marijuana Products Manufacturer only produces Solvent-Based Medical Marijuana Concentrate using ethanol or isopropanol at its Licensed Premises and no other solvent, then it shall be considered exempt from the requirements in paragraph D of this Rule and instead must follow the requirements in paragraph C of this Rule. Regardless of which rule is followed, the ethanol or isopropanol must be food grade or at least 99% pure and denatured alcohol cannot be used. The Medical Marijuana Products Manufacturer shall comply with contaminant testing required in Rule ~~4-2154-120(C)(3)~~.
- F. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 5-320**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-401(2)(a)(III), and 44-10-503 C.R.S. The purpose of this rule is to establish the circumstances under which a Medical Marijuana Products Manufacturer may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado's regulated Medical Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager may receive in a calendar month and imposes inventory tracking, reporting, and recordkeeping requirements on a Medical Marijuana Products Manufacturer that Transfer Sampling Units. This Rule 5-320 was previously Rule M 606, 1 CCR 212-1.

**5-320 – Medical Marijuana Products Manufacturer: Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, a Medical Marijuana Products Manufacturer may designate no more than five Sampling Managers in the Inventory Tracking System.
  - 1. Only management personnel of the Medical Marijuana Products Manufacturer who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  - 2. An individual designated as a Sampling Manager by a Medical Marijuana Products Manufacturer must possess a valid patient registry card.
  - 3. An individual may be designated as a Sampling Manager by more than one Medical Marijuana Business.
  - 4. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.
  - 5. A Medical Marijuana Products Manufacturer that wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling Manager ~~S~~standard ~~O~~perating ~~P~~rocedures that explain the requirements of

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section 44-10-503(10), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 5-320. See also Rule 3-905 – Business Records Required. A Medical Marijuana Products Manufacturer shall maintain and update such Sstandard Operating Procedures as necessary to reflect accurately any changes in the relevant statutes and rules.

B. Sampling Unit Limits. Only one Sampling Unit may be designated per Production Batch. A Sampling Unit shall not be designated until the Production Batch has satisfied the testing requirements in ~~4-2004-100~~ Series Rules – Regulated Marijuana Testing Program.

1. A Sampling Unit of Edible Medical Marijuana Product shall not exceed one serving size. Before designating any Sampling Units, a Medical Marijuana Products Manufacturer shall establish the specific serving size for each Edible Medical Marijuana Product it produces and maintain a record of the serving size in its Sstandard Operating Procedures provided pursuant to subparagraph (A)(5).
2. A Sampling Unit of non-Edible Medical Marijuana Product shall not exceed the equivalent of one serving size. Before designating any Sampling Units, a Medical Marijuana Products Manufacturer shall establish the specific serving size for each non-Edible Medical Marijuana Product it produces and maintain a record of the serving size in its Sstandard Operating Procedures provided pursuant to subparagraph (A)(5).
3. A Sampling Unit of Medical Marijuana Concentrate shall not exceed one-quarter of one gram; except that a Sampling Unit of Medical Marijuana Concentrate which has the intended use of being delivered in a vaporized form shall not exceed one-half of one gram.

C. Transfer Restrictions.

1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Medical Marijuana Products Manufacturer as a Sampling Manager for the calendar month in which the Transfer occurs.
3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than:
  - a. Fourteen servings of Medical Marijuana Products; and
  - b. Fifteen grams of Medical Marijuana Concentrate.
4. The monthly limit established in subparagraph (C)(3) applies to each Sampling Manager, regardless of the number of Medical Marijuana Businesses with which the Sampling Manager is associated.

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5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (C)(3). Before Transferring any Sampling Units, a Medical Marijuana Products Manufacturer shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limit established in subparagraph (C)(3).
  6. A Sampling Manager shall not Transfer any Sampling Unit to any other Person, including but not limited to any Person designated as a Sampling Manager.
- D. Compensation Prohibited. A Medical Marijuana Products Manufacturer may not use Sampling Units to compensate a Sampling Manager.
- E. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.
- F. Acceptable Purposes. Sampling Units shall only be designated and Transferred for purposes of quality control and product development in accordance with section 44-10-503(10), C.R.S.
- G. Record keeping requirements. A Medical Marijuana Products Manufacturer shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule 3-905 – Business Records Required. At a minimum, A Medical Marijuana Products Manufacturer shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of either quality control or product development. A Medical Marijuana Products Manufacturer shall also maintain copies of the Medical Marijuana Products Manufacturer's Standard Operating Procedures provided to Sampling Managers.
- H. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 5-325**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(i), 44-10-203(3)(b), 44-10-203(2)(d), 44-10-203(3)(a), 44-10-401(2)(a)(III), 44-10-503, and 44-10-701(3)(c), C.R.S. The purpose of this rule is to define requirements for manufacture of Audited Product for administration by: (1) metered dose nasal spray, (2) vaginal administration, or (3) rectal administration which may raise public health concerns. This rule defines audit, insurance, minimum product requirements, minimum production process requirements, and pre-production testing requirements for Medical Marijuana Products Manufacturers that manufacture Audited Products. The purpose of this rule further recognizes that Alternative Use Product not within an intended use identified in Rule 3-1015 may raise public health concerns that outweigh its manufacturer or Transfer entirely or that require additional safeguards to protect public health and safety prior to manufacturer or Transfer. This rule identifies general requirements for Medical Marijuana Products Manufacturer to seek an Alternative Use Designation from the State Licensing Authority to manufacture any type of Medical Marijuana Product that is not within an intended use identified in Rule 3-1015. This Rule 5-325 was previously Rule M 607, 1 CCR 212-1.

**5-325 – Medical Marijuana Products Manufacturer: Audited Product and Alternative Use Product**

- A. General Rule. A Medical Marijuana Products Manufacturer shall not Transfer Audited Product to a Medical Marijuana Store, another Medical Marijuana Products Manufacturer, or a Medical Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit except in accordance with all requirements of this Rule 5-325. The requirements of this Rule 5-325 are in addition to all other Rules that apply to Medical Marijuana Products Manufacturers; except where the context otherwise clearly requires this Rule 5-325 controls.
- B. Audited Products – Mandatory Audit Prior to Transfer. Following submission of an independent third-party audit to the Division and to the Local Licensing Authority as required by this Rule, a Medical Marijuana Products Manufacturer may Transfer Audited Product with an intended use of: (1) metered dose nasal spray, (2) vaginal administration, or (4) rectal administration to another Medical Marijuana Products Manufacturer, a Medical Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit, or a Medical Marijuana Store.
1. A written audit report from an independent third-party auditor that was completed within the last twenty-four (24) months shall be submitted to the Division and to the Local Licensing Authority: (i) before the first Transfer of Audited Product to any Medical Marijuana Store, (ii) prior to Transfer of any Audited Product following a Material Change to any Sstandard Operating Procedure or master formulation record regarding the Audited Product, and (iii) with the Medical Marijuana Products Manufacturer's renewal application if the Medical Marijuana Products Manufacturer will Transfer Audited Product after renewal.
  2. The independent third-party audit shall be performed by either a certified quality auditor or a certified GMP auditor. The Medical Marijuana Products Manufacturer shall be responsible for all costs associated with obtaining the independent third-party audit.
  3. The independent third-party written audit report shall include the following minimum requirements:
    - a. The independent third-party auditor's qualifications and an attestation that the certified quality auditor or certified GMP auditor has no conflict of interest;
    - b. Establish that the Medical Marijuana Products Manufacturer and the Audited Product meet all requirements of this Rule 5-325, including but not limited to the specific requirements of this Rule 5-325(C), 5-325(D), 5-325(E), 5-325(G), and 5-325(H);
    - c. Verify the written Sstandard Operating Procedure(s) for Audited Product include sufficient and detailed step-by-step instructions on how to produce the Audited Product in a manner that prevents contamination and protects the public health and safety;

- d. Verify, based upon a physical inspection, the manufacture of Audited Product by the Medical Marijuana Products Manufacturer adheres to all applicable ~~S~~standard ~~O~~perating ~~P~~rocedures;
  - e. Verify, based upon a physical inspection, of any Licensed Premises that such Licensed Premises complies with the requirements of this Rule 5-325(E), including any Limited Access Area where the Audited Product is to be manufactured;
  - f. Include the independent third-party auditor's findings;
  - g. Include the plan of correction identifying any corrective actions and/or preventative actions implemented as a result of the findings of the independent third-party audit; and
  - h. Include the independent third-party auditor's assessment that the Medical Marijuana Products Manufacturer demonstrated compliance with all requirements of Rule 5-325 and with the requirements of all ~~S~~standard ~~O~~perating ~~P~~rocedures, master formulation records, and Batch manufacturing records that apply to the Audited Product.
- C. Products Liability Insurance. Any Medical Marijuana Products Manufacturer that intends to Transfer Audited Product shall first obtain products liability insurance providing coverage for liability arising from manufacture or Transfer of Audited Product and shall provide an unredacted certificate of product liability insurance to the Division and the independent third-party auditor.
- D. Audited Product Requirements. Audited Product shall meet the following minimum product requirements:
  - 1. Inactive Ingredients. Audited Product must meet the requirements outlined in Rule 3-335 – Production of Regulated Marijuana Products.
    - a. If the Audited Product contains a fungicidal or bactericidal Ingredient listed in, and with a concentration that is at or below the maximum concentration permitted in, the Federal Food and Drug Administration Inactive Ingredients Database, <https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>, the Audited Product is not required to undergo microbial contaminant testing required by Rules ~~4-2154-115 and 4-120~~.
  - 2. Required Product Development Testing. The Medical Marijuana Products Manufacturer must establish the Audited Product meets the following through independent third-party testing:
    - a. The Audited Product must deliver the amount of each ~~e~~Cannabinoid identified on the label throughout the entire volume of the Audited Product using the intended delivery device and in accordance with the instructions provided by the Medical Marijuana Products Manufacturer, as demonstrated by testing at a Medical Marijuana Testing Facility.

- i. For Audited Product with an intended use of metered dose nasal spray, compliance with this requirement shall be established by test results verifying the delivered dose of each **eC**annabinoid identified on the label using the methods described in The United States Pharmacopeia Physical Test and Determination Chapter 601, *Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers*.
    - ii. For Audited Product with an intended use of either vaginal administration or rectal administration, compliance with this testing requirement shall be established by test results demonstrating that each **eC**annabinoid identified on the label is within +/- 15% of the amount identified on the label.
  - b. The expiration date identified on the label of the Audited Product is appropriate when the Audited Product is stored at room temperature, as demonstrated by testing from a Medical Marijuana Testing Facility.
  - c. Identification of all non-marijuana derived Ingredients and constituents in the Audited Product at concentrations of 1%, which verification is obtained from one or more of the following:
    - i. Testing by a Medical Marijuana Testing Facility;
    - ii. Testing by a laboratory that is ISO 17025 accredited but is not a Medical Marijuana Testing Facility, except that no Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product may be Transferred to such a laboratory; and/or
    - iii. One or more certificate(s) of analysis from the manufacturer of any Ingredient or constituent included in the Audited Product.
- E. Additional Production Requirements for Audited Product. In addition to all other requirements applicable to Medical Marijuana Products Manufacturers, a Medical Marijuana Products Manufacturer that manufactures and Transfers Audited Product shall meet the following additional requirements:
  - 1. Personnel Training. All personnel directly involved in the manufacture and handling of Audited Product must be trained, must demonstrate competency, and must undergo annual refresher training, which shall be documented and maintained at the Medical Marijuana Products Manufacturer's Licensed Premises. Personnel directly involved in the manufacture and handling of Audited Product must be trained and demonstrate proficiency in hand hygiene, cleaning and sanitizing, performing necessary calculations, measuring and mixing, and documenting the manufacturing process including master formulation records and batch manufacturing records.
  - 2. Facility Requirements. A Medical Marijuana Products Manufacturer must have a space that is specifically designated for the manufacture of Audited Products that is designed and operated to prevent cross contamination from other areas of the

Licensed Premises. The surfaces, walls, floors, fixtures, shelving, work surfaces, and cabinets in this designated area must be non-porous and cleanable.

3. Cleaning and Sanitizing. A Medical Marijuana Products Manufacturer must clean and sanitize surfaces where Audited Product is manufactured and handled on a regular basis and at a minimum, work surfaces and floors must be cleaned and sanitized daily. All other surfaces must be cleaned and sanitized at least every three months. A Medical Marijuana Products Manufacturer must clean and sanitize all surfaces when a spill occurs and when surfaces, floors, and walls are visibly soiled.
4. Hand Hygiene. Hand hygiene is required when entering and re-entering any area where Audited Product is manufactured and handled. Hand hygiene includes washing hands and forearms up to the elbows with soap and water for at least 30 seconds followed by drying completely with disposable towels. Alcohol hand sanitizers alone are not sufficient.
  - a. Gloves are required to be worn for all mixing activities. Other garb such as shoe covers, head and facial hair covers, face masks, and gowns must be worn as appropriate to protect Employee Licensees and/or prevent contamination of the Audited Product.
5. Equipment. Mechanical, electronic, and other types of equipment used in mixing, measuring, or testing of Audited Product must be inspected prior to use and verified for accuracy at the frequency recommended by the manufacturer, and at least annually.
6. Ingredient Quality. All Ingredients used to manufacture Audited Product must be handled and stored in accordance with the manufacturer's instructions. Ingredients that lack a manufacturer's expiration date shall not be used if a reasonable manufacturer would not use the Ingredient or after 1 year from the date of receipt, whichever period is shorter.
7. Master Formulation Record. A master formulation record must be prepared and maintained for each unique Audited Product a Medical Marijuana Products Manufacturer manufactures. A master formulation record must include at least the following information:
  - a. Name of the Audited Product;
  - b. Ingredient identities and amounts;
  - c. Specifications on the delivery device (if applicable);
  - d. Complete instructions for preparing the Audited Product, including equipment, supplies, and description of the manufacturing steps;
  - e. Quality control procedures; and
  - f. Any other information needed to describe the Medical Marijuana Products Manufacturer's production and ensure its repeatability.



8. Batch Manufacturing Records. A batch manufacturing record shall be created for each Production Batch of Audited Product. This record shall include at the least the following information:
- a. Name of the Audited Product;
  - b. Master formulation record reference for the Audited Product;
  - c. Date and time of preparation of the Audited Product;
  - d. Production Batch number;
  - e. Signature or initials of individuals involved in each manufacturing step;
  - f. Name, vendor, or manufacturer, Production Batch number, and expiration date of each Ingredient;
  - g. Weight or measurement of each Ingredient;
  - h. Documentation of quality control procedures;
  - i. Any deviations from the master formulation record, and any problems or errors experienced during the manufacture; and
  - j. Total quantity of the Audited Product manufactured.
- F. Audited Product Testing. For each Production Batch, the Audited Product shall undergo all required testing in the ~~4-2004-100~~ Series Rules for Medical Marijuana Product and/or Audited Product. ~~See also Rule 4-115—Regulated Marijuana Testing Program: Sampling and Testing Program.~~
- G. Packaging and Labeling of Audited Product. Audited Product must be packaged and labeled in accordance with all requirements of the 3-1000 Series Rules regarding packaging and labeling for Transfer to a patient prior to any Transfer.
- H. Adverse Event Reporting. A Medical Marijuana Products Manufacturer must report Adverse Health Events pursuant to Rule 3-920.
- I. Alternative Use Designation – Any Other Method of Consumption or Administration. A Medical Marijuana Products Manufacturer shall not Transfer to a Medical Marijuana Store, to another Medical Marijuana Products Manufacturer, or a Medical Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit any Medical Marijuana Concentrate or Medical Marijuana Product that is not within any intended use identified in Rule 3-1015(B) until it applies for and receives an Alternative Use Designation from the State Licensing Authority in consultation with the Colorado Department of Public Health and Environment. In the process of applying for an Alternative Use Designation, the Medical Marijuana Products Manufacturer shall work with the Division and the Colorado Department of Public Health and Environment to determine whether the proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when particular independent review factors, safeguards, and tests are in place. The following are minimum requirements for any application for an Alternative Use Designation:



1. The Medical Marijuana Products Manufacturer shall identify provisions of this Rule 5-325 that apply to its Alternative Use Product, any proposed additional or alternative requirements, and how any proposed alternatives protect public health and safety. The Medical Marijuana Products Manufacturer shall also provide any additional information as may be requested by the Division, in consultation with the Colorado Department of Public Health and Environment.
  2. The Medical Marijuana Products Manufacturer bears the burden of proving its proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when the identified independent review factors, safeguards and tests are in place.
  3. A Medical Marijuana Products Manufacturer seeking an Alternative Use Designation shall cooperate with the Division. Failure to cooperate with the Division is grounds for denial of an Alternative Use Designation.
  4. The granting of an Alternative Use Designation shall rest in the discretion of the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment. The State Licensing Authority may in his or her discretion deny an Alternative Use Designation where the Medical Marijuana Products Manufacturer does not meet the burden established in this Rule 5-325.
- J. Alternative Use Designation – Packaging and Labeling Requirements. If the Division recommends, and the State Licensing Authority grants, an Alternative Use Designation, the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment shall provide the Medical Marijuana Products Manufacturer the appropriate statement of intended use label to be affixed to the Alternative Use Product, and any additional or distinct packaging and labeling requirements applicable to the Alternative Use Product. See Rules 3-1010 and 3-1015.
- K. Required Records. A Medical Marijuana Products Manufacturer manufacturing or Transferring Audited Product and/or Alternative Use Product shall maintain accurate and comprehensive records on the Licensed Premises regarding the manufacturing process, a list of all active and inactive Ingredients used in the Audited Product and/or Alternative Use Product, and such other documentation as required by this Rule 5-325. See Rule 3-905 – Business Records Required.

**5-330 – Recall of Medical Marijuana Concentrate or Medical Marijuana Product—  
~~Repealed effective January 1, 2021.~~**

**5-400 Series – Medical Marijuana Testing Facilities**

**Basis and Purpose – 5-405**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-313(14), 44-10-401(2)(a)(IV), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1), and 44-10-504(2), C.R.S. The purpose of this rule is to establish the license privileges of a Medical Marijuana Testing Facility. This Rule 5-405 was previously Rule M 701.5, 1 CCR 212-1.

**5-405 - Medical Marijuana Testing Facilities: License Privileges**

- A. Licensed Premises. A separate License is required for each specific Medical Marijuana Testing Facility and only those privileges granted by the Marijuana Code and any rules promulgated pursuant to it may be exercised on the Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Medical Marijuana Testing Facility may share and operate at the same Licensed Premises with a Retail Marijuana Testing Facility with identical ownership.
- B. Testing of Medical Marijuana Authorized. A Medical Marijuana Testing Facility may accept Test Batches of Medical Marijuana from Medical Marijuana Businesses for testing and research purposes only, which purposes may include the provision of testing services for Test Batches submitted by a Medical Marijuana Business for the purpose of product development. The Division may require a Medical Marijuana Business to submit a Test Batch of Medical Marijuana to a Medical Marijuana Testing Facility upon demand.
- C. Testing of Hemp Product Authorized.
1. A Medical Marijuana Testing Facility may accept and test samples of Hemp Products.
  2. Before a Medical Marijuana Testing Facility accepts a sample of Hemp Product, the Medical Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Colorado Department of Public Health and Environment as a Hemp Product Manufacturer pursuant to section 25-5-42~~7~~6, C.R.S.
  3. A Medical Marijuana Testing Facility is responsible for entering and tracking samples of Hemp Product in the inventory tracking system pursuant to the 3-800 Series Rules.
  4. A Medical Marijuana Testing Facility shall be permitted to test Hemp Product only in the category(ies) that the Medical Marijuana Testing Facility is certified to perform testing in pursuant to Rule 5-415 – Medical Marijuana Testing Facilities: Certification Requirements.
  5. A Medical Marijuana Testing Facility may provide the results of any testing performed on Hemp Product to the Person submitting the sample of Hemp Product.
  6. Nothing in these rules shall be construed to require a Medical Marijuana Testing Facility to accept and/or test samples of Hemp Product.
- D. Testing Medical Marijuana for Patients in Research Project. A Medical Marijuana Testing Facility is authorized to accept ~~S~~samples of Medical Marijuana from an individual person for testing under only the following conditions:
1. The individual person is:
    - a. A currently registered patient pursuant to section 25-1.5-106, C.R.S.; and

- b. A participant in an approved clinical or observational study conducted by a Marijuana Research and Development Facility.
  - 2. The Medical Marijuana Testing Facility shall require the patient to produce a valid patient registry card and a current and valid photo identification. See Rule 3-405(A) – Acceptable Forms of Identification.
  - 3. The Medical Marijuana Testing Facility shall require the patient to produce verification on a form approved by the Division from the Marijuana Research and Development Facility that the patient is a participant in an approved clinical or observational Research Project conducted by the Marijuana Research and Development Facility and that the testing will be in furtherance of the approved Research Project.
  - 4. A primary caregiver may transport Medical Marijuana on behalf of a patient to the Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility shall require the following documentation before accepting Medical Marijuana from a primary caregiver:
    - a. A copy of the patient registry card and valid photo identification for the patient;
    - b. A copy of the caregiver's registration with the State Department of Health pursuant to section 25-1.5-106, C.R.S. and a current and valid photo identification, see Rule 3-405 – Acceptable Forms of Identification; and
    - c. A copy of the Marijuana Research and Development Facility's verification on a form approved by the Division that the patient is participating in an approved clinical or observational Research Project being conducted by the Marijuana Research and Development Facility and that the testing will be in furtherance of the approved Research Project.
  - 5. The Medical Marijuana Testing Facility shall report all results of testing performed pursuant to this Paragraph (C.5) to the Marijuana Research and Development Facility identified in the verification form submitted pursuant to Paragraph (D)(3) or (4)(c), or as otherwise directed by the approved Research Project being conducted by the Marijuana Research and Development Facility. Testing result reporting shall conform with the requirements under these Rules.
- E. Product Development Authorized. A Medical Marijuana Testing Facility may develop Medical Marijuana Product, but is not authorized to engage in the manufacturing privileges described in section 44-10-503, C.R.S. and Rule 5-305 – Medical Marijuana Products Manufacturer: License Privileges.
- F. Transferring Test Batches to Another Licensed and Certified Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility may Transfer Test Batches to another Medical Marijuana Testing Facility for testing. All laboratory reports provided to or by a Medical Marijuana Business, or to a patient or primary caregiver must identify the Medical Marijuana Testing Facility that actually conducted the test.

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- G. Authorized Medical Marijuana Transport. A Medical Marijuana Testing Facility is authorized to utilize a licensed Medical Marijuana Transporter to transport Test Batches of Medical Marijuana for testing, in accordance with the Marijuana Code and the rules adopted pursuant thereto, between the originating Medical Marijuana Business requesting testing services and the destination Medical Marijuana Testing Facility performing testing services. Nothing in this Rule requires a Medical Marijuana Business to utilize a Medical Marijuana Transporter to transport Test Batches of Medical Marijuana for testing.
- H. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 5-410**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1), and 44-10-504(2), 44-10-701, and 35-61-105.5, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Medical Marijuana Testing Facility. This Rule 5-410 was previously Rule M 702, 1 CCR 212-1.

**5-410 – Medical Marijuana Testing Facilities: General Limitations or Prohibited Acts**

- A. Prohibited Financial Interest. A Person who is a Controlling Beneficial Owner or Passive Beneficial Owner of a Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturing Facility, Medical Marijuana Store, Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, or a Retail Marijuana Store shall not be a Controlling Beneficial Owner or Passive Beneficial Owner of a Medical Marijuana Testing Facility.
- B. Conflicts of Interest. The Medical Marijuana Testing Facility shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the Medical Marijuana Testing Facility's testing processes or results, or that may diminish public confidence in the competency, impartiality, and integrity of the Medical Marijuana Testing Facility's testing processes or results. At a minimum, employees, owners or agents of a Medical Marijuana Testing Facility who participate in any aspect of the analysis and results of a Test Batch Sample are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any on-going financial, employment, personal or business relationship with the Medical Marijuana Business that provided the Test Batch Sample.
- C. Transfer of Medical Marijuana Prohibited. A Medical Marijuana Testing Facility shall not Transfer Medical Marijuana to a Medical Marijuana Business, a consumer, a patient, or primary caregiver, except that a Medical Marijuana Testing Facility may Transfer a Test Batch Sample to another Medical Marijuana Testing Facility.
- D. Destruction of Received Test Batches. A Medical Marijuana Testing Facility shall properly dispose of all Test Batches it receives, that are not Transferred to another Medical

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Marijuana Testing Facility, after all necessary tests have been conducted and any required period of storage. See Rule 3-230 – Waste Disposal.

- E. ~~Repealed. Sample Rejection. A Medical Marijuana Testing Facility shall reject any Sample where the condition of the Sample at receipt indicates that that the Sample may have been tampered with.~~
- F. Medical Marijuana Business Requirements Applicable. A Medical Marijuana Testing Facility shall be considered a Licensed Premises. A Medical Marijuana Testing Facility shall be subject to all requirements applicable to Medical Marijuana Businesses.
- G. Medical Marijuana Testing Facility – Inventory Tracking System Required. A Medical Marijuana Testing Facility must use the Inventory Tracking System to ensure all Test Batches containing Medical Marijuana are identified and tracked from the point they are Transferred from a Medical Marijuana Business, a patient, or a patient's primary caregiver through the point of Transfer, destruction, or disposal. The Inventory Tracking System reporting shall include the results of any tests that are conducted on Medical Marijuana. See Rule 3-805 – Regulated Marijuana Business: Inventory Tracking System, Rule 3-825 – Reporting and Inventory Tracking System, and Rule 5-405(D)(5). The Medical Marijuana Testing Facility must have the ability to reconcile its Test Batch Sample records with the Inventory Tracking System and the associated transaction history. See Rule 3-905 – Business Records Required and Rule 3-825 Reporting and Inventory Tracking
- H. Hemp Testing Prohibited. A Medical Marijuana Testing Facility shall not perform testing on Hemp.
- I. Testing of Unregistered or Untracked Hemp Products Prohibited. A Medical Marijuana Testing Facility is authorized to accept or test Hemp Product only if (1) the entity providing the Test Batches of Hemp Product is registered and regulated pursuant to Article 4 or Title 25, C.R.S., and (2) the Hemp Product being submitted for testing is tracked in the Inventory Tracking System.
- J. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~
- K. Standard Minimum Weight of Test Batches and Photo Documentation.
  - 1. Standard Minimum Weight of Test Batches.
    - a. Medical Marijuana and Medical Marijuana Concentrate. A Medical Marijuana Testing Facility must establish a standard minimum weight of Medical Marijuana and Medical Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.
    - b. Medical Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana. Medical Marijuana Testing Facilities must establish a standard number of Sample Increments required to be included in each Test Batch of Medical Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana for every type of test that it conducts. See Rule 4-225 – Regulated Marijuana Testing Program – Sampling Procedures.

2. Photo Documentation of Test Batches.

- a. A Medical Marijuana Testing Facility shall digitally photograph each Test Batch it receives to document the Sample Increments collected, condition of the Test Batch, and compliance with these Rules.
- b. The Medical Marijuana Testing Facility must maintain the digital photographs of each Test Batch as business records. See Rule 3-905 - Required Business Records.
- c. Upon request by the Division, a Medical Marijuana Testing Facility must provide copies of the digital photographs of Test Batches within seven days of the request unless a different deadline is agreed to.

L. Rejection of Test Batches.

- 1. A Medical Marijuana Testing Facility shall not accept a Test Batch that is smaller than its standard minimum amount.
- 2. A Medical Marijuana Testing Facility shall not accept a Test Batch that does not contain the minimum number and weight of Sample Increments, or the Medical Marijuana Testing Facility has reason to believe it was not collected in accordance with Test Batch collection requirements in Rule 4-225.
- 3. If a Medical Marijuana Testing Facility suspects or has reason to suspect a Sample Increment or Test Batch has been adulterated, the Medical Marijuana Testing Facility must:
  - a. Notify the Division; and
  - b. Quarantine the Sample Increment or Test Batch for a minimum of 48 hours from the time of notification to the Division before proceeding with any testing.

**Basis and Purpose – 5-415**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish a frame work for certification for Medical Marijuana Testing Facilities. This Rule 5-415 was previously Rule M 703, 1 CCR 212-1.

**5-415 – Medical Marijuana Testing Facilities: Certification Requirements**

- A. Certification Types. If certification in a testing category is required by the Division, then the Medical Marijuana Testing Facility must be certified in the category in order to perform that type of testing.
  - 1. Microbials;
  - 2. Mycotoxins;
  - 3. Residual solvents;

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4. Pesticides;
  5. THC and other Cannabinoid potency;
  6. Elemental Impurities; and
  7. Water Activity.
- B. In order to obtain certification for Pesticide testing, a Medical Marijuana Testing Facility must also obtain certification for mycotoxin testing.
- C. Certification Procedures. The Medical Marijuana Testing Facility certification program is contingent upon successful on-site inspection, successful participation in Proficiency Testing, and ongoing compliance with the applicable requirements in this Rule.
1. Certification Inspection. A Medical Marijuana Testing Facility must be inspected prior to initial certification and annually thereafter by an inspector approved by the Division.
  2. Standards for Certification. A Medical Marijuana Testing Facility must meet standards of performance, as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: personnel qualifications, ~~S~~standard ~~O~~operating ~~P~~procedure manual, analytical processes, Proficiency Testing, quality control, quality assurance, security, chain of custody, ~~Test Batch~~~~Sample~~ retention, space, records, and results reporting. In addition, a Medical Marijuana Testing Facility must be accredited under the International Organization for Standardization/International Electrotechnical Commission 17025:2005 Standard, or any subsequent superseding ISO/IEC 17025 standard. In order to obtain certification in a testing category from the Division, the Medical Marijuana Testing Facility's scope of accreditation must specify that particular testing category.
    - a. Subsequent to initial approval of a Medical Marijuana Testing Facility License, the Division may grant provisional certification if the Applicant has not yet obtained ISO/IEC 17025:2005 accreditation, but meets all other Division requirements. Such provisional certification shall be for a period not to exceed twelve months.
  3. Personnel Qualifications.
    - a. Laboratory Director. A Medical Marijuana Testing Facility must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. See Rule 5-420 – Medical Marijuana Testing Facilities: Personnel.
    - b. Employee Competency. A Medical Marijuana Testing Facility must ~~have a written and documented system to~~ evaluate and document that employees are competent to perform all aspects of laboratory work which the employee is responsible.~~the competency in performing authorized tests for employees.~~



- ~~i4. Prior to independently analyzing Test Batches, testing personnel employees must demonstrate acceptable performance on precision, accuracy, and specificity, ~~reportable ranges, blanks, and unknown challenge samples (pProficiency Test samples or internally generated quality controls).~~~~
    - ~~ii. Continued employee competency assessment must be conducted annually and may be conducted using either internally or externally prepared competency tests.~~
    - ~~iii. Qualitative and quantitative information regarding the analytes being assessed shall remain unknown to the employee(s) performing the assessment until the competency assessment has been completed.~~
4. Standard Operating Procedure Manual. A Medical Marijuana Testing Facility must have a written ~~s~~Standard ~~e~~Operating ~~p~~Procedure manual meeting the minimum standards set forth in these rules detailing the performance of all methods employed by the facility used to test the analytes it reports and made available for testing analysts to follow at all times.
  - a. The current laboratory director must approve, sign and date each procedure. If any modifications are made to those procedures, the laboratory director must approve, sign and date the revised version prior to use.
  - b. A Medical Marijuana Testing Facility must maintain a copy of all ~~s~~Standard ~~e~~Operating ~~p~~Procedures to include any revised copies for a minimum of three years. See Rule 5-450 – Medical Marijuana Testing Facilities: Records Retention and Rule 3-905 – Business Records Required.
  - ~~c. A Medical Marijuana Testing Facility must inform the Colorado Department of Public Health and Environment and the Division of any major method changes to Standard Operating Procedures pertaining to certified analytical methods, prior to implementing the changes. Major method changes include, but are not limited to: modifications to sample preparation, column type, enrichment media, solvent(s) used, instrumentation or instrumentation parameters.~~
5. Analytical Processes. A Medical Marijuana Testing Facility must maintain a listing of all analytical methods used and all analytes tested and reported. The Medical Marijuana Testing Facility must provide this listing to the Division upon request.
6. Proficiency Testing. A Medical Marijuana Testing Facility must successfully participate in a Division approved Proficiency Testing program in order to obtain and maintain certification.
7. Quality Assurance and Quality Control. A Medical Marijuana Testing Facility must establish and follow a quality assurance and quality control program to ensure sufficient monitoring of laboratory processes and quality of results reported.



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8. Security. A Medical Marijuana Testing Facility must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.
9. Chain of Custody. A Medical Marijuana Testing Facility must establish a system to document the complete chain of custody for Test Batches from receipt through disposal.
10. Space. A Medical Marijuana Testing Facility must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state and local requirements.
11. Records. A Medical Marijuana Testing Facility must establish a system to retain and maintain all required records. See Rule 5-450 – Medical Marijuana Testing Facilities: Records Retention and Rule 3-905 – Business Records Required.
12. Results Reporting. A Medical Marijuana Testing Facility must establish processes to ensure results are reported in a timely and accurate manner. See Rule 3-825 – Reporting and Inventory Tracking System. A Medical Marijuana Testing Facility's process may require that the Regulated Marijuana Business remit payment for any test conducted by the Testing Facility prior to entry of the results of that test into the Inventory Tracking System. A Medical Marijuana Testing Facility's process established under this subparagraph (12) must be maintained on the Licensed Premises of the Medical Marijuana Testing Facility.
13. Conduct While Seeking Certification. A Medical Marijuana Testing Facility, and its agents and employees, shall provide all documents and information required or requested by the Colorado Department of Public Health and Environment and its employees, and the Division and its employees in a full, faithful, truthful, and fair manner.

D. ~~Repealed. Violation Affecting Public Safety. A violation of this Rule may be considered a license violation affecting public safety.~~

**Basis and Purpose – 5-420**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish personnel standards for the operation of a Medical Marijuana Testing Facility. This Rule 5-420 was previously Rule M 704, 1 CCR 212-1.

**5-420 – Medical Marijuana Testing Facilities: Personnel**

- A. Laboratory Director. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Medical Marijuana Testing Facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in this Rule.

1. The laboratory director may also serve as a supervisory analyst, quality assurance manager or testing analyst, or a combination of these roles.~~both~~, for a Medical Marijuana Testing Facility. If the laboratory director is serving as a combination of roles, a secondary review of data and quality documentation must be performed by qualified personnel that did not generate the data, report, or quality documentation.
  2. The laboratory director for a Medical Marijuana Testing Facility must meet one of the following qualification requirements:
    - a. The laboratory director must be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body;
    - b. The laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body;
    - c. The laboratory director must hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
    - d. The laboratory director must hold a bachelor's degree in one of the natural sciences and have at least seven years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.
- B. What the Laboratory Director May Delegate. The laboratory director may delegate the responsibilities assigned under this Rule to a qualified supervisory analyst or quality assurance manager, provided that such delegation is made in writing and a record of the delegation is maintained. See Rule 3-905 – Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.
- C. Responsibilities of the Laboratory Director. The laboratory director must:
1. Ensure that the Medical Marijuana Testing Facility has adequate space, equipment, materials, and controls available to perform the tests reported;
  2. Establish and adhere to a written Sstandard Operating Procedure used to perform the tests reported;
  3. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test

performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

4. Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;
5. Ensure that the test methodologies selected have the capability of providing the quality of results required for the level of testing the laboratory is certified to perform;
6. Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
7. Ensure that testing analysts perform the test methods as required for accurate and reliable results;
8. Ensure that the laboratory is enrolled in and successfully participates in a Division approved Proficiency Testing program;
9. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
10. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
11. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;
12. Ensure that reports of test results include pertinent information required for interpretation;
13. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;
14. Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results;
15. Ensure that prior to testing any samplesTest Batches, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;
16. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process Test Batches, perform test procedures and report test results promptly and

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proficiently, avoid actual and apparent conflicts of interest, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

17. Ensure that an approved Sstandard Operating Procedure manual is available to all personnel responsible for any aspect of the testing process; ~~and~~
  18. Specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for Sample processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results; ~~and~~
  19. Ensure internal and vendor audits are completed regularly at a frequency established by the Regulated Marijuana Testing Facility; and
  20. Ensure that quality anomalies and Nonconformances are regularly reviewed and documented as open or completed. Open Nonconformances should be reviewed at least annually, and; high impact Nonconformances must be reviewed at least monthly.
- D. Change in Laboratory Director. In the event that the laboratory director leaves employment at the Medical Marijuana Testing Facility, the Medical Marijuana Testing Facility shall:
1. Provide written notice to the Colorado Department of Public Health and Environment and the Division within seven days of the laboratory director's departure; and
  2. Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.
  3. The Medical Marijuana Testing Facility must hire a permanent laboratory director within 60 days from the date of the previous laboratory director's departure.
  4. Notwithstanding the requirement of subparagraph (D)(3), the Medical Marijuana Testing Facility may submit a waiver request to the Division Director to receive an additional 60 days to hire a permanent laboratory director provided that the Medical Marijuana Testing Facility submits a detailed oversight plan along with the waiver request.
- E. Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and two years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the two years of full-time laboratory experience.
- F. Laboratory Testing Analyst.

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1. Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst or:
  - a. Have a bachelor's degree in one of the natural sciences; or
  - b. Have an associate degree in a laboratory science from an accredited institution; or
  - c. Have education and training equivalent to that specified in subparagraph (F)(1) of this Rule that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include:
    - i. 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and twelve semester hours of chemistry, biology, or cannabis laboratory sciences in any combination; and
    - ii. Have a laboratory training that includes at least three months documented laboratory training each testing category in which the individual performs testing; or
  - d. Have at least five years of full time experience in laboratory testing and have laboratory training that includes at least three months of documented laboratory training in each testing category in which the individual performs testing.
2. Responsibilities. In order to independently perform any test for a Medical Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

G. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

H. ~~Quality Assurance Manager. Quality assurance manager must meet one of the qualifications for laboratory director or have at least a bachelor's degree in one of the natural sciences and two years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the two years of full-time laboratory experience.~~

**Basis and Purpose – 5-425**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish ~~S~~standard ~~O~~perating ~~P~~rocedures manual ~~standards-expectations~~ for the operation of a Medical Marijuana Testing Facility. This Rule 5-425 was previously Rule M 705, 1 CCR 212-1.

**5-425 – Medical Marijuana Testing Facilities: Standard Operating Procedure Manual**

- A. A ~~s~~S~~e~~standard ~~e~~O~~p~~erating ~~p~~P~~r~~cedure manual must include, but need not be limited to, procedures for:

1. Test Batch receiving ~~and handling, including: accessioning, recording and reporting discrepancies identified during Test Batch receiving and storage, and identifying, rejecting, and reporting unacceptable Test Batches; security of Test Batches; aliquot and extract records; and disposal of Test Batches;~~
  - a. ~~All Test Batches must be tested as received, must not be inappropriately manipulated, and tested in a manner that ensures results are representative of the Test Batch as it is received.~~
2. ~~Repealed. Test Batch accessioning;~~
3. ~~Repealed. Test Batch storage;~~
4. ~~Repealed. Identifying, rejecting, and reporting unacceptable Test Batches;~~
5. ~~Repealed. Recording and reporting discrepancies during Test Batch receiving and accessioning;~~
6. ~~Repealed. Security of Test Batches, aliquots and extracts and records;~~
7. Validating a new or revised method prior to testing of Test Batches to include: accuracy, precision, analytical sensitivity, analytical specificity (interferences), LOD, LOQ, and verification of the reportable range;
8. Test Batch preparation, including but not limited to, sub-sampling for testing, homogenization, and aliquoting Test Batches to avoid contamination and carry-over;
9. Test Batch archive retention to assure stability, as follows:
  - a. For Test Batches submitted for testing other than Pesticide contaminant testing, Test Batch archive retention for 14 days;
  - b. For Test Batches submitted for Pesticide contaminant testing, Test Batch retention for 90 days.
10. ~~Repealed. Disposal of Test Batches;~~
11. ~~Repealed. The theory and principles behind each assay;~~
12. ~~Repealed. Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to National Institute of Standards of Technology ("NIST");~~
13. ~~Repealed. Special requirements and safety precautions involved in performing assays;~~
14. ~~Repealed. Frequency and number of control and calibration materials;~~
15. ~~Repealed. Recording and reporting assay results;~~
16. ~~Repealed. Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;~~
17. ~~Repealed. Pertinent literature references for each method;~~

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18. ~~Repealed. Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;~~
  19. ~~Repealed. Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns;~~
  20. A documented system for reviewing the results of testing calibrators, controls, standards, and Test Batch results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results and are corrective actions implemented and documented, ~~and does the laboratory contact the requesting entity;~~
  21. Policies and procedures to follow when Test Batches are requested for referral and testing by another certified Medical Marijuana Testing Facility or an approved local state agency's laboratory;
  22. Investigating and documenting existing or potential Nonconformances and implementing Corrective Actions and/or Preventive Actions;
  23. Contacting the requesting entity about existing Nonconformances; ~~and~~
  24. Retesting or additional analyses of Test Batches, including but need ed not be limited to, when it is appropriate to retest or perform an additional analysis of the Test Batch, when it is appropriate for the requesting entity to request retesting (e.g., after failing Pesticide testing or elemental impurity testing on Regulated Marijuana flower, trim, shake, or wet whole plant as permitted by Rule 4-240(B); and 4-135(D) and 4-135(D.1)).
  25. Procedures for internal audits, including the frequency and the documentation of the results. Internal audit reports must include, but need not be limited to: audit title, scope, name(s) of personnel and auditors, audit date, introduction, problems noted, findings, observations/opportunities noted, date issued.
- B. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~
- C. Individual Standard Operating Procedures for analytical methods must include, but need not be limited to:
1. Responsibilities of staff;
  2. SOP history and summary of revisions;
  3. The theory and principles behind each assay;
  4. Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to a certified vendor that meets the accreditation requirements of the laboratory, such as National Institute of Standards of Technology (NIST), ISO 17034, or other similar entities;
  5. Special requirements and safety precautions involved in performing assays;



6. Frequency and number of control and calibration materials;
7. Recording and reporting assay results;
8. Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;
9. Pertinent literature references for each method;
10. Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;
11. Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns.
12. Protocol and criteria for calculating and applying measurement uncertainty;
13. Policies and procedures including the titles and required training of individuals responsible for the transport of biohazardous materials (when applicable); and
14. Procedures and/or protocols for general laboratory upkeep and cleaning, including specific procedures to eliminate or avoid cross-contamination.

**Basis and Purpose – 5-430**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish analytical processes standards for the operation of a Medical Marijuana Testing Facility. This Rule 5-430 was previously Rule M 706, 1 CCR 212-1.

**5-430 – Medical Marijuana Testing Facilities: Analytical Processes**

- A. Gas Chromatography (“GC”). A Medical Marijuana Testing Facility using GC must:
1. Document the conditions of the gas chromatograph, including the detector response;
  2. Perform and document preventive maintenance as required by the manufacturer and SOPs;
  3. Ensure that records are maintained and readily available to the staff operating the equipment;
  4. Document the performance of new columns before use;
  5. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;
  6. Establish criteria of acceptability for variances between different aliquots and different columns; and
  7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system-;



8. Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing Test Batches; and
9. Monitor and document the performance of the instrument each day of testing.

B. Gas Chromatography Mass Spectrometry ("GC/MS"). A Medical Marijuana Testing Facility using GC/MS must:

1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
2. Document the changes of septa as specified in the Sstandard Operating Procedure;
3. Document liners being cleaned or replaced as specified in the Sstandard Operating Procedure;
4. Ensure that records are maintained and readily available to the staff operating the equipment;
5. Maintain records of mass spectrometer errie tuning;
6. Establish written criteria for an acceptable mass spectrometer mass spectrometer tuning parameters rie tune;
7. Document eCorrective Actions if a mass -spectrometer errie tune is unacceptable;
8. Monitor analytic analyses to check for contamination and carry-over;
9. Use selected ion monitoring within each run to assure that the laboratory compares ion ratios and retention times between calibrators, controls and Test Batches samples for identification of an analyte;
10. Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
11. Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;
12. Define the criteria for designating qualitative results as positive;
13. When a library is used to qualitatively identify an analyte, the identity of the analyte must be confirmed before reporting results by comparing the relative retention time and mass spectrum to that of a known standard or control run on the same system; and
14. Evaluate the performance of the instrument after routine and preventive maintenance (e.g. clipping or replacing the column or cleaning the source) prior to analyzing subject Test Batches :-
15. Monitor gas phase standards frequently by comparison to the initial calibration curve. Fresh standards must be prepared if this check exceeds 20% drift. Gas standards must be replaced after one week or as recommended by the standard

manufacturer. Alternatively, standards must be replaced after an established period of time for which the Regulated Marijuana Testing Facility has demonstrated the stability of the standard;

16. Monitor non-gas standards frequently by comparison to the initial calibration. Fresh standards must be prepared if this check exceeds 20% drift. Non-gas standards must be replaced after one month for working standards and three months for opened stocks or as recommended by the standard manufacturer. Alternatively, standards must be replaced after an established period of time for which the Regulated Marijuana Testing Facility has demonstrated the stability of the standard; and

17. Monitor and document the performance of the instrument each day of testing.

C. Immunoassays. A Medical Marijuana Testing Facility using Immunoassays must:

1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Test Batch~~sample~~ is not included within the sample types and/or matrices~~types of samples~~ approved by the manufacturer; and
4. Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.

D. ~~Repealed. Thin Layer Chromatography ("TLC"). A Medical Marijuana Testing Facility using TLC must:~~

- ~~1. Apply unextracted standards to each thin layer chromatographic plate;~~
- ~~2. Include in their written procedure the preparation of mixed solvent systems, spray reagents and designation of lifetime;~~
- ~~3. Include in their written procedure the storage of unused thin layer chromatographic plates;~~
- ~~4. Evaluate, establish, and document acceptable performance for new thin layer chromatographic plates before placing them into service;~~
- ~~5. Verify that the spotting technique used precludes the possibility of contamination and carry-over;~~
- ~~6. Measure all appropriate R<sub>F</sub> values for qualitative identification purposes;~~
- ~~7. Use and record sequential color reactions, when applicable;~~
- ~~8. Maintain records of thin layer chromatographic plates; and~~
- ~~9. Analyze an appropriate matrix blank with each batch of samples analyzed.~~

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E. High Performance Liquid Chromatography ("HPLC"). A Medical Marijuana Testing Facility using HPLC must:

1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Monitor and document the performance of the HPLC instrument each day of testing;
4. Evaluate the performance of new columns before use;
5. Create written standards for acceptability when eluting solvents are recycled;
6. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay; ~~and~~
7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system; ~~and~~
8. Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing Test Batches.

F. Liquid Chromatography Mass Spectroscopy ("LC/MS"). A Medical Marijuana Testing Facility using LC/MS must:

1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Maintain records of mass spectrometer ~~erie~~ tuning;
4. Document ~~e~~Corrective actions if a mass ~~-~~spectrometer ~~erie~~ tune is unacceptable;
5. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
6. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;
7. Compare two transitions and retention times between calibrators, controls and Test Batches ~~samples~~ within each run;
8. Document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument; ~~and~~
9. Evaluate the performance of the instrument when changes in: source, source conditions, eluent, or column are made prior to reporting test results; ~~and~~ and.

10. Ensure ion ratios do not exceed plus or minus 30% relative to the average of calibration standards from the same sequence.

F.5. Inductively Coupled Plasma Mass Spectrometry (ICP/MS). A Medical Marijuana Testing Facility using ICP must:

1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Establish written criteria for acceptable mass spectrometer tuning parameters;
4. Maintain records of mass spectrometer tuning;
5. Document Corrective Actions if mass spectrometer tune is unacceptable;
6. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
7. Document the monitoring of the response (counts per second) of the internal standard to ensure consistency over time of the analytical system;
8. Compare mass-to-charge ratios between calibrators, controls and Test Batches within each run;
9. Monitor analyses to check for contamination and carry-over;
10. Evaluate and document the performance of the instrument after routine and preventive maintenance and when changes in: source, conditions, or detector are made prior to reporting test results; and
11. Monitor and document the performance of the instrument each day of testing.

G. Microbial Assays. A Medical Marijuana Testing Facility using microbial assays must:

1. Perform and document preventive maintenance as required by the manufacturer and ~~s~~Standard ~~e~~Operating ~~p~~Procedures;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Test Batch~~test sample~~ submitted for testing is not included within sample types and/or matrices~~the types of Test Batches~~ approved by the manufacturer;
4. Verify the method at the regulatory ~~action levels~~limit for each analyte. Verification at the qualitative presence/absence limit shall include a fractional recovery study. ~~unless otherwise completed by the manufacturer and approved by an independent scientific body.~~

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5. Include controls for each ~~analytical run of batch of t~~Test Batches samples. Quantitative microbial methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;
6. For molecular methods, the Medical Marijuana Testing Facility shall include controls for each individual analytical run. Quantitative molecular methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;
7. PCR-based and qPCR-based methods must include validated internal amplification controls;
8. Microbial methods must include steps to confirm presumptive positive results; confirmation methods may be molecular or cultural or both. Confirmation methods must include quality controls that match the organism which is being confirmed; ~~and-~~
9. Verify the stated Limit of Detection of qualitative assays through “dilution to extinction” studies in which the calculated extinction dilution is corroborated with cultural data.

H. Water Activity. A Medical Marijuana Testing Facility analyzing water activity must:

1. Perform and document preventive maintenance as required by the manufacturer and ~~s~~Standard ~~e~~Operating ~~p~~Procedures;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Specify all unique method parameters, such as temperature, test sample surface area, volatile compound interferences, including but not limited to temperature;
4. Evaluate the performance of the method after routine and preventive maintenance prior to analyzing the Test Batch; ~~and~~
5. Establish criteria for acceptable instrument performance.

I. Analytical Methodology Validation. A Medical Marijuana Testing Facility must validate new methodology and revalidate any changes to approved methodology prior to ~~analyzing/testing~~ Test Batches. ~~A Medical Marijuana Testing Facility must:~~

1. The laboratory must implement a performance-based measurement system for the selected methodology and validate the method following good laboratory practices in accordance with AOAC, United States Pharmacopeia (USP), United States Food and Drug Administration (FDA) United States Department of Agriculture (USDA), or other reputable validation guidelines and methodology prior to reporting results. Validation, verification, or matrix extension of ~~Implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices prior to reporting results. Validation of other or new~~ methodology must include when applicable, but is not limited to:

- a. Verification of Accuracy<sub>i</sub>;
  - b. Verification of Precision<sub>i</sub>;
  - c. Verification of Analytical Sensitivity<sub>i</sub>;
  - d. Verification of Analytical Specificity<sub>i</sub>;
  - e. Verification of the LOD<sub>i</sub>;
  - f. Verification of the LOQ<sub>i</sub>;
  - g. Verification of the Reportable Range<sub>i</sub>;
  - h. Identification of Interfering Substances<sub>i</sub>;
  - i. Exclusivity, which means the specificity of the test method for validating microbial testing methods. It evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms;
  - j. Inclusivity, which means, related to microbiological method validation, the sensitivity of the test method. It evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness;
  - k. Verification of Recovery. The laboratory shall take action to remediate recovery issues where matrix effects affect recovery at  $>\pm 20\%$  of the theoretical value;
  - l. Measurement Uncertainty. Subsequent to initial validation, measurement uncertainty must be re-evaluated at least annually or whenever method modifications are made. "Measurement uncertainty" is defined as a parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.
2. Validation of the other or new methodology must be documented.
  3. Prior to use, other or new methodology must have a ~~s~~Standard ~~e~~Operating ~~p~~Procedure approved and signed by the laboratory director.
  4. Testing analysts must have documentation of competency assessment prior to testing ~~samples~~Test Batches.
  5. Any changes to the approved other or new methodology must be revalidated and documented prior to testing ~~samples~~Test Batches.
  6. The demonstration of testing validity must ensure consistent, accurate and reproducible analytical performance in the matrices tested by the laboratory.
  7. Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of Rule 5-440(B).

8. To the extent practicable, laboratory test methods must meet AOAC International standard method performance requirements.
9. For qualitative methods, a minimum of three spiking/naturally occurring levels of target analyte must be included assessing accuracy, precision and specificity per each matrix validated (microbiological methods shall be considered accurate/precise if fractional results are obtained when limits are <1 CFU preanalytical portion): one negative level in which no analyte is present, one low level at which analyte is present at the regulatory limit and one high level at which the analyte is present at 10x the regulatory limit.
10. For quantitative methods, laboratories must include a minimum of four spiked levels or more, covering the analytical range must be included assessing accuracy, precision and specificity per each matrix validated: one negative level in which no analyte is present, one low level at which analyte is present at the regulatory limit, one medium level for which the analyte is present at a concentration close to the middle calibrator and one high level at which the analyte is present at the upper level of the calibration.
11. For qualitative methods, at least two levels must be included for the negative and high level spikes - at least ten replicates must be included at the fractional level, per analyte, per matrix.
12. For quantitative methods, at least two replicates must be performed at each spiked level per each matrix validated.
13. Software must be validated prior to testing samples, including but not limited to: analytical software, application programming interface(s) (APIs), laboratory information management systems (LIMS), etcetera.
14. Validation or verification of methodology must be documented in a validation report. The validation report shall include, but is not limited to, the following:
  - a. Validation plan;
  - b. Introduction and summary;
  - c. Materials, to include identification of Certified Reference Materials, and preparation methods;
  - d. Method parameters;
  - e. Raw data, including instrument raw data such as chromatograms, for each test method and each instrument, if any;
  - f. Instrument calibration data, if any;
  - g. Data, calculations, and results;
  - h. Method Acceptability Criteria performance data;
  - i. Interlaboratory comparison;

j. Verification of spreadsheets and/or laboratory information management system;

k. Conclusion and discussion; and

l. References.

15. Laboratories must validate or verify instrumentation and methodology immediately and prior to use following a change in location.

J. Testing and Validation of Complex Matrices. A Medical Marijuana Testing Facility must include a variety of matrices as part of the validation/verification process. During method validation/verification, a Medical Marijuana Testing Facility must:

1. Select matrices which best represent each category of products to be tested as listed in Rule ~~4-2154-115(D)~~. The laboratory shall independently determine the category of matrix a product falls within; properties to consider include fat content, ~~c~~cannabinoid content, pH, salt content, sugar content, water activity, the presence of known chemical compounds, microbial flora and antimicrobial compounds.
2. Perform a new matrix validation, prior to reporting results, on matrices which are either a new category of matrix or are considerably different from the original matrix validated within the category.
  - a. For example, the Medical Marijuana Testing Facility intends to receive the topical product “bath bombs” for testing, but previous validation studies for topical product included lotion and massage oil. A new validation should be performed for the product prior to testing since salt content and other properties differ vastly from the original matrices validated.
3. Perform a matrix verification (a client matrix spike or similar consisting of the target analyte(s) at the time of analysis) on matrices submitted for testing which differ slightly from those initially validated but which fall within a category already validated.
  - a. For example, the Medical Marijuana Testing Facility laboratory receives a new edible type matrix for testing (snickerdoodle cookies) but previous validation included gummies and hard candy. A spike of a portion of the submitted material must be analyzed prior to, or at the time of, sample analysis.

K. All Test Batches and Hemp Product must be tested as received, must not be manipulated, and must be tested in a manner that ensures results are representative of ~~sample the Test Batch~~ as it is received.

L. ~~Repealed Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

M. General Quantitative Method Quality Parameters: A Medical Marijuana Testing Facility must meet the following Acceptability Criteria for quantitative method controls.



1. Chemical quality controls must not exceed plus or minus 10.0% recovery of the target value when analytes are greater than or equal to 100 parts per million (ppm).
2. Chemical quality controls must not exceed plus or minus 30.0% for residual solvent gas standards; or plus or minus 20.0% recovery of the target value when analytes are greater than or equal to 10 ppm.
3. Chemical quality controls must not exceed plus or minus 30.0% for residual solvent gas standards; or plus or minus 20.0% recovery of the target value when analytes are greater than or equal to 1.0 ppm.
4. Chemical quality controls must not exceed plus or minus 30.0% for residual solvent gas standards; or plus or minus 20.0% recovery of the target value when analytes are greater than or equal to 100 parts per billion (ppb) or greater.
5. Chemical quality controls must not exceed plus or minus 40.0% recovery of the target value when analytes are greater than or equal to 10 ppb.
6. Chemical quality controls must not exceed plus or minus 60.0% recovery of the target value when analytes are greater than or equal to 1.0 ppb.
7. Microbiology quality controls must not exceed plus or minus 20.0% recovery of the target value.

N. General Laboratory Equipment. A Medical Marijuana Testing Facility must:

1. Track, verify, and apply correction factors where applicable;
2. Perform annual calibration, monthly spore ampule checks, and daily temperature checks of autoclaves;
3. Verify pipette calibration on a monthly basis across the volume range the pipette is used;
4. Perform annual calibration of balances and analytical weights. Balances must be verified across the appropriate mass range on each day of use;
5. Perform verification of laboratory dispensers on each day of use;
6. Perform annual gravimetric verification of volumetric glassware;
7. Calibrate pH meters on each day of use with buffers across the analytical range (i.e. 4, 7, 10);
8. Perform annual calibration of thermometers to a NIST traceable reference thermometer. Correction factors must be applied when such a factor could impact the final result; and
9. Calibrate analytical timers annually.

**Basis and Purpose – 5-435**

**Marijuana Enforcement Division**

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The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish a proficiency testing program for Medical Marijuana Testing Facilities. This Rule 5-435 was previously Rule M 707, 1 CCR 212-1.

**5-435 – Medical Marijuana Testing Facilities: Proficiency Testing**

- A. Proficiency Testing Required. A Medical Marijuana Testing Facility must participate in a Proficiency Testing Program for each approved category in which it seeks certification under Rule 5-415 – Medical Marijuana Testing Facilities: Certification Requirements.
- B. Participation in Designated Proficiency Testing Event. If required by the Division as part of certification, the Medical Marijuana Testing Facility must have successfully participated in a proficiency test in the category for which it seeks certification, within the preceding 12 months.
  - 1. The laboratory shall have the Proficiency Testing provider send results concurrently to the Colorado Department of Public Health and Environment and the Division or the laboratory shall provide the Proficiency Testing results to the Colorado Department of Public Health and Environment and the Division within 3 business days after the laboratory receives notification of their results.
- C. Continued Certification. To maintain continued certification, a Medical Marijuana Testing Facility must participate in the designated proficiency testing program with continued satisfactory performance as determined by the Division as part of certification. The Division may designate a local agency, state agency, or independent third-party to provide Proficiency Testing.
- D. Analyzing Proficiency Testing Samples. A Medical Marijuana Testing Facility must analyze Proficiency Testing Samples using the same procedures with the same number of replicate analyses, standards, testing analysts, and equipment as used in its ~~S~~standard ~~O~~perating ~~P~~rocedures.
- E. Proficiency Testing Attestation. The laboratory director and all testing analysts that participated in a Proficiency Testing must sign corresponding attestation statements.
- F. Laboratory Director Must Review Results. The laboratory director must review and evaluate all Proficiency Testing results.
- G. Remedial Action. A Medical Marijuana Testing Facility must take and document remedial action when a score of less than 100% is achieved on any test during a Proficiency Test. Remedial action documentation must include a review of Test Batches tested and results reported since the last successful proficiency testing event. A requirement to take remedial action does not necessarily indicate unsatisfactory participation in a Proficiency Testing event.
- H. Unsatisfactory Participation in Proficiency Testing Event. Unless the Medical Marijuana Testing Facility positively identifies at least 80% of the target analytes tested, participation in the Proficiency Testing will be considered unsatisfactory. A positive identification must include accurate quantitative and qualitative results as applicable. Any

false positive results reported will be considered an unsatisfactory score for the proficiency testing event.

- I. Consequence of Unsatisfactory Participation in Proficiency Testing Event. Unsuccessful participation in a Proficiency Testing event may result in limitation, suspension or revocation of Rule 5-415 certification. A Medical Marijuana Testing Facility's certification may be suspended for the relevant testing category if two consecutive unsatisfactory Proficiency Testing events occur, or if two out of three consecutive unsatisfactory Proficiency Testing events occur. Certification may be reinstated after successful participation in the next Proficiency Testing event. Failure to achieve a satisfactory score in the next test event will result in the revocation of the certification and will require two successful consecutive Proficiency Testing events before the Testing Facility may be eligible to reapply for certification.
- J. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

### **Basis and Purpose – 5-440**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish quality assurance and quality assurance standards for a Medical Marijuana Testing Facility. This Rule 5-440 was previously Rule M 708, 1 CCR 212-1.

### **5-440 – Medical Marijuana Testing Facilities: Quality Assurance and Quality Control**

- A. Quality Assurance Program Required. A Medical Marijuana Testing Facility must establish, monitor, and document the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory preanalytic, analytic and postanalytic systems when they occur. The review of the quality assurance program must adhere with Rule 3-825(A), and must include, at a minimum the following but is not limited to:
1. Review of instrument preventive maintenance, repair, troubleshooting and ~~e~~Corrective ~~a~~Actions documentation must be performed by the laboratory director or designated quality assurance managers~~supervisory analyst~~ on an ongoing basis to ensure the effectiveness of actions taken over time;
  2. Review by the laboratory director or designated quality assurance managers~~supervisory analyst~~ of all ongoing quality assurance; and
  3. Review of the performance of validated methods used by the Medical Marijuana Testing Facility to include calibration standards, controls and the ~~S~~standard ~~O~~perating ~~P~~rocedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.
  4. Review of Nonconformance reports at an appropriate specified frequency. Nonconforming work which is deemed high impact must be reviewed at least monthly until a resolution is reached and a root cause identified. High impact nonconforming work may include, but is not limited to, any situation in which the

laboratory is in violation of the rules outlined herein or where the quality of the data released is impacted.

B. Quality Control Measures Required. A Medical Marijuana Testing Facility must establish, monitor, and document on an ongoing basis the quality control measures taken by the laboratory to ensure the proper functioning of equipment, validity of Sstandard Operating Procedures and accuracy of results reported. Such quality control measures must include, but shall not be limited to:

1. Documentation of instrument preventive maintenance, repair, troubleshooting and eCorrective actions taken when performance does not meet established levels of quality;
2. Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;
3. Cleaning, maintaining and calibrating as needed the analytical balances and in addition, verifying the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory;
4. Annually verifying working thermometers against a certified reference thermometer. Certified reference thermometers shall be calibrated traceable to the SI (International System of Units) through NIST, or equivalent by an ISO/IEC 17025 accredited calibration laboratory with a listed certification date and documenting the accuracy of thermometers using a NIST traceable reference thermometer;
5. Recording temperatures on all equipment when in use where temperature control is specified in the Sstandard Operating Procedures manual, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;
6. Properly labeling reagents as to the identity, the concentration, date of preparation, storage conditions, lot number tracking, expiration date and the identity of the preparer;
7. Avoiding mixing different lots of reagents in the same analytical run;
8. Performing and documenting a calibration curve with each analysis using at minimum three~~five~~ calibrators throughout the reporting range;
  - a. The laboratory shall not remove data points from within a calibration range while still retaining the extreme ends of the calibration range. If a calibration point fails, the laboratory must re-prepare and re-analyze the calibration standard;
  - b. The laboratory must use an appropriate curve-fitting algorithm (e.g. linear, quadratic, with or without weighing.) The acceptance criteria for concentrations of the calibration standards shall adhere to the recovery requirements outlined in Rule 5-430(J); and

c. The lowest calibration level shall not be greater than the regulatory limits as stated in Rule 4-215(J).

9. For qualitative analyses, analyzing, at minimum, a negative and a positive control with each analytical run of Test Batches ~~batch of samples analyzed~~;
10. For quantitative analyses, analyzing, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve;
11. Using a control material or materials that differ in either source or, lot number, or concentration from the calibration material used with each analytical run;
12. For multi-analyte assays, performing and documenting calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run;
13. Analyzing an appropriate matrix blank and control with each analytical run, when available;
14. Analyzing calibrators and controls in the same manner as unknowns;
15. Documenting the performance of calibration standards and controls for each analytical run to ensure the ~~a~~Aceptability ~~e~~Criteria as defined in the Standard Operating Procedure is met;
16. Documenting all ~~e~~Corrective ~~a~~Actions taken when unacceptable calibration, control, and standard or instrument performance does not meet ~~a~~Aceptability ~~e~~Criteria as defined in the Standard Operating Procedure;
17. Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; ~~and~~
18. Performing testing analysts that follow the current ~~s~~Standard ~~e~~Operating ~~p~~Procedures manual for the test or tests to be performed.

19. The LOQ must be 50% of the limit or less for all analytes within all assays with the exception of pesticides and mycotoxins;

20. Duplicate Test Batch results shall not exceed 30% relative percent difference (RPD); and

21. LOD and LOQ must be scientifically valid and experimentally determined.

~~C. Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

D. Nonconforming Work. A Medical Marijuana Testing Facility shall have a documented system by which it investigates Nonconformances within its quality management system. This system must include a standardized process for documenting Nonconformances which must include, but shall not be limited to, the following items:

1. A detailed description of what occurred to include, as appropriate, instrument ID, sample ID, batch ID, SOP number or title, quality control failure, client complaint, date of occurrence;
  2. An estimate of the severity of the consequences of the Nonconformance;
  3. The impact of the Nonconformance;
  4. Person(s) responsible for any part of the generation or review of the nonconforming work;
  5. A thorough investigation to determine a root cause of the Nonconformance by a prescribed analysis process, to include the person(s) assigned to the root cause investigation and associated deadlines for completion;
  6. A list of any analytical batches that were impacted and a list of Test Batches results recalled;
  7. Whether or not work was stopped;
  8. Corrective and/or Preventative Actions identified to include deadlines and the person(s) assigned to implement the action and actual dates of implementation;
  9. The Nonconformance report must not be closed until all identified Corrective and Preventative Actions are implemented. The closed report shall be reviewed, signed, and dated by the laboratory director or delegated quality assurance manager; and
  10. An assigned deadline for future review to evaluate the effectiveness of Corrective and Preventative Actions.
- E. Laboratory Reanalysis. A Medical Marijuana Testing Facility must establish a policy regarding the retesting of client Test Batches. For the purposes of this rule, retesting does not include reanalysis of Test Batches performed because quality control requirements were not met as described in the applicable Standard Operating Procedure, or retesting of Test Batches in accordance with Rule 4-240.
1. Reanalysis policies must specify the laboratory testing must be performed on the same homogenized Test Batch that was submitted to the laboratory and include criteria by which the original result is confirmed or invalidated. The laboratory must contact the submitting client when reanalysis is performed. A Medical Marijuana Testing Facility shall follow the Nonconforming work process outlined in Rule 5-440(D) for every reanalysis.
    - a. Prior to reporting a result that differs from the original data point, a Nonconformance for retests outlined in Rule 5-440 (D) must be submitted to the CDPHE and the Division.
    - b. Failure to do a scientifically valid investigation, a root cause analysis, or monthly review of open Nonconformances where no root cause has been determined will be considered a violation of rule.

2. Multiple amended test results for the same cause or same test type may indicate that test results are not accurate, precise, or scientifically valid. In the event of three or more invalidated results within a six-month period, the Medical Marijuana Testing Facility shall evaluate all relevant aspects of the pre-analytic, analytic, and post-analytic systems to determine the source of the error and implement Corrective Actions.
3. Failure to complete the Nonconforming work process outlined in Rule 5-440(D) in a manner that is sufficient to identify and prevent the recurrence of analytical errors constitutes a violation affecting public health and safety and is cause for suspension or revocation of Certification for the affected test category.

### **Basis and Purpose – 5-441**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish minimum requirements for the procedures and requirements a Medical Marijuana Testing Facility must comply with.

### **5-441 – Medical Marijuana Testing Facility: Certificate of Analysis (COA)**

- A. The laboratory shall generate a Certificate of Analysis (COA) for each Test Batch that the laboratory analyzes.
- B. The COA shall indicate that the reported results are for compliance testing purposes for all Test Batches analyzed.
- C. The laboratory shall ensure that the COA contains the results of all requested analyses performed for the Test Batch.
- D. The COA shall contain, at minimum, the following information:
  1. Laboratory's name, address, and contact information;
  2. Marijuana cultivator or product manufacturer's name, address, and license number;
  3. Test Batch identifying information, including matrix type and unique sample identifiers, including Batch Number when applicable;
  4. Test Batch received date, and the date(s) of analyses and corresponding testing results;
  5. Units of measure;
  6. The analytical methods, analytical instrumentation used, and corresponding Limits of Detection (LOD) and Limits of Quantitation (LOQ);
  7. Reported Cannabinoid results must include the range of estimated uncertainty which shall be reported as a  $\pm$  value in the same units of measure as the test result, following best practices for significant figures and rounding;



8. A dedicated area to include any qualifiers or comments needed for interpretation, (when applicable to the test method and results being reported) to include any identified and documented discrepancies;
  9. The COA may contain additional information at the discretion of the laboratory and submitting client; and
  10. Identify the Medical Marijuana Testing Facility that actually conducted the test.
- E. The laboratory shall report test results for each representative Test Batch on the COA as follows:
1. When reporting qualitative results for each analyte, the laboratory shall indicate presence or absence;
  2. When reporting quantitative results for each analyte, the laboratory shall only report a numeric value when results are above the lower Limit of Quantitation;
  3. When reporting results for any analytes that were detected below the analytical method LOQ and above the LOD, indicate "<LOQ"; and
  4. When reporting results for any analytes that were not detected or detected below the LOD, indicate "ND" or "<LOD".
- F. The laboratory director or supervisory analyst shall ensure the accuracy of the information contained on the COA.

### **Basis and Purpose – 5-445**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish chain of custody standards for a Medical Marijuana Testing Facility. In addition, it establishes the requirement that a Medical Marijuana Testing Facility follow an adequate chain of custody for Test Batches it maintains. This Rule 5-445 was previously Rule M 709, 1 CCR 212-1.

### **5-445 – Medical Marijuana Testing Facilities: Chain of Custody**

- A. General Requirements. A Medical Marijuana Testing Facility must establish an adequate Cchain of Ceustody procedure that, at a minimum, and Test Batch requirement instructions that must include, but not be limited to;
1. Issue instructions for the minimum Test Batch requirements and storage requirements;
  2. Document the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the Test Batch;
  3. Document the condition and amount of Test Batch provided at the time of receipt;
  4. Document all persons handling the original Test Batches, aliquots, and extracts;
  5. Document all Transfers of Test Batches, aliquots, and extracts referred to another certified Medical Marijuana Testing Facility Licensee for additional testing or whenever requested by a client;



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6. Maintain a current list of authorized personnel and restrict entry to the laboratory to only those authorized;
7. Secure the Laboratory during non-working hours;
8. Secure short and long-term storage areas when not in use;
9. Utilize a secured area to log-in and aliquot Test Batches;
10. Ensure Test Batches are stored appropriately;
11. Document the disposal of Test Batches, aliquots, and extracts; ~~and~~
12. Document the License number, Inventory Tracking System number, photograph(s), and the reason for rejection of Test Batches that were rejected to the Division within 7 days of Test Batch submission; ~~and-~~

13. Assign and document a unique Test Batch identifier;

- B. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 5-450**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish records retention standards for a Medical Marijuana Testing Facility. This Rule 5-450 was previously Rule M 710, 1 CCR 212-1.

**5-450 – Medical Marijuana Testing Facilities: Records Retention**

- A. General Requirement. A Medical Marijuana Testing Facility must maintain all required business records. See Rule 3-905 - Business Records Required.
- B. Specific Business Records Required: Records Retention. A Medical Marijuana Testing Facility must establish processes to preserve records in accordance with Rule 3-905 that includes, but is not limited to;
1. Test Results, including final and amended reports, and identification of analyst and date of analysis;
  2. Quality Control and Quality Assurance Records, including Nonconformance reports, accession numbers, Test Batch type, and acceptable reference range parameters;
  3. Standard Operating Procedures;
  4. Personnel ~~R~~records;
  5. Chain of Custody ~~R~~records, including documentation of rejected Test Batches;
  6. Proficiency Testing ~~R~~records; and
  7. Analytical Data to include data generated by the instrumentation, raw data calibration standards, and curves.

- C. ~~Repealed Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 5-455**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1), and 44-10-504(2), C.R.S. The purpose of this rule is to require Medical Marijuana Testing Facilities to provide failed test results to the Medical Marijuana Business or Person submitting the sample and to report any failed test result in the inventory tracking system. This Rule 5-455 was previously Rule M 712(D), 1 CCR 212-1.

**5-455 – Notification of Medical Marijuana Business**

If Medical Marijuana failed a contaminant test, then the Medical Marijuana Testing Facility must immediately (1) notify the Medical Marijuana Business that submitted the Test Batch ~~or Sample~~ for testing and any Person as directed by an approved Research Project being conducted by a Marijuana Research and Development Facility; and (2) report the failure in accordance with the Inventory Tracking System reporting requirements in Rule 3-825(C), except as otherwise authorized in Rule 5-415(C)(12).

**Basis and Purpose – 5-460**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(4), 44-10-203(1)(k), 44-10-203(2)(a), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(3)(c), 44-10-401(2)(b)(IV), and 44-10-~~65~~04, C.R.S. The purpose of this rule is to establish a framework for suspending and reinstating a testing category certification for Medical Marijuana Testing Facilities. This rule also provides the ability for a Medical Marijuana Testing Facility to request a hearing following suspension of a testing category certification.

**5-460 – Medical Marijuana Testing Facilities: Certification Suspension, Recertification, and Request for Hearing**

- A. Certification Suspension. When the Division has objective and reasonable grounds to believe and finds that a Medical Marijuana Testing Facility has been guilty of deliberate and willful violation(s) or that the public health, safety, or welfare imperatively require emergency action, the Division may immediately suspend the Medical Marijuana Testing Facility's testing category certification in accordance with section 24-4-104, C.R.S., and the 8-200 Series Rules. Further, the Division may suspend certification when a laboratory has three or more repeated inspection findings which impact the quality of the data produced by the laboratory.
- B. Re-certification. A Medical Marijuana Testing Facility must provide evidence of corrective actions taken to resolve the certification suspension and may request that the Division re-certify the Medical Marijuana Testing Facility for a particular testing category in accordance with the requirements in Rule 5-415, if the Medical Marijuana Testing Facility provides documentation requested by the Division and/or the CDPHE demonstrating such corrective actions.

**5-500 Series – Medical Marijuana Transporters****Basis and Purpose – 5-505**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-313(14), 44-10-401(2)(a)(V), 44-10-505, C.R.S. The purpose of this rule is to establish the license privileges of Medical Marijuana Transporter Licensees. This Rule 5-505 was previously Rule M 1601, 1 CCR 212-1.

**5-505 – Medical Marijuana Transporter: License Privileges**

- A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Medical Marijuana Transporter may share a location with an identically owned Retail Marijuana Transporter. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- B. Transportation of Medical Marijuana and Medical Marijuana Product Authorized. A Medical Marijuana Transporter may take transportation orders, receive, transport, temporarily store, and deliver Medical Marijuana to a Medical Marijuana Business, a Retail Marijuana Cultivation Facility or Accelerator Cultivator in accordance with Rules 5-235, 6-230, and 6-730, or to a Pesticide Manufacturer. A Medical Marijuana Transporter may not sell, give away, buy, or receive complimentary Medical Marijuana under any circumstances. A Medical Marijuana Transporter does not include a Licensee that transports its own Medical Marijuana.
- C. Authorized Sources of Medical Marijuana. A Medical Marijuana Transporter may only transport and store Medical Marijuana that it receives directly from a Medical Marijuana Business in accordance with the 3-600 Series Rules.
- D. Authorized On-Premises Storage. A Medical Marijuana Transporter is authorized to store transported Medical Marijuana on its Licensed Premises or permitted off-premises storage facility. All transported Medical Marijuana must be secured in a Limited Access Area, and tracked consistently with the inventory tracking rules.
- E. Delivery to Patients Pursuant to Delivery Permit.
  - 1. Prior to January 2, 2021, all Medical Marijuana Transporters are prohibited from delivering Regulated Marijuana to patients.
  - 2. After January 2, 2021, only Medical Marijuana Transporters that possess a valid delivery permit may deliver Medical Marijuana pursuant to contracts with Medical Marijuana Stores that also possess valid delivery permits. All deliveries of Medical Marijuana to patients must comply with all requirements of Rule 3-615.
  - 3. ~~Repealed. License Violation Affecting Public Safety. Any violation of subparagraph E of this Rule is a license violation affecting public safety.~~

**Basis and Purpose – 5-510**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-401(2)(a)(V), 44-10-505, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by a Medical Marijuana Transporter. This Rule 5-510 was previously Rule M 1602, 1 CCR 212-1.

### **5-510 – Medical Marijuana Transporter: General Limitations or Prohibited Acts**

- A. Sales, Liens, and Secured Interests Prohibited. A Medical Marijuana Transporter is prohibited from buying, selling, or giving away Medical Marijuana or from receiving complimentary Medical Marijuana. A Medical Marijuana Transporter shall not place or hold a lien or secured interest on Medical Marijuana.
- B. Licensed Premises Permitted. A Medical Marijuana Transporter shall maintain a Licensed Premises if it: (1) temporarily stores any Medical Marijuana, or (2) modifies any information in the Inventory Tracking System generated transport manifest. The Licensed Premises shall be in a local jurisdiction that authorizes the operation of Medical Marijuana Stores.
1. If a Medical Marijuana Transporter Licensed Premises is shared with a Retail Marijuana Transporter Licensed Premises, then the combined Licensed Premises shall be in a local jurisdiction that authorizes the operation of both Medical Marijuana Stores and Retail Marijuana Stores.
2. A Medical Marijuana Transporter may add or remove a Licensed Premises, other than an Off-Premises Storage Facility, pursuant to Rule 2-255, Change of Location of a Regulated Marijuana Business.
- C. Off-Premises Storage Permit. A Medical Marijuana Transporter may maintain one or more permitted off-premises storage facilities. See Rule 3-610 – Off-Premises Storage of Regulated Marijuana and Regulated Marijuana Product: All Regulated Marijuana Businesses.
- D. Storage Duration. A Medical Marijuana Transporter shall not store Medical Marijuana for longer than seven days from receiving it at its Licensed Premises or off-premises storage facility. The total allowable seven day storage duration begins and applies regardless of which of the Medical Marijuana Transporter's premises receives the Medical Marijuana first, (i.e. the Medical Marijuana Transporter's Licensed Premises, or any of its off-premises storage facilities). A Medical Marijuana Transporter with a valid delivery permit may store Medical Marijuana for delivery to patients pursuant to the delivery permit for no longer than seven days from receipt at its Licensed Premises or off-premises storage facility.
- E. Control of Medical Marijuana. A Medical Marijuana Transporter is responsible for the Medical Marijuana once it takes control of the Medical Marijuana and until the Medical Marijuana Transporter delivers it to another Medical Marijuana Business, Retail Marijuana Cultivation Facility or Accelerator Cultivator in accordance with Rules 5-235, 6-230, and 6-730, Pesticide Manufacturer, or deliveries to a patient, parent, or guardian pursuant to a valid delivery permit. For purposes of this Rule, taking control of the Medical Marijuana means removing it from the Medical Marijuana Business's Licensed

Premises and placing the Medical Marijuana in the transport vehicle or the Delivery Motor Vehicle.

- F. Location of Orders Taken and Delivered. A Medical Marijuana Transporter is permitted to take orders on the Licensed Premises of any Medical Marijuana Business to transport Medical Marijuana between Medical Marijuana Businesses. The Medical Marijuana Transporter shall deliver the Medical Marijuana to the Licensed Premises of a licensed Medical Marijuana Business, or Pesticide Manufacturer. A Medical Marijuana Transporter may also deliver Medical Marijuana to patients, parents, or guardians pursuant to a contract with a Medical Marijuana Store if it possesses a valid delivery permit.
- G. A Medical Marijuana Transporter shall receive Medical Marijuana from the originating Licensee packaged in the way that it is intended to be delivered to the final destination Licensee, or Pesticide Manufacturer. The Medical Marijuana Transporter shall deliver the Medical Marijuana in the same, unaltered packaging to the final destination Licensee.
- H. A Medical Marijuana Transporter with a valid delivery permit shall receive Medical Marijuana that has been weighed, packaged, prepared, and labeled for delivery on the Licensed Premises of a Medical Marijuana Store or at the Medical Marijuana Store's off-premises storage facility after receipt of a delivery order. Medical Marijuana cannot be placed into a Delivery Motor Vehicle until after an order has been received and the Medical Marijuana has been packaged and labeled for delivery to the patient, parent, or guardian as required by the 3-1000 Series Rules.
- I. A Medical Marijuana Transporter must not deliver Medical Marijuana to patients, parents, or guardians while also transporting Regulated Marijuana between Licensed Premises in the Delivery Motor Vehicle.
- J. Opening of Sealed Packages or Containers and Re-Packaging Prohibited. A Medical Marijuana Transporter shall not open Containers of Medical Marijuana. Medical Marijuana Transporters are prohibited from re-packaging Medical Marijuana.
- K. Temperature-Controlled Transport Vehicles. A Medical Marijuana Transporter shall utilize temperature-controlled transport vehicles when necessary to prevent spoilage of the transported Medical Marijuana.
- L. Damaged, Refused, or Undeliverable Medical Marijuana. Any damaged Medical Marijuana that is undeliverable to the final destination Medical Marijuana Business, or any Medical Marijuana that is refused by the final destination Medical Marijuana Business shall be transported back to the originating Medical Marijuana Business. Any Medical Marijuana that cannot be delivered to the patient, parent, or guardian pursuant to a valid delivery permit shall be returned to the originating Medical Marijuana Store or the Medical Marijuana Store's off-premises storage facility within the same business day or pursuant to paragraph D of this Rule.
- M. Transport of Medical Marijuana Vegetative Plants Authorized. Medical Marijuana Vegetative plants may only be transported between Licensed Premises and such transport shall only be permitted due to an approved change of location pursuant to Rule 2-255 or due to a one-time Transfer pursuant to Rule 3-805. Transportation of Vegetative

plants to a permitted off-premises storage facility shall not be allowed. This restriction shall not apply to Immature ~~P~~plants.

- N. Only persons licensed by the State Licensing Authority may occupy a transport vehicle while transporting Regulated Marijuana.

## **5-600 Series – Medical Marijuana Business Operators**

### **Basis and Purpose – 5-610**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(o), 44-10-401(2)(a)(VI), and 44-10-506, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Medical Marijuana Business Operator. This Rule 5-610 was previously Rule M 1702, 1 CCR 212-1.

### **5-610 – Medical Marijuana Business Operators: General Limitations or Prohibited Acts**

- A. Financial Interest. A Person who holds an Owner's Interest in a Medical Marijuana Business Operator may also hold an Owner's Interest in another Medical Marijuana Business. A Medical Marijuana Business may be operated by a Medical Marijuana Business Operator where each has one or more Controlling Beneficial Owners or Passive Beneficial Owners in common. A Person may receive compensation for services provided by a Medical Marijuana Business Operator in accordance with these rules.
- B. Sale of Marijuana Prohibited. A Medical Marijuana Business Operator is prohibited from selling, distributing, or Transferring Medical Marijuana to another Medical Marijuana Business, a patient, or a consumer, except when acting as an agent of a Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator.
- C. Consumption Prohibited. A Medical Marijuana Business Operator, and its Controlling Beneficial Owners, Passive Beneficial Owners, agents and employees, shall not permit the consumption of marijuana or marijuana products at its separate place of business.
- D. Inventory Tracking System. A Medical Marijuana Business Operator, and any of its Controlling Beneficial Owners, agents, or employees engaged in the operation of the Medical Marijuana Business(es) it operates, must use the Inventory Tracking System account of the Medical Marijuana Business(es) it operates, in accordance with all requirements, limitations, and prohibitions applicable to the Medical Marijuana Business(es) it operates.
- E. Compliance with Requirements and Limitations Applicable to the Medical Marijuana Business(es) Operated. In operating any other Medical Marijuana Business(es), a Medical Marijuana Business Operator, and its Controlling Beneficial Owners, agents and employees, shall comply with all requirements, limitations and prohibitions applicable to the type(s) of Medical Marijuana Business(es) being operated, under state and local laws, ordinances, rules, and regulations, and may be disciplined for violation of the same.
- F. Inventory Tracking System Access. A Medical Marijuana Business may grant access to its Inventory Tracking System account to the Controlling Beneficial Owners who are required to hold Owner Licenses, as well as the licensed agents and employees of a

Medical Marijuana Business Operator having duties related to Inventory Tracking System activities of the Medical Marijuana Business(s) being operated.

1. The Controlling Beneficial Owners, agents, and employees of a Medical Marijuana Business Operator granted access to a Medical Marijuana Business's Inventory Tracking System account, shall comply with all Inventory Tracking System rules.
2. At least one Controlling Beneficial Owner or their designee of a Medical Marijuana Business being operated by a Medical Marijuana Business Operator must be an Inventory Tracking System Trained Administrator for the Medical Marijuana Business's Inventory Tracking System account. That Inventory Tracking System Trained Administrator shall control access to its Inventory Tracking System account, and shall promptly terminate the access of the Medical Marijuana Business Operator's Controlling Beneficial Owners, agents, and employees:
  - a. When its contract with the Medical Marijuana Business Operator expires by its terms;
  - b. When its contract with the Medical Marijuana Business Operator is terminated by any party; or
  - c. When it is notified that the license of the Medical Marijuana Business Operator, or a specific Controlling Beneficial Owner, agent or employee of the Medical Marijuana Business Operator, has expired, or has been suspended or revoked.

G. Limitations on Use of Documents and Information Obtained from Medical Marijuana Businesses. A Medical Marijuana Business Operator, and its agents and employees, shall maintain the confidentiality of documents and information obtained from the other Medical Marijuana Business(es) it operates, and shall not use or disseminate documents or information obtained from a Medical Marijuana Business it operates for any purpose not authorized by the Marijuana Code and the rules promulgated pursuant thereto, and shall not engage in data mining or other use of the information obtained from a Medical Marijuana Business to promote the interests of the Medical Marijuana Business Operator or its Controlling Beneficial Owners, Passive Beneficial Owners, Indirect Financial Interest Holders, agents or employees, or any Person other than the Medical Marijuana Business it operates.

H. Form and Structure of Allowable Agreement(s) Between Operators and Owners. Any agreement between a Medical Marijuana Business and a Medical Marijuana Business Operator:

1. Must acknowledge that the Medical Marijuana Business Operator, and its Controlling Beneficial Owners, agents and employees who are engaged, directly or indirectly, in operating the Medical Marijuana Business, are agents of the Medical Marijuana Business being operated, and must not disclaim an agency relationship;



2. May provide for the Medical Marijuana Business Operator to receive direct remuneration from the Medical Marijuana Business, including a portion of the profits of the Medical Marijuana Business being operated, subject to the following limitations:
  - a. The portion of the profits to be paid to the Medical Marijuana Business Operator shall be commercially reasonable, and in any event shall not exceed the portion of the net profits to be retained by the Medical Marijuana Business being operated;
  - b. The Medical Marijuana Business Operator shall not be granted, and may not accept:
    - i. A security interest in the Medical Marijuana Business being operated, or in any assets of the Medical Marijuana Business;
    - ii. An ownership or membership interest, shares, or shares of stock, or any right to obtain any direct or indirect beneficial ownership interest in the Medical Marijuana Business being operated, or a future or contingent right to the same, including but not limited to options or warrants;
  - c. The Medical Marijuana Business Operator shall not guarantee the Medical Marijuana Business's debts or production levels.
3. Shall permit the Medical Marijuana Business being operated to terminate the contract with the Medical Marijuana Business Operator at any time, with or without cause.
- I. A Medical Marijuana Business Operator may engage in dual operation of a Medical Marijuana Business and a Retail Marijuana Business at a single location, to the extent the Medical Marijuana Business being operated is permitted to do so pursuant to subsection 44-10-501(2)(a), C.R.S., and the Medical Marijuana Business Operator shall comply with the rules promulgated pursuant to the Marijuana Code, including the requirement of obtaining a valid license as a Retail Marijuana Business Operator.
- J. Any Medical Marijuana Business Operators and the Medical Marijuana Business Operator's Owner Licensee(s) that are appointed by a court to serve as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person and take possession of, operate, manage, or control a Medical Marijuana Business must comply with Rule 2-275(F).

## **5-700 Series – Marijuana Research and Development Facilities**

### **Basis and Purpose – 5-705**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(k), 44-10-203(2)(s), 44-10-401(1)(a)(VII), and 44-10-507, C.R.S. The purpose of this rule is to establish and clarify the distinct license privilege granted to Marijuana Research and Development Facilities by the State Licensing Authority. This Rule 5-705 was previously Rule M 1901, 1 CCR 212-1.



**5-705 – Marijuana Research and Development Facilities: License Privileges****A. License Privileges.**

1. Licensed Premises. A Marijuana Research and Development Facility may share a Licensed Premises with a commonly owned Medical Marijuana Testing Facility. Additionally, a Marijuana Research and Development Facility with an R&D Co-Location Permit may share a Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility.
  - a. If a Marijuana Research and Development Facility shares its Licensed Premises with a commonly owned Medical Marijuana Testing Facility, the Licensees shall physically segregate all Medical Marijuana used for research purposes in order to prevent contamination or any other effect on Medical Marijuana submitted to the Medical Marijuana Testing Facility for testing.
  - b. If a Marijuana Research and Development Facility shares its Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility, the Marijuana Research and Development Facility must first obtain an R&D Co Location Permit for that Licensed Premises and must comply with all terms and conditions of the R&D Co-Location Permit.
2. Authorized Sources of Medical Marijuana. A Medical Marijuana Cultivation Facility and Medical Marijuana Products Manufacturer may Transfer Medical Marijuana to a Marijuana Research and Development Facility.
  - a. A Marijuana Research and Development Facility may also accept and possess Regulated Marijuana obtained in accordance with an approved Research Project.
  - b. Upon receipt of Regulated Marijuana pursuant to Rule 5-705(A)(2)(a), a Marijuana Research and Development Facility shall immediately enter the Regulated Marijuana as Medical Marijuana in its Inventory Tracking System and shall follow all requirements of the Marijuana Code and these Rules including but not limited to inventory tracking and packaging and labeling. As part of and in compliance with the conditions of an approved Research Project, a Marijuana Research and Development Facility may Transfer the Medical Marijuana to another Marijuana Research and Development Facility or to a Medical or Retail Marijuana Testing Facility. In no event shall any marijuana obtained or Transferred pursuant to this Rule be consumed by humans or utilized in human subject research.
3. Cultivation of Marijuana Authorized. A Marijuana Research and Development Facility may grow, cultivate, possess, and Transfer Medical Marijuana for use in research only.

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4. Production of Marijuana Concentrate. A Marijuana Research and Development Facility and a Medical Marijuana Cultivation Facility are subject to the same restrictions concerning Medical Marijuana Concentrate production. Therefore, a Marijuana Research and Development Facility may produce Medical Marijuana Concentrate only as allowed by, and in conformance with, Rule 5-220(A)-(B).
  5. Production of Marijuana Products. A Marijuana Research and Development Facility and a Medical Marijuana Products Manufacturer are subject to the same restrictions concerning Medical Marijuana Product manufacturing. Therefore, a Marijuana Research and Development Facility may manufacture Medical Marijuana Product only as allowed by, and in conformance with, Rule 5-305.
  - 5.5. Production of Semi-Synthetic Cannabinoids. A Marijuana Research and Development Facility may manufacture ~~s~~Semi-synthetic ~~e~~Cannabinoids derived from Medical Marijuana.
  6. Authorized Marijuana Transport. A Marijuana Research and Development Facility is authorized to utilize a licensed Medical Marijuana Transporter for transportation of Medical Marijuana to other Marijuana Research and Development Facility Licensees so long as the place where transportation orders are taken and delivered is a Marijuana Research and Development Facility. Nothing in this Rule prevents a Marijuana Research and Development Facility from transporting its own Medical Marijuana to other Marijuana Research and Development Facilities.
- B. R&D Co-Location Permit. A Marijuana Research and Development Facility may obtain an R&D Co-Location Permit to operate at the same Licensed Premises as a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility under the following circumstances:
1. The Marijuana Research and Development Facility must apply on current Division forms and pay any applicable fees.
  2. A Marijuana Research and Development Facility may only apply for and hold an R&D Co-Location Permit if the Local Licensing Authority or Local Jurisdiction allow for Marijuana Research and Development Facility to operate at the same location as the specified Regulated Marijuana Business. Any R&D Co-Location Permit issued by the Division is conditioned upon the Marijuana Research and Development Facility's receipt of all required Local Licensing Authority or Local Jurisdiction approvals or acknowledgements.
  3. The Marijuana Research and Development Facility and the specified Regulated Marijuana Business shall be commonly owned.
  4. Prior to operating in the same Licensed Premises pursuant to an R&D Co-Location Permit, the Marijuana Research and Development Facility shall submit a co-location plan and ~~S~~standard ~~O~~perating ~~P~~rocedures to the Division. The co-location plan and ~~S~~standard ~~O~~perating ~~P~~rocedures shall demonstrate

protocols to prevent cross-contamination and protect public health and safety, including but not limited to:

- a. Standards and controls for maintaining physical separation between the Marijuana Research and Development Facility's research activities and the cultivating or manufacturing activities of the co-located Regulated Marijuana Business; and
  - b. Standards and controls for maintaining physical separation between the Marijuana Research and Development Facility's Medical Marijuana and the co-located Regulated Marijuana Business's Regulated Marijuana.
5. The Division may request the assistance of the Colorado Department of Public Health and Environment or any other state or local agency in reviewing the co-location plan and Sstandard Operating Procedures, and in determining whether the co-location plan and Sstandard Operating Procedures demonstrate protocols to prevent cross-contamination and protect public health and safety.
  6. Modifying the co-location plan and Sstandard Operating Procedures shall be considered a significant change to the Licensed Premises. See Rule 2-260 – Changing, Altering, or Modifying the Licensed Premises.
  7. Record keeping, inventory tracking, packaging and labeling for the Marijuana Research and Development Facility and co-located Regulated Marijuana Business must enable the Division, Local Licensing Authority, or Local Jurisdiction to clearly distinguish the inventory, transactions, and activities of the Marijuana Research and Development Facility from the inventory, transactions, and activities of the co-located Regulated Marijuana Business.

### **Basis and Purpose – 5-720**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(1)(i), 44-10-203(2)(s), 44-10-401(1)(a)(VII), and 44-10-507, C.R.S. The purpose of this rule is to establish the limited research purposes authorized for Marijuana Research and Development Facilities. The purpose of this rule is also to establish additional requirements for Research Projects involving human subjects and animal subjects, as well as restrictions on the use of Pesticides. The rule also establishes reporting requirements and explains when the State Licensing Authority may require a Marijuana Research and Development Facility to undergo an audit of its research activities. This Rule 5-720 was previously Rule M 1905, 1 CCR 212-1.

### **5-720 – Marijuana Research and Development Facility: Authorized Research Activities**

- A. Authorized Research. A Marijuana Research and Development Facility is authorized to engage in the following research at its Licensed Premises:
  1. Chemical Potency and Composition Levels.
  2. Clinical Investigations of Marijuana-Derived Products.
  3. Efficacy and Safety of Administering Marijuana as Part of Medical Treatment.

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4. Genomic Research.
  5. Horticultural Research.
  6. Agricultural Research.
  7. Marijuana-Affiliated Products or Systems. A marijuana-affiliated product or system includes products or systems such as marijuana delivery systems and cultivation or processing equipment.
- B. Pesticide Research. A Marijuana Research and Development Facility shall not engage in any research activities involving Pesticides unless the Marijuana Research and Development Facility has applied for and received any necessary license, registration, certification, or permit from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S., and/or the Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S.
1. A Marijuana Research and Development Facility engaged in research activities involving Pesticide shall at all times comply with the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S., Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S., and all rules promulgated pursuant thereto.
- C. Research Involving Human Subjects. A Marijuana Research and Development Facility shall not conduct any research involving human subjects unless all aspects of its proposed Research Project have been reviewed and approved by an Institutional Review Board that is registered and in good standing with Office for Human Research Protections, U.S. Department of Health and Human Services.
1. A Marijuana Research and Development Facility shall include proof of approval and ongoing oversight and review by an Institutional Review Board as part of its Research Project proposal. A Research Project may be approved conditioned upon subsequent Institutional Review Board approval. A Licensee shall not engage in any Research Project involving human subjects until it receives approval by the Institutional Review Board and its Research Project is approved. A Marijuana Research and Development Facility conducting research involving human subjects shall also comply with any ongoing monitoring required by the Institutional Review Board.
  2. A Marijuana Research and Development Facility conducting research involving human subjects shall at all times comply with the U.S. Department of Health and Human Services' requirements for protection of human research subjects, including additional safeguards necessary for vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, 45 C.F.R. part 46, and all other relevant federal and/or state laws and regulations regarding research on human subjects, as well as all prevailing ethical standards and requirements for research involving human subjects.
  3. A Marijuana Research and Development Facility conducting research involving human subjects shall obtain informed consent from any individual participating in such research prior to the individual's participation in the research. A Marijuana

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Research and Development Facility shall comply with U.S. Food and Drug Administration requirements for informed consent and additional safeguards for children in clinical investigations, 21 C.F.R. part 50, as part of approval and ongoing oversight and review by an Institutional Review Board.

- D. Research Involving Animal Subjects. A Marijuana Research and Development Facility shall not conduct any research involving animal subjects as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g) unless the Marijuana Research and Development Facility is registered with the U.S. Department of Agriculture pursuant to the Animal Welfare Act, 7 U.S.C. §§ 2131 *et seq.*
1. A Marijuana Research and Development Facility shall include proof of its current registration with the U.S. Department of Agriculture as part of its Research Project proposal. Failure to be registered with the U.S. Department of Agriculture shall be grounds for denial of Research Project proposal involving animal subjects.
  2. A Marijuana Research and Development Facility shall at all times treat animal subjects as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g) involved in research humanely and consistent with all relevant federal and/or state laws and regulations, as well as all prevailing ethical standards and requirements for research on such animals.
- E. Research Involving Testing of Marijuana. A Marijuana Research and Development Facility may only engage in research regarding the testing of Medical Marijuana if the following criteria are met:
1. Testing Qualifications. A Marijuana Research and Development Facility must meet at least one of the following standards:
    - a. The Marijuana Research and Development Facility also holds a Medical Marijuana Testing Facility license and has been certified pursuant to Rule 5-415;
    - b. The Marijuana Research and Development Facility is accredited to the International Organization for Standardization/International Electrotechnical Commission 17025:2005 Standard, or any subsequent superseding ISO 17025 standard; or
    - c. The Marijuana Research and Development Facility is part of an institution of higher education whose protocols have been approved by the Colorado Department of Public Health and Environment.
  2. A Marijuana Research and Development Facility proposing to engage in research regarding the testing of Medical Marijuana shall include in its Research Project proposal documentation establishing its testing qualification pursuant to Paragraph (E)(1) of this Rule. See Rule 5-715 – Marijuana Research and Development Facilities: Project Approval.
- F. Transfers of Marijuana Used in Research. A Marijuana Research and Development Facility shall not Transfer to any Person any Medical Marijuana unless such Transfer is

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authorized under Rule 5-710. Otherwise, a Marijuana Research and Development Facility shall at the conclusion of its research destroy all remaining Medical Marijuana subject to the Marijuana Research and Development Facility's approved Research Project. Unless otherwise provided, a Research Project will be deemed concluded on its defined end date as provided in the Marijuana Research and Development Facility's Research Project proposal that was submitted to and approved by the Division. The Marijuana Research and Development Facility shall ensure destruction of such remaining Medical Marijuana is destroyed in conformance with Rule 3-230.

- G. Periodic Reporting. A Marijuana Research and Development Facility shall submit to the Division a report regarding the status of approved Research Projects every six months following the Division's approval of its Research Project.
1. The periodic reports shall address the Marijuana Research and Development Facility's compliance and progress with its approved Research Project.
  2. The periodic reports shall include any protocol changes or reported protocol deviations, as well as enrollment numbers and adverse events for studies involving human subjects.
  3. If the Marijuana Research and Development Facility is conducting its Research Project in whole or in part with a Public Institution or Public Money, the Division shall submit the Marijuana Research and Development Facility's periodic reports to the Scientific Advisory Council for review.
  4. If an adverse event occurs, the Marijuana Research and Development Facility shall immediately notify the Division of the adverse event on the form prepared by the Division.
- H. Suspension or Revocation of Project Approval. Research Project approval is subject to revocation or suspension if the Marijuana Research and Development Facility's research has materially diverged from the Marijuana Research and Development Facility's approved Research Project, violates the Marijuana Code or the rules promulgated thereto, or presents a risk to public health and safety. See 8-200 Series Rules – Discipline.
- I. Reporting of Research Results. A Marijuana Research and Development Facility shall supply the Division with copies of all final reports, findings, or documentation regarding the outcomes of approved Research Projects.
- J. Independent Research Audit. The State Licensing Authority in its discretion may at any time require that a Marijuana Research and Development Facility undergo an audit of its research activities.
1. Circumstances Justifying Independent Research Audit. The following is a non-exhaustive list of examples that may justify an independent research audit:
    - a. The Division has reasonable grounds to believe that the Marijuana Research and Development Facility is in violation of one or more of the requirements set forth in these rules or other applicable statutes or regulations;

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- b. The Division has reasonable grounds to believe that the Marijuana Research and Development Facility's research activities present a danger to the public health and/or safety; or
    - c. The Division has reasonable grounds to believe that the Marijuana Research and Development Facility has been or is engaged in research activities that have not received prior Division approval.
  - 2. Selection of An Independent Consultant. The Division and the Marijuana Research and Development Facility may attempt to mutually agree upon the selection of an independent consultant to perform a research audit. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.
  - 3. Costs. The Marijuana Research and Development Facility subject to an independent research audit will be responsible for all costs associated with the independent research audit, including but not limited to the auditor's fees.
  - 4. Compliance Required. A Marijuana Research and Development Facility must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent research audit in conformance with this Rule.
- K. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Part 6 – Retail Marijuana Business License Types****6-100 Series – Retail Marijuana Stores****Basis and Purpose – 6-105**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(dd), 44-10-313(14), 44-10-401(2)(b)(I), 44-10-601, and 44-10-605, C.R.S. The purpose of this rule is to the license privileges of a Retail Marijuana Store licensee. This Rule 6-105 was previously Rule R 401.

**6-105 – Retail Marijuana Store: License Privileges**

- A. Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Business– Shared Licensed Premises and Operational Separation, a Retail Marijuana Store may share, and operate at, the same Licensed Premises with a commonly-owned Medical Marijuana Store. However, a separate License is required for each specific business or business entity, regardless of geographical location.
- B. Authorized Sources of Retail Marijuana. A Retail Marijuana Store may only Transfer Retail Marijuana that was obtained from another Retail Marijuana Business.
- B.5. Authorized Transfers to Retail Marijuana Businesses. A Retail Marijuana Store may Transfer Retail Marijuana to a customer or other Retail Marijuana Businesses.
- C. Test Batches Provided for Testing. A Retail Marijuana Store may provide Test Batches of its products for testing and research purposes to a Retail Marijuana Testing Facility. The

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Retail Marijuana Store shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.

- D. Authorized On-Premises Storage. A Retail Marijuana Store is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules.
- E. Authorized Marijuana Transport. A Retail Marijuana Store is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents a Retail Marijuana Store from transporting its own Retail Marijuana.
- F. Performance-Based Incentives. A Retail Marijuana Store may compensate its employees using performance-based incentives, including sales-based performance-based incentives.
- G. Authorized Transfers of Hemp Products. This rule is effective July 1, 2020. A Retail Marijuana Store may Transfer Hemp Product to a consumer only after it has confirmed:
1. That the Hemp Product has passed all required testing pursuant to the ~~4-2004-100~~ Series Rules at a Retail Marijuana Testing Facility; and
  2. That the Person Transferring the Hemp Product to the Retail Marijuana Store is registered with the Colorado Department of Public Health and Environment as a Hemp Product Manufacturer pursuant to section 25-5-427~~6~~, C.R.S.
- G.5 Authorized Food Transfers. Retail Marijuana Store may sell food that is not infused with marijuana if the annual gross revenues from the sale of food does not exceed twenty (20) percent of the Retail Marijuana Store's total annual gross revenues.
- H. Retail Marijuana Store Delivery Permit.
1. Prior to January 2, 2021, all Retail Marijuana Stores are prohibited from delivering Regulated Marijuana to consumers.
  2. After January 2, 2021, a Retail Marijuana Store with a valid delivery permit may accept delivery orders deliver Retail Marijuana to consumers pursuant to Rule 3-615.
  3. A Retail Marijuana Store that does not possess a valid delivery permit cannot deliver Retail Marijuana.
- I. Automated Dispensing Machines: A Retail Marijuana Store may use an automated machine in the Restricted Access Area of its Licensed Premises to dispense Regulated Marijuana to consumers without interaction with an Owner Licensee or Employee Licensee if the automated machine is reasonably monitored and complies with all requirements of these rules including but not limited to:
1. Health and safety standards,
  2. Testing,



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3. Packaging and labeling requirements,
  4. Inventory tracking,
  5. Identification requirements, and
  6. Transfer limits to consumers.
- J. Walk-up Window or Drive-up Window. A Retail Marijuana Store may serve customers through a walk-up window or drive-up window pursuant to the requirements of this Rule.
1. ~~Repealed. Modification of Premises Required. Before accepting orders for sales of Retail Marijuana to a customer through either a walk-up window or drive-up window, a Retail Marijuana Store shall apply for, and obtain approval of, an application for a modification of its Licensed Premises for the addition of a walk-up window or drive-up window.~~
  2. The area immediately outside the walk-up window or drive-up window must be under the Licensee's possession and control and cannot include any public property such as public streets, public sidewalks, or public parking lots.
  3. Order and Identification Requirements.
    - a. Prior to accepting an order or Transferring Retail Marijuana to a customer, the Employee Licensee or Owner Licensee must physically view and inspect the consumer's identification and ensure that the consumer is 21 years of age or older.
    - b. The Retail Marijuana Store may accept telephone or internet orders or may accept orders from the customer at the walk-up window or drive-up window.
    - c. All orders received through a walk-up window or a drive-up window must be placed by the customer from a menu. The Retail Marijuana Store may not display Retail Marijuana at the walk-up or drive-up window.
  4. Payment Requirements. Cash, credit, debit, cashless ATM, or other payment methods, including online payments are permitted for Retail Marijuana at the walk-up window or drive-up window.
  5. Video Surveillance Requirements. For every Transfer of Regulated Marijuana through either a walk-up window or drive-up window, the Retail Marijuana Store's video surveillance must enable the recording of the consumer's identity (and consumer's vehicle in the event of drive-up window), and must enable the recording of the Licensee verifying the consumer's identification and completion of the transaction through the Transfer of Regulated Marijuana.
  6. Packaging and Labeling Requirements. A Retail Marijuana Store utilizing a walk-up window or drive-up window must ensure that all Retail Marijuana is packaged and labeled in accordance with Rule 3-1010 and Rule 3-1015 prior to Transfer to the consumer.

7. Local Restrictions. Transfers of Regulated Marijuana using a walk-up window or drive-up window are subject to requirements and restrictions imposed by the relevant Local Jurisdiction.
- K. Sales over the Internet. A Retail Marijuana Store may accept orders and payment for Retail Marijuana over the internet.
  1. Online Order Requirements.
    - a. Online orders must include the customer's name and date of birth.
    - b. Prior to accepting the order, the store must provide and the customer must acknowledge receipt of:
      - i. A digital copy of the pregnancy warning required in Rule 6-115; and
      - ii. If accepting an order for Retail Marijuana Concentrate, the Retail Marijuana Store must also provide the educational resource required in Rule 6-110(C.5).
    - c. Licensees must maintain Sstandard Operating Procedures documenting their compliance with the requirements of this subparagraph (K).
  2. Transfer of Retail Marijuana to the Customer.
    - a. A cCustomer must be physically present on the Licensed Premises to take possession of Retail Marijuana.
    - b. The Retail Marijuana Store must verify the customer's physical identification matches the name and date of birth the customer provided at the time of the order, and verify that the customer is twenty-one years of age or older, in accordance with these Rules.
  3. Delivery. A Retail Marijuana Store that holds a valid delivery permit may make sales of Retail Marijuana over the internet in accordance with Rule 3-615.
  4. Approved Sources of Payment. A Retail Marijuana store may accept payment using any legal method of payment, gift card pre-payments, or pre-payment accounts established with a Retail Marijuana Store except that any payment with an Electronic Benefits Transfer Services Card is not permitted.
    - a. A Local Licensing Authority or Local Jurisdiction may further restrict legal methods of payment not expressly permitted by section 44-10-203(2)(dd)(XV), C.R.S.

### **Basis and Purpose – 6-110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(4)(b), 44-10-203(1)(k), 44-10-401(2)(b)(I), 44-10-701(1)(a), 44-10-701(3)(d) and (f), and 44-10-601, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsections 16(3)(a), 16(5)(a)(V) and 16(5)(a)(VIII). The purpose of

this rule is to clarify those acts that are limited in some fashion, or prohibited, by a licensed Retail Marijuana Store.

Regarding quantity limitations on sales, equivalencies for Retail Marijuana Concentrate and Retail Marijuana Product to Retail Marijuana flower have been included in this rule pursuant to the mandate of House Bill 14-1361. The establishment of equivalencies also provides information to stakeholders including Licensees, the general public, and law enforcement to aid in the enforcement of and compliance with the lawful personal possession limit of one ounce or less of marijuana. Setting these equivalencies provides Retail Marijuana Stores and their employees with necessary information to avoid being complicit in a patron acquiring more marijuana than is lawful to possess under the Colorado Constitution pursuant to Article XVIII, Subsection 16(3)(a).

This Rule 6-110 was previously Rule R 402, 1 CCR 212-2.

### **6-110 – Retail Marijuana Sales: General Limitations or Prohibited Acts**

- A. Sales to Persons Under 21 Years. Licensees are prohibited from Transferring, giving, or distributing Retail Marijuana to persons under 21 years of age. Licensees are prohibited from permitting a person under the age of 21 years of age from entering the Restricted Access Area.
- B. Age Verification. Licensees must verify on two separate occasions that a Person is 21 years of age or older. First, prior to permitting a Person to enter the Restricted Access Area, a Licensee must verify that the Person has a valid government-issued photo identification showing that the Person is 21 years of age or older. Second, prior to initiating the Transfer of Retail Marijuana, a Licensee must verify that the purchaser has a valid government-issued photo identification showing that the purchaser is 21 years of age or older.
- C. Quantity Limitations On Sales.
  - 1. A Retail Marijuana Store and its employees are prohibited from Transferring more than one ounce of Retail Marijuana flower or its equivalent in Retail Marijuana Concentrate or Retail Marijuana Product to a consumer in a single transaction. A Retail Marijuana Store may also Transfer up to six (6) seeds in addition to the one ounce of Retail Marijuana flower or its equivalent in Retail Marijuana Concentrate or Retail Marijuana Product to a consumer in a single transaction. A single transaction includes multiple Transfers to the same consumer during the same business day where the Retail Marijuana Store employee knows or reasonably should know that such Transfer would result in that consumer possessing more than one ounce of marijuana. In determining the imposition of any penalty for violation of this Rule 6-110(C), the State Licensing Authority will consider any mitigating and aggravating factors set forth in Rule 8-235(C).
  - 2. Equivalency. Non-edible, non-psychoactive Retail Marijuana Products including ointments, lotions, balms, and other non-transdermal topical products are exempt from the one-ounce quantity limit on Transfers. For all other Retail Marijuana Products or Retail Marijuana Concentrate, the following equivalency applies for the one-ounce quantity Transfer limit:

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- a. One ounce of Retail Marijuana flower shall be equivalent to eight grams of Retail Marijuana Concentrate.
  - b. One ounce of Retail Marijuana flower shall be equivalent to 80 ten-milligram servings of THC in Retail Marijuana Product.
- C.5. Educational Resource. When completing a sale of Retail Marijuana Concentrate, a Retail Marijuana Store shall ~~provide the consumer with~~ physically attach to the consumer's receipt of sale, product container, or exit packaging the tangible educational resource created by the State Licensing Authority regarding the use of Regulated Marijuana Concentrate.
- D. Licensees May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to Transfer Retail Marijuana to a consumer.
- E. Repealed.
- F. Delivery Outside Colorado Prohibited. A Retail Marijuana Store holding a valid delivery permit shall not deliver Retail Marijuana to an address that is outside the state of Colorado.
- G. Prohibited Items. A Retail Marijuana Store is prohibited from selling or giving away ~~any consumable product that is not a Retail Marijuana Product or a Hemp Product including, but not limited to,~~ cigarettes or tobacco products, and alcohol beverages, ~~and food products or non-alcohol beverages that are not Retail Marijuana Product.~~
- H. Free Product Prohibited. A Retail Marijuana Store may not give away Retail Marijuana to a consumer for any reason.
- I. Nicotine or Alcohol Prohibited. A Retail Marijuana Store is prohibited from Transferring Retail Marijuana that contain nicotine or alcohol, if the sale of the alcohol would require a license pursuant to Articles 3, 4, or 5 of Title 44, C.R.S.
- J. Storage and Display Limitations.
  - 1. A Retail Marijuana Store shall not display Retail Marijuana outside of a designated Restricted Access Area or in a manner in which Retail Marijuana can be seen from outside the Licensed Premises. Storage of Retail Marijuana shall otherwise be maintained in Limited Access Areas or a designated Restricted Access Area.
  - 2. Any Retail Marijuana Concentrate displayed in a Retail Marijuana Store must include the potency of the concentrate on a sign next to the name of the product.
    - a. The font on the sign must be large enough for a consumer to reasonably see from the location where a consumer would usually view the concentrate.
    - b. The potency displayed on the sign must be within plus or minus fifteen percent of the concentrate's actual potency.
- K. Transfer of Expired Product Prohibited. A Retail Marijuana Store shall not Transfer any expired Edible Retail Marijuana Product, Vaporizer Delivery Device, Pressurized

Metered Dose Inhaler, Audited Marijuana Product, or Alternative Use Product to a consumer.

L. Transfer Restriction.

1. Sampling Units. A Retail Marijuana Store may not possess or Transfer Sampling Units.
2. Research Transfers Prohibited. A Retail Marijuana Store shall not Transfer any Retail Marijuana to a Pesticide Manufacturer, or a Marijuana Research and Development Facility.

L.5. Standard Operating Procedures. A Retail Marijuana Store must establish written Sstandard Operating Procedures for the management and storage of Retail Marijuana inventory and the sale of Retail Marijuana to consumers. A written copy of the Sstandard Operating Procedures must be maintained on the Licensed Premises.

1. A Retail Marijuana Store must provide adequate training to every Owner Licensee and Employee Licensee who performs a task or set of tasks that are referenced in the Sstandard Operating Procedures. Adequate training must include, but need not be limited to, providing a copy of the Sstandard Operating Procedures for that Licensed Premises detailing at least all of the topics required to be included in the Sstandard Operating Procedures.

M. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit.

1. The sale of Edible Retail Marijuana Products in the following shapes is prohibited:
  - a. The distinct shape of a human, animal, or fruit; or
  - b. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
2. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Retail Marijuana Business. Nothing in this subparagraph (M)(2) alters or eliminates a Licensee's obligation to comply with the requirements of the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
3. Edible Retail Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and
4. Edible Retail Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible.

N. Adverse Health Event Reporting. A Retail Marijuana Store must report Adverse Health Events pursuant to Rule 3-920.

O. Corrective and Preventive Action. This paragraph O shall be effective January 1, 2021. A Retail Marijuana Store shall establish and maintain written procedures for implementing Corrective Action and Preventive Action. The written procedures shall include the requirements listed below as determined by the Licensee. All activities required under

this Rule, and their results, shall be documented and kept as business records. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:

1. What constitutes a Nonconformance in the Licensee's business operation;
2. Analyzing processes, work operations, reports, records, service records, complaints, returned product, and/or other sources of data to identify existing and potential root causes of Nonconformances or other quality problems;
3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
7. Ensuring the information related to quality problems or Nonconformances is disseminated to those directly responsible for assuring the quality of products or the prevention of such problems; and
8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.

- P. ~~Repeated. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

### **Basis and Purpose – 6-115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(z), and 44-10-202(3)(h), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsections 16(5)(a)(V) and 16(5)(a)(VIII). The purpose of this rule is to establish that a Retail Marijuana Store must control and safeguard access to certain areas where Retail Marijuana and Retail Marijuana Product will be sold to the general public and prevent the diversion of Retail Marijuana and Retail Marijuana Product to people under 21 years of age. This Rule 6-115 was previously Rule R 403, 1 CCR 212-2.

### **6-115 – Point of Sale: Restricted Access Area**

- A. Identification of Restricted Access Area. All areas where Retail Marijuana are sold, possessed for sale, displayed, or dispensed for sale shall be identified as a Restricted Access Area and shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, "Restricted Access Area – No One Under 21 Years of Age Allowed."
- B. Consumers in Restricted Access Area. The Restricted Access Area must be supervised by a Licensee at all times when consumers are present to ensure that only persons who

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are 21 years of age or older are permitted to enter. When allowing a customer access to a Restricted Access Area, Owner Licensees and Employee Licensees shall make reasonable efforts to limit the number of consumers in relation to the number of Owners Licensees and Employee Licensees in the Restricted Access Area at any time.

- C. Display of Retail Marijuana. The display of Retail Marijuana for sale is allowed only in Restricted Access Areas. Any product displays that are readily accessible to the consumer must be supervised by the Owner Licensee or Employee Licensees at all times when consumers are present.
- D. Pregnancy Warning. Retail Marijuana Stores must post, at all times and in a prominent place at every point-of-sale inside the Restricted Access Area, a warning that is at minimum three inches high and six inches wide that reads:

**WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.

**6-200 Series – Retail Marijuana Cultivation Facilities****Basis and Purpose – 6-205**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(j), 44-10-203(2)(r), 44-10-203(3)(c), 44-10-313(14), 44-10-401(2)(b)(II), and 44-10-602, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to a Retail Marijuana Cultivation Facility. This Rule 6-205 was previously Rule R 501, 1 CCR 212-2.

**6-205 – Retail Marijuana Cultivation Facility: License Privileges**

- A. Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Cultivation Facility may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Cultivation Facility. However, a separate license is required for each specific business or business entity, regardless of geographical location. In addition, a Retail Marijuana Cultivation Facility may share, and operate at, the same Licensed Premises as a Marijuana Research and Development Facility so long as:
1. Each business or business entity holds a separate license;
  2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;
  3. Both the Marijuana Research and Development Facility and the Retail Marijuana Cultivation Facility comply with all terms and conditions of the R&D Co-Location Permit; and
  4. Both the Marijuana Research and Development Facility and the Retail Marijuana Cultivation Facility comply with all applicable rules. See 5-700 Series Rules.



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- B. Cultivation of Retail Marijuana and Production of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Retail Marijuana Concentrate Authorized. A Retail Marijuana Cultivation Facility may propagate, cultivate, harvest, prepare, cure, package, store, and label Retail Marijuana and Physical Separation-Based Retail Marijuana Concentrate. A Retail Marijuana Cultivation Facility may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Retail Marijuana Concentrate.
- C. Authorized Transfers. A Retail Marijuana Cultivation Facility may only Transfer Retail Marijuana and Physical Separation-Based Retail Marijuana Concentrate to another Retail Marijuana Business. A Retail Marijuana Cultivation Facility and an Accelerator Cultivator may also Transfer to a Medical Marijuana Cultivation Facility in compliance with Rules 6-230 and 6-730.
1. A Retail Marijuana Cultivation Facility shall not Transfer Flowering plants. A Retail Marijuana Cultivation Facility may only Transfer Vegetative plants as authorized pursuant to Rule 3-605.
  2. A Retail Marijuana Cultivation Facility may Transfer Sampling Units of Retail Marijuana or Retail Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-602(6), C.R.S., and Rule 6-225.
  3. A Retail Marijuana Cultivation Facility may Transfer Retail Marijuana or Retail Marijuana Concentrate to another Retail Marijuana Cultivation Facility prior to testing required by these rules only if such Transfer is in accordance with one of the two options below.
    - a. The Retail Marijuana Cultivation Facility may Transfer Retail Marijuana ~~or~~ Retail Marijuana Concentrate, Pre-Rolled Marijuana, or Infused Pre-Rolled Marijuana to another Retail Marijuana Cultivation Facility prior to testing if such Transfer is to perform a Microbial Control Step and only after all other steps outlined in the Retail Marijuana Cultivation Facility's Sstandard Operating Procedures have been completed, including but not limited to drying, curing, and trimming; or
    - b. The Retail Marijuana Cultivation Facility may Transfer Retail Marijuana or Retail Marijuana Concentrate to another Retail Marijuana Cultivation Facility prior to testing, drying, curing, trimming, or completion of any other steps in the Retail Marijuana Cultivation Facility's Sstandard Operating Procedures, subject to the following additional requirements:
      - i. The Retail Marijuana Cultivation Facility receiving the Transfer is identified as a centralized processing hub in the Inventory Tracking System and must have identical Controlling Beneficial Owner(s) with the originating Retail Marijuana Cultivation Facility;
      - ii. An originating Retail Marijuana Cultivation Facility may only Transfer Retail Marijuana to one receiving Retail Marijuana



- Cultivation Facility that will be serving as a centralized processing hub;
- iii. The Retail Marijuana or Retail Marijuana Concentrate is weighed prior to leaving the originating Retail Marijuana Cultivation Facility and immediately upon receipt at the receiving Retail Marijuana Cultivation Facility and in accordance with Rule 3-605;
  - iv. The Transfer, weighing and entry into the Inventory Tracking System are all completed within 24 hours from initiating the Transfer;
  - v. The receiving Retail Marijuana Cultivation Facility is responsible for compliance with all testing requirements regardless of any testing performed prior to Transfer. If the receiving Retail Marijuana Cultivation Facility is pursuing a Reduced Testing Allowance, a Reduced Testing Allowance must be achieved separately for marijuana received from each originating Retail Marijuana Cultivation Facility. A Retail Marijuana Cultivation Facility that has achieved a Reduced Testing Allowance must maintain and produce complete testing records that can verify that facility's compliance with testing and Reduced Testing Allowance requirements; and
  - vi. The ~~S~~standard ~~O~~perating ~~P~~rocedures for the originating Retail Marijuana Cultivation Facility and receiving Retail Marijuana Cultivation Facility clearly reflect the steps taken by each facility to Transfer, transport, receive, process, and test Harvest Batches.
- 4. A Retail Marijuana Cultivation Facility may transfer Retail Marijuana to a Pesticide Manufacturer.
  - 5. A Retail Marijuana Cultivation Facility may Transfer Retail Marijuana to a Medical Marijuana Cultivation Facility in accordance with Rules 5-235 and 6-230.
  - 6. A Retail Marijuana Cultivation Facility may ~~sell, Transfer, or ship Immature Plants, Retail Marijuana seeds, and~~ Genetic Material in accordance with section 44-10-602(12)(b), C.R.S. to a Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator. Transfers made under this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.
- D. Authorized On-Premises Storage. A Retail Marijuana Cultivation Facility is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area and tracked consistently with the inventory tracking rules.
- E. Test Batches Provided for Testing. A Retail Marijuana Cultivation Facility may provide Test Batches of its Retail Marijuana to a Retail Marijuana Testing Facility for testing and research purposes. The Retail Marijuana Cultivation Facility shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.

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- F. Authorized Marijuana Transport. A Retail Marijuana Cultivation Facility is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents a Retail Marijuana Cultivation Facility from transporting its own Retail Marijuana.
- G. Performance-Based Incentives. A Retail Marijuana Cultivation Facility may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Retail Marijuana Cultivation Facility may not compensate a Sampling Manager using Sampling Units. See Rule 6-225 – Sampling Unit Protocols.
- H. Authorized Sources of Retail Marijuana, ~~Seeds, Immature Plants,~~ and Genetic Material.
1. A Retail Marijuana Cultivation Facility may obtain Retail Marijuana ~~seeds or Immature Plants from its own Retail Marijuana, properly Transferred Medical Marijuana cultivated at a Medical Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or~~ properly Transferred from another Retail Marijuana Business pursuant to the inventory tracking requirements in the 3-800 Series Rules. A Retail Marijuana Cultivation facility may not bring ~~seeds, Immature Plants, or other~~ marijuana that is not Regulated Marijuana onto the Licensed Premises at any time.
  2. A Retail Marijuana Cultivation Facility may obtain ~~Regulated Marijuana seeds, Immature Plants, and~~ Genetic Material in accordance with section 44-10-602(12)(a), C.R.S. from:
    - a. ~~Another Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility;~~
    - b. ~~A Retail Marijuana Testing Facility;~~
    - c. ~~A marijuana cultivation or testing facility licensed or otherwise approved pursuant to a permit or registration issued by a government agency to operate in another state or territory of the United States;~~
    - d. ~~An individual licensed as an Employee Licensee in Colorado, or holding a permit, registration, or license to work in another state or territory of the United States that regulates marijuana; or~~
    - e. ~~Pursuant to any federal statute or regulation.~~
  3. Transfers made under subparagraph (H)(2) of this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.
- I. Centralized Distribution Permit. A Retail Marijuana Cultivation Facility may apply to the State Licensing Authority for a Centralized Distribution Permit for authorization to temporarily store Retail Marijuana Concentrate and Retail Marijuana Product received from a Retail Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Retail Marijuana Stores.
1. For purposes of a Centralized Distribution Permit only, the term “commonly owned” means at least one natural person has a minimum of five percent

ownership in both the Retail Marijuana Cultivation Facility possessing a Centralized Distribution Permit and the Retail Marijuana Store to which the Retail Marijuana Concentrate and Retail Marijuana Product will be Transferred.

2. To apply for a Centralized Distribution Permit, a Retail Marijuana Cultivation Facility may submit an addendum to its new or renewal application or a separate addendum prior to a renewal application on forms prepared by the Division to request a Centralized Distribution Permit. The Retail Marijuana Cultivation Facility shall send a copy of its Centralized Distribution Permit addendum to the Local Licensing Authority in the jurisdiction in which the Centralized Distribution Permit is proposed at the same time it submits the addendum to the State Licensing Authority.
  3. A Retail Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit and has obtained all required approvals from the local licensing jurisdiction where it is located, if any, may accept Transfers of Retail Marijuana Concentrate and Retail Marijuana Product from a Retail Marijuana Products Manufacturer for the sole purpose of temporary storage and Transfer to commonly owned Retail Marijuana Stores.
    - a. A Retail Marijuana Cultivation Facility may only accept Retail Marijuana Concentrate and Retail Marijuana Product that is packaged and labeled for sale to a consumer pursuant to the 3-1000 Series Rules.
    - b. A Retail Marijuana Cultivation Facility storing Retail Marijuana Concentrate and Retail Marijuana Product pursuant to a Centralized Distribution Permit shall not store such Retail Marijuana Concentrate or Retail Marijuana Product on the Retail Marijuana Cultivation Facility's Licensed Premises for more than 90 days from the date of receipt.
    - c. All Transfers of Retail Marijuana Concentrate and Retail Marijuana Product by a Retail Marijuana Cultivation Facility shall be without consideration.
  4. All security and surveillance requirements that apply to a Retail Marijuana Cultivation Facility apply to activities conducted pursuant to the privileges of a Centralized Distribution Permit.
- J. Transition Permit. A Retail Marijuana Cultivation Facility may only operate at two geographical locations pursuant to Rule 2-255(D).

### **Basis and Purpose – 6-215**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(r), 44-10-401(2)(b)(II), and 44-10-602, C.R.S. The purpose of this rule is to establish the categories of Retail Marijuana Concentrate that may be produced at a Retail Marijuana Cultivation Facility and standards for the production of Retail Marijuana Concentrate. This Rule 6-215 was previously Rule R 505, 1 CCR 212-2.

### **6-215 – Retail Marijuana Cultivation Facilities: Retail Marijuana Concentrate Production**

- A. Permitted Production of Certain Categories of Retail Marijuana Concentrate. A Retail Marijuana Cultivation Facility may only produce Physical Separation-Based Retail Marijuana Concentrate on its Licensed Premises and only in an area clearly designated as a Limited Access Area. See Rule 3-905- Business Records Required. No other method of production or extraction for Retail Marijuana Concentrate may be conducted within the Licensed Premises of a Retail Marijuana Cultivation Facility unless the Controlling Beneficial Owner(s) of the Retail Marijuana Cultivation Facility also has a valid Retail Marijuana Products Manufacturer license and the room in which Retail Marijuana Concentrate is to be produced is physically separated from all cultivation areas and has clear signage identifying the room.
- B. Safety and Sanitary Requirements for Concentrate Production. If a Retail Marijuana Cultivation Facility produces Retail Marijuana Concentrate, then all areas in which the Retail Marijuana Concentrate are produced and all Controlling Beneficial Owners and Employee Licensees engaged in the production of the Retail Marijuana Concentrate shall be subject to all of the requirements imposed upon a Retail Marijuana Products Manufacturer that produces Retail Marijuana Concentrate, including all general requirements. See 3-300 Series Rules – Health and Safety Regulations and Rule 6-315 – Retail Marijuana Products Manufacturer: Retail Marijuana Concentrate Production.
- C. Possession of Other Categories of Retail Marijuana Concentrate.
1. It shall be considered a violation of this Rule if a Retail Marijuana Cultivation Facility possesses a Retail Marijuana Concentrate other than a Physical Separation-Based Retail Marijuana Concentrate on its Licensed Premises unless: the Controlling Beneficial Owner(s) of the Retail Marijuana Cultivation Facility also has a valid Retail Marijuana Products Manufacturer license; or the Retail Marijuana Cultivation Facility has been issued a Centralized Distribution Permit and is in possession of the Retail Marijuana Concentrate in compliance with Rule 6-205(I).
  2. Notwithstanding subparagraph (C)(1) of this Rule 6-215, a Retail Marijuana Cultivation Facility shall be permitted to possess Solvent-Based Retail Marijuana Concentrate only when the possession is due to the Transfer of Retail Marijuana flower or trim that failed microbial testing to a Retail Marijuana Products Manufacturing Facility for processing into a Solvent-Based Retail Marijuana Concentrate, and the Retail Marijuana Products Manufacturer Transfers the resultant Solvent-Based Retail Marijuana Concentrate back to the originating Retail Marijuana Cultivation Facility.
    - a. The Retail Marijuana Cultivation Facility shall comply with all requirements in Rule ~~4-2404-135(C)~~ when having Solvent-Based Retail Marijuana Concentrate manufactured out of Retail Marijuana flower or trim that failed microbial testing.
    - b. The Retail Marijuana Cultivation Facility is responsible for submitting the Solvent-Based Retail Marijuana Concentrate for all required testing for contaminants pursuant to Rule ~~4-2154-120~~ – Regulated Marijuana Testing Program – Contaminant Testing, for potency pursuant to Rule ~~4-2104-125~~

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- Regulated Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Marijuana Rules or the Marijuana Code.
- c. Nothing in this Rule removes or alters the responsibility of the Retail Marijuana Cultivation Facility that Transfers the Retail Marijuana that failed microbial testing from complying with the requirement to pay excise tax pursuant to Rule 6-210(C).
- D. Production of Alternative Use Product or Audited Product Prohibited. A Retail Marijuana Cultivation Facility shall not produce an Alternative Use Product or Audited Product.
- E. Possession of Alternative Use Product or Audited Product. A Retail Marijuana Cultivation Facility is authorized to possess or Transfer Alternative Use Product and/or Audited Product only if the Retail Marijuana Cultivation Facility received the Alternative Use Product and/or Audited Product pursuant to a Centralized Distribution Permit from a Retail Marijuana Products Manufacturer that is manufacturing and Transferring the Alternative Use Product or Audited Product in accordance with Rule 6-325.

**Basis and Purpose – 6-220**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(6), 44-10-401(2)(b)(II), and 44-10-602, C.R.S. The rule establishes a means by which to manage the overall production of Retail Marijuana in the state of Colorado. The intent of this rule is to encourage responsible production to meet demand for retail marijuana consumers, while also avoiding overproduction or underproduction. The establishment of production management is necessary to ensure there is not significant under or over production, either of which will increase incentives to engage in diversion and facilitate the continuation of the sale of illegal marijuana.

Existing and prospective licensees should be on notice that the new or revised regulations may impact the production limits provided for in this rule. Additionally, throughout the rulemaking process stakeholders expressed concern over ensuring an adequate amount of licensed Retail Marijuana Stores exist to sell the amount of Retail Marijuana being produced at licensed Retail Marijuana Cultivation Facilities. Scaling the number of interests a Person may hold in Retail Marijuana Cultivation Facility licenses relative to the number of controlling interests the Person has in Retail Marijuana Store(s) has been incorporated in the production management rules as a means to address this production management concern.

The Rule 6-220 was previously Rule R 506, 1 CCR 212-2.

**6-220 – Retail Marijuana Cultivation Facility: Production Management**

- A. One Retail Cultivation License per Licensed Premises.
  - 1. One Retail Marijuana Cultivation License per Licensed Premises. Except as permitted by subparagraph (A)(2) only one Retail Marijuana Cultivation Facility License shall be permitted at each Licensed Premises and each Licensed Premises must be located at a distinct address recognized by the Local Jurisdiction.
  - 2. Collapse after January 1, 2019. After January 1, 2019, collapse of more than one Retail Marijuana Cultivation Facility license at a single Licensed Premises

through an approved change of location application shall be permitted if all Retail Marijuana Cultivation Facility licenses for which the collapse is sought meet the following requirements:

- a. All Retail Marijuana Cultivation Facility licenses sought to be collapsed have been continuously operating for at least 180 days prior to the proposed collapse;
- b. All Retail Marijuana Cultivation Facility licenses sought to be collapsed have identical Controlling Beneficial Owners holding identical ownership percentages;
- c. There is no pending administrative action regarding any of the Retail Marijuana Cultivation Facility licenses sought to be collapsed;
- d. The tier for the surviving Retail Marijuana Cultivation Facility license has not been decreased in the 180 days prior to the change of location application.
- e. All Retail Marijuana Cultivation Facility Licensees identify the desired surviving license and agree that all other Retail Marijuana Cultivation Facility licenses will be surrendered at the time of collapse; and
- f. Determining Tier for Surviving License.
  - i. Surviving License Tier Will Not Decrease. The tier for the surviving license will not be decreased as a result of any approved change of location application.
  - ii. Surrendered License is Tier 1 or Tier 2. For the surviving license to increase one tier or one increment of 3,600 plants if already tier 5 or higher, during the 180 days prior to the change of location application, the surrendered license must have cultivated at least 50% of the maximum authorized plant count and Transferred at least 85% of the inventory it produced during that time.
  - iii. Surrendered License is Tier 3 or Higher. For the surviving license to increase by the maximum authorized plant count of the surrendered license, during the 180 days prior to the change of location application the surrendered license must have cultivated at least 50% of the maximum authorized plant count and Transferred at least 85% of the inventory it produced during that time. If during the 180 days prior to the change of location application, the surrendering license did not cultivate at least 50% of the maximum authorized plant count and Transfer at least 85% of the inventory it produced, the surviving license will only increase one tier or one increment of 3,600 plants if already a tier 5 or higher.
  - iv. Division Determination of Tier. If a collapse results in a maximum authorized plant count in the middle of a tier, the surviving

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license's maximum authorized plant count will be rounded up to the top of that tier.

B. Production Management.

1. Production Management Tiers.

- a. Tier 1: 1 - 1,800 plants
- b. Tier 2: 1,801 – 3,600 plants
- c. Tier 3: 3,601 – 6,000 plants
- d. Tier 4: 6,001 – 10,200 plants
- e. Tier 5: 10,201 – 13,800+ plants
  - i. Tier 5 shall not have a cap on the maximum authorized plant count.
  - ii. The maximum authorized plant count above 10,200 plants shall increase in one or two increments of 3,600 plants. A Retail Marijuana Cultivation Facility Licensee shall be allowed to increase its maximum authorized plant count one or two increments of 3,600 plants at a time upon application and approval by the Division pursuant to the requirements of paragraph (E) of this Rule 6-220.

2. All Retail Marijuana Cultivation Facility licenses granted on or after November 30, 2015 will be issued as a Tier 1 License.

3. Immature Plants. For purposes of calculating the maximum number of authorized plants, Immature Plants are excluded, but must be fully accounted for in the Inventory Tracking System.

4. Ground for Denial. The Division may deny an application for additional plants pursuant to paragraph E of this Rule if the Licensee exceeded the authorized plant count during the relevant time period for production.

5. ~~Repealed. Violation Affecting Public Safety. It may be considered a license violation affecting public safety for a Licensee to exceed the authorized plant count pursuant to these Rules.~~

C. Inventory Management.

1. Inventory Management for Retail Cultivation Facilities that Have One or Two Harvest Seasons a Year. Beginning the 721<sup>st</sup> day from the commencement of its first cultivation activities, a Retail Marijuana Cultivation Facility that has one or two harvest seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Retail Marijuana flower and trim the Licensee reported as a package in the Inventory Tracking System that was Transferred to another Retail Marijuana Business in the previous 720 days.

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2. Inventory Management for Retail Cultivation Facilities That Have More Than Two Harvest Seasons a Year. Beginning the 181<sup>st</sup> day from the commencement of its first cultivation activities, a Retail Marijuana Cultivation Facility that has more than two harvest seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Retail Marijuana flower and trim the Licensee reported as a package in the Inventory Tracking System that was Transferred to another Retail Marijuana Business in the previous 180 days.
- D. Tier Decrease. For Retail Marijuana Cultivation Facilities that are authorized to cultivate more than 1,800 plants, the Division may review the purchases, Transfers, and cultivated plant count of the Retail Marijuana Cultivation Facility Licensee in connection with the license renewal process or after an investigation. Based on the Division's review, the Division may reduce the Licensee's maximum allowed plant count to a lower production management tier pursuant to subparagraph (C)(1) of this Rule. When determining whether to reduce the maximum authorized plant count, the Division may consider the following non-exhaustive factors including but not limited to:
1. The Licensee sold less than 70% of what the inventory it reported as packaged in the Inventory Tracking System during any 180 day review period;
  2. On average during the previous 180 days the Licensee actually cultivated less than 90% of the maximum number of plants authorized by the next lower production management tier;
  3. Whether the plants/inventory suffered a catastrophic event during the review period;
  4. Excise tax payment history;
  5. Existing inventory and inventory history;
  6. Sales contracts; and
  7. Any other factors relevant to ensuring responsible cultivation, production, and inventory management.
- E. Application for Additional Plants.
1. Retail Marijuana Cultivation Facilities That Have One or Two Harvest Seasons Per Year.
    - a. After accruing at least one harvest season of Transfers, a Retail Marijuana Cultivation Facility Licensee may apply to the Division for a production management tier increase to be authorized to cultivate the number of plants in the next highest production management tier. The Division may consider the following in determining whether to approve the production management tier increase:
      - i. That during the previous harvest season prior to the tier increase application, it consistently cultivated an average amount of plants that is at least 85% of its maximum authorized plant count;



- ii. That the Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System in the previous 360 days to another Retail Marijuana Business;
  - iii. The Division may also consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the previous 360 days, if the Licensee cultivated between 75% and 85% of its maximum authorized plant count; and
  - iv. Any other information requested to aid the Division in its evaluation of the production management tier increase application.
- b. If the Division approves the production management tier increase application, the Licensee shall pay the applicable ~~E~~expanded ~~p~~Pproduction ~~m~~Mmanagement ~~t~~Tier ~~f~~Fee in Rule 2-125 prior to cultivating the additional authorized plants. ~~See Rule 2-205—Fees.~~
- c. For a Licensee with an authorized plant count in tiers 2-5 to continue producing at its expanded authorized plant count, the Licensee shall pay the requisite Retail Marijuana Cultivation Facility license fee and the applicable ~~E~~expanded ~~P~~production ~~M~~management ~~T~~tier ~~F~~fee in Rule 2-125 at license renewal. ~~See Rule 2-205—Fees.~~
- d. After accruing one harvest season during which the Retail Marijuana Cultivation Facility Transferred and consistently cultivated the Licensee may apply to increase its authorized plant count by: (a) two production management tiers or (b) if already authorized to cultivate at a production management tier 5, two increments of 3,600 plants (7,200 plants total), every 360 days. It is within the Division's discretion to determine whether or not to grant the requested two tiers or increments of 3,600 plants (7,200 plants total).
  - i. The Licensee must demonstrate:
    - A. That the Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count; and
    - B. That the Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Retail Marijuana Business.
    - C. If the Retail Marijuana Cultivation Facility cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a package in the Inventory Tracking System during that time period and/or

Transfers into the Retail Marijuana Cultivation Facility or related Retail Marijuana Store(s).

- ii. In making its determination, the Division may consider the following exclusive factors:
  - A. The Retail Marijuana Cultivation currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two tiers or two 3,600 plant increments;
  - B. The Retail Marijuana Cultivation Facility cultivated at least 90% of its maximum authorized plant count and during the preceding 360 days the Retail Marijuana Cultivation Facility and/or any commonly owned Retail Marijuana Store Transferred in Retail Marijuana from one or more unrelated Retail Marijuana Cultivation Facility(ies);
  - C. The Retail Marijuana Cultivation has contracts for the sale of Retail Marijuana in the next 360 days supporting the requested two tiers or two increments of 3,600 plants;
  - D. An established history of responsible cultivation and Transfer by the Retail Marijuana Cultivation;
  - E. Any history of noncompliance with the Retail Code, Marijuana Code, and/or Rules by the Retail Marijuana Cultivation Facility, or any commonly owned Retail Marijuana Business, and/or any investigation of, or administrative action(s) against, the Retail Marijuana Cultivation Facility, or any commonly owned Retail Marijuana Business; or
  - F. Any other pertinent facts or circumstances regarding responsible production and inventory management.
- 2. Retail Marijuana Cultivation Facilities that have more than two harvest seasons per year.
  - a. After a 180-day period during which the Retail Marijuana Cultivation Facility Transferred and consistently cultivated, the Licensee may apply to the Division for a production management tier increase to be authorized to cultivate the number of plants in the next highest production management tier. The Division may consider the following in determining whether to approve the production management tier increase:
    - i. That for 180 days prior to the tier increase application, the Licensee consistently cultivated an average amount of plants that is at least 85% of its maximum authorized plant count, and

- ii. That the Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Retail Marijuana Business.
  - iii. The Division may also consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the 180-day time period if the Licensee cultivated between 75% and 85% of its maximum authorized plant count.
  - iv. Any other information requested to aid the Division in its evaluation of the tier increase application.
- b. If the Division approves the production management tier increase application, the Licensee shall pay the applicable ~~E~~expanded ~~P~~roduction ~~M~~anagement ~~T~~ier ~~F~~ee in Rule 2-125 prior to cultivating the additional authorized plants. ~~See Rule 2-205—Fees.~~
- c. For a Licensee with an authorized plant count in tier 2-5 to continue producing at its expanded authorized plant count, the Licensee shall pay the requisite Retail Marijuana Cultivation Facility license fee and the applicable ~~e~~Expanded ~~p~~roduction ~~m~~anagement ~~t~~ier ~~f~~ee in Rule 2-125 at ~~L~~icense renewal. ~~See Rule 2-205—Fees.~~
- d. After accruing 180 days during which the Retail Marijuana Cultivation Facility Transferred and consistently cultivated the Licensee may apply to increase its authorized plant count by: (a) two production management tiers or (b) if already authorized to cultivate at a tier 5, two increments of 3,600 plants (7,200 plants total) every 180 days. It is within the Division's discretion to determine whether or not to grant the requested two tier or two increments of 3,600 plants (7,200 plants total).
- i. The Licensee must demonstrate:
- A. That the Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count; and
  - B. That the Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Retail Marijuana Business;
  - C. If the Retail Marijuana Cultivation Facility cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a package in the Inventory Tracking system during that time period and/or Transfers into the Retail Marijuana Cultivation Facility or related Retail Marijuana Store(s).

- ii. In making its determination, the Division may consider the following exclusive factors:
  - A. The Retail Marijuana Cultivation currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two tiers or two increments of 3,600 plants;
  - B. The Retail Marijuana Cultivation Facility cultivated at least 90% of its maximum authorized plant count and during the preceding 180 days the Retail Marijuana Cultivation Facility and/or any commonly owned Retail Marijuana Store Transferred in Retail Marijuana from one or more unrelated Retail Marijuana Cultivation Facility(ies);
  - C. The Retail Marijuana Cultivation has entered into a written agreement(s) or contract(s) for the sale of Retail Marijuana in the next 180 days supporting the requested two tiers or two increments of 3,600 plants;
  - D. An established history of responsible cultivation and Transfer by the Retail Marijuana Cultivation;
  - E. Any history of noncompliance with the Retail Code, Marijuana Code, and/or Rules by the Retail Marijuana Cultivation Facility or any commonly owned Retail Marijuana Business(es), and/or any investigation of, or administrative action(s) against, the Retail Marijuana Cultivation Facility or any commonly owned Retail Marijuana Business;
  - F. Any other pertinent facts or circumstances regarding responsible production and inventory management.
- e. A Retail Marijuana Cultivation Facility that does not have 180 days of cultivating history may apply to increase its plant count to tier 2 or tier 3 pursuant only to this subparagraph (E)(2)(e). A Retail Marijuana Cultivation Facility applying for a tier increase request under this subparagraph (E)(2)(e) must demonstrate all of the following at the time of application:
  - i. The Retail Marijuana Cultivation Facility making the tier increase request also owns at least three Retail Marijuana Stores with identical Controlling Beneficial Owners;
  - ii. The Controlling Beneficial Owners of the Retail Marijuana Cultivation Facility and three Retail Marijuana Stores used to support the tier increase request have owned the aforementioned Retail Marijuana Store licenses for at least the preceding 180 days;

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- iii. The three Retail Marijuana Stores used to support the tier increase request have consistently Transferred Regulated Marijuana to consumers in the preceding 180 days and have a history of wholesale purchases that justify the need for a tier increase above a tier 1;
    - iv. In the 180 days preceding the Licensee's tier increase request pursuant to this subparagraph (e), the Retail Marijuana Cultivation Facility, three Retail Marijuana Stores, and identical Controlling Beneficial Owners have not been subject to an administrative action issued by the State Licensing Authority;
    - v. The Retail Marijuana Cultivation Facility making the tier increase request has an established history of responsible cultivation and Transfers of its Regulated Marijuana inventory; and
    - vi. The Retail Marijuana Cultivation Facility subject to the tier increase request has not previously requested a tier increase pursuant to this subparagraph (e).
  - 3. Application for Tier Increase. Applications for a tier increase that include any artificial increase of plant count, manipulation of Transfer history, or other misrepresentation will be denied. ~~In addition to denial, any artificial increase of plant count, manipulation of Transfer history, or other misrepresentation is a public safety violation that may result in administrative action.~~
- F. Maximum Allowed Retail Marijuana Cultivation Facility Licenses.
- 1. A Person that is a Controlling Beneficial Owner in Three or More Retail Marijuana Cultivation Facility Licenses. For every multiple of three Retail Marijuana Cultivation Facility licenses in which a Person is a Controlling Beneficial Owner, the Person must also be a Controlling Beneficial Owner in at least one Retail Marijuana Store. For example: (1) a Person that is a Controlling Beneficial Owner in three, four, or five Retail Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least one Retail Marijuana Store; (2) a Person that is a Controlling Beneficial Owner in six, seven, or eight Retail Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least two Retail Marijuana Stores; (3) a Person that is a Controlling Beneficial Owner in nine, ten, or eleven Retail Marijuana Cultivation Facility licenses also must be a Controlling Beneficial Owner in at least three Retail Marijuana Stores; etc.
  - 2. A Person that is a Controlling Beneficial Owner in Less than Three Retail Marijuana Cultivation Facility Licenses. A Person that is a Controlling Beneficial Owner in less than three Retail Marijuana Cultivation Facility licenses shall not be required to be a Controlling Beneficial Owner in a Retail Marijuana Store.
- G. The State Licensing Authority, at its sole discretion, may adjust any of the plant limits described in this Rule on an industry-wide aggregate basis for all Retail Marijuana Cultivation Facility Licensees subject to that limitation.

**Basis and Purpose – 6-225**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-401(2)(b)(II), and 44-10-602(6), C.R.S. The purpose of this rule is to establish the circumstances under which a Retail Marijuana Cultivation Facility may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado's Regulated Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager may receive in a calendar month and imposes inventory tracking, reporting and recordkeeping requirements on a Retail Marijuana Cultivation Facility that Transfer Sampling Units. This Rule 6-225 was previously Rule R 507, 1 CCR 212-2.

**6-225 – Retail Marijuana Cultivation Facility: Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, a Retail Marijuana Cultivation Facility may designate no more than five Sampling Managers in the Inventory Tracking System.
1. Only management personnel of the Retail Marijuana Cultivation Facility who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  2. A person may be designated as a Sampling Manager by more than one Medical Marijuana Business or Retail Marijuana Business.
  3. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.
  4. A Retail Marijuana Cultivation Facility that wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling Manager Standard Operating Procedures that explain the requirements of section 44-10-602(6), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 6-225. See *also* Rule 3-905 – Business Records Required. A Retail Marijuana Cultivation Facility shall maintain and update such Standard Operating Procedures as necessary to reflect accurately any changes in the relevant statutes and Rules.
- B. Sampling Unit Limits. Only one Sampling Unit may be designated per Harvest Batch or Production Batch. A Sampling Unit shall not be designated until the Harvest Batch or Production Batch has satisfied the testing requirements in the 4-2004-100 Series Rules – Regulated Marijuana Testing Program.
1. A Sampling Unit of Retail Marijuana flower or trim shall not exceed one gram.
  2. A Sampling Unit of Retail Marijuana Concentrate shall not exceed one-quarter of one gram; except that a Sampling Unit of Retail Marijuana Concentrate which has the intended use of being delivered in a vaporized form shall not exceed one-half of one gram.

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- C. Excise Tax Requirements. A Retail Marijuana Cultivation Facility must pay excise tax on Sampling Units of Retail Marijuana flower or trim, based on the average market rate of the unprocessed Retail Marijuana.
- D. Transfer Restrictions.
1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
  2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Retail Marijuana Cultivation Facility as a Sampling Manager for the calendar month in which the Transfer occurs.
  3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than one ounce of Retail Marijuana or eight grams of Retail Marijuana Concentrate.
  4. The monthly limit established in subparagraph (D)(3) applies to each Sampling Manager, regardless of the number of Retail Marijuana Businesses with which the Sampling Manager is associated.
  5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (D)(3). Before Transferring any Sampling Units, a Retail Marijuana Cultivation Facility shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limits established in subparagraph (D)(3).
  6. A Sampling Manager shall not Transfer any Sampling Unit to any other Person, including but not limited to any other Person designated as a Sampling Manager.
- E. Compensation Prohibited. A Retail Marijuana Cultivation Facility may not use Sampling Units to compensate a Sampling Manager.
- F. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.
- G. Acceptable Purposes. Sampling Units shall only be designated and Transferred for the purposes of quality control and product development in accordance with section 44-10-602(6), C.R.S.
- H. Record keeping requirements. A Retail Marijuana Cultivation Facility shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule 3-905 – Business Records Required. At a minimum, a Retail Marijuana Cultivation Facility shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of quality control or product development. A Retail Marijuana Cultivation Facility shall also maintain copies of the Retail Marijuana Cultivation Facility's ~~S~~standard ~~O~~perating ~~P~~rocedures provided to Sampling Managers

- I. ~~Repealed Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 6-230**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-401(2)(b)(II), 44-10-602(13)(a)-(c), 44-10-602(13.5), 44-10-603(10)(b), and 39-28.8-299, C.R.S. The purpose of this rule is to allow a Medical Marijuana Cultivation Facility to receive Transfers of Retail Marijuana from a Retail Marijuana Cultivation Facility in order to change its designation from “Retail” to “Medical.”

**6-230 – Retail Marijuana Cultivation Facility: Ability to Change Designation of Regulated Marijuana**

- A. Changing Designation from Retail Marijuana to Medical Marijuana: Beginning July 1, 2022, a Retail Marijuana Cultivation Facility may Transfer Retail Marijuana to a Medical Marijuana Cultivation Facility in order to change its designation from Retail Marijuana to Medical Marijuana pursuant to the following requirements:
1. The Retail Marijuana Cultivation Facility may only Transfer Retail Marijuana that has passed all required testing;
  2. The Medical Marijuana Cultivation Facility and the Retail Marijuana Cultivation Facility share a Licensed Premises in accordance with Rule 3-215;
  3. The Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility have at least one identical Controlling Beneficial Owner;
  4. The Retail Marijuana Cultivation Facility must report the Transfer in the Inventory Tracking System the same day that the change in designation from Retail Marijuana to Medical Marijuana occurs;
  5. After the designation change, the Medical Marijuana cannot be Transferred to the originating or any other Retail Marijuana Business or otherwise be treated as Retail Marijuana. The Inventory is Medical Marijuana and is subject to all permissions and limitations in the 5-200 series rules;
  6. Both the Retail Marijuana Cultivation Facility and the Medical Marijuana Cultivation Facility must remain at, or under, its respective inventory limit before and after the Retail Marijuana changes its designation to Medical Marijuana; and
  7. The Transfer and change of designation does not create a right to a refund of any Retail Marijuana excise tax incurred or paid prior to the Transfer and change of designation.
- B. Changing Designation from Medical Marijuana to Retail Marijuana: Beginning January 1, 2023, a Retail Marijuana Cultivation Facility may accept Medical Marijuana from a Medical Marijuana Cultivation Facility in order to change its designation from Medical Marijuana to Retail Marijuana pursuant to the following requirements:



1. The Retail Marijuana Cultivation Facility may only accept Medical Marijuana that has passed all required testing in accordance with the ~~4-2004-100~~ Series Rules – Regulated Marijuana Testing Program;
2. The Retail Marijuana Cultivation Facility and the Medical Marijuana Cultivation Facility share a Licensed Premises in accordance with Rule 3-215, unless:
  - a. The Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility have at least one identical Controlling Beneficial Owner; and
  - b. The Medical Marijuana Cultivation Facility and Retail Marijuana Cultivation Facility cannot share a Licensed Premises because the Local Licensing Authority or Local Jurisdiction prohibits the operation of either a Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility.
3. The Retail Marijuana Cultivation Facility and the Medical Marijuana Cultivation Facility have at least one identical Controlling Beneficial Owner;
4. The Retail Marijuana Cultivation Facility must receive the Transfer and designate the inventory as Retail Marijuana in the Inventory Tracking System the same day. The Retail Marijuana Cultivation Facility must assign and attach an Inventory Tracking System tag reflecting its Retail Marijuana License number to the Retail Marijuana following completion of the Transfer in the Inventory Tracking System.
5. After the designation change, the Retail Marijuana cannot be Transferred to the originating or any other Medical Marijuana Business or otherwise be treated as Medical Marijuana. The inventory is Retail Marijuana and is subject to all permissions and limitations in these 6-200 Series Rules.
6. Both the Retail Marijuana Cultivation Facility and the Medical Marijuana Cultivation Facility must remain at, or under, its inventory limit before and after the Medical Marijuana changes its designation to Retail Marijuana;
7. The Retail Marijuana Cultivation Facility shall pay any Retail Marijuana excise tax that is imposed pursuant to section 39-28.8-302, C.R.S.;
8. The Retail Marijuana Cultivation Facility shall notify the Local Licensing Authority and Local Jurisdiction where the Retail Marijuana Cultivation Facility and Medical Marijuana Cultivation Facility operate and pay any applicable excise tax on the Retail Marijuana in the manner determine by the Local Licensing Authority or Local Jurisdiction; and
9. Pursuant to the requirements of this subparagraph (B), a Retail Marijuana Cultivation Facility may receive a virtual Transfer of Medical Marijuana that is reflected in the Inventory Tracking System even if the Medical Marijuana is not physically moved prior to the change of designation to Retail Marijuana.

**Basis and Purpose – 6-235**

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The Statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(j.5), 44-10-203(1)(k), 44-10-401(2)(b)(II), and 44-10-502(10)(a)-(c) The purpose of this rule is to allow a Retail Marijuana Cultivation Facility Licensees that plan to cultivate Retail Marijuana outdoors to submit a contingency plan to the Division for approval in anticipation of an Adverse Weather Event.

**6-235 Retail Marijuana Cultivation Facility: Contingency Plan for Outdoor Cultivation****A. Submission of Contingency Plan.**

1. Beginning January 1, 2022, Retail Marijuana Cultivation Facility Licensees that plan to cultivate Retail Marijuana outdoors may submit a contingency plan to the Division for approval in anticipation of an Adverse Weather Event. The Retail Marijuana Cultivation Facility shall also submit a copy of the plan to the Local Licensing Authority in the local jurisdiction where the Licensee operates, and if Transferring Retail Marijuana to the Licensed Premises of a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or an off-premises storage facility outside of that jurisdiction, the Local Licensing Authority in that jurisdiction.
2. A Retail Marijuana Cultivation Facility may submit a contingency plan at any time, but it must be filed at least 7 days prior to taking action pursuant to the contingency plan and must be approved by the State Licensing Authority prior to taking action pursuant to the contingency plan.
3. After initial submission and approval of a contingency plan, a contingency plan must be submitted with the Retail Marijuana Cultivation Facility's license renewal application. Any significant change to a contingency plan prior to a renewal application must be submitted for review and approval pursuant to sub~~paragraph~~section (A)(2) above prior to taking action pursuant to the revised contingency plan.
4. The Division shall notify the appropriate Local Licensing Authorities of the approval of the contingency plan.

**B. Requirements for Outdoor Contingency Plans.**

1. Identification of the type of Adverse Weather Event that the plan applies to, including any deviations based on the type of Adverse Weather Event.
2. Primary contact. A primary contact for the Retail Marijuana Cultivation Facility must be identified on the contingency plan, including the: name, title, phone number, and email address of the primary contact. The Retail Marijuana Cultivation Facility shall notify the Division of any change to the primary contact or required contact information within 48 hours of the change.
3. Transport Manifest. If the contingency plan provides for the Transfer of Retail Marijuana, a Retail Marijuana Cultivation Facility shall submit a standing transport manifest that could be used by a Licensee upon approval during an Adverse Weather Event if creating a transport manifest through the Inventory

Tracking System is impracticable. The standing transport manifest shall include: identification and address of the receiving Licensee.

4. Disclosure of Receiving Licensed Premises.

- a. Retail Marijuana may only be Transferred to the Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and/or an off-premises storage facility.
- b. If Retail Marijuana will be Transferred to the Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and/or off-premises storage facility pursuant to a contingency plan, that plan must include the name, ownership, and address of the receiving Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and/or off-premises storage facility, along with a diagram of the proposed receiving Licensed Premises.
- c. The receiving Licensed Premises shall be an existing location that currently holds an approved state and local license or an off-premises storage facility permit. The receiving Licensee is not required to share any Controlling Beneficial Owners with the Transferring Retail Marijuana Cultivation Facility.
- d. A Retail Marijuana Cultivation Facility that cultivates outdoors may identify and Transfer Retail Marijuana to no more than five receiving Licensed Premises' as part of a contingency plan.

5. Disclosure of Modifications to the Premises and Security and Surveillance.

Proposed modifications to the Licenses Premises and any anticipated impacts to compliance with security and surveillance requirements pursuant to Rules 3-225 (C)(1), 3-225 (C)(5) and 3-225 (C)(6).

C. License Requirements when Acting Pursuant to a Contingency Plan. To the extent that this sub~~paragraph~~section (C) conflicts with other rule sections, this sub~~paragraph~~section shall control during the time that a Licensee is acting pursuant to a contingency plan.

1. Notification.

- a. Notification of action pursuant to an approved contingency plan shall be made to the Division within 24 hours after initiating action pursuant to a contingency plan. A Retail Marijuana Cultivation Facility that cultivates outdoors must also notify the Local Licensing Authority in the local jurisdiction where the licensee operates, and if Transferring Retail Marijuana to the Licensed Premises of a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or an off-premises storage facility outside of that jurisdiction, the Local Licensing Authority in that jurisdiction.
- b. Notification of ceasing action pursuant to the approved contingency plan shall be made to the Division within 24 hours of returning to normal business operations. If action will continue more than 7 days after

initiating action pursuant to a contingency plan, the Licensee shall contact the Division and explain why it cannot return to normal business operations.

- c. Any notification shall be made in writing and can be made by email to the Division.
2. Production Management. Retail Marijuana Transferred to a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility pursuant to a contingency plan is not included in the receiving Licensed Premises' inventory limit until the Retail Marijuana Cultivation Facility acting pursuant to the contingency plan returns to normal business operations.
3. Modification of Premises. ~~Notification for a modification of a Licensed Premises is not required as part of a contingency plan unless the modification of premises becomes a permanent modification. If that change becomes a permanent change, notification is required pursuant to Rule 2-260. An application for a modification of a Licensed Premises is not required as part of a contingency plan unless the modification or change in premises becomes a permanent modification. If that change becomes a permanent change, a modification of premises application must be submitted within 14 days.~~
4. Security Requirements. All security and surveillance requirements that apply to a Retail Marijuana Cultivation Facility apply to activities conducted pursuant to the contingency plan. If the contingency plan does not require the Transfer of Regulated Marijuana to another Licensed Premises, but requires plants to be covered or video surveillance to be otherwise temporarily obstructed, exemptions to the video surveillance requirements in Rules 3-225 (C)(1), 3-225 (C)(5) and 3-225 (C)(6) may be approved as part of the contingency plan.
5. Inventory Tracking Requirements. Licensees must use the Inventory Tracking System to ensure Retail Marijuana is identified and tracked during all times that action is being taken pursuant to a contingency plan. If a Retail Marijuana Cultivation Facility harvests, Transfers, or packages Retail Marijuana it must be fully reconciled in the Inventory Tracking System within 48 hours of initiating action pursuant to the contingency plan.
  - a. Harvest Requirements. If Retail Marijuana is harvested, the weight of Retail Marijuana can be captured on a per harvest level and equally applied to individual plants rather than requiring the initial wet weight of each plant. This initial harvest weight may be captured at a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility upon arrival at the Licensed Premises approved as part of the contingency plan. Harvest Batches and Inventory Tracking System packages must be reported by the Retail Marijuana Cultivation Facility acting pursuant to the contingency plan in the Inventory Tracking System.

- b. Transport Manifest. The Retail Marijuana Cultivation Facility acting pursuant to the contingency plan must report all Retail Marijuana that is Transferred to a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility on a transport manifest.
    - i. A Licensee may use the approved standing transport manifest during an Adverse Weather Event only when using the Inventory Tracking System is not possible.
    - ii. The Licensee shall manually fill out the dates, times, and individual transporting Retail Marijuana on a copy of the standing transport manifest.
    - iii. The Licensee shall ensure the standing transport manifest and copy of the approved Contingency plan remain in the Licensee's possession during any transport of Retail Marijuana when it is not possible to use an Inventory Tracking System generated transportation manifest at the time of the Adverse Weather Event.
- 6. Transfers. If Retail Marijuana is Transferred to another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility it is exempted from the packaging and labeling requirements in Rule 3-1005(B).
- 7. Virtual and Physical Separation. If Retail Marijuana is Transferred to a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility that inventory must be virtually separated by Harvest Batch and must also be virtually and physically separated from the receiving Licensee's inventory. Harvest Batches must also be clearly identified at the receiving Licensed Premises with the Harvest Batch name and date of harvest.
- 8. Finishing Product. After Transferring Retail Marijuana to another Licensed Premises, a Retail Marijuana Cultivation Facility may finish that harvest at the receiving Licensed Premises if all Retail Marijuana is accounted for in the Inventory Tracking System and the Licensed Premises is in compliance with all surveillance requirements.
- 9. Testing. The originating Licensee acting pursuant to a contingency plan is responsible for the submission of Test Batch(es).
  - a. Each Harvest Batch or Production Batch Transferred pursuant to a contingency plan must be submitted for all required tests and is not eligible for a Reduced Testing Allowance or otherwise exempt from required testing.
  - b. Any passing or failing tests of a Harvest Batch or Production Batch Transferred pursuant to a contingency plan will not count for or against a Licensee's Reduced Testing Allowance.

**6-300 Series – Retail Marijuana Products Manufacturing Facilities****Basis and Purpose – 6-305**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-307(1)(j), 44-10-313(14), 44-10-401(2)(b)(III), and 44-10-603, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to a Retail Marijuana Products Manufacturer. This Rule 6-305 was previously Rule R 601, 1 CCR 212-2.

**6-305 – Retail Marijuana Products Manufacturer: License Privileges**

- A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location. In addition, a Retail Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises as a Marijuana Research and Development Facility so long as:
1. Each business or business entity holds a separate license;
  2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;
  3. Both the Marijuana Research and Development Facility and the Retail Marijuana Products Manufacturer comply with all terms and conditions of the R&D Co-Location Permit; and
  4. Both the Marijuana Research and Development Facility and the Retail Marijuana Products Manufacturer comply with all applicable rules. See 5-700 Series Rules.
- B. Authorized Transfers. A Retail Marijuana Products Manufacturer is authorized to Transfer Retail Marijuana as follows:
1. Retail Marijuana Concentrate and Retail Marijuana Product.
    - a. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana Concentrate or Retail Marijuana Product to Retail Marijuana Stores, other Retail Marijuana Products Manufacturers, Retail Marijuana Testing Facilities, Retail Marijuana Hospitality and Sales Businesses, and Pesticide Manufacturers.
    - b. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana Product and Retail Marijuana Concentrate to a Retail Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit.
      - i. Prior to any Transfer pursuant to this Rule 6-305(B)(1)(b), a Retail Marijuana Products Manufacturer shall verify the Retail Marijuana Cultivation Facility possesses a valid Centralized Distribution

Permit. See Rule 6-205 – Retail Marijuana Cultivation Facility: License Privileges.

- ii. For any Transfer pursuant to this Rule 6-305(B)(1)(b), a Retail Marijuana Products Manufacturer shall only Transfer Retail Marijuana Product and Retail Marijuana Concentrate that is packaged and labeled for Transfer to a consumer. See 3-1000 Series Rules.
      - c. A Retail Marijuana Products Manufacturer and Accelerator Manufacturer may Transfer Retail Marijuana Concentrate to a Medical Marijuana Products Manufacturer in compliance with Rules 6-335 and 6-830.
  2. Retail Marijuana. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana to other Retail Marijuana Products Manufacturer, Retail Marijuana Testing Facilities, and Retail Marijuana Stores.
  3. Sampling Units. A Retail Marijuana Products Manufacturer may also Transfer Sampling Units of its own Retail Marijuana Concentrate or Retail Marijuana Product to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-603(10), C.R.S., and Rule 6-320.
  4. Decontaminated Retail Marijuana. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana back to the Retail Marijuana Cultivation Facility that Transferred the Retail Marijuana for Decontamination.
- C. Manufacture of Retail Marijuana Concentrate, Retail Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana Authorized. A Retail Marijuana Products Manufacturer may manufacture, prepare, package, store, and label Retail Marijuana Concentrate and Retail Marijuana Product comprised of Retail Marijuana and other Ingredients intended for use or consumption, such as Edible Retail Marijuana Products, ointments, or tinctures. A Retail Marijuana Products Manufacturer may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana.
  1. Hemp Product Authorized. A Retail Marijuana Products Manufacturer that uses Hemp Product as an Ingredient in the manufacture and preparation of Retail Marijuana Product must comply with this subparagraph (C)(1) of this Rule.
    - a. Prior to accepting and taking possession of any Hemp Product for use as an Ingredient in a Retail Marijuana Product the Retail Marijuana Products Manufacturer shall verify the following:
      - i. That the Hemp Product has passed all required testing pursuant to the ~~4-2004-100~~ Series Rules at a Retail Marijuana Testing Facility; and
      - ii. That the Person Transferring the Hemp Product to the Retail Marijuana Products Manufacturer is registered with the Colorado Department of Public Health and Environment as a Hemp Product Manufacturer pursuant to section 25-5-42~~7~~6, C.R.S.

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- D. Location Prohibited. A Retail Marijuana Products Manufacturer may not manufacture, prepare, package, store, or label Retail Marijuana Concentrate or Retail Marijuana Product in a location that is operating as a retail food establishment.
- E. Test Batches Provided for Testing. A Retail Marijuana Products Manufacturer may provide Test Batches of its Retail Marijuana Concentrate or Retail Marijuana Product to a Retail Marijuana Testing Facility for testing and research purposes. The Retail Marijuana Products Manufacturer shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- F. Authorized Marijuana Transport. A Retail Marijuana Products Manufacturer is authorized to utilize a Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken is a Retail Marijuana Business and the transportation order is delivered to a Retail Marijuana Business, or Pesticide Manufacturer. Nothing in this Rule prevents a Retail Marijuana Products Manufacturer from transporting its own Retail Marijuana.
- G. Performance-Based Incentives. A Retail Marijuana Products Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Retail Marijuana Products Manufacturer may not compensate a Sampling Manager using Sampling Units. See Rule 6-320 – Sampling Unit Protocols.

**Basis and Purpose – 6-310**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-203(3)(d), 44-10-401(2)(b)(III), 44-10-603, and 44-10-701(2)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(V). The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by a Retail Marijuana Products Manufacturer. This Rule 6-310 was previously Rule R 602, 1 CCR 212-2.

**6-310 – Retail Marijuana Products Manufacturer: General Limitations or Prohibited Acts**

- A. Packaging and Labeling Standards Required. A Retail Marijuana Products Manufacturer is prohibited from Transferring Retail Marijuana Concentrate or Retail Marijuana Product that are not properly packaged and labeled. See 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
- B. THC Content Container Restriction. Each individually packaged Edible Retail Marijuana Product, even if comprised of multiple servings, may include no more than a total of 100 milligrams of active THC. See Rule 3-1010 – Packaging and Labeling – General Requirements Prior to Transfer to a Consumer.
1. Exception for Bulk Transfers to Retail Marijuana Hospitality and Sales Businesses. An individually packaged Edible Retail Marijuana Product comprised of multiple servings that is Transferred in bulk to a Retail Marijuana Hospitality and Sales Establishment may include more than a total of 100 milligrams of active THC.



- i. A Retail Marijuana Products Manufacturer shall develop and maintain Standard Operating Procedures, and any additional equipment necessary, to ensure that a Retail Marijuana Hospitality and Sales Business receiving bulk Transfers of Edible Retail Marijuana Product can measure accurately the Edible Retail Marijuana Product in single serving sizes equal to or less than 10 milligrams of active THC per serving.
- C. Transfer to Consumer Prohibited. A Retail Marijuana Products Manufacturer is prohibited from Transferring Retail Marijuana to a consumer. This prohibition does not apply to Transfers to a Sampling Manager that comply with section 44-10-603(10), C.R.S., and Rule 6-320.
- D. Adequate Care of Perishable Product. A Retail Marijuana Products Manufacturer must provide adequate refrigeration for perishable Retail Marijuana Product that will be consumed and shall utilize adequate storage facilities and transport methods.
- E. Homogeneity of Edible Retail Marijuana Product. A Retail Marijuana Products Manufacturer must ensure that its manufacturing processes are designed so that the Cannabinoid content of any Edible Retail Marijuana Product is homogenous.
- F. Use of Ingredients. A Retail Marijuana Products Manufacturer must obtain and maintain certificates of analysis or other records demonstrating the full composition of each Ingredient used in the manufacture of Vaporizer Delivery Devices or Pressurized Metered Dose Inhalers.
- G. Corrective and Preventive Action. This paragraph G shall be effective January 1, 2021. A Retail Marijuana Products Manufacturer shall establish and maintain written procedures for implementing Corrective Action and Preventive Action. The written procedures shall include the requirements listed below as determined by the Licensee. All activities required under this Rule, and their results, shall be documented and kept as business records. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:
1. What constitutes a Nonconformance in the Licensee's business operation.
  2. Analyzing processes, work operations, reports, records, service records, complaints, returned product, and/or other sources of data to identify existing and potential root causes of Nonconformances or other quality problems;
  3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
  4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
  5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
  6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

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7. Ensuring the information related to quality problems or Nonconformances is disseminated to those directly responsible for assuring the quality of products or the prevention of such problems; and
  8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.
- H. Adverse Health Event Reporting. A Retail Marijuana Products Manufacturer must report Adverse Health Events pursuant to Rule 3-920.

**Basis and Purpose – 6-315**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-401(2)(b)(III), and 44-10-603, C.R.S. The purpose of this rule is to establish the categories of Retail Marijuana Concentrate that may be produced at a Retail Marijuana Products Manufacturer and establish standards for the production of Retail Marijuana Concentrate. Nothing in this rule authorizes the unlicensed practice of engineering under Article 25 of Title 12, C.R.S. This Rule 6-315 was previously Rule R 605, 1 CR 212-2.

**6-315 – Retail Marijuana Products Manufacturer: Retail Marijuana Concentrate Production.**

- A. Permitted Categories of Retail Marijuana Concentrate Production.
1. A Retail Marijuana Products Manufacturer may produce Physical Separation-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate and Heat/Pressure-Based Retail Marijuana Concentrate.
  2. A Retail Marijuana Products Manufacturer may also produce Solvent-Based Retail Marijuana Concentrate using only the following solvents: butane, propane, CO<sub>2</sub>, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent is expressly prohibited unless it is approved by the Division.
  3. A Retail Marijuana Products Manufacturer may submit a request to the Division to consider the approval of solvents not permitted for use under this Rule during the next formal rulemaking.
- B. General Applicability. A Retail Marijuana Products Manufacturer that engages in the production of Retail Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:
1. Ensure that the space in which any Retail Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule 3-905- Business Records Required.
  2. Ensure that all applicable sanitary rules are followed. See 3-300 Series Rules.

3. Ensure that the ~~S~~standard ~~O~~perating ~~P~~procedure for each method used to produce a Retail Marijuana Concentrate includes, but need not be limited to, step-by-step instructions on how to safely and appropriately:
  - a. Conduct all necessary safety checks prior to commencing production;
  - b. Prepare Retail Marijuana for processing;
  - c. Extract Cannabinoids and other essential components of Retail Marijuana;
  - d. Purge any solvent or other unwanted components from a Retail Marijuana Concentrate,
  - e. Clean all equipment, counters and surfaces thoroughly; and
  - f. Dispose of any waste produced during the processing of Retail Marijuana in accordance with all applicable local, state and federal laws, rules and regulations. See Rule 3-230 – Waste Disposal.
4. Establish written and documentable quality control procedures designed to maximize safety for Owner Licensees and Employee Licensees and minimize potential product contamination.
5. Establish written emergency procedures to be followed by Owner Licensees or Employee Licensees in case of a fire, chemical spill or other emergency.
6. Have a comprehensive training manual that provides step-by-step instructions for each method used to produce a Retail Marijuana Concentrate. The training manual must include, but need not be limited to, the following topics:
  - a. All ~~S~~standard ~~O~~perating ~~P~~procedures for each method of concentrate production used;
  - b. The Retail Marijuana Products Manufacturer's quality control procedures;
  - c. The emergency procedures;
  - d. The appropriate use of any necessary safety or sanitary equipment;
  - e. The hazards presented by all solvents used as described in the safety data sheet for each solvent;
  - f. Clear instructions on the safe use of all equipment involved in each process and in accordance with manufacturer's instructions, where applicable; and
  - g. Any additional periodic cleaning required to comply with all applicable sanitary rules.
7. Provide adequate training to every Owner Licensee or Employee Licensee prior to that individual undertaking any step in the process of producing a Retail Marijuana Concentrate.

- a. Adequate training must include, but need not be limited to, providing a copy of the training manual for that Licensed Premises and live, in-person instruction detailing at least all of the topics required to be included in the training manual.
  - b. The individual training an Owner Licensee or Employee Licensee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner Licensee or Employee Licensee can safely produce a Retail Marijuana Concentrate. See Rule 3-905 – Business Records Required.
  - c. The Owner Licensee or Employee Licensee that received the training must sign and date a document attesting that he or she can safely implement all ~~S~~standard ~~O~~perating ~~P~~rocedures, quality control procedures, and emergency procedures, operate all closed-loop extraction systems, use all safety, sanitary and other equipment and understands all hazards presented by the solvents to be used within the Licensed Premises and any additional periodic cleaning required to maintain compliance with all applicable sanitary rules. See Rule 3-905 – Business Records Required.
8. Maintain clear and comprehensive records of the name, signature and Owner Licensee or Employee License number of every individual who engaged in any step related to the creation of a Production Batch of Retail Marijuana Concentrate and the step that individual performed. See Rule 3-905 – Business Records Required.
- C. Physical Separation-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate and Heat/Pressure-Based Retail Marijuana Concentrate. A Retail Marijuana Products Manufacturer that engages in the production of a Retail Marijuana Concentrate must:
  1. Ensure that all equipment, counters and surfaces used in the production of Retail Marijuana Concentrate is food-grade including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials, molds and fungi and can be easily cleaned.
  2. Ensure that all equipment, counters, and surfaces used in the production of a Retail Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.
  3. Ensure that any room in which dry ice is stored or used in processing Retail Marijuana into a Retail Marijuana Concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO<sub>2</sub>.
  4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner Licensee or Employee Licensee engaged in the production of a Retail Marijuana Concentrate.

5. Ensure that only finished drinking water and ice made from finished drinking water is used in the production of a Physical Separation-Based Retail Marijuana Concentrate.
  6. Ensure that if propylene glycol or glycerin is used in the production of a Food-Based Retail Marijuana Concentrate, then the propylene glycol or glycerin to be used is food-grade.
  7. Follow all of the rules related to the production of a Solvent-Based Retail Marijuana Concentrate if a pressurized system is used in the production of a Retail Marijuana Concentrate.
- D. Solvent-Based Retail Marijuana Concentrate. A Retail Marijuana Products Manufacturer that engages in the production of Solvent-Based Retail Marijuana Concentrate must:
1. Obtain a report from an Industrial Hygienist or a Professional Engineer that certifies that the equipment, Licensed Premises and ~~S~~standard ~~O~~perating ~~P~~rocedures comply with these rules and all applicable local and state building codes, fire codes, electrical codes and other laws. If a Local Jurisdiction has not adopted a local building code or fire code or if local regulations do not address a specific issue, then the Industrial Hygienist or Professional Engineer shall certify compliance with the International Building Code of 2012 (<http://www.iccsafe.org>), the International Fire Code of 2012 (<http://www.iccsafe.org>) or the National Electric Code of 2014 (<http://www.nfpa.org>), as appropriate. Note that this Rule does not include any later amendments or editions to each Code. The Division has maintained a copy of each code, each of which is available to the public;
    - a. Flammable Solvent Determinations. If a Flammable Solvent is to be used in the processing of Retail Marijuana into a Retail Marijuana Concentrate, then the Industrial Hygienist or Professional Engineer must:
      - i. Establish a maximum amount of Flammable Solvents and other flammable materials that may be stored within that Licensed Premises in accordance with applicable laws, rules and regulations;
      - ii. Determine what type of electrical equipment, which may include but need not be limited to outlets, lights and junction boxes, must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored in accordance with applicable laws, rules and regulations;
      - iii. Determine whether a gas monitoring system must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations; and
      - iv. Determine whether fire suppression system must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored, and if required

the system's specifications, in accordance with applicable laws, rules and regulations.

- b. CO<sub>2</sub> Solvent Determination. If CO<sub>2</sub> is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO<sub>2</sub> gas monitoring system must be installed within the room in which Retail Marijuana Concentrate is to be produced or CO<sub>2</sub> is stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
  - c. Exhaust System Determination. The Industrial Hygienist or Professional Engineer must determine whether a fume vent hood or exhaust system must be installed within the room in which Retail Marijuana Concentrate is to be produced, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
  - d. Material Change. If a Retail Marijuana Products Manufacturer makes a Material Change to its equipment or a concentrate production procedure, in addition to all other requirements, it must obtain a report from an Industrial Hygienist or Professional Engineer re-certifying its ~~S~~standard ~~O~~perating ~~P~~rocedures and, if changed, its equipment as well.
  - e. Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Retail Marijuana Products Manufacturer by the designer or manufacturer of any equipment used in the processing of Retail Marijuana into a Retail Marijuana Concentrate.
  - f. Records Retention. A Retail Marijuana Products Manufacturer must maintain copy of all reports received from an Industrial Hygienist and Professional Engineer on its Licensed Premises. Notwithstanding any other law, rule, or regulation, compliance with this Rule is not satisfied by storing these reports outside of the Licensed Premises. Instead the reports must be maintained on the Licensed Premises until the Licensee ceases production of Retail Marijuana Concentrate on the Licensed Premises.
2. Ensure that all equipment, counters and surfaces used in the production of a Solvent-Based Retail Marijuana Concentrate are food-grade and do not react adversely with any of the solvents to be used in the Licensed Premises. Additionally, all counters and surface areas must be constructed in a manner that reduces the potential development of microbials, molds and fungi and can be easily cleaned;
  3. Ensure that the room in which Solvent-Based Retail Marijuana Concentrate shall be produced must contain an emergency eye-wash station;
  4. Ensure that only a professional grade, closed-loop extraction system capable of recovering the solvent is used to produce Solvent-Based Retail Marijuana Concentrate;

- a. UL or ETL Listing.
    - i. If the system is UL or ETL listed, then a Retail Marijuana Products Manufacturer may use the system in accordance with the manufacturer's instructions.
    - ii. If the system is UL or ETL listed but the Retail Marijuana Products Manufacturer intends to use a solvent in the system that is not listed in the manufacturer's instructions for use in the system, then, prior to using the unlisted solvent within the system, the Retail Marijuana Products Manufacturer must obtain written approval for use of the non-listed solvent in the system from either the system's manufacturer or a Professional Engineer after the Professional Engineer has conducted a peer review of the system. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
    - iii. If the system is not UL or ETL listed, then there must a designer of record. If the designer of record is not a Professional Engineer, then the system must be peer reviewed by a Professional Engineer. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
  - b. Ethanol or Isopropanol. A Retail Marijuana Products Manufacturer need not use a professional grade, closed-loop system extraction system capable of recovering the solvent for the production of a Solvent-Based Retail Marijuana Concentrate if ethanol or isopropanol are the only solvents being used in the production process.
5. Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;
- a. A Retail Marijuana Products Manufacturer must obtain a safety data sheet for each solvent used or stored on the Licensed Premises. A Retail Marijuana Products Manufacturer must maintain a current copy of the safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule 3-905 – Business Records Required.
  - b. A Retail Marijuana Products Manufacturer is prohibited from using denatured alcohol to produce a Retail Marijuana Concentrate, unless the denaturant is an approved solvent listed in Rule 6-315(A)(2) and the alcohol and the denaturant meet all other requirements set forth in this Rule.
6. Ensure that all Flammable Solvents or other flammable materials, chemicals and waste are stored in accordance with all applicable laws, rules and regulations. At no time may a Retail Marijuana Products Manufacturer store more Flammable

Solvent on its Licensed Premises than the maximum amount established for that Licensed Premises by the Industrial Hygienist or Professional Engineer;

7. Ensure that the appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner Licensee or Employee Licensee engaged in the production of a Solvent-Based Retail Marijuana Concentrate; and
8. Ensure that a trained Owner Licensee or Employee Licensee is present at all times during the production of a Solvent-Based Retail Marijuana Concentrate whenever an extraction process requires the use of pressurized equipment.
9. Retail Marijuana Products Manufacturers Engaged in the Remediation of Retail Marijuana for elemental impurities. Retail Marijuana Products Manufacturers engaged in the Remediation of Retail Marijuana for elemental impurities shall:
  - a. Implement effective cleaning procedures, additional testing plans, and other measures that will be performed to prevent cross contamination.
    - i. If potentially contaminated equipment, ingredients, or solvents used in the Remediation process are used for processing other 'non remediated' material, the subsequent Production Batch made using the equipment, ingredients, or solvent must then be tested for elemental impurities, and the Production Batch made using that equipment, ingredients, or solvents is not eligible for a Reduced Testing Allowance or otherwise exempt from required testing.
    - ii. Manufacturers must document the equipment and lots of ingredients/solvents used in Remediation to ensure this requirement is met.
  - b. Register as a hazardous waste generator, obtain a U.S. Environmental Protection Agency ID number for manifesting hazardous waste, and must have a disposal contract in place with a hazardous waste management company prior to attempting Remediation.
  - c. Have a staff member who has received basic training in hazardous waste identification, storage, and disposal procedures, or hire a consultant who satisfies this criteria.
  - d. Regardless of which type of analyte, if the Retail Marijuana flower, wet whole plant, or trim has failed elemental impurities, the Licensee must implement Standard Operating Procedures to ensure:
    - i. That contaminated material is stored in a labelled container identifying the material as potentially hazardous, and that the container seals in such a way to prevent the risk of cross contamination or inhalation of dusts.
    - ii. That when material is removed from the sealed container and handled in any fashion (preparation, the extraction or other



Remediation process, wasting, etc.), any workers exposed to dusts or particulates generated from the material must wear appropriate personal protective equipment (PPE), including at minimum: gloves, American National Standards Institute (ANSI) Z87.1 safety glasses, and a respirator rated to protect them from airborne dusts or particulates that may contain elemental impurities. Respirators should utilize National Institute for Occupational Safety and Health rated particulate filters of sufficient grade to prevent exposure to airborne dusts that could contain elemental impurities.

- A. Workers utilizing a respirator must comply with applicable Occupational Safety and Health Administration regulations regarding respirator use before handling contaminated material. This includes receiving respirator clearance from a qualified professional and passing a respirator fit test before using a respirator.
- e. Additional forms of environmental airborne particulate control, such as industrial air filtration systems, handling material inside of enclosures, etc. must be implemented by the Licensee to minimize the risk of exposure or cross contamination of contaminated dusts.
- f. These steps must be documented in the Licensee's respiratory protection program that all employees exposed to plant material or waste products contaminated with the elemental impurities must be trained on.
- g. The Licensee must establish and train employees on SOPs designed to safely handle this contaminated material and prevent cross contamination.
- h. Mercury poses additional workplaces hazards since it is easily volatilized and since mercury vapor is highly toxic. Before attempting to remediate any Regulated Marijuana flower, wet whole plant, or trim that has failed elemental impurities testing and contains mercury, Licensees must additionally:
  - i. Work with a certified industrial hygienist to develop and implement some form of monitoring program that is capable of detecting mercury vapor concentrations in the areas where material contaminated with mercury will be processed and can be used to generate time weighted average exposures to mercury vapor. The monitoring system must be sufficient to ensure airborne concentrations of mercury do not exceed Occupational Safety and Health Administration Permissible Exposure Limits for Airborne Contaminants.
  - ii. Have a certified industrial hygienist approve the Licensee's air handling system for managing mercury vapors in a fashion that is

compliant with the Occupational Safety and Health Administration, and other applicable federal, state, and local regulations.

- iii. Utilize a National Institute for Occupational Safety and Health rated half mask respirator with cartridges rated specifically for mercury vapor.

- i. A Licensee must ensure their processes and safety practices comply with applicable federal, state, and local environmental health and safety regulations.

10. Retail Marijuana Products Manufacturer Engaged in the Remediation of Retail Marijuana for Microbial Contamination. Retail Marijuana Products Manufacturers engaged in the Remediation of Retail Marijuana for microbial contamination shall:

- a. Implement effective cleaning procedures, additional testing plans, and other measures that will be performed to prevent cross contamination.
- b. Ensure that contaminated material is stored in a labeled container identifying the material as potentially hazardous, and that the container seals in such a way to prevent the risk of cross contamination or inhalation of dusts.
- c. Ensure that when material is removed from the sealed container and handled in any fashion (preparation, the extraction or other Remediation process, wasting, etc.), any workers exposed to dusts or particulates generated from the material must wear appropriate personal protective equipment (PPE), including at minimum: gloves, American National Standards (ANSI) Z87.1 safety glasses, and a respirator rated to protect them from airborne dusts or particulates that may contain elemental impurities. Respirators should utilize National Institute for Occupational Safety and Health rated particulate filters of sufficient grade to prevent exposure to airborne dusts that could contain elemental impurities.
  - i. Workers utilizing a respirator must comply with applicable Occupational Safety and Health Administration regulations regarding respirator use before handling contaminated material. This includes receiving respirator clearance from a qualified professional and passing a respirator fit test before using a respirator.
- d. Implement additional forms of environmental airborne particulate control, such as industrial air filtration systems, handling material inside of enclosures, etc. must be implemented by the Licensee to minimize the risk of exposure or cross contamination of contaminated dusts.
- e. These steps must be documented in the Licensee's respiratory protection program that all employees exposed to plant material or waste products contaminated with elemental impurities must be trained on.

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- f. The Licensee must establish and train employees on ~~S~~standard ~~O~~perating ~~P~~rocedures designed to safely handle this contaminated material and prevent cross contamination.
  - g. The Licensee must ensure their processes and safety practices comply with applicable federal, state, and local environmental health and safety regulations.
- E. Ethanol and Isopropanol. If a Retail Marijuana Products Manufacturer only produces Solvent-Based Retail Marijuana Concentrate using ethanol or isopropanol at its Licensed Premises and no other solvent, then it shall be considered exempt from paragraph D of this Rule and instead must follow the requirements in paragraph C of this Rule. Regardless of which rule is followed, the ethanol or isopropanol must be food grade or at least 99% pure and denatured alcohol cannot be used. The Retail Marijuana Products Manufacturer shall comply with contaminant testing required in Rule ~~4-2154-120(C)(4)~~.
- F. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 6-320**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(2)(d), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-401(2)(b)(III), and 44-10-603(10), C.R.S. The purpose of this rule is to establish the circumstances under which a Retail Marijuana Products Manufacturer may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado's regulated Retail Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager may receive in a calendar month and imposes inventory tracking, reporting and recordkeeping requirements on a Retail Marijuana Products Manufacturer that Transfer Sampling Units. This Rule 6-320 was previously Rule R 606, 1 CCR 212-2.

**6-320 – Retail Marijuana Products Manufacturer: Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, a Retail Marijuana Products Manufacturer may designate no more than five Sampling Managers in the Inventory Tracking System.
  - 1. Only management personnel of the Retail Marijuana Products Manufacturer who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  - 2. An individual may be designated as a Sampling Manager by more than one Retail Marijuana Business.
  - 3. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.
  - 4. A Retail Marijuana Products Manufacturer who wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling

Manager ~~S~~standard ~~O~~perating ~~P~~rocedures that explain the requirements of section 44-10-603(10), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 6-320. See *also* Rule 3-905 – Business Records Required. A Retail Marijuana Products Manufacturer shall maintain and update such ~~S~~standard ~~O~~perating ~~P~~rocedures as necessary to reflect accurately any changes in the relevant statutes and rules.

B. Sampling Unit Limits. Only one Sampling Unit may be designated per Production Batch. A Sampling Unit shall not be designated until the Production Batch has satisfied the testing requirements in the ~~4-2004-100~~ Series Rules – Regulated Marijuana Testing Program.

1. A Sampling Unit of Retail Marijuana Product shall not exceed one Standardized Serving of Marijuana.
2. A Sampling Unit of Retail Marijuana Concentrate shall not exceed one quarter of one gram; except that a Sampling Unit of Retail Marijuana Concentrate which has the intended use of being delivered in a vaporized form shall not exceed one-half of one gram.

C. Transfer Restrictions.

1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Retail Marijuana Products Manufacturer as a Sampling Manger for the calendar month in which the Transfer occurs.
3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than:
  - a. With respect to Retail Marijuana Product, fourteen Standardized Servings of Marijuana; and
  - b. Eight grams of Retail Marijuana Concentrate.
4. The monthly limit established in subparagraph (C)(3) applies to each Sampling Manager, regardless of the number of Retail Marijuana Businesses with which the Sampling Manager is associated.
5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (C)(3). Before Transferring any Sampling Units, a Retail Marijuana Products Manufacturer shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limit established in subparagraph (C)(3).
6. A Sampling Manager shall not Transfer any Sampling Unit to any other Person, including but not limited to any other Person designated as a Sampling Manager.

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- D. Compensation Prohibited. A Retail Marijuana Products Manufacturer may not use Sampling Units to compensate a Sampling Manager.
- E. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.
- F. Acceptable Purposes. Sampling Units shall only be designated and Transferred for purposes of quality control and product development in accordance with section 44-10-603(10), C.R.S.
- G. Record keeping requirements. A Retail Marijuana Products Manufacturer shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule 3-905 – Business Records Required. At a minimum, a Retail Marijuana Products Manufacturer shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of either quality control or product development. A Retail Marijuana Products Manufacturer shall also maintain copies of the Retail Marijuana Products Manufacturer's Sstandard Operating Procedures provided to Sampling Managers.
- H. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 6-325**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-203(3)(b), 44-10-203(3)(e), 44-10-401(2)(b)(III), 44-10-603, and 44-10-701(3)(c), C.R.S. The purpose of this rule is to define requirements for manufacture of Audited Product for administration by: (1) metered dose nasal spray, (2) vaginal administration, or (3) rectal administration which may raise public health concerns. This rule defines audit, insurance, minimum product requirements, minimum production process requirements, and pre-production testing requirements for Retail Marijuana Products Manufacturers that manufacture Audited Products. The purpose of this rule further recognizes that Alternative Use Product not within an intended use identified in Rule 3-1015 may raise public health concerns that outweigh its manufacture or Transfer entirely or that require additional safeguards to protect public health and safety prior to manufacturer or Transfer. This rule identifies general requirements for Retail Marijuana Products Manufacturer to seek an Alternative Use Designation from the State Licensing Authority to manufacture any type of Retail Marijuana Product that is not within an intended use identified in Rule 3-1015. This Rule 6-325 was previously Rule R 607, 1 CCR 212-2.

**6-325 – Retail Marijuana Products Manufacturing Facility: Audited Product and Alternative Use Product**

- A. General Rule. A Retail Marijuana Products Manufacturer shall not Transfer Audited Product to a Retail Marijuana Store, another Retail Marijuana Products Manufacturer, or a Retail Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit except in accordance with all requirements of this Rule 6-325. The requirements of this Rule 6-325 are in addition to all other Rules that apply to Retail Marijuana Products

Manufacturers; except where the context otherwise clearly requires this Rule 6-325 controls.

- B. Audited Products – Mandatory Audit Prior to Transfer. Following submission of an independent third-party audit to the Division and, if applicable, to the Local Jurisdiction as required by this Rule, a Retail Marijuana Products Manufacturer may Transfer Audited Product with an intended use of: (1) metered dose nasal spray, (2) vaginal administration, or (3) rectal administration.
1. A written audit report from an independent third-party auditor that was completed within the last 24 months shall be submitted to the Division and, if applicable to the Local Licensing Authority: (i) before the first Transfer of Audited Product to any Retail Marijuana Store, (ii) prior to Transfer of any Audited Product following a Material Change to any ~~S~~standard ~~O~~perating ~~P~~rocedure or master formulation record regarding the Audited Product, and (iii) with the Retail Marijuana Products Manufacturer's renewal application if the Retail Marijuana Products Manufacturer will Transfer Audited Product after renewal.
  2. The independent third-party audit shall be performed by either a certified quality auditor or a certified GMP auditor. The Retail Marijuana Products Manufacturer shall be responsible for all costs associated with obtaining the independent third-party audit.
  3. The independent third-party written audit report shall include the following minimum requirements:
    - a. The independent third-party auditor's qualifications and an attestation that the certified quality auditor or certified GMP auditor has no conflict of interest;
    - b. Establish that the Retail Marijuana Products Manufacturer and the Audited Product meet all requirements of this Rule 6-325, including but not limited to the specific requirements of this Rule 6-325(C), 6-325(D), 6-325(E), 6-325(G), and 6-325(H);
    - c. Verify the written ~~S~~standard ~~O~~perating ~~P~~rocedure(s) for Audited Product include sufficient and detailed step-by-step instructions on how to produce the Audited Product in a manner that prevents contamination and protects the public health and safety;
    - d. Verify, based upon a physical inspection, the manufacture of Audited Product by the Retail Marijuana Products Manufacturer adheres to all applicable ~~S~~standard ~~O~~perating ~~P~~rocedures;
    - e. Verify, based upon a physical inspection, of any Licensed Premises that such Licensed Premises complies with the requirements of this Rule 6-325(E), including any Limited Access Area where the Audited Product is to be manufactured;
    - f. Include the independent third-party auditor's findings;

- g. Include the plan of correction identifying any corrective actions and/or preventative actions implemented as a result of the findings of the independent third-party audit; and
    - h. Include the independent third-party auditor's assessment that the Retail Marijuana Products Manufacturer demonstrated compliance with all requirements of Rule 6-325 and with the requirements of all ~~S~~standard ~~O~~perating ~~P~~rocedures, master formulation records, and Batch manufacturing records that apply to the Audited Product.
- C. Products Liability Insurance. Any Retail Marijuana Products Manufacturer that intends to Transfer Audited Product shall first obtain products liability insurance providing coverage for liability arising from manufacture or Transfer of Audited Product and shall provide an unredacted certificate of product liability insurance to the Division and the independent third-party auditor.
- D. Audited Product Requirements. Audited Product shall meet the following minimum product requirements:
  - 1. Inactive Ingredients. Audited Product must meet the requirements in Rule 3-335 – Production of Regulated Marijuana Products.
    - a. If the Audited Product contains a fungicidal or bactericidal Ingredient listed in, and with a concentration that is at or below the maximum concentration permitted in, the Federal Food and Drug Administration Inactive Ingredients Database, <https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>, the Audited Product is not required to undergo microbial contaminant testing required by Rules ~~4-115 and 4-1204-215~~.
  - 2. Required Product Development Testing. The Retail Marijuana Products Manufacturer must establish the Audited Product meets the following through independent third-party testing:
    - a. The Audited Product must deliver the amount of each ~~e~~Cannabinoid identified on the label throughout the entire volume of the Audited Product using the intended delivery device and in accordance with the instructions provided by the Retail Marijuana Products Manufacturer, as demonstrated by testing at a Retail Marijuana Testing Facility.
      - i. For Audited Product with an intended use of metered dose nasal spray, compliance with this requirement shall be established by test results verifying the delivered dose of each ~~e~~Cannabinoid identified on the label using the methods described in The United States Pharmacopeia Physical Test and Determination Chapter 601, *Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers*.
      - ii. For Audited Product with an intended use of either vaginal administration or rectal administration, compliance with this testing requirement shall be established by test results demonstrating that

each ~~e~~Cannabinoid identified on the label is within +/- 15% of the amount identified on the label.

- b. The expiration date identified on the label of the Audited Product is appropriate when the Audited Product is stored at room temperature, as demonstrated by testing from a Retail Marijuana Testing Facility.
- c. Identification of all non-cannabis derived Ingredients and constituents in the Audited Product at concentrations of 1%, which verification is obtained from one or more of the following:
  - i. Testing by a Retail Marijuana Testing Facility;
  - ii. Testing by a laboratory that is ISO 17025 accredited but is not a Retail Marijuana Testing Facility, except that no Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product may be Transferred to such a laboratory; and/or
  - iii. One or more certificate(s) of analysis from the manufacturer of any Ingredient or constituent included in the Audited Product.

E. Additional Production Requirements for Audited Product. In addition to all other requirements applicable to Retail Marijuana Products Manufacturer, a Retail Marijuana Products Manufacturer that manufactures and Transfers Audited Product shall meet the following additional requirements:

- 1. Personnel Training. All personnel directly involved in the manufacture and handling of Audited Product must be trained, must demonstrate competency, and must undergo annual refresher training, which shall be documented and maintained at the Retail Marijuana Products Manufacturer's Licensed Premises. Personnel directly involved in the manufacture and handling of Audited Product must be trained and demonstrate proficiency in hand hygiene, cleaning and sanitizing, performing necessary calculations, measuring and mixing, and documenting the manufacturing process including master formulation records and batch manufacturing records.
- 2. Facility Requirements. A Retail Marijuana Products Manufacturer must have a space that is specifically designated for the manufacture of Audited Products that is designed and operated to prevent cross contamination from other areas of the Licensed Premises. The surfaces, walls, floors, fixtures, shelving, work surfaces, and cabinets in this designated area must be non-porous and cleanable.
- 3. Cleaning and Sanitizing. A Retail Marijuana Products Manufacturer must clean and sanitize surfaces where Audited Product is manufactured and handled on a regular basis and at a minimum, work surfaces and floors must be cleaned and sanitized daily. All other surfaces must be cleaned and sanitized at least every three months. A Retail Marijuana Products Manufacturer must clean and sanitize all surfaces when a spill occurs and when surfaces, floors, and walls are visibly soiled.



4. Hand Hygiene. Hand hygiene is required when entering and re-entering any area where Audited Product is manufactured and handled. Hand hygiene includes washing hands and forearms up to the elbows with soap and water for at least 30 seconds followed by drying completely with disposable towels. Alcohol hand sanitizers alone are not sufficient.
  - a. Gloves are required to be worn for all mixing activities. Other garb such as shoe covers, head and facial hair covers, face masks, and gowns must be worn as appropriate to protect Licensees and/or prevent contamination of the Audited Product.
5. Equipment. Mechanical, electronic, and other types of equipment used in mixing, measuring, or testing of Audited Product must be inspected prior to use and verified for accuracy at the frequency recommended by the manufacturer, and at least annually.
6. Ingredient Quality. All Ingredients used to manufacture Audited Product must be handled and stored in accordance with the manufacturer's instructions. Ingredients that lack a manufacturer's expiration date shall not be used if a reasonable manufacturer would not use the Ingredient or after 1 year from the date of receipt, whichever period is shorter.
7. Master Formulation Record. A master formulation record must be prepared and maintained for each unique Audited Product a Retail Marijuana Products Manufacturer manufactures. A master formulation record must include at least the following information:
  - a. Name of the Audited Product;
  - b. Ingredient identities and amounts;
  - c. Specifications on the delivery device (if applicable);
  - d. Complete instructions for preparing the Audited Product, including equipment, supplies, and description of the manufacturing steps;
  - e. Quality control procedures; and
  - f. Any other information needed to describe the Retail Marijuana Products Manufacturer's production and ensure its repeatability.
8. Batch Manufacturing Records. A batch manufacturing record shall be created for each Production Batch of Audited Product. This record shall include at the least the following information:
  - a. Name of the Audited Product;
  - b. Master formulation record reference for the Audited Product;
  - c. Date and time of preparation of the Audited Product;
  - d. Production Batch number;
  - e. Signature or initials of individuals involved in each manufacturing step;

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- f. Name, vendor, or manufacturer, Production Batch number, and expiration date of each Ingredient;
  - g. Weight or measurement of each Ingredient;
  - h. Documentation of quality control procedures;
  - i. Any deviations from the master formulation record, and any problems or errors experienced during the manufacture; and
  - j. Total quantity of the Audited Product manufactured.
- F. Audited Product Testing. For each Production Batch, the Audited Product shall undergo all required testing in the ~~4-2004-100~~ Series Rules for Retail Marijuana Product and/or Audited Product. ~~See also Rule 4-115—Regulated Marijuana Testing Program: Sampling and Testing Program.~~
- G. Packaging and Labeling of Audited Product. Audited Product must be packaged and labeled in accordance with all requirements of the 3-1000 Series Rules regarding packaging and labeling for Transfer to a consumer prior to any Transfer.
- H. Adverse Health Event Reporting. A Retail Marijuana Products Manufacturer must report Adverse Health Events pursuant to Rule 3-920.
- I. Alternative Use Designation – Any Other Method of Consumption or Administration. A Retail Marijuana Products Manufacturer shall not Transfer to a Retail Marijuana Store, another Retail Marijuana Products Manufacturer, or Retail Marijuana Cultivation Facility that has obtained a Centralized Distribution Permit any Retail Marijuana Concentrate or Retail Marijuana Product that is not within any intended use identified in Rule 3-1015(B) until it applies for and receives an Alternative Use Designation from the State Licensing Authority in consultation with the Colorado Department of Public Health and Environment. In the process of applying for an Alternative Use Designation, the Retail Marijuana Products Manufacturer shall work with the Division and the Colorado Department of Public Health and Environment to determine whether the proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when particular independent review factors, safeguards, and tests are in place. The following are minimum requirements for any application for an Alternative Use Designation:
  - 1. The Retail Marijuana Products Manufacturer shall identify provisions of this Rule 6-325 that apply to its Alternative Use Product, any proposed additional or alternative requirements, and how any proposed alternatives protect public health and safety. The Retail Marijuana Products Manufacturer shall also provide any additional information as may be requested by the Division, in consultation with the Colorado Department of Public Health and Environment.
  - 2. The Retail Marijuana Products Manufacturer bears the burden of proving its proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when the identified independent review factors, safeguards, and tests are in place.

3. A Retail Marijuana Products Manufacturer seeking an Alternative Use Designation shall cooperate with the Division. Failure to cooperate with the Division is grounds for denial of an Alternative Use Designation.
  4. The granting of an Alternative Use Designation shall rest in the discretion of the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment. The State Licensing Authority may in his or her discretion deny an Alternative Use Designation where the Retail Marijuana Products Manufacturer does not meet the burden established in this Rule 6-325.
- J. Alternative Use Designation – Packaging and Labeling Requirements. If the Division recommends, and the State Licensing Authority grants, an Alternative Use Designation, the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment shall provide the Retail Marijuana Products Manufacturer the appropriate statement of intended use label to be affixed to the Alternative Use Product, and any additional or distinct packaging and labeling requirements applicable to the Alternative Use Product. See Rules 3-1010 and 3-1015.
- K. Required Records. A Retail Marijuana Products Manufacturer manufacturing or Transferring Audited Product and/or Alternative Use Product shall maintain accurate and comprehensive records on the Licensed Premises regarding the manufacturing process, a list of all active and inactive Ingredients used in the Audited Product and/or Alternative Use Product, and such other documentation as required by this Rule 6-325. See Rule 3-905 – Business Records Required.

**6-330 – Recall of Retail Marijuana Concentrate and Retail Marijuana Product – Repealed effective January 1, 2021.**

**6-400 Series – Retail Marijuana Testing Facilities**

**Basis and Purpose – 6-405**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(4), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-203(2)(h), 44-10-203(2)(y), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-313(8)(a), 44-10-313(14), 44-10-401(2)(b)(IV), 44-10-604, 35-61-104, and 35-61-105.5, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to Retail Marijuana Testing Facilities. This Rule 6-405 was previously Rule R 701.

**6-405 – Retail Marijuana Testing Facilities: License Privileges**

- A. Licensed Premises. A separate License is required for each specific Retail Marijuana Testing Facility and only those privileges granted by the Marijuana Code and any rules promulgated pursuant to it may be exercised on the Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Testing Facility may share and operate at the same Licensed Premises with a Medical Marijuana Testing Facility with identical ownership.

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- B. Testing of Retail Marijuana Authorized. A Retail Marijuana Testing Facility may accept Test Batches of Retail Marijuana from Retail Marijuana Businesses for testing and research purposes only. The Division may require a Retail Marijuana Business to submit a Test Batch of Retail Marijuana to a Retail Marijuana Testing Facility upon demand.
- C. Product Development Authorized. A Retail Marijuana Testing Facility may develop Retail Marijuana Product, but is not authorized to engage in the manufacturing privileges described in section 44-10-603, C.R.S., and Rule 6-305 – Retail Marijuana Manufacturing Facilities: License Privileges.
- D. Transferring Test Batches to Another Licensed and Certified Retail Marijuana Testing Facility. A Retail Marijuana Testing Facility may Transfer Test Batches to another Retail Marijuana Testing Facility for testing. All laboratory reports provided to or by a Retail Marijuana Business must identify the Retail Marijuana Testing Facility that actually conducted the test.
- E. Testing of Registered and Tracked Hemp Authorized.
1. A Retail Marijuana Testing Facility may accept and test Hemp as regulated by Article 61 of Title 35, C.R.S.
  2. Before a Retail Marijuana Testing Facility accepts a sample of Hemp, the Retail Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-104, C.R.S.
  3. A Retail Marijuana Testing Facility is responsible for entering samples of Hemp in the Inventory Tracking System pursuant to the 3-800 Series Rules.
  4. A Retail Marijuana Testing Facility shall be permitted to test Hemp only in the category(ies) that the Retail Marijuana Testing Facility is certified to perform testing in pursuant to Rule 6-415 – Retail Marijuana Testing Facilities: Certification Requirements.
  5. In accordance with section 35-61-105.5, C.R.S., a Retail Marijuana Testing Facility shall provide the results of any testing performed on Hemp to the Person submitting the sample of Hemp and to the Colorado Department of Agriculture.
  6. Nothing in these ~~R~~rules shall be construed to require a Retail Marijuana Testing Facility to accept and/or test ~~S~~samples of Hemp.
- F. Testing of Hemp Product Authorized.
1. A Retail Marijuana Testing Facility may accept and test samples of Hemp Products.
  2. Before a Retail Marijuana Testing Facility accepts a sample of Hemp Product, the Retail Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Colorado Department of Public Health and Environment as a Hemp Product Manufacturer pursuant to section 25-5-42~~76~~, C.R.S.

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3. A Retail Marijuana Testing Facility is responsible for entering and tracking samples of Hemp Product in the inventory tracking system pursuant to the 3-800 Series Rules.
  4. A Retail Marijuana Testing Facility shall be permitted to test Hemp Product only in the category(ies) that the Retail Marijuana Testing Facility is certified to perform testing in pursuant to Rule 6-415 – Retail Marijuana Testing Facilities: Certification Requirements.
  5. A Retail Marijuana Testing Facility may provide the results of any testing performed on Hemp Product to the Person submitting the sample of Hemp Product.
  6. Nothing in these rules shall be construed to require a Retail Marijuana Testing Facility to accept and/or test samples of Hemp Product.
- G. Authorized Retail Marijuana Transport. A Retail Marijuana Testing Facility is authorized to utilize a licensed Retail Marijuana Transporter to transport Test Batches of Retail Marijuana for testing, in accordance with the Marijuana Code and Marijuana Rules, between the originating Retail Marijuana Business requesting testing services and the destination Retail Marijuana Testing Facility performing testing services. Nothing in this Rule requires a Retail Marijuana Business to utilize a Retail Marijuana Transporter to transport Test Batches of Retail Marijuana for testing.
- H. Authorized Transfers.
1. A Retail Marijuana Testing Facility may Transfer ~~Immature Plants, Regulated Marijuana seeds, and~~ Genetic Material to a Regulated Marijuana Cultivation Facility. Any Transfers made under this Rule must be in compliance with the 3-800 and the 3-900 Series Rules.
  2. It shall be considered a conflict of interest and a Retail Marijuana Testing Facility shall not perform testing required under the ~~4-2004-100~~ Series Rules for a Regulated Marijuana Business Licensee to which the Retail Marijuana Testing Facility has Transferred ~~Immature Plants, Regulated Marijuana seeds, or~~ Genetic Material.
- I. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 6-410**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-202(4), 44-10-203(2)(h), 44-10-203(2)(y), 44-10-203(3)(c), 44-10-203(2)(d), 44-10-401(2)(b)(IV), 44-10-604, 44-10-701, 35-61-104, and 35-61-105.5, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Retail Marijuana Testing Facility. This Rule 6-410 was previously Rule R 702, 1 CCR 212-2.

**6-410 – Retail Marijuana Testing Facilities: General Limitations or Prohibited Acts**

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- A. Prohibited Financial Interest. A Person who is Controlling Beneficial Owner or Passive Beneficial of a Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, Retail Marijuana Store, Medical Marijuana Store, Medical Marijuana Cultivation Facility, or a Medical Marijuana Products Manufacturer shall not be a Controlling Beneficial Owner or Passive Beneficial Owner of a Retail Marijuana Testing Facility.
- B. Conflicts of Interest. The Retail Marijuana Testing Facility shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the Retail Marijuana Testing Facility's testing processes or results, or that may diminish public confidence in the competency, impartiality and integrity of the Retail Marijuana Testing Facility's testing processes or results. At a minimum, employees, owners or agents of a Retail Marijuana Testing Facility who participate in any aspect of the analysis and results of a ~~Sample or~~ Test Batch are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any on-going financial, employment, personal or business relationship with the Retail Marijuana Business that provided the ~~Sample~~Test Batch.
- C. Transfer of Retail Marijuana Prohibited. A Retail Marijuana Testing Facility shall not Transfer Retail Marijuana to another Retail Marijuana Business or a consumer, except that a Retail Marijuana Testing Facility may Transfer a ~~Sample-Test Batch~~ to another Retail Marijuana Testing Facility.
- D. Destruction of Received Test Batches. A Retail Marijuana Testing Facility shall properly dispose of all Test Batches it receives, that are not Transferred to another Retail Marijuana Testing Facility, after all necessary tests have been conducted and any required period of storage. See Rule 3-230 – Waste Disposal.
- E. ~~Repealed Sample Rejection. A Retail Marijuana Testing Facility shall reject any Sample where the condition of the Sample at receipt indicates that the Sample may have been tampered with.~~
- F. Retail Marijuana Business Requirements Applicable. A Retail Marijuana Testing Facility shall be considered a Licensed Premises. A Retail Marijuana Testing Facility shall be subject to all requirements applicable to Retail Marijuana Businesses.
- G. Retail Marijuana Testing Facility – Inventory Tracking System Required. A Retail Marijuana Testing Facility must use the Inventory Tracking System to ensure all Test Batches containing Retail Marijuana are identified and tracked from the point they are Transferred from a Retail Marijuana Business through the point of Transfer or destruction or disposal. A Retail Marijuana Testing Facility that performs testing on Hemp must use the Inventory Tracking System to ensure all samples of Hemp are identified and tracked from the point they are Transferred from a cultivator registered with the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-104, C.R.S., to the point of Transfer or destruction or disposal. The Inventory Tracking System reporting shall include the results of any tests that are conducted on Retail Marijuana or Hemp. See also Rule 3-805 – Regulated Marijuana Businesses: Inventory Tracking System and Rule 3-825 – Reporting and Inventory Tracking System. The Retail Marijuana Testing Facility must have the ability to reconcile its ~~Test Batch~~Sample records with the Inventory

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Tracking System and the associated transaction history. See *also* Rule 3-905 – Business Records Required and Rule 3-825.

H. Testing of Unregistered or Untracked Hemp or Hemp Products Prohibited.

1. A Retail Marijuana Testing Facility is authorized to accept or test Hemp only if (1) the entity providing the Test Batches of Hemp is regulated by Article 61 of Title 35, C.R.S., (2) the Hemp is submitted by a registered cultivator, and (3) the Hemp is tracked in the Inventory Tracking System.
2. A Retail Marijuana Testing Facility is authorized to accept or test Hemp Product only if (1) the entity providing the ~~s~~ Samples of Hemp Product is registered and regulated pursuant to Article 4 or Title 25, C.R.S., and (2) the Hemp Product being submitted for testing is tracked in the Inventory Tracking System.

I. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

J. Standard Minimum Weight of Test Batches and Photo Documentation.

1. Standard Minimum Weight of Test Batches.

- a. Retail Marijuana and Retail Marijuana Concentrate. A Retail Marijuana Testing Facility must establish a standard minimum weight of Retail Marijuana and Retail Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.
- b. Retail Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana. Retail Marijuana Testing Facilities must establish a standard number of Sample Increments required to be included in each Test Batch of Retail Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana for every type of test that it conducts. See Rule 4-225 – Regulated Marijuana Testing Program – Sampling Procedures.

2. Photo Documentation of Test Batches.

- a. A Retail Marijuana Testing Facility shall digitally photograph each Test Batch it receives to document the Sample Increments collected, condition of the Test Batch, and compliance with these Rules.
- b. The Retail Marijuana Testing Facility must maintain the digital photographs of each Test Batch as business records. See Rule 3-905 - Required Business Records.
- c. Upon request by the Division, a Retail Marijuana Testing Facility must provide copies of the digital photographs of Test Batches within seven days of the request unless a different deadline is agreed to.

K. Rejection of Test Batches.

1. A Retail Marijuana Testing Facility shall not accept a Test Batch that is smaller than its standard minimum amount.

2. A Retail Marijuana Testing Facility shall not accept a Test Batch that does not contain the minimum number and weight of Sample Increments, or the Retail Marijuana Testing Facility has reason to believe it was not collected in accordance with Test Batch collection requirements in Rule 4-225.
3. If a Retail Marijuana Testing Facility suspects or has reason to suspect a Sample Increment or Test Batch has been adulterated, the Retail Marijuana Testing Facility must:
  - a. Notify the Division; and
  - b. Quarantine the Sample Increment or Test Batch for a minimum of 48 hours from the time of notification to the Division before proceeding with any testing.

**Basis and Purpose – 6-415**

The statutory authority for this rule includes but is not limited to section 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(4), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-203(2)(h), 44-10-203(2)(y), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish a frame work for certification for Retail Marijuana Testing Facilities. This Rule 6-415 was previously Rule R 703, 1 CCR 212-2.

**6-415 – Retail Marijuana Testing Facilities: Certification Requirements**

- A. Certification Types. If certification in a testing category is required by the Division, then the Retail Marijuana Testing Facility must be certified in the category in order to perform that type of testing.
  1. Residual solvents;
  2. Microbials;
  3. Mycotoxins;
  4. Pesticides;
  5. THC and other Cannabinoid potency;
  6. Elemental Impurities; and
  7. Water Activity.
- B. In order to obtain a certification for Pesticide testing, a Retail Marijuana Testing Facility must also obtain certification for mycotoxin testing.
- C. Certification Procedures. The Retail Marijuana Testing Facility certification program is contingent upon successful on-site inspection, successful participation in ~~p~~Proficiency ~~t~~Testing, and ongoing compliance with the applicable requirements in this Rule.
  1. Certification Inspection. A Retail Marijuana Testing Facility must be inspected prior to initial certification and annually thereafter by an inspector approved by the Division.



2. Standards for Certification. A Retail Marijuana Testing Facility must meet standards of performance, as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: personnel qualifications, ~~S~~standard ~~O~~perating ~~P~~procedure manual, analytical processes, Proficiency Testing, quality control, quality assurance, security, chain of custody, ~~Sample-Test Batch~~ retention, space, records, and results reporting. In addition, a Retail Marijuana Testing Facility must be accredited under the International Organization for Standardization/International Electrotechnical Commission 17025:2005 Standard, or any subsequent superseding ISO/IEC 17025 standard. In order to obtain certification in a testing category from the Division, the Retail Marijuana Testing Facility's scope of accreditation must specify that particular testing category.
  - a. Subsequent to initial approval of a Retail Marijuana Testing Facility License, the Division may grant provisional certification if the Applicant has not yet obtained ISO/IEC 17025:2005 accreditation, but meets all other requirements. Such provisional certification shall be for a period not to exceed twelve months.
3. Personnel Qualifications.
  - a. Laboratory Director. A Retail Marijuana Testing Facility must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. See Rule 6-420 – Retail Marijuana Testing Facilities: Personnel.
  - b. Employee Competency. A Retail Marijuana Testing Facility must ~~have a written and documented system to~~ evaluate and document ~~that employees are competent to perform all aspects of laboratory work which the employee is responsible for the competency in performing authorized tests for employees.~~
    - i. ~~Prior to independently analyzing Test Batches, testing personnel employees must demonstrate acceptable performance on precision, accuracy, and specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls).~~
    - ii. Continued employee competency assessment must be conducted annually and may be conducted using either internally or externally prepared competency tests.
    - iii. Qualitative and quantitative information regarding the analytes being assessed shall remain unknown to the employee(s) performing the assessment until the competency assessment has been completed.
4. Standard Operating Procedure Manual. A Retail Marijuana Testing Facility must have a written ~~s~~Standard ~~e~~Operating ~~p~~Procedure manual meeting the minimum

standards set forth in these rules detailing the performance of all methods employed by the facility used to test the analytes it reports and made available for testing analysts to follow at all times.

- a. The current laboratory director must approve, sign and date each procedure. If any modifications are made to those procedures, the laboratory director must approve, sign, and date the revised version prior to use.
  - b. A Retail Marijuana Testing Facility must maintain a copy of all ~~S~~standard ~~O~~perating ~~P~~rocedures to include any revised copies for a minimum of three years. See Rule 6-450 – Retail Marijuana Testing Facilities: Records Retention, and Rule 3-905 – Business Records Required.
  - c. A Retail Marijuana Testing Facility must inform the Colorado Department of Public Health and Environment and the Division of any major method changes to Standard Operating Procedures pertaining to certified analytical methods prior to implementing the changes. Major method changes include, but are not limited to, modifications to sample preparation, column type, enrichment media, solvent(s) used, instrumentation, or instrumentation parameters.
5. Analytical Processes. A Retail Marijuana Testing Facility must maintain a listing of all analytical methods used and all analytes tested and reported. The Retail Marijuana Testing Facility must provide this listing to the Division upon request.
  6. Proficiency Testing. A Retail Marijuana Testing Facility must successfully participate in a Division approved Proficiency Testing program in order to obtain and maintain certification.
  7. Quality Assurance and Quality Control. A Retail Marijuana Testing Facility must establish and follow a quality assurance and quality control program to ensure sufficient monitoring of laboratory processes and quality of results reported.
  8. Security. A Retail Marijuana Testing Facility must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.
  9. Chain of Custody. A Retail Marijuana Testing Facility must establish a system to document the complete chain of custody for Test Batches from receipt through disposal.
  10. Space. A Retail Marijuana Testing Facility must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state, and local requirements.
  11. Records. A Retail Marijuana Testing Facility must establish a system to retain and maintain records for a period not less than three years. See Rules 6-450 – Retail Marijuana Testing Facilities - Records Retention and Rule 3-905 – Business Records Required.

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12. Results Reporting. A Retail Marijuana Testing Facility must establish processes to ensure results are reported in a timely and accurate manner. See Rule 3-825 – Reporting and Inventory Tracking System. A Retail Marijuana Testing Facility's process may require that the Regulated Marijuana Business remit payment for any test conducted by the Testing Facility prior to entry of the results of that test into the Inventory Tracking System. A Retail Marijuana Testing Facility's process established under this subparagraph (12) must be maintained on the Licensed Premises of the Retail Marijuana Testing Facility.
  13. Conduct While Seeking Certification. A Retail Marijuana Testing Facility, and its agents and employees, shall provide all documents and information required or requested by the Colorado Department of Public Health and Environment and its employees, and the Division and its employees in a full, faithful, truthful, and fair manner.
- D. ~~Repealed. Violation Affecting Public Safety. A violation of this Rule may be considered a license violation affecting public safety.~~

**Basis and Purpose - 6-420**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-401(2)(b)(IV), 44-10-604, C.R.S. The purpose of this rule is to establish personnel standards for the operation of a Retail Marijuana Testing Facility. This Rule 6-420 was previously Rule R 704, 1 CCR 212-2.

**6-420 – Retail Marijuana Testing Facilities: Personnel**

- A. Laboratory Director. The laboratory director is responsible for the overall analytical operation and quality of the results reported by the Retail Marijuana Testing Facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in this Rule.
1. The laboratory director may also serve as a supervisory analyst, quality assurance manager, or testing analyst, or a combination of these roles~~both~~, for a Retail Marijuana Testing Facility. If the laboratory director is serving as a combination of roles a secondary review of data and quality documentation must be performed by qualified personnel that did not generate the data, report, or quality documentation.
  2. The laboratory director for a Retail Marijuana Testing Facility must meet one of the following qualification requirements:
    - a. The laboratory director must be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or

- b. The laboratory director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body;
  - c. The laboratory director must hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
  - d. The laboratory director must hold a bachelor's degree in one of the natural sciences and have at least seven years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.
- B. What the Laboratory Director May Delegate. The laboratory director may delegate the responsibilities assigned under this Rule to a qualified supervisory analyst or quality assurance manager, provided that such delegation is made in writing and a record of the delegation is maintained. See Rule 3-905 – Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.
- C. Responsibilities of the Laboratory Director. The laboratory director must:
  - 1. Ensure that the Retail Marijuana Testing Facility has adequate space, equipment, materials, and controls available to perform the tests reported;
  - 2. Establish and adhere to a written ~~s~~Standard ~~e~~Operating ~~p~~Procedure used to perform the tests reported;
  - 3. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;
  - 4. Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;
  - 5. Ensure that the test methodologies selected have the capability of providing the quality of results required for the level of testing the laboratory is certified to perform;
  - 6. Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
  - 7. Ensure that testing analysts perform the test methods as required for accurate and reliable results;

8. Ensure that the laboratory is enrolled in and successfully participates in a Division approved Proficiency Testing program;
9. Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
10. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
11. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;
12. Ensure that reports of test results include pertinent information required for interpretation;
13. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;
14. Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results;
15. Ensure that prior to testing any Test Batch samples, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;
16. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process Test Batches, perform test procedures and report test results promptly and proficiently, avoid actual and apparent conflicts of interests, and whenever necessary, identify needs for remedial training or continuing education to improve skills;
17. Ensure that an approved Sstandard Operating Procedure manual is available to all personnel responsible for any aspect of the testing process; ~~and~~
18. Specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for Sample processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results; ~~:-~~
19. Ensure internal and vendor audits are completed regularly at a frequency established by the Regulated Marijuana Testing Facility; and

20 Ensure the quality anomalies and Nonconformances are reviewed regularly and documented as open or completed. Open Nonconformances should be reviewed at least annually, and high impact Nonconformances must be reviewed at least monthly.

- D. Change in Laboratory Director. In the event that the laboratory director leaves employment at the Retail Marijuana Testing Facility, the Retail Marijuana Testing Facility shall:
1. Provide written notice to the Colorado Department of Public Health and Environment and the Division within seven days of the laboratory director's departure; and
  2. Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.
  3. The Retail Marijuana Testing Facility must hire a permanent laboratory director within 60 days from the date of the previous laboratory director's departure.
  4. Notwithstanding the requirement of subparagraph (D)(3), the Retail Marijuana Testing Facility may submit a waiver request to the Division Director to receive an additional 60 days to hire a permanent laboratory director provided that the Retail Marijuana Testing Facility submits a detailed oversight plan along with the waiver request.
- E. Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and two years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the two years of full-time laboratory experience.
- F. Laboratory Testing Analyst.
1. Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst or:
    - a. Have a bachelor's degree in one of the natural sciences; or
    - b. Have an associate degree in a laboratory science from an accredited institution; or
    - c. Have education and training equivalent to that specified in subparagraph (F)(1) of this Rule that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include:
      - i. 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and twelve semester hours of chemistry biology, or cannabis laboratory sciences in any combination; and

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- ii. Have a laboratory training that includes at least three months documented laboratory training each testing category in which the individual performs testing; or
  - d. Have at least five years of full time experience in laboratory testing and have laboratory training that includes at least three months documented laboratory training in each testing category in which the individual performs testing.
- 2. Responsibilities. In order to independently perform any test for a Retail Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

G. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

H. Quality Assurance Manager. Quality assurance manager must meet one of the qualifications for laboratory director or have at least a bachelor's degree in one of the natural sciences and two years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the two years of full-time laboratory experience.

**Basis and Purpose – 6-425**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-202(4), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish ~~s~~Standard ~~e~~Operating ~~p~~Procedure manual ~~standards expectations~~ for the operation of a Retail Marijuana Testing Facility. This Rule 6-425 was previously Rule R 705, 1 CCR 212-2.

**6-425 –Retail Marijuana Testing Facilities: Standard Operating Procedure Manual**

- A. A ~~s~~Standard ~~e~~Operating ~~p~~Procedure manual must include, but need not be limited to, procedures for:
  - 1. Test Batch receiving and handling, including: accessioning, recording and reporting discrepancies identified during Test Batch receiving and storage, and identifying, rejecting, and reporting unacceptable Test Batches; security of Test Batches; aliquot and extract records; and disposal of Test Batches;
    - a. All Test Batches must be tested as received, must not be inappropriately manipulated, and tested in a manner that ensures results are representative of the Test Batch as received.;
  - 2. ~~Repealed. Test Batch accessioning;~~
  - 3. ~~Repealed. Test Batch storage;~~
  - 4. ~~Repealed. Identifying, rejecting, and reporting unacceptable Test Batches;~~
  - 5. ~~Repealed. Recording and reporting discrepancies during Test Batch receiving and accessioning;~~



6. ~~Repealed. Security of Test Batches, aliquots and extracts and records;~~
7. Validating a new or revised method prior to testing of Test Batches to include: accuracy, precision, analytical sensitivity, analytical specificity (interferences), LOD, LOQ, and verification of the reportable range;
8. Test Batch preparation, including but not limited to, sub-sampling for testing, homogenization, and aliquoting Test Batches to avoid contamination and carry-over;
9. Test Batch archive retention to assure stability, as follows:
  - a. For Test Batches submitted for testing other than Pesticide contaminant testing, Test Batch retention for 14 days;
  - b. For Test Batch submitted for Pesticide contaminant testing, Test Batch retention for 90 days.
10. ~~Repealed. Disposal of Test Batches;~~
11. ~~Repealed. The theory and principles behind each assay;~~
12. ~~Repealed. Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to National Institute of Standards of Technology ("NIST");~~
13. ~~Repealed. Special requirements and safety precautions involved in performing assays;~~
14. ~~Repealed. Frequency and number of control and calibration materials;~~
15. ~~Repealed. Recording and reporting assay results;~~
16. ~~Repealed. Protocol and criteria for accepting or rejecting analytical Procedure to verify the accuracy of the final report;~~
17. ~~Repealed. Pertinent literature references for each method;~~
18. ~~Repealed. Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;~~
19. ~~Repealed. Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns;~~
20. A documented system for reviewing the results of testing calibrators, controls, standards, and Test Batch results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results and are ~~e~~Corrective ~~a~~Actions implemented and documented, ~~and does the laboratory contact the requesting entity;~~
21. Policies and procedures to follow when Test Batch are requested for referral and testing by another certified Retail Marijuana Testing Facility or an approved local or state agency's laboratory;



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22. Testing Hemp, if the Retail Marijuana Testing Facility tests Hemp;
  23. Investigating and documenting existing or potential Nonconformances and implementing Corrective Actions and/or Preventive Actions;
  24. Contacting the requesting entity about existing Nonconformances; ~~and~~
  25. Retesting or additional analyses of Test Batches, including but need not be limited to, when it is appropriate to retest or perform an additional analysis of the Test Batch, when it is appropriate to request a new Test Batch from the requesting entity, and when it is appropriate for the requesting entity to request retesting (e.g., after failing Pesticide testing or elemental impurity testing on Regulated Marijuana flower, trim, shake, or wet whole plant as permitted by Rule 4-240(B); 4-135(d) and 4-135(D.1)); ~~and~~
  26. Procedures for internal audits, including the frequency and the documentation of the results. Internal audit reports must include, but need not be limited to: audit title, scope, name(s) of personnel and auditors, audit date, introduction, problems noted, findings, observations/opportunities noted, date issued.
- ~~B. Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~
- C. Individual Standard Operating Procedures for analytical methods must include, but need not be limited to:
1. Responsibilities of staff;
  2. SOP history and summary of revisions;
  3. The theory and principles behind each assay;
  4. Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to a certified vendor that meets the accreditation requirements of the laboratory, such as National Institute of Standards of Technology (NIST), ISO 17034, or other similar entities;
  5. Special requirements and safety precautions involved in performing assays;
  6. Frequency and number of control and calibration materials;
  7. Recording and reporting assay results;
  8. Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;
  9. Pertinent literature references for each method;
  10. Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;
  11. Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns.

12. Protocol and criteria for calculating and applying measurement uncertainty;
13. Policies and procedures including the titles and required training of individuals responsible for the transport of biohazardous materials (when applicable); and
14. Procedures and/or protocols for general laboratory upkeep and cleaning, including specific procedures to eliminate or avoid cross-contamination.

**Basis and Purpose – 6-430**

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-202(4), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish analytical processes standards for the operation of a Retail Marijuana Testing Facility. This Rule 6-430 was previously Rule R 706, 1 CCR 212-2.

**6-430 –Retail Marijuana Testing Facilities: Analytical Processes****A. Gas Chromatography (“GC”).** A Retail Marijuana Testing Facility using GC must:

1. Document the conditions of the gas chromatograph, including the detector response;
2. Perform and document preventive maintenance as required by the manufacturer and SOPs;
3. Ensure that records are maintained and readily available to the staff operating the equipment;
4. Document the performance of new columns before use;
5. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;
6. Establish criteria of acceptability for variances between different aliquots and different columns; ~~and~~
7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.
8. Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing Test Batches; and
9. Monitor and document the performance of the instrument each day of testing.

**B. Gas Chromatography Mass Spectrometry (“GC/MS”).** A Retail Marijuana Testing Facility using GC/MS must:

1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
2. Document the changes of septa as specified in the ~~s~~Standard ~~e~~Operating ~~p~~Procedure;
3. Document liners being cleaned or replaced as specified in the ~~s~~Standard ~~e~~Operating ~~p~~Procedure;

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4. Ensure that records are maintained and readily available to the staff operating the equipment;
  5. Maintain records of mass spectrometer~~erie~~ tuning;
  6. Establish written criteria for ~~an~~ acceptable mass spectrometer tuning parameters~~mass-spectrometric tune~~;
  7. Document ~~e~~Corrective ~~a~~Actions if a mass spectrometer tune~~mass-spectrometric tune~~ is unacceptable;
  8. Monitor analytic analyses to check for contamination and carry-over;
  9. Use selected ion monitoring within each run to assure that the laboratory compares ion ratios and retention times between calibrators, controls and Test Batches~~Samples~~ for identification of an analyte;
  10. Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
  11. Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;
  12. Define the criteria for designating qualitative results as positive;
  13. When a library is used to qualitatively identify an analyte, the identity of the analyte must be confirmed before reporting results by comparing the relative retention time and mass spectrum to that of a known standard or control run on the same system;~~and~~
  14. Evaluate the performance of the instrument after routine and preventive maintenance (e.g. clipping or replacing the column or cleaning the source) prior to analyzing ~~subject samples~~Test Batches;
  15. Monitor gas phase standards frequently by comparison to the initial calibration curve. Fresh standards must be prepared if this check exceeds 20% drift. Gas standards must be replaced after one week or as recommended by the standard manufacturer. Alternatively, standards must be replaced after an established period of time for which the Regulated Marijuana Testing Facility has demonstrated the stability of the standard;
  16. Monitor non-gas standards frequently by comparison to the initial calibration. Fresh standards must be prepared if this check exceeds 20% drift. Non-gas standards must be replaced after one month for working standards and three months for opened stocks or as recommended by the standard manufacturer. Alternatively, standards must be replaced after an established period of time for which the Regulated Marijuana Testing Facility has demonstrated the stability of the standard; and
  17. Monitor and document the performance of the instrument each day of testing.
- C. Immunoassays. A Retail Marijuana Testing Facility using Immunoassays must:

1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
  2. Ensure that records are maintained and readily available to the staff operating the equipment;
  3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Test Batch sample is not included within the sample types and/or matrices approved of samples approved by the manufacturer; and
  4. Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.
- D. ~~Repealed. Thin Layer Chromatography ("TLC"). A Retail Marijuana Testing Facility using TLC must:~~
- ~~1. Apply unextracted standards to each thin layer chromatographic plate;~~
  - ~~2. Include in their written procedure the preparation of mixed solvent systems, spray reagents and designation of lifetime;~~
  - ~~3. Include in their written procedure the storage of unused thin layer chromatographic plates;~~
  - ~~4. Evaluate, establish, and document acceptable performance for new thin layer chromatographic plates before placing them into service;~~
  - ~~5. Verify that the spotting technique used precludes the possibility of contamination and carry-over;~~
  - ~~6. Measure all appropriate RF values for qualitative identification purposes;~~
  - ~~7. Use and record sequential color reactions, when applicable;~~
  - ~~8. Maintain records of thin layer chromatographic plates; and~~
  - ~~9. Analyze an appropriate matrix blank with each batch of Samples analyzed.~~
- E. High Performance Liquid Chromatography ("HPLC"). A Retail Marijuana Testing Facility using HPLC must:
1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
  2. Ensure that records are maintained and readily available to the staff operating the equipment;
  3. Monitor and document the performance of the HPLC instrument each day of testing;
  4. Evaluate the performance of new columns before use;
  5. Create written standards for acceptability when eluting solvents are recycled;

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6. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay; ~~and~~
7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system; ~~and-~~
8. Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing Test Batches.

F. Liquid Chromatography Mass Spectroscopy ("LC/MS"). A Retail Marijuana Testing Facility using LC/MS must:

1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Maintain records of mass spectrometer ~~erie~~ tuning;
4. Document ~~e~~Corrective ~~a~~Actions if a mass spectrometer tune~~mass-spectrometric tune~~ is unacceptable;
5. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
6. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;
7. Compare two transitions and retention times between calibrators, controls and Test Batches~~samples~~ within each run;
8. Document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument; ~~and~~
9. Evaluate the performance of the instrument when changes in: source, source conditions, eluent, or column are made prior to reporting test results; ~~and-~~
10. Ensure ion ratios do not exceed plus or minus 30% relative to the average of calibration standards from the same sequence.

F.5. Inductively Coupled Plasma Mass Spectrometry (ICP/MS). A Retail Marijuana Testing Facility using ICP must:

1. Perform and document preventive maintenance as required by the manufacturer and SOPs;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Establish written criteria for acceptable mass spectrometer tuning parameters;

4. Maintain records of mass spectrometer tuning;
5. Document Corrective Actions if mass spectrometer tune is unacceptable;
6. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
7. Document the monitoring of the response (counts per second) of the internal standard to ensure consistency over time of the analytical system;
8. Compare mass-to-charge ratios between calibrators, controls and Test Batches within each run;
9. Monitor analyses to check for contamination and carry-over;
10. Evaluate and document the performance of the instrument after routine and preventive maintenance and when changes in: source, conditions, or detector are made prior to reporting test results; and
11. Monitor and document the performance of the instrument each day of testing.

G. Microbial Assays. A Retail Marijuana Testing Facility using microbial assays must:

1. Perform and document preventive maintenance as required by the manufacturer and ~~s~~Standard ~~e~~Operating ~~p~~Procedures;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Test Batch is not included within the sample types and/or matrices approved by the manufacturer; ~~test sample is not included within the types of Test Batches approved by the manufacturer;~~
4. Verify the method at the regulatory action-levels limit for each analyte. Verification at the qualitative presence/absence limit shall include a fractional recovery study; ~~unless otherwise completed by the manufacturer and approved by an independent scientific body.~~
5. Include controls for each analytical run of Test Batches ~~batch of test samples~~. Quantitative microbial methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;
6. For molecular methods, the Retail Marijuana Testing Facility shall include controls for each individual analytical run. Quantitative molecular methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;
7. PCR-based and qPCR-based methods must include validated internal amplification controls;
8. Microbial methods must include steps to confirm presumptive positive results; confirmation methods may be molecular or cultural or both. Confirmation

methods must include quality controls that match the organism which is being confirmed; and;

9. Verify the stated Limit of Detection of qualitative assays through “dilution to extinction” studies in which the calculated extinction dilution is corroborated with cultural data.

H. Water Activity. A Retail Marijuana Testing Facility analyzing water activity must:

1. Perform and document preventive maintenance as required by the manufacturer and ~~s~~Standard ~~e~~Operating ~~p~~Procedures;
2. Ensure that records are maintained and readily available to the staff operating the equipment;
3. Specify all unique method parameters, such as temperature, sample surface area, volatile compound interferences, including but not limited to temperature;
4. Evaluate the performance of the method after routine and preventive maintenance prior to analyzing the Test Batch; and
5. Establish criteria for acceptable instrument performance.

I. Analytical Methodology Validation. A Retail Marijuana Testing Facility must validate new methodology and revalidate any changes to approved methodology prior to analyzing~~testing~~ Test Batches. ~~A Retail Marijuana Testing Facility must:~~

1. The laboratory must implement a performance-based measurement system for the selected methodology and validate the method following good laboratory practices in accordance with AOAC, United States Pharmacopeia (USP), United States Food and Drug Administration (FDA) United States Department of Agriculture (USDA), or other reputable validation guidelines and methodology prior to reporting results. Validation, verification, or matrix extension of ~~Implement a performance-based measurement system for the selected methodology and validate the method following good laboratory practices prior to reporting results. Validation of other or~~ new methodology must include when applicable, but is not limited to:
  - a. Verification of Accuracy<sub>i</sub>
  - b. Verification of Precision<sub>i</sub>
  - c. Verification of Analytical Sensitivity<sub>i</sub>
  - d. Verification of Analytical Specificity<sub>i</sub>
  - e. Verification of the LOD<sub>i</sub>
  - f. Verification of the LOQ<sub>i</sub>
  - g. Verification of the Reportable Range<sub>i</sub>
  - h. Identification of Interfering Substances<sub>i</sub>

- i. Exclusivity, which means the specificity of the test method for validating microbial testing methods. It evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms;
  - j. Inclusivity, which means, related to microbiological method validation, the sensitivity of the test method. It evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness; and
  - k. Verification of Recovery. The laboratory shall take action to remediate recovery issues where matrix effects affect recovery at  $>\pm 20\%$  of the theoretical value.
  - l. Measurement Uncertainty. Subsequent to initial validation, measurement uncertainty must be re-evaluated at least annually or whenever method modifications are made. "Measurement uncertainty" is defined as a parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.
- 2. Validation of the other or new methodology must be documented.
  - 3. Prior to use, other or new methodology must have a ~~s~~Sandard ~~o~~Operating ~~p~~Procedure approved and signed by the laboratory director.
  - 4. Testing analysts must have documentation of competency assessment prior to testing Test Batches.
  - 5. Any changes to the approved other or new methodology must be revalidated and documented prior to testing Test Batches.
  - 6. The demonstration of testing validity must ensure consistent, accurate and reproducible analytical performance in the matrices tested by the laboratory.
  - 7. Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of Rule 5-440(B).
  - 8. To the extent practicable, laboratory test methods must meet AOAC International standard method performance requirements.
  - 9. For qualitative methods, a minimum of three spiking/naturally occurring levels of target analyte must be included assessing accuracy, precision and specificity per each matrix validated (microbiological methods shall be considered accurate/precise if fractional results are obtained when limits are  $<1$  CFU preanalytical portion): one negative level in which no analyte is present, one low level at which analyte is present at the regulatory limit and one high level at which the analyte is present at 10x the regulatory limit.
  - 10. For quantitative methods, laboratories must include a minimum of four spiked levels or more, covering the analytical range must be included assessing accuracy, precision and specificity per each matrix validated: one negative level in which no analyte is present, one low level at which analyte is present at the



regulatory limit, one medium level for which the analyte is present at a concentration close to the middle calibrator and one high level at which the analyte is present at the upper level of the calibration.

11. For qualitative methods, at least two levels must be included for the negative and high level spikes - at least ten replicates must be included at the fractional level, per analyte, per matrix.
12. For quantitative methods, at least two replicates must be performed at each spiked level per each matrix validated.
13. Software must be validated prior to testing Test Batches, including but not limited to: analytical software, application programming interface(s) (APIs), laboratory information management systems (LIMS), etcetera.
14. Validation or verification of methodology must be documented in a validation report. The validation report shall include, but is not limited to, the following:
  - a. Validation plan;
  - b. Introduction and summary;
  - c. Materials, to include identification of Certified Reference Materials, and preparation methods;
  - d. Method parameters;
  - e. Raw data, including instrument raw data such as chromatograms, for each test method and each instrument, if any;
  - f. Instrument calibration data, if any;
  - g. Data, calculations, and results;
  - h. Method Acceptability Criteria performance data;
  - i. Interlaboratory comparison;
  - j. Verification of spreadsheets and/or laboratory information management system;
  - k. Conclusion and discussion; and
  - l. References.
15. Laboratories must validate or verify instrumentation and methodology immediately and prior to use following a change in location.

J. Testing Validation of Complex Matrices. A Retail Marijuana Testing Facility must include a variety of matrices as part of the validation/verification process. During method validation/verification, a Retail Marijuana Testing Facility must:

1. Select matrices which best represent each category of products to be tested as listed in Rule ~~4-2154-115(D)~~. The laboratory shall independently determine the category of matrix a product falls within; properties to consider include fat

content, ~~e~~Cannabinoid content, pH, salt content, sugar content, water activity, the presence of know chemical compounds, microbial flora and antimicrobial compounds.

2. Perform a new matrix validation, prior to reporting results, on matrices which are either A) a new category of matrix or B) considerably different from the original matrix validated within the category.
  - a. For example, the Retail Marijuana Testing Facility intends to receive the topical product “bath bombs” for testing, but previous validation studies for topical product included lotion and massage oil. A new validation should be performed for the product prior to testing since salt content and other properties differ vastly from the original matrices validated.
3. Perform a matrix verification (a client matrix spike or similar consisting of the target analyte(s) at the time of analysis) on matrices submitted for testing which differ slightly from those initially validated but which fall within a category already validated.
  - a. For example, the Retail Marijuana Testing Facility receives a new edible type matrix for testing (snickerdoodle cookies) but previous validation included gummies and hard candy. A spike of a portion of the submitted material must be analyzed prior to, or at the time of, sample analysis.
- K. All Test Batches and Hemp Product must be tested as received, must not be manipulated, and must be tested in a manner that ensures results are representative of sample the Test Batch as it is received.
- L. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~
- M. General Quantitative Method Quality Parameters. A Retail Marijuana Testing Facility must meet the following Acceptability Criteria for quantitative method controls.
  1. Chemical quality controls must not exceed plus or minus 10.0% recovery of the target value and/or when analytes are greater than or equal to 100 parts per million (ppm).
  2. Chemical quality controls must not exceed plus or minus 30.0% for residual solvent gas standards; or plus or minus 20.0% recovery of the target value when analytes are greater than or equal to 10 ppm.
  3. Chemical quality controls must not exceed plus or minus 30.0% for residual solvent gas standards; or plus or minus 20.0% recovery of the target value when analytes are greater than or equal to 1 ppm.
  4. Chemical quality controls must not exceed plus or minus 30.0% for residual solvent gas standards; or plus or minus 20.0% recovery of the target value when analytes are greater than or equal to 100 parts per billion (ppb) or greater.
  5. Chemical quality controls must not exceed plus or minus 40.0% recovery of the target value when analytes are greater than or equal to 10 ppb.

6. Chemical quality controls must not exceed plus or minus 60.0% recovery of the target value when analytes are greater than or equal to 1.0 ppb.

7. Microbiology quality controls must not exceed plus or minus 20.0% recovery of the target value.

N. General Laboratory Equipment. A Medical Marijuana Testing Facility must:

1. Track, verify, and apply correction factors where applicable;

2. Perform annual calibration, monthly spore ampule checks, and daily temperature checks of autoclaves;

3. Verify pipette calibration on a monthly basis across the volume range the pipette is used;

4. Perform annual calibration of balances and analytical weights. Balances must be verified across the appropriate mass range on each day of use;

5. Perform verification of laboratory dispensers on each day of use;

6. Perform annual gravimetric verification of volumetric glassware;

7. Calibrate pH meters on each day of use with buffers across the analytical range (i.e. 4, 7, 10);

8. Perform annual calibration of thermometers to a NIST traceable reference thermometer. Correction factors must be applied when such a factor could impact the final result; and

9. Calibrate analytical timers annually.

### **Basis and Purpose - 6-435**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish a proficiency testing program for Retail Marijuana Testing Facilities. This Rule 6-435 was previously Rule R 707, 1 CCR 212-2.

### **6-435 – Retail Marijuana Testing Facilities: Proficiency Testing**

A. Proficiency Testing Required. A Retail Marijuana Testing Facility must participate in a Proficiency Testing program for each approved category in which it seeks certification under Rule 6-415 – Retail Marijuana Testing Facilities: Certification Requirements.

B. Participation in Designated Proficiency Testing Event. If required by the Division as part of certification, the Retail Marijuana Testing Facility must have successfully participated in Proficiency Testing in the category for which it seeks certification, within the preceding 12 months.

1. The laboratory shall have the Proficiency Testing provider to send results concurrently to the Colorado Department of Public Health and Environment and the Division, or the laboratory shall provide the Proficiency Testing results to the

Colorado Department of Public Health and Environment and the Division within 3 business days after the laboratory receives notification of their results.

- C. Continued Certification. To maintain continued certification, a Retail Marijuana Testing Facility must participate in the designated Proficiency Testing program with continued satisfactory performance as determined by the Division as part of certification. The Division may designate a local agency, state agency, or independent third-party to provide Proficiency Testing.
- D. Analyzing Proficiency Testing Samples. A Retail Marijuana Testing Facility must analyze Proficiency Test Samples using the same procedures with the same number of replicate analyses, standards, testing analysts and equipment as used in its ~~S~~standard ~~O~~perating ~~P~~rocedures.
- E. Proficiency Testing Attestation. The laboratory director and all testing analysts who participated in Proficiency Testing must sign corresponding attestation statements.
- F. Laboratory Director Must Review Results. The laboratory director must review and evaluate all Proficiency Testing results.
- G. Remedial Action. A Retail Marijuana Testing Facility must take and document remedial action when a score of less than 100% is achieved on any test during Proficiency Testing. Remedial action documentation must include a review of Test Batches tested and results reported since the last successful Proficiency Testing event. A requirement to take remedial action does not necessarily indicate unsatisfactory participation in a Proficiency Testing event.
- H. Unsatisfactory Participation in a Proficiency Testing Event. Unless the Retail Marijuana Testing Facility positively identifies at least 80% of the target analytes tested, participation in the Proficiency Testing event will be considered unsatisfactory. A positive identification must include accurate quantitative and qualitative results as applicable. Any false positive result reported will be considered unsatisfactory participation in the Proficiency Testing event.
- I. Consequence of Unsatisfactory Participation in Proficiency Testing Event. Unsatisfactory participation in a Proficiency Testing event may result in limitation, suspension or revocation of Rule 6-415 certification. A Retail Marijuana Testing Facility's certification will be suspended for the relevant testing category if two consecutive unsatisfactory Proficiency Testing events occur, or if two out of three consecutive unsatisfactory Proficiency Testing events occur. Certification may be reinstated after successful participation in the next Proficiency Testing event. Failure to achieve a satisfactory score in the next test event will result in the revocation of the certification and will require two successful consecutive Proficiency Testing events before the Testing Facility may be eligible to reapply for certification.
- J. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 6-440**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish quality assurance and quality assurance standards for a Retail Marijuana Testing Facility. This Rule 6-440 was previously Rule R 708, 1 CCR 212-2.

#### **6-440 – Retail Marijuana Testing Facilities: Quality Assurance and Quality Control**

- A. Quality Assurance Program Required. A Retail Marijuana Testing Facility must establish, monitor, and document the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory preanalytic, analytic and postanalytic systems when they occur. The review of the quality assurance program must adhere with Rule 3-825(A), and must include, at a minimum the following but is not limited to:
1. Review of instrument preventive maintenance, repair, troubleshooting and ~~e~~C~~orrective~~ ~~a~~A~~ctions~~ documentation must be performed by the laboratory director or designated ~~supervisory analyst~~quality assurance manager on an ongoing basis to ensure the effectiveness of actions taken over time;
  2. Review by the laboratory director or designated ~~supervisory analyst~~quality assurance manager of all ongoing quality assurance; and
  3. Review of the performance of validated methods used by the Retail Marijuana Testing Facility to include calibration standards, controls and the ~~s~~S~~tandard~~ ~~e~~O~~perating~~ ~~p~~P~~rocedures~~ used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.
  4. Review of Nonconformance reports at an appropriate specified frequency. Nonconforming work which is deemed high impact must be reviewed at least monthly until a resolution is reached and a root cause identified. High impact nonconforming work may include, but is not limited to, any situation in which the laboratory is in violation of the rules outlined herein or where the quality of the data released is impacted.
- B. Quality Control Measures Required. A Retail Marijuana Testing Facility must establish, monitor and document on an ongoing basis the quality control measures taken by the laboratory to ensure the proper functioning of equipment, validity of ~~s~~S~~tandard~~ ~~e~~O~~perating~~ ~~p~~P~~rocedures~~ and accuracy of results reported. Such quality control measures must include, but shall not be limited to:
1. Documentation of instrument preventive maintenance, repair, troubleshooting and ~~e~~C~~orrective~~ ~~a~~A~~ctions~~ taken when performance does not meet established levels of quality;
  2. Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;
  3. Cleaning, maintaining and calibrating as needed the analytical balances and in addition, verifying the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory;

4. Annually verifying working thermometers against a certified reference thermometer. Certified reference thermometers shall be calibrated traceable to the SI (International System of Units) through NIST, or equivalent by an ISO/IEC 17025 accredited calibration laboratory with a listed certification date and documenting the accuracy of thermometers using a NIST traceable reference thermometer;
5. Recording temperatures on all equipment when in use where temperature control is specified in the ~~s~~Sandard ~~e~~Operating ~~p~~Procedures manual, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;
6. Properly labeling reagents as to the identity, the concentration, date of preparation, storage conditions, lot number tracking, expiration date and the identity of the preparer;
7. Avoiding mixing different lots of reagents in the same analytical run;
8. Performing and documenting a calibration curve with each analysis using at minimum ~~three~~five calibrators throughout the reporting range;
  - a. The laboratory shall not remove data points from within a calibration range while still retaining the extreme ends of the calibration range. If a calibration point fails, the laboratory must re-prepare and re-analyze the calibration standard;
  - b. The laboratory must use an appropriate curve-fitting algorithm (e.g. linear, quadratic, with or without weighing.) The acceptance criteria for concentrations of the calibration standards shall adhere to the recovery requirements outlined in 5-430(J); and
  - c. The lowest calibration level shall not be greater than the regulatory limits as stated in Rule 4-215(J).
9. For qualitative analyses, analyzing, at minimum, a negative and a positive control with each analytical run of Test Batches ~~batch of Sample Increments analyzed;~~
10. For quantitative analyses, analyzing, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve;
11. Using a control material or materials that differ in either source or, lot number, or concentration from the calibration material used with each analytical run;
12. For multi-analyte assays, performing and documenting calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run;
13. Analyzing an appropriate matrix blank and control with each analytical run, when available;
14. Analyzing calibrators and controls in the same manner as unknowns;

15. Documenting the performance of calibration standards and controls for each analytical run to ensure the acceptability criteria as defined in the ~~s~~SStandard ~~e~~Operating ~~p~~Procedure is met;
16. Documenting all corrective actions taken when unacceptable calibration, control, and standard or instrument performance does not meet acceptability criteria as defined in the ~~s~~SStandard ~~e~~Operating ~~p~~Procedure;
17. Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; ~~and~~
18. Performing testing analysts that follow the current Standard Operating Procedures Manual for the test or tests to be performed.
- ~~19. The LOQ must be 50% of the limit or less for all analytes within all assays with the exception of pesticides and mycotoxins;~~
- ~~20. Duplicate Test Batch results shall not exceed 30% relative percent difference (RPD); and~~
- ~~21. LOD and LOQ must be scientifically valid and experimentally determined.~~
- C. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~
- D. ~~Nonconforming Work. A Retail Marijuana Testing Facility shall have a documented system by which it investigates Nonconformances within its quality management system. This system must include a standardized process for documenting Nonconformances which must include, but shall not be limited to, the following items:~~
  - ~~1. A detailed description of what occurred to include, as appropriate, instrument ID, sample ID, batch ID, SOP number or title, quality control failure, client complaint, date of occurrence);~~
  - ~~2. An estimate of the severity of the consequences of the Nonconformance;~~
  - ~~3. The impact of the Nonconformance;~~
  - ~~4. Person(s) responsible for any part of the generation or review of the nonconforming work;~~
  - ~~5. A thorough investigation to determine a root cause of the Nonconformance by a prescribed analysis process, to include the person(s) assigned to the root cause investigation and associated deadlines for completion;~~
  - ~~6. A list of any analytical batches that were impacted and a list of Test Batch results recalled;~~
  - ~~7. Whether or not work was stopped;~~
  - ~~8. Corrective and/or Preventative Actions identified to include deadlines and the person(s) assigned to implement the action and actual dates of implementation;~~



9. The Nonconformance report must not be closed until all identified actions are implemented. The closed report shall be reviewed, signed, and dated by the laboratory director or delegated quality assurance manager; and
  10. An assigned deadline for future review to evaluate the effectiveness of Corrective and Preventative Actions.
- E. Laboratory Reanalysis. A Retail Marijuana Testing Facility must establish a policy regarding the retesting of client Test Batches. For the purposes of this rule, retesting does not include reanalysis of Test Batches performed because quality control requirements were not met as described in the applicable Standard Operating Procedure, or retesting of Test Batches in accordance with Rule 4-240.
1. Reanalysis policies must specify that the laboratory testing must be performed on the same homogenized Test Batch that was submitted to the laboratory and include criteria by which the original result is confirmed or invalidated. The laboratory must contact the submitting client when reanalysis is required. A Retail Marijuana Testing Facility shall follow the Nonconforming work process outlined in Rule 6-440(D) for every reanalysis.
    - a. Prior to reporting a result that differs from the original data point, a Nonconformance for retests outlined in Rule 6-440(D) must be submitted to the CDPHE and the Division.
    - b. Failure to do a scientifically valid investigation, a root cause analysis, or monthly review of open Nonconformances where no root cause has been determined will be considered a violation of rule.
  2. Multiple amended test results for the same cause or same test type may indicate that test results are not accurate, precise, or scientifically valid. In the event of three or more invalidated results within a six-month period, the Retail Marijuana Testing Facility shall evaluate all relevant aspects of the pre-analytic, analytic, and post-analytic systems to determine the source of the error and implement Corrective Actions.
  3. Failure to complete the Nonconforming work process outlined in Rule 6-440(D) in a manner that is sufficient to identify and prevent the recurrence of analytical errors constitutes a violation affecting public health and safety and is cause for suspension or revocation of Certification for the affected test category.

### **Basis and Purpose – 6-441**

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish minimum requirements for the procedures and requirements a Retail Marijuana Testing Facility must comply with.

### **6-441 – Retail Marijuana Testing Facility: Certificate of Analysis (COA)**

- A. The laboratory shall generate a Certificate of Analysis (COA) for each Test Batch that the laboratory analyzes.



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- B. The COA shall indicate that the reported results are for compliance testing purposes for all Test Batches analyzed.
- C. The laboratory shall ensure that the COA contains the results of all requested analyses performed for the Test Batch.
- D. The COA shall contain, at minimum, the following information:
1. Laboratory's name, address, and contact information;
  2. Marijuana cultivator or product manufacturer's name, address, and license number;
  3. Test Batch identifying information, including matrix type and unique sample identifiers, including Batch Number when applicable;
  4. Test Batch received date, and the date(s) of analyses and corresponding testing results;
  5. Units of measure;
  6. The analytical methods, analytical instrumentation used, and corresponding Limits of Detection (LOD) and Limits of Quantitation (LOQ);
  7. Reported Cannabinoid results must include the range of estimated uncertainty which shall be reported as a  $\pm$  value in the same units of measure as the test result, following best practices for significant figures and rounding;
  8. A dedicated area to include any qualifiers or comments needed for interpretation, (when applicable to the test method and results being reported) to include any identified and documented discrepancies;
  9. The COA may contain additional information at the discretion of the laboratory and submitting client; and
  10. Identify the Retail Marijuana Testing Facility that actually conducted the test.
- E. The laboratory shall report test results for each representative Test Batch on the COA as follows:
1. When reporting qualitative results for each Analyte, the laboratory shall indicate presence or absence;
  2. When reporting quantitative results for each Analyte, the laboratory shall only report a numeric value when results are above the lower Limit of Quantitation;
  3. When reporting results for any Analytes that were detected below the analytical method LOQ and above the LOD, indicate "<LOQ"; and
  4. When reporting results for any Analytes that were not detected or detected below the LOD, indicate "ND" or "<LOD".
- F. The laboratory director or supervisory analyst shall ensure the accuracy of the information contained on the COA.

**Basis and Purpose – 6-445**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish chain of custody standards for a Retail Marijuana Testing Facility. In addition, it establishes the requirement that a Retail Marijuana Testing Facility follow an adequate chain of custody for Test Batches it maintains. This Rule 6-445 was previously Rule R 709, 1 CCR 212-2.

**6-445 –Retail Marijuana Testing Facilities: Chain of Custody**

- A. General Requirements. A Retail Marijuana Testing Facility must establish an adequate chain of custody procedure and Test Batch requirement instructions that, at a minimum, must ~~include, but not limited to:~~
1. Issue instructions for the minimum Test Batch requirements and storage requirements;
  2. Document the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the Test Batch;
  3. Document the condition and amount of Test Batch provided at the time of receipt;
  4. Document all persons handling the original Test Batches, aliquots, and extracts;
  5. Document all Transfers of Test Batches, aliquots, and extracts referred to another certified Retail Marijuana Testing Facility Licensee for additional testing or whenever requested by a client;
  6. Maintain a current list of authorized personnel and restrict entry to the laboratory to only those authorized;
  7. Secure the Laboratory during non-working hours;
  8. Secure short and long-term storage areas when not in use;
  9. Utilize a secured area to log-in and aliquot Test Batches;
  10. Ensure Test Batches are stored appropriately;
  11. Document the disposal of Test Batches, aliquots, and extracts; ~~and~~
  12. Document the License number, Inventory Tracking System number, photograph(s), and the reason for rejection of Test Batches that were rejected to the Division within 7 days of Test Batch submission; and
  13. Assign and document a unique Test Batch indicator.
- B. ~~Repealed Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 6-450**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The

purpose of this rule is to establish records retention standards for a Retail Marijuana Testing Facility. This Rule 6-450 was previously Rule R 710, 1 CCR 212-2.

#### **6-450 –Retail Marijuana Testing Facilities: Records Retention**

- A. General Requirement. A Retail Marijuana Testing Facility must maintain all required business records. See Rule 3-905 - Business Records Required.
- B. Specific Business Records Required: Record Retention. A Retail Marijuana Testing Facility must establish processes to preserve records in accordance with Rule 3-905 that includes, but is not limited to;
1. Test Results, including final and amended reports, and identification of analyst and date of analysis;
  2. Quality Control and Quality Assurance ~~R~~records, including Nonconformance reports, accession numbers, Test Batch type, and acceptable reference range parameters;
  3. Standard Operating Procedures;
  4. Personnel ~~R~~records;
  5. Chain of Custody ~~R~~records, including documentation of rejected Test Batches;
  6. Proficiency Testing ~~R~~records; and
  7. Analytical Data to include data generated by the instrumentation, raw data of calibration standards and curves.
- C. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

#### **Basis and Purpose – 6-455**

The statutory authority for this rule includes but is not limited to sections 44-10-202(4), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to clarify a Retail Marijuana Testing Facility's responsibility to notify the Retail Marijuana Business and accurately report in the inventory tracking system any failed contaminant test result. This Rule 6-455 was previously Rule R 712(D), 1 CCR 212-2.

#### **6-455 – Notification of Retail Marijuana Business**

If Retail Marijuana failed a contaminant test, then the Retail Marijuana Testing Facility must immediately (1) notify the Retail Marijuana Business that submitted the Test Batch ~~or Sample~~ for testing and any Person as directed by an approved Research Project (2) report the failure in accordance with the Inventory Tracking System reporting requirements in Rule 3-825(B), except as otherwise authorized in Rule 6-415(C)(12).

#### **Basis and Purpose – 6-460**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(4), 44-10-203(1)(k), 44-10-203(2)(a), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(3)(c), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of

this rule is to establish a framework for suspending and reinstating a testing category certification for Retail Marijuana Testing Facilities. This rule also provides the ability for a Retail Marijuana Testing Facility to request a hearing following suspension of a testing category certification.

#### **6-460 – Retail Marijuana Testing Facilities: Certification Suspension, Recertification, and Request for Hearing**

- A. Certification Suspension. When the Division has objective and reasonable grounds to believe and finds that a Retail Marijuana Testing Facility has been guilty of deliberate and willful violation(s) or that the public health, safety, or welfare imperatively requires emergency action, the Division may immediately suspend the Retail Marijuana Testing Facility's testing category certification in accordance with section 24-4-104, C.R.S., and the 8-200 Series Rules. Further, the Division may suspend certification when a laboratory has three or more repeated inspection findings which impact the quality of the data produced by the laboratory.
- B. Re-certification. A Retail Marijuana Testing Facility must provide evidence of corrective actions taken to attempt to resolve the certification suspension and may request that the Division re-certify the Retail Marijuana Testing Facility for a particular testing category in accordance with the requirements in Rule 5-415, if the Retail Marijuana Testing Facility provides documentation requested by the Division and/or the CDPHE demonstrating such corrective actions.

#### **6-500 Series – Retail Marijuana Transporters**

##### **Basis and Purpose – 6-505**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-313(14), 44-10-401(2)(b)(V), and 44-10-605, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to Retail Marijuana Transporters. This Rule 6-505 was previously Rule R 1601, 1 CCR 212-2.

##### **6-505 – Retail Marijuana Transporter: License Privileges**

- A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Transporter may share a location with an identically owned Medical Marijuana Transporter. However, a separate license is required for each specific business or business entity, regardless of geographical location.
- B. Transportation of Retail Marijuana and Retail Marijuana Product Authorized. A Retail Marijuana Transporter may take transportation orders, receive, transport, temporarily store, and deliver Retail Marijuana to Retail Marijuana Businesses.
- C. Authorized Sources of Retail Marijuana and Retail Marijuana Product. A Retail Marijuana Transporter may only transport and store Retail Marijuana that it receives directly from a Retail Marijuana Business in accordance with the 3-600 Series Rules.

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- D. Authorized On-Premises Storage. A Retail Marijuana Transporter is authorized to store transported Retail Marijuana on its Licensed Premises or permitted off-premises storage facility. All transported Retail Marijuana must be secured in a Limited Access Area, and tracked consistently with the inventory tracking rules.
- E. Delivery to Consumers Pursuant to Delivery Permit.
1. Prior to January 2, 2021, all Retail Marijuana Transporters are prohibited from delivering Regulated Marijuana to consumers.
  2. After January 2, 2021, only Retail Marijuana Transporters that possess a valid delivery permit may delivery Retail Marijuana pursuant to contracts with Retail Marijuana Stores that also possess valid delivery permits. All deliveries of Retail Marijuana consumers must also comply with all requirements of Rule 3-615.
  3. ~~Repealed. Violation affecting Public Safety. Any violation of paragraph E of this Rule is a license violation affecting public safety.~~

**Basis and Purpose – 6-510**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(n), 44-10-203(3)(c), 44-10-401(2)(b)(V), and 44-10-605, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by a Retail Marijuana Transporter. This Rule 6-510 was previously Rule R 1602, 1 CCR 212-2.

**6-510 – Retail Marijuana Transporter: General Limitations or Prohibited Acts**

- A. Sales, Liens, and Secured Interests Prohibited. A Retail Marijuana Transporter is prohibited from buying, selling, or giving away Retail Marijuana or from receiving complimentary Retail Marijuana. A Retail Marijuana Transporter shall not place or hold a lien or secured interest on Retail Marijuana.
- B. Licensed Premises Permitted. A Retail Marijuana Transporter shall maintain a Licensed Premises if it: (1) temporarily stores any Retail Marijuana or (2) modifies any information in the Inventory Tracking System generated transport manifest. The Licensed Premises shall be in a Local Jurisdiction that authorizes the operation of Retail Marijuana Stores.
1. If a Retail Marijuana Transporter Licensed Premises shares a Licensed Premises in accordance with Rule 3-215 with a Medical Marijuana Transporter Licensed Premises, then the combined Licensed Premises shall be in a Local Jurisdiction that authorizes the operation of both Retail Marijuana Stores and Medical Marijuana Stores.
  2. ~~A Retail Marijuana Transporter may add or remove a Licensed Premises, other than an Off-Premises Storage Facility, pursuant to Rule 2-255, Change of Location of a Regulated Marijuana Business.~~
- C. Off-Premises Storage Permit. A Retail Marijuana Transporter may maintain one or more permitted off-premises storage facilities. See Rule 3-610 – Off-Premises Storage of Regulated Marijuana: All Regulated Marijuana Businesses.

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- D. Storage Duration. A Retail Marijuana Transporter shall not store Retail Marijuana for longer than seven days from receiving it at its Licensed Premises or off-premises storage facility. The total allowable seven day storage duration begins and applies regardless of which of the Retail Marijuana Transporter's premises receives the Retail Marijuana first, i.e. the Retail Marijuana Transporter's Licensed Premises, or any of its off-premises storage facilities. A Retail Marijuana Transporter with a valid delivery permit may store Retail Marijuana for delivery to consumers pursuant to the delivery permit for no longer than seven days from receipt at its Licensed Premises or off-premises storage facility.
- E. Control of Retail Marijuana. A Retail Marijuana Transporter is responsible for the Retail Marijuana once it takes control of the Retail Marijuana and until the Retail Marijuana Transporter delivers it to another Retail Marijuana Business, Accelerator Cultivator, Medical Marijuana Cultivation Facility in accordance with Rules 5-235, 6-230, and 6-730, Pesticide Manufacturer, or to a consumer pursuant to a valid delivery permit. For purposes of this Rule, taking control of the Retail Marijuana means removing it from the Retail Marijuana Business's Licensed Premises and placing the Retail Marijuana in the transport vehicle or the Delivery Motor Vehicle.
- F. Location of Orders Taken and Delivered. A Retail Marijuana Transporter is permitted to take orders on the Licensed Premises of any Retail Marijuana Business to transport Retail Marijuana between Retail Marijuana Businesses. The Retail Marijuana Transporter shall deliver the Retail Marijuana to the Licensed Premises of a licensed Retail Marijuana Business, or a Pesticide Manufacturer. A Retail Marijuana Transporter may also deliver Retail Marijuana to consumers pursuant to a contract with a Retail Marijuana Store if it possesses a valid delivery permit.
- G. A Retail Marijuana Transporter shall receive Retail Marijuana from the originating Licensee packaged in the way that it is intended to be delivered to the final destination Licensee or Pesticide Manufacturer. The Retail Marijuana Transporter shall deliver the Retail Marijuana in the same, unaltered packaging to the final destination Licensee.
- H. A Retail Marijuana Transporter with a valid delivery permit shall receive Retail Marijuana that has been weighed, packaged, prepared, and labeled for delivery on the Licensed Premises of a Retail Marijuana Store or at the Retail Marijuana Store's off-premises storage facility or at the Accelerator Store or the Accelerator Store's off-premises storage facility after receipt of a delivery order. Retail Marijuana cannot be placed into a Delivery Motor Vehicle until after an order has been received and the Retail Marijuana has been packaged and labeled for delivery to the consumer as required by the 3-1000 Series Rules.
- I. A Retail Marijuana Transporter must not deliver Retail Marijuana to consumers while also transporting Regulated Marijuana between Licensed Premises in the Delivery Motor Vehicle.
- J. Opening of Bulk Packages or Containers and Re-Packaging Prohibited. A Retail Marijuana Transporter shall not open Containers of Retail Marijuana. Retail Marijuana Transporters are prohibited from re-packaging Retail Marijuana.

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- K. Temperature-Controlled Transport Vehicles. A Retail Marijuana Transporter shall utilize temperature-controlled transport vehicles when necessary to prevent spoilage of the transported Retail Marijuana.
- L. Damaged, Refused, or Undeliverable Retail Marijuana. Any damaged Retail Marijuana that is undeliverable to the final destination Retail Marijuana Business, or any Retail Marijuana that is refused by the final destination Retail Marijuana Business shall be transported back to the originating Retail Marijuana Business. Any Retail Marijuana that cannot be delivered to a consumer pursuant to a valid delivery permit shall be returned to the originating Retail Marijuana Store or the Retail Marijuana Store's off-premises storage facility within the same business day or pursuant to paragraph D of this Rule.
- M. Transport of Retail Marijuana Vegetative Plants Authorized. Retail Marijuana Vegetative plants may only be transported between Licensed Premises and such transport shall only be permitted due to an approved change of location pursuant to Rule 2-255. Transportation of Vegetative plants to a permitted off-premises storage facility shall not be allowed.
- N. Only persons licensed by the State Licensing Authority may occupy a transport vehicle while transporting Regulated Marijuana.

**6-600 Series – Retail Marijuana Business Operators****Basis and Purpose – 6-610**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(o), 44-10-401(2)(b)(VI), and 44-10-606, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Retail Marijuana Business Operator. This Rule 6-610 was previously Rule R 1702, 1 CCR 212-2.

**6-610 – Retail Marijuana Business Operators: General Limitations or Prohibited Acts**

- A. Financial Interest. A Person who holds an Owner's Interest in a Retail Marijuana Business Operator may hold an Owner's Interest in another Retail Marijuana Business. A Retail Marijuana Business may be operated by a Retail Marijuana Business Operator where each has one or more Controlling Beneficial Owners or Passive Beneficial Owners in common. A Person may receive compensation for services provided by a Retail Marijuana Business Operator in accordance with these rules.
- B. Sale of Marijuana Prohibited. A Retail Marijuana Business Operator is prohibited from selling, distributing, or Transferring Retail Marijuana to another Retail Marijuana Business or a consumer, except when acting as an agent of a Retail Marijuana Business (s) operated by the Retail Marijuana Business Operator.
- C. Consumption Prohibited. A Retail Marijuana Business Operator, and its Controlling Beneficial Owners, Passive Beneficial Owners, agents and employees, shall not permit the consumption of marijuana or marijuana products at its separate place of business.
- D. Inventory Tracking System. A Retail Marijuana Business Operator, and any of its Controlling Beneficial Owners, agents or employees engaged in the operation of the Retail Marijuana Business(es) it operates, must use the Inventory Tracking System

account of the Retail Marijuana Business(es) it operates, in accordance with all requirements, limitations and prohibitions applicable to the Retail Marijuana Business(es) it operates.

- E. Compliance with Requirements and Limitations Applicable to the Retail Marijuana Business(es) Operated. In operating any other Retail Marijuana Business, a Retail Marijuana Business Operator, and its Controlling Beneficial Owners who are required to hold Owner Licenses, as well as the agents and employees of the Retail Marijuana Business Operator, shall comply with all requirements, limitations and prohibitions applicable to the type(s) of Retail Marijuana Business(es) being operated, under state and local laws, ordinances, rules, and regulations, and may be disciplined for violation of the same.
- F. Inventory Tracking System Access. A Retail Marijuana Business may grant access to its Inventory Tracking System account to the Controlling Beneficial Owners, agents and employees of a Retail Marijuana Business Operator having duties related to Inventory Tracking System activities of the Retail Marijuana Business(es) being operated.
1. The Controlling Beneficial Owners, agents and employees of a Retail Marijuana Business Operator granted access to a Retail Marijuana Business's Inventory Tracking System account, shall comply with all Inventory Tracking System rules.
  2. At least one Controlling Beneficial Owner or their designee of a Retail Marijuana Business being operated by a Retail Marijuana Business Operator must be an Inventory Tracking System Trained Administrator for the Retail Marijuana Business's Inventory Tracking System account. That Inventory Tracking System Trained Administrator shall control access to its Inventory Tracking System account, and shall promptly terminate the access of the Retail Marijuana Business Operator's Controlling Beneficial Owners, agents and employees:
    - a. When its contract with the Retail Marijuana Business Operator expires by its terms;
    - b. When its contract with the Retail Marijuana Business Operator is terminated by any party; or
    - c. When it is notified that the License of the Retail Marijuana Business Operator, or a specific Controlling Beneficial Owner, agent or employee of the Retail Marijuana Business Operator, has expired, or has been suspended or revoked.
- G. Limitations on Use of Documents and Information Obtained from Retail Marijuana Businesses. A Retail Marijuana Business Operator, and its agents and employees, shall maintain the confidentiality of documents and information obtained from the other Retail Marijuana Business(es) it operates, and shall not use or disseminate documents or information obtained from a Retail Marijuana Business it operates for any purpose not authorized by the Marijuana Code and the rules promulgated pursuant thereto, and shall not engage in data mining or other use of the information obtained from a Retail Marijuana Business to promote the interests of the Retail Marijuana Business Operator



or its Controlling Beneficial Owners, Passive Beneficial Owners, agents or employees, or any Person other than the Retail Marijuana Business it operates.

- H. Form and Structure of Allowable Agreement(s) Between Operators and Owners. Any agreement between a Retail Marijuana Business and a Retail Marijuana Business Operator:
1. Must acknowledge that the Retail Marijuana Business Operator, and its Controlling Beneficial Owners, agents and employees who are engaged, directly or indirectly, in operating the Retail Marijuana Business, are agents of the Retail Marijuana Business being operated, and must not disclaim an agency relationship;
  2. May provide for the Retail Marijuana Business Operator to receive direct remuneration from the Retail Marijuana Business, including a portion of the profits of the Retail Marijuana Business being operated, subject to the following limitations:
    - a. The portion of the profits to be paid to the Retail Marijuana Business Operator shall be commercially reasonable, and in any event shall not exceed the portion of the net profits to be retained by the Retail Marijuana Business being operated;
    - b. The Retail Marijuana Business Operator shall not be granted, and may not accept:
      - i. A security interest in the Retail Marijuana Business being operated, or in any assets of the Retail Marijuana Business;
      - ii. An ownership or membership interest, shares, or shares of stock, or any right to obtain any direct or indirect beneficial ownership interest in the Retail Marijuana Business being operated, or a future or contingent right to the same, including but not limited to options or warrants;
    - c. The Retail Marijuana Business Operator shall not guarantee the Retail Marijuana Business's debts or production levels.
  3. Shall permit the Retail Marijuana Business being operated to terminate the contract with the Retail Marijuana Business Operator at any time, with or without cause.
- I. A Retail Marijuana Business Operator may engage in dual operation of a Retail Marijuana Business and a Medical Marijuana Business at a single location, to the extent the Retail Marijuana Business being operated is permitted to do so, the Retail Marijuana Business Operator shall comply with the rules promulgated pursuant to the Marijuana Code, including the requirement of obtaining a valid registration as a Medical Marijuana Business Operator.
- J. Any Retail Marijuana Business Operators and the Retail Marijuana Business Operator's Owner Licensee(s) that are appointed by a court to serve as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly

situated Person and take possession of, operate, manage, or control a Retail Marijuana Business must comply with Rule 2-275(F).

## **6-700 Series – Accelerator Cultivator Licenses**

### **Basis and Purpose – 6-705**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(j), 44-10-203(2)(r), 44-10-203(2)(aa), 44-10-203(3)(c), 44-10-401(2)(b)(VII), 44-10-602, and 44-10-607 C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to an Accelerator Cultivator Licensee.

### **6-705 – Accelerator Cultivator: License Privileges**

#### **A. Licensed Premises.**

1. Shared Licensed Premises. An Accelerator Cultivator may operate on the same Licensed Premises as a Retail Marijuana Cultivation Facility that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.
2. Separate Licensed Premises. An Accelerator Cultivator may operate on a separate premises in the possession of a Retail Marijuana Cultivation Facility that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.
3. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Cultivation Facility may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Cultivation Facility. However, a separate license is required for each specific business or business entity, regardless of geographical location. A Regulated Marijuana Business that is operating at the same premises as a commonly owned Medical Marijuana Business may become an Accelerator-Endorsed Licensee. An Accelerator Cultivator may operate at the premises where the Accelerator-Endorsed Licensee operates along with the commonly owned Medical Marijuana Cultivation Facility.

#### **B. Cultivation of Retail Marijuana and Production of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Retail Marijuana Concentrate Authorized.** An Accelerator Cultivator may propagate, cultivate, harvest, prepare, cure, package, store, and label Retail Marijuana and Physical Separation-Based Retail Marijuana Concentrate. An Accelerator Cultivator may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Retail Marijuana Concentrate.

#### **C. Authorized Transfers.** An Accelerator Cultivator may only Transfer Retail Marijuana and Physical Separation-Based Retail Marijuana Concentrate to another Retail Marijuana Business or to a Medical Marijuana Cultivation Facility in compliance with Rule 6-230.

1. An Accelerator Cultivator shall not Transfer Flowering plants. An Accelerator Cultivator may only Transfer Vegetative plants as authorized pursuant to Rule 3-605.

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2. An Accelerator Cultivator may Transfer Sampling Units of Retail Marijuana or Retail Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-602(6), C.R.S., and Rule 6-725.
  3. An Accelerator Cultivator may Transfer Retail Marijuana or Retail Marijuana Concentrate to another Accelerator Cultivator or Retail Marijuana Cultivation Facility prior to testing required by these rules to perform a Microbial Control Step only after all other steps outlined in the Accelerator Cultivator's ~~Standard~~ ~~Operating~~ ~~Procedures~~ have been completed, including but not limited to drying, curing, and trimming.
  4. An Accelerator Cultivator may ~~sell, Transfer, or ship Immature Plants, Retail Marijuana seeds, and~~ Genetic Material in accordance with section 44-10-602(12)(b), C.R.S. to a Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator. Transfers made under this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.
- D. Authorized On-Premises Storage. An Accelerator Cultivator is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area and tracked consistently with the inventory tracking rules.
- E. Test Batches Provided for Testing. An Accelerator Cultivator may provide Test Batches of its Retail Marijuana to a Retail Marijuana Testing Facility for testing and research purposes. The Accelerator Cultivator shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- F. Authorized Marijuana Transport. An Accelerator Cultivator is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents an Accelerator Cultivator from transporting its own Retail Marijuana.
- G. Performance-Based Incentives. An Accelerator Cultivator may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, an Accelerator Cultivator may not compensate a Sampling Manager using Sampling Units. See Rule 6-725 – Sampling Unit Protocols.
- H. Authorized Sources of Retail Marijuana, ~~Seeds, Immature Plants,~~ and Genetic Material.
1. An Accelerator Cultivator may obtain Retail Marijuana ~~seeds or Immature Plants from its own Retail Marijuana, properly Transferred Medical Marijuana cultivated at a Medical Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or~~ properly Transferred from another Retail Marijuana Business pursuant to the inventory tracking requirements in the 3-800 Series Rules. An Accelerator Cultivator may not bring ~~seeds, Immature Plants, or other~~ marijuana that is not Regulated Marijuana onto the Licensed Premises at any time.
  2. An Accelerator Cultivator may obtain ~~Retail Marijuana seeds, Immature Plants, and~~ Genetic Material in accordance with section 44-10-602(12)(a), C.R.S. from:

- ~~a. Another Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility;~~
- ~~b. A Retail Marijuana Testing Facility;~~
- ~~c. A marijuana cultivation or testing facility licensed or otherwise approved pursuant to a permit or registration issued by a government agency to operate in another state or territory of the United States;~~
- ~~d. An individual licensed as an Employee Licensee in Colorado, or holding a permit, registration, or license to work in another state or territory of the United States that regulates marijuana; or~~
- ~~e. Pursuant to any federal statute or regulation.~~

3. Transfers made under subparagraph (H)(2) of this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.

- I. Centralized Distribution Permit. An Accelerator Cultivator may apply to the State Licensing Authority for a Centralized Distribution Permit for authorization to temporarily store Retail Marijuana Concentrate and Retail Marijuana Product received from a Retail Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Accelerator Stores.

1. For purposes of a Centralized Distribution Permit only, the term “commonly owned” means at least one natural person has a minimum of five percent ownership in both the Accelerator Cultivator possessing a Centralized Distribution Permit and the Accelerator Store to which the Retail Marijuana Concentrate and Retail Marijuana Product will be Transferred.
2. To apply for a Centralized Distribution Permit, an Accelerator Cultivator may submit an addendum to its new or renewal application or a separate addendum prior to a renewal application on forms prepared by the Division to request a Centralized Distribution Permit. The Accelerator Cultivator shall send a copy of its Centralized Distribution Permit addendum to the Local Licensing Authority in the jurisdiction in which the Centralized Distribution Permit is proposed at the same time it submits the addendum to the State Licensing Authority.
3. An Accelerator Cultivator that has been issued a Centralized Distribution Permit and has obtained all required approvals from the local licensing jurisdiction where it is located, if any, may accept Transfers of Retail Marijuana Concentrate and Retail Marijuana Product from a Retail Marijuana Products Manufacturer for the sole purpose of temporary storage and Transfer to commonly owned Accelerator Stores.
  - a. An Accelerator Cultivator may only accept Retail Marijuana Concentrate and Retail Marijuana Product that is packaged and labeled for sale to a consumer pursuant to the 3-1000 Series Rules.
  - b. An Accelerator Cultivator storing Retail Marijuana Concentrate and Retail Marijuana Product pursuant to a Centralized Distribution Permit shall not store such Retail Marijuana Concentrate or Retail Marijuana Product on

the Accelerator Cultivator's Licensed Premises for more than 90 days from the date of receipt.

- c. All Transfers of Retail Marijuana Concentrate and Retail Marijuana Product by an Accelerator Cultivator pursuant to a Centralized Distribution Permit shall be without consideration.
  - 4. All security and surveillance requirements that apply to an Accelerator Cultivator apply to activities conducted pursuant to the privileges of a Centralized Distribution Permit.
- J. Transition Permit. An Accelerator Cultivator may only operate at two geographical locations pursuant to Rule 2-255(D).

### **Basis and Purpose – 6-715**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(r), 44-10-401(2)(b)(VII), and 44-10-602, C.R.S. The purpose of this rule is to establish the categories of Retail Marijuana Concentrate that may be produced at Accelerator Cultivator and standards for the production of Retail Marijuana Concentrate.

### **6-715 – Accelerator Cultivator: Retail Marijuana Concentrate Production**

- A. Permitted Production of Certain Categories of Retail Marijuana Concentrate. An Accelerator Cultivator may only produce Physical Separation-Based Retail Marijuana Concentrate on its Licensed Premises and only in an area clearly designated as a Limited Access Area. See Rule 3-905- Business Records Required. No other method of production or extraction for Retail Marijuana Concentrate may be conducted within the Licensed Premises of An Accelerator Cultivator unless the Controlling Beneficial Owner(s) of the Accelerator Cultivator also has a valid Accelerator Manufacturer license and the room in which Retail Marijuana Concentrate is to be produced is physically separated from all cultivation areas and has clear signage identifying the room.
- B. Safety and Sanitary Requirements for Concentrate Production. If an Accelerator Cultivator produces Retail Marijuana Concentrate, then all areas in which the Retail Marijuana Concentrate are produced and all Controlling Beneficial Owners and Employee Licensees engaged in the production of the Retail Marijuana Concentrate shall be subject to all of the requirements imposed upon an Accelerator Manufacturer that produces Retail Marijuana Concentrate, including all general requirements. See 3-300 Series Rules – Health and Safety Regulations and Rule 6-815 – Accelerator Manufacturer: Retail Marijuana Concentrate Production.
- C. Possession of Other Categories of Retail Marijuana Concentrate.
  - 1. It shall be considered a violation of this Rule if an Accelerator Cultivator possesses a Retail Marijuana Concentrate other than a Physical Separation-Based Retail Marijuana Concentrate on its Licensed Premises unless: the Controlling Beneficial Owner(s) of the Accelerator Cultivator also has a valid Accelerator Manufacturer license; or the Accelerator Cultivator has been issued a

Centralized Distribution Permit and is in possession of the Retail Marijuana Concentrate in compliance with Rule 6-705(I).

2. Notwithstanding subparagraph (C)(1) of this Rule 6-715, an Accelerator Cultivator shall be permitted to possess Solvent-Based Retail Marijuana Concentrate only when the possession is due to the Transfer of Retail Marijuana flower or trim that failed microbial testing to an Accelerator Manufacturer for processing into a Solvent-Based Retail Marijuana Concentrate, and the Accelerator Manufacturer Transfers the resultant Solvent-Based Retail Marijuana Concentrate back to the originating Accelerator Cultivator.
  - a. The Accelerator Cultivator shall comply with all requirements in Rule ~~4-2404-135(G)~~ when having Solvent-Based Retail Marijuana Concentrate manufactured out of Retail Marijuana flower or trim that failed microbial testing.
  - b. The Accelerator Cultivator is responsible for submitting the Solvent-Based Retail Marijuana Concentrate for all required testing for contaminants pursuant to Rule ~~4-2154-120~~ – Regulated Marijuana Testing Program – Contaminant Testing, for potency pursuant to Rule ~~4-2104-125~~ – Regulated Marijuana Testing Program – Potency Testing, and any other testing required or allowed by the Marijuana Rules or the Marijuana Code.
  - c. Nothing in this Rule removes or alters the responsibility of the Accelerator Cultivator that Transfers the Retail Marijuana that failed microbial testing from complying with the requirement to pay excise tax pursuant to Rule 6-210(C).
- D. Production of Alternative Use Product or Audited Product Prohibited. An Accelerator Cultivator shall not produce an Alternative Use Product or Audited Product.
- E. Possession of Alternative Use Product or Audited Product. An Accelerator Cultivator is authorized to possess or Transfer Alternative Use Product and/or Audited Product only if the Accelerator Cultivator received the Alternative Use Product and/or Audited Product pursuant to a Centralized Distribution Permit from an Accelerator Manufacturer that is manufacturing and Transferring the Alternative Use Product or Audited Product in accordance with Rule 6-325.

### **Basis and Purpose – 6-720**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(6), 44-10-401(2)(b)(VII), 44-10-602 and 44-10-607 C.R.S. The rule establishes a means by which to manage the overall production of Retail Marijuana in the state of Colorado. The intent of this rule is to encourage responsible production to meet demand for Retail Marijuana consumers, while also avoiding overproduction or underproduction. The establishment of production management is necessary to ensure there is not significant under or over production, either of which will increase incentives to engage in diversion and facilitate the continuation of the sale of illegal marijuana. Existing and prospective ~~h~~licensees should be on notice that the new or revised regulations may impact the production limits provided for in this rule.

**6-720 - Accelerator Cultivator: Production Management****A. Number of Accelerator Cultivators per Licensed Premises**

1. An Accelerator Cultivator may only own and operate a single Accelerator Cultivation per Licensed Premises.
2. A Retail Marijuana Cultivation Facility Licensee that is an Accelerator-Endorsed Licensee may host more than one Accelerator Cultivation owned by different Social Equity Licensees at a single Licensed Premises.

**B. Production Management.****1. Production Management Tiers.**

- a. Tier 1: 1 - 1,800 plants
- b. Tier 2: 1,801 – 3,600 plants
- c. Tier 3: 3,601 – 6,000 plants
- d. Tier 4: 6,001 – 10,200 plants
- e. Tier 5: 10,201 – 13,800+ plants
  - i. Tier 5 shall not have a cap on the maximum authorized plant count.
  - ii. The maximum authorized plant count above 10,200 plants shall increase in one or two increments of 3,600 plants. An Accelerator Cultivator shall be allowed to increase its maximum authorized plant count one or two increments of 3,600 plants at a time upon application and approval by the Division pursuant to the requirements of paragraph (E) of this Rule 6-720.

2. All Accelerator Cultivator licenses granted on or after January 1, 2020, will be issued as a Tier 1 License.

3. Immature Plants. For purposes of calculating the maximum number of authorized plants, Immature Plants are excluded.

4. Ground for Denial. The Division may deny an application for additional plants pursuant to paragraph E of this Rule if the Licensee exceeded the authorized plant count during the relevant time period for production.

5. ~~Repealed. Violation Affecting Public Safety. It may be considered a license violation affecting public safety for a Licensee to exceed the authorized plant count pursuant to these Rules.~~

**C. Inventory Management.**

1. Inventory Management for Accelerator Cultivators that Have One or Two Harvest Seasons a Year. Beginning the 721<sup>st</sup> day from the commencement of its first cultivation activities, an Accelerator Cultivator that has one or two harvest

seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Retail Marijuana flower and trim the Licensee reported as a package in the Inventory Tracking System that was Transferred to another Retail Marijuana Business in the previous 720 days.

2. Inventory Management for Accelerator Cultivators That Have More Than Two Harvest Seasons a Year. Beginning the 181<sup>st</sup> day from the commencement of its first cultivation activities, an Accelerator Cultivator that has more than two harvest seasons a year may not accumulate Harvested Marijuana in excess of the total amount of Retail Marijuana flower and trim the Licensee reported as a package in the Inventory Tracking System that was Transferred to another Retail Marijuana Business in the previous 180 days.

- D. Tier Decrease. For Accelerator Cultivators that are authorized to cultivate more than 1,800 plants, the Division may review the purchases, Transfers, and cultivated plant count of the Accelerator Cultivator in connection with the license renewal process or after an investigation. Based on the Division's review, the Division may reduce the Accelerator Cultivator's maximum allowed plant count to a lower production management tier pursuant to subparagraph (C)(1) of this Rule. When determining whether to reduce the maximum authorized plant count, the Division may consider the following non-exhaustive factors including but not limited to:

1. The Accelerator Licensee sold less than 70% of what the inventory it reported as packaged in the Inventory Tracking System during any 180 day review period;
2. On average during the previous 180 days the Accelerator Licensee actually cultivated less than 90% of the maximum number of plants authorized by the next lower production management tier;
3. Whether the plants/inventory suffered a catastrophic event during the review period;
4. Excise tax payment history;
5. Existing inventory and inventory history;
6. Sales contracts; and
7. Any other factors relevant to ensuring responsible cultivation, production, and inventory management.

- E. Application for Additional Plants.

1. Accelerator Cultivators That Have One or Two Harvest Seasons Per Year.
  - a. After accruing at least one harvest season of Transfers, an Accelerator Cultivator may apply to the Division for a production management tier increase to be authorized to cultivate the number of plants in the next highest production management tier. The Division may consider the following in determining whether to approve the production management tier increase:



- i. That during the previous harvest season prior to the tier increase application, it consistently cultivated an average amount of plants that is at least 85% of its maximum authorized plant count;
  - ii. That the Accelerator Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System in the previous 360 days to another Retail Marijuana Business;
  - iii. The Division may also consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the previous 360 days, if the Licensee cultivated between 75% and 85% of its maximum authorized plant count; and
  - iv. Any other information requested to aid the Division in its evaluation of the production management tier increase application.
- b. If the Division approves the production management tier increase application, the Accelerator Licensee shall pay the applicable expanded production management tier fee prior to cultivating the additional authorized plants.
- c. For an Accelerator Licensee with an authorized plant count in tiers 2-5 to continue producing at its expanded authorized plant count, the Accelerator Licensee shall pay the requisite Accelerator Cultivator license fee and the expanded production management tier fee, if applicable, at license renewal.
- d. After accruing one harvest season during which the Accelerator Cultivator Transferred and consistently cultivated the Accelerator Licensee may apply to increase its authorized plant count by: (a) two production management tiers or (b) if already authorized to cultivate at a production management Tier 5, two increments of 3,600 plants (7,200 plants total), every 360 days. It is within the Division's discretion to determine whether or not to grant the requested two tiers or increments of 3,600 plants (7,200 plants total).
  - i. The Accelerator Licensee must demonstrate:
    - A. That the Accelerator Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count; and
    - B. That the Accelerator Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Retail Marijuana Business.

- C. If the Accelerator Cultivator cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a package in the Inventory Tracking System during that time period and/or Transfers into the Accelerator Cultivator or related Accelerator Store(s).
  - ii. In making its determination, the Division may consider the following exclusive factors:
    - A. The Accelerator Cultivator currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two tiers or two 3,600 plant increments;
    - B. The Accelerator Cultivator cultivated at least 90% of its maximum authorized plant count and during the preceding 360 days the Accelerator Cultivator and/or any commonly owned Accelerator Store Transferred in Retail Marijuana from one or more unrelated Accelerator Cultivator(s) or Retail Marijuana Cultivation Facility(ies);
    - C. The Accelerator Cultivator has contracts for the sale of Retail Marijuana in the next 360 days supporting the requested two tiers or two increments of 3,600 plants;
    - D. An established history of responsible cultivation and Transfer by the Accelerator Cultivator;
    - E. Any history of noncompliance with the Marijuana Code and/or Rules by the Accelerator Cultivator, or any commonly owned Retail Marijuana Business, and/or any investigation of, or administrative action(s) against, the Accelerator Cultivator, or any commonly owned Retail Marijuana Business; or
    - F. Any other pertinent facts or circumstances regarding responsible production and inventory management.
- 2. Accelerator Cultivators that have more than two harvest seasons per year.
  - a. After a 180-day period during which the Accelerator Cultivator Transferred and consistently cultivated, the Accelerator Licensee may apply to the Division for a production management tier increase to be authorized to cultivate the number of plants in the next highest production management tier. The Division may consider the following in determining whether to approve the production management tier increase:
    - i. That for 180 days prior to the tier increase application, the Accelerator Licensee consistently cultivated an average amount of

- plants that is at least 85% of its maximum authorized plant count, and
- ii. That the Accelerator Licensee Transferred at least 85% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Retail Marijuana Business.
  - iii. The Division may also consider Transfers of over 85% of the inventory it reported as a package in the Inventory Tracking System during the 180-day time period if the Licensee cultivated between 75% and 85% of its maximum authorized plant count.
  - iv. Any other information requested to aid the Division in its evaluation of the tier increase application.
- b. If the Division approves the production management tier increase application, the Accelerator Licensee shall pay the applicable expanded production management tier fee, if applicable, prior to cultivating the additional authorized plants.
- c. For an Accelerator Licensee with an authorized plant count in tier 2-5 to continue producing at its expanded authorized plant count, the Accelerator Licensee shall pay the requisite Accelerator Cultivator license fee and the applicable expanded production management tier fee, if applicable, at license renewal.
- d. After accruing 180 days during which the Accelerator Cultivator Transferred and consistently cultivated the Accelerator Licensee may apply to increase its authorized plant count by: (a) two production management tiers or (b) if already authorized to cultivate at a tier 5, two increments of 3,600 plants (7,200 plants total) every 180 days. It is within the Division's discretion to determine whether or not to grant the requested two tier or two increments of 3,600 plants (7,200 plants total).
- i. The Accelerator Licensee must demonstrate:
    - A. That the Accelerator Licensee consistently cultivated an average amount of plants that is at least 90% of its maximum authorized plant count; and
    - B. That the Accelerator Licensee Transferred at least 90% of the inventory it reported as a package in the Inventory Tracking System during that time period to another Retail Marijuana Business;
    - C. If the Accelerator Cultivator cultivated between 80% and 90% of its maximum authorized plant count, the Division may also consider Transfers of over 90% of the inventory it reported as a package in the Inventory Tracking system

during that time period and/or Transfers into the Accelerator Cultivator or related Accelerator Store(s).

- ii. In making its determination, the Division may consider the following exclusive factors:
  - A. The Accelerator Cultivator currently has possession of, or has entered into a written agreement or contract to possess, sufficient space to grow the requested two tiers or two increments of 3,600 plants;
  - B. The Accelerator Cultivator cultivated at least 90% of its maximum authorized plant count and during the preceding 180 days the Accelerator Cultivator and/or any commonly owned Accelerator Store Transferred in Retail Marijuana from one or more unrelated Accelerator Cultivator(s) or Retail Marijuana Cultivation Facility(ies);
  - C. The Accelerator Cultivator has entered into a written agreement(s) or contract(s) for the sale of Retail Marijuana in the next 180 days supporting the requested two tiers or two increments of 3,600 plants;
  - D. An established history of responsible cultivation and Transfer by the Accelerator Cultivator;
  - E. Any history of noncompliance with the Marijuana Code and/or Rules by the Accelerator Cultivator or any commonly owned Retail Marijuana Business(es), and/or any investigation of, or administrative action(s) against, the Accelerator Cultivator or any commonly owned Retail Marijuana Business;
  - F. Any other pertinent facts or circumstances regarding responsible production and inventory management.
- 3. Application for Tier Increase. Applications for a tier increase that include any artificial increase of plant count, manipulation of Transfer history, or other misrepresentation will be denied. ~~In addition to denial, any artificial increase of plant count, manipulation of Transfer history, or other misrepresentation is a public safety violation that may result in administrative action.~~

### **Basis and Purpose – 6-725**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-401(2)(b)(VII), 44-10-602(6) and 44-10-607, C.R.S. The purpose of this rule is to establish the circumstances under which an Accelerator Cultivator may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado's Regulated Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager

may receive in a calendar month and imposes inventory tracking, reporting and recordkeeping requirements on an Accelerator Cultivator that Transfer Sampling Units.

#### **6-725 – Accelerator Cultivator - Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, an Accelerator Cultivator may designate no more than five Sampling Managers in the Inventory Tracking System.
1. Only management personnel of the Accelerator Cultivator who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  2. A person may be designated as a Sampling Manager by more than one Medical Marijuana Business or Retail Marijuana Business.
  3. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.
  4. An Accelerator Cultivator that wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling Manager Standard Operating Procedures that explain the requirements of section 44-10-602(6), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 6-225. See also Rule 3-905 – Business Records Required. An Accelerator Cultivator shall maintain and update such Standard Operating Procedures as necessary to reflect accurately any changes in the relevant statutes and rules.
- B. Sampling Unit Limits. Only one Sampling Unit may be designated per Harvest Batch or Production Batch. A Sampling Unit shall not be designated until the Harvest Batch or Production Batch has satisfied the testing requirements in the ~~4-2004-100~~ Series Rules – Regulated Marijuana Testing Program.
1. A Sampling Unit of Retail Marijuana flower or trim shall not exceed one gram.
  2. A Sampling Unit of Retail Marijuana Concentrate shall not exceed one-quarter of one gram; except that a Sampling Unit of Retail Marijuana Concentrate which has the intended use of being delivered in a vaporized form shall not exceed one-half of one gram.
- C. Excise Tax Requirements. An Accelerator Cultivator must pay excise tax on Sampling Units of Retail Marijuana flower or trim, based on the average market rate of the unprocessed Retail Marijuana.
- D. Transfer Restrictions.
1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.

2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Accelerator Cultivator as a Sampling Manager for the calendar month in which the Transfer occurs.
  3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than one ounce of Retail Marijuana or eight grams of Retail Marijuana Concentrate.
  4. The monthly limit established in subparagraph (D)(3) applies to each Sampling Manager, regardless of the number of Retail Marijuana Businesses with which the Sampling Manager is associated.
  5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (D)(3). Before Transferring any Sampling Units, an Accelerator Cultivator shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limits established in subparagraph (D)(3).
  6. A Sampling Manager shall not Transfer any Sampling Unit to any other Person, including but not limited to any other Person designated as a Sampling Manager.
- E. Compensation Prohibited. An Accelerator Cultivator may not use Sampling Units to compensate a Sampling Manager.
- F. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.
- G. Acceptable Purposes. Sampling Units shall only be designated and Transferred for the purposes of quality control and product development in accordance with section 44-10-602(6), C.R.S.
- H. Record keeping requirements. An Accelerator Cultivator shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule 3-905 – Business Records Required. At a minimum, an Accelerator Cultivator shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of quality control or product development. An Accelerator Cultivator shall also maintain copies of the Accelerator Cultivator ~~S~~standard ~~O~~perating ~~P~~rocedures provided to Sampling Managers.
- I. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

### **Basis and Purpose – 6-730**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-401(2)(b)(II), 44-10-602(13)(a)-(c), 44-10-602(13.5), 44-10-607, and 39-28.8-301, C.R.S. The purpose of this rule is to allow a Medical Marijuana Cultivation Facility to receive Transfers of Retail Marijuana from a Retail Marijuana Cultivation Facility in order to change its designation from “Retail” to “Medical.”

### **6-730 – Accelerator Cultivator: Ability to Change Designation of Regulated Marijuana**

*Marijuana Enforcement Division*

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- A. Changing Designation from Retail Marijuana to Medical Marijuana. Beginning July 1, 2022, an Accelerator Cultivator may Transfer Retail Marijuana to a Medical Marijuana Cultivation Facility in order to change its designation from Retail Marijuana to Medical Marijuana pursuant to the following requirements:
1. The Accelerator Cultivator may only Transfer Retail Marijuana that has passed all required testing;
  2. The Medical Marijuana Cultivation Facility and the Accelerator Cultivator share a Licensed Premises in accordance with Rule 3-215;
  3. The Medical Marijuana Cultivation Facility and Accelerator Cultivator have at least one identical Controlling Beneficial Owner;
  4. The Accelerator Cultivator must report the Transfer in the Inventory Tracking System the same day that the change in designation from Retail Marijuana to Medical Marijuana occurs;
  5. After the designation change, the Medical Marijuana cannot be Transferred to the originating Accelerator Cultivator or any other Retail Marijuana Business or otherwise be treated as Retail Marijuana. The Inventory is Medical Marijuana and is subject to all permissions and limitations in the 5-200 series rules;
  6. Both the Accelerator Cultivator and the Medical Marijuana Cultivation Facility must remain at, or under, its respective inventory limit before and after the Retail Marijuana changes its designation to Medical Marijuana; and
  7. The Transfer and change of designation does not create a right to a refund of any Retail Marijuana excise tax incurred or paid prior to the Transfer and change of designation.
- B. Changing Designation from Medical Marijuana to Retail Marijuana. Beginning January 1, 2023, an Accelerator Cultivator may accept Medical Marijuana from a Medical Marijuana Cultivation Facility in order to change its designation from Medical Marijuana to Retail Marijuana pursuant to the following requirements:
1. The Accelerator Cultivator may only accept Medical Marijuana that has passed all required testing in accordance with the ~~4-2004-100~~ Series Rules – Regulated Marijuana Testing Program;
  2. The Accelerator Cultivator and the Medical Marijuana Cultivation Facility share a Licensed Premises in accordance with Rule 3-215, unless:
    - a. The Accelerator Cultivator and Medical Marijuana Cultivation Facility have at least one identical Controlling Beneficial Owner; and
    - b. The Accelerator Cultivator and the Medical Marijuana Cultivation Facility cannot share a Licensed Premises because the Local Licensing Authority or Local Jurisdiction prohibits the operation of either a Retail Marijuana Cultivation Facility or a Medical Marijuana Cultivation Facility.

3. The Accelerator Cultivator and Medical Marijuana Cultivation Facility have at least one identical Controlling Beneficial Owner;
4. The Accelerator Cultivator must receive the Transfer and designate the inventory as Retail Marijuana in the Inventory Tracking System the same day. The Accelerator Cultivator must assign and attach an Inventory Tracking System tag reflecting its Accelerator Cultivator License number to the Retail Marijuana following completion of the Transfer in the Inventory Tracking System;
5. After the designation change, the Retail Marijuana cannot be Transferred to the originating or any other Medical Marijuana Business or otherwise be treated as Medical Marijuana. The inventory is Retail Marijuana and is subject to all permissions and limitations in the 6-200 Series Rules and these 6-700 Series Rules;
6. Both the Accelerator Cultivator and the Medical Marijuana Cultivation Facility must remain at, or under, its inventory limit before and after the Medical Marijuana changes its designation to Retail Marijuana;
7. The Accelerator Cultivator shall pay any Retail Marijuana excise tax that is imposed pursuant to section 39-28.8-302, C.R.S.;
8. The Accelerator Cultivator shall notify the Local Licensing Authority and Local Jurisdiction where the Accelerator Cultivator and the Medical Marijuana Cultivation Facility operate and pay any applicable excise tax on the Retail Marijuana in the manner determined by the Local Licensing Authority and Local Jurisdiction; and
9. Pursuant to the requirements of this subparagraph (B), an Accelerator Cultivator may receive a virtual Transfer of Medical Marijuana that is reflected in the Inventory Tracking System even if the Medical Marijuana is not physically moved prior to the change of designation to Retail Marijuana.

**Basis and Purpose – 6-735**

The Statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(j.5), 44-10-203(1)(k), 44-10-401(2)(b)(II), and 44-10-502(10)(a)-(c) The purpose of this rule is to allow an Accelerator Cultivator ~~Licensees~~ licensees that plan to cultivate Retail Marijuana outdoors to submit a contingency plan to the Division for approval in anticipation of an Adverse Weather Event.

**6-735 Accelerator Cultivator: Contingency Plan for Outdoor Cultivation****A. Submission of Contingency Plan.**

1. Beginning January 1, 2022, Accelerator Cultivator Licensees that plan to cultivate Retail Marijuana outdoors may submit a contingency plan to the Division for approval in anticipation of an Adverse Weather Event. The Accelerator Cultivator shall also submit a copy of the plan to the Local Licensing Authority in the local jurisdiction where the licensee operates, and if Transferring Retail Marijuana to the Licensed Premises of a Medical Marijuana Cultivation Facility, Retail



Marijuana Cultivation Facility and/or an off-premises storage facility outside of that jurisdiction, the Local Licensing Authority in that jurisdiction.

2. An Accelerator Cultivator may submit a contingency plan at any time, but it must be filed at least 7 days prior to taking action pursuant to the contingency plan and must be approved by the State Licensing Authority prior to taking action pursuant to the contingency plan.
3. After initial submission and approval of a contingency plan, a contingency plan must be submitted with the Accelerator Cultivator's license renewal application. Any significant change to a contingency plan prior to a renewal application must be submitted for review and approval pursuant to sub~~paragraph~~section (A)(2) above prior to taking action pursuant to the revised contingency plan.
4. The Division shall notify the appropriate Local Licensing Authorities of the approval of the contingency plan.

B. Requirements for Outdoor Contingency Plans.

1. Identification of the type of Adverse Weather Event that the plan applies to, including any deviations based on the type of Adverse Weather Event.
2. Primary contact. A primary contact for the Accelerator Cultivator must be identified on the contingency plan, including the: name, title, phone number, and email address of the primary contact. The Accelerator Cultivator shall notify the Division of any change to the primary contact or required contact information within 48 hours of the change.
3. Transport Manifest. If the contingency plan provides for the Transfer of Retail Marijuana, an Accelerator Cultivator shall submit a standing transport manifest that could be used by a Licensee upon approval during an Adverse Weather Event if creating a transport manifest through the Inventory Tracking System is impracticable. The standing transport manifest shall include: identification and address of the receiving Licensee.
4. Disclosure of Receiving Licensed Premises.
  - a. Retail Marijuana may only be Transferred to the Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and/or an off-premises storage facility.
  - b. If Retail Marijuana will be Transferred to the Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and/or off-premises storage facility pursuant to a contingency plan, that plan must include the name, ownership, and address of the receiving Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and/or off-premises storage facility, along with a diagram of the proposed receiving Licensed Premises.
  - c. The receiving Licensed Premises shall be an existing location that currently holds an approved state and local license or an off-premises storage facility permit. The receiving Licensee is not required to share any

Controlling Beneficial Owners with the Transferring Retail Marijuana Cultivation Facility.

- d. An Accelerator Cultivator that cultivates outdoors may identify and Transfer Retail Marijuana to no more than five receiving Licensed Premises' as part of a contingency plan.

- 5. Disclosure of Modifications to the Premises and Security and Surveillance. Proposed modifications to the Licenses Premises and any anticipated impacts to compliance with security and surveillance requirements pursuant to Rules 3-225 (C)(1), 3-225 (C)(5) and 3-225 (C)(6).

- C. License Requirements when Acting Pursuant to a Contingency Plan. To the extent that this sub~~paragraph~~~~section~~ (C) conflicts with other rule sections, this sub~~paragraph~~~~section~~ shall control during the time that a Licensee is acting pursuant to a contingency plan.

- 1. Notification.

- a. Notification of action pursuant to an approved contingency plan shall be made to the Division within 24 hours after initiating action pursuant to a contingency plan. An Accelerator Cultivator that cultivates outdoors must also notify the Local Licensing Authority in the local jurisdiction where the ~~the~~ Licensee operates, and if Transferring Retail Marijuana to the Licensed Premises of a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or an off-premises storage facility outside of that jurisdiction, the Local Licensing Authority in that jurisdiction.
- b. Notification of ceasing action pursuant to the approved contingency plan shall be made to the Division within 24 hours of returning to normal business operations. If action will continue more than 7 days after initiating action pursuant to a contingency plan, the Licensee shall contact the Division and explain why it cannot return to normal business operations.
- c. Any notification shall be made in writing and can be made by email to the Division.

- 2. Production Management. Retail Marijuana Transferred to a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility pursuant to a contingency plan is not included in the receiving Licensed Premises' inventory limit until the Accelerator Cultivator acting pursuant to the contingency plan returns to normal business operations.

- 3. Modification of Premises. ~~Notification for a modification of a Licensed Premises is not required as part of a contingency plan unless the modification of premises becomes a permanent modification. If that change becomes a permanent change, notification is required pursuant to Rule 2-260. An application for a modification of a Licensed Premises is not required as part of a contingency plan unless the modification or change in premises becomes a permanent~~

~~modification. If that change becomes a permanent change, a modification of premises application must be submitted within 14 days.~~

4. Security Requirements. All security and surveillance requirements that apply to an Accelerator Cultivator apply to activities conducted pursuant to the contingency plan. If the contingency plan does not require the Transfer of Regulated Marijuana to another Licensed Premises, but requires plants to be covered or video surveillance to be otherwise temporarily obstructed, exemptions to the video surveillance requirements in Rules 3-225 (C)(1), 3-225 (C)(5) and 3-225 (C)(6) may be approved as part of the contingency plan.
5. Inventory Tracking Requirements. Licensees must use the Inventory Tracking System to ensure Retail Marijuana is identified and tracked during all times that action is being taken pursuant to a contingency plan. If an Accelerator Cultivator harvests, Transfers, or packages Retail Marijuana it must be fully reconciled in the Inventory Tracking System within 48 hours of initiating action pursuant to the contingency plan.
  - a. Harvest Requirements. If Retail Marijuana is harvested, the weight of Retail Marijuana can be captured on a per harvest level and equally applied to individual plants rather than requiring the initial wet weight of each plant. This initial harvest weight may be captured at a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility upon arrival at the Licensed Premises approved as part of the contingency plan. Harvest Batches and Inventory Tracking System packages must be reported by the Retail Marijuana Cultivation Facility acting pursuant to the contingency plan in the Inventory Tracking System.
  - b. Transport Manifest. The Accelerator Cultivator acting pursuant to the contingency plan must report all Retail Marijuana that is Transferred to a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility on a transport manifest.
    - i. A Licensee may use the approved standing transport manifest during an Adverse Weather Event only when using the Inventory Tracking System is not possible.
    - ii. The Licensee shall manually fill out the dates, times, and individual transporting Retail Marijuana on a copy of the standing transport manifest.
    - iii. The Licensee shall ensure the standing transport manifest and copy of the approved Contingency plan remain in the Licensee's possession during any transport of Retail Marijuana when it is not possible to use an Inventory Tracking System generated transportation manifest at the time of the Adverse Weather Event.

6. Transfers. If Retail Marijuana is Transferred to another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility it is exempted from the packaging and labeling requirements in Rule 3-1005(B).
7. Virtual and Physical Separation. If Retail Marijuana is Transferred to a receiving Licensed Premises of another Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility and/or off-premises storage facility that inventory must be virtually separated by Harvest Batch and must also be virtually and physically separated from the receiving Licensee's inventory. Harvest Batches must also be clearly identified at the receiving Licensed Premises with the Harvest Batch name and date of harvest.
8. Finishing Product. After Transferring Retail Marijuana to another Licensed Premises, an Accelerator Cultivator may finish that harvest at the receiving Licensed Premises if all Retail Marijuana is accounted for in the Inventory Tracking System and the Licensed Premises is in compliance with all surveillance requirements.
9. Testing. The originating Licensee acting pursuant to a contingency plan is responsible for the submission of Test Batch(es).
  - a. Each Harvest Batch or Production Batch Transferred pursuant to a contingency plan must be submitted for all required tests and is not eligible for a Reduced Testing Allowance or otherwise exempt from required testing.
  - b. Any passing or failing tests of a Harvest Batch or Production Batch Transferred pursuant to a contingency plan will not count for or against a Licensee's Reduced Testing Allowance.

## **6-800 Series – Accelerator Manufacturer Licenses**

### **Basis and Purpose – 6-805**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-203(2)(aa), 44-10-307(1)(j), 44-10-401(2)(b)(VIII), 44-10-603 and 44-10-608, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to an Accelerator Manufacturer.

### **6-805 – Accelerator Manufacturer: License Privileges**

- A. Licensed Premises.
  1. Shared Licensed Premises. An Accelerator Manufacturer may operate on the same Licensed Premises as a Retail Marijuana Products Manufacturer that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.
  2. Separate Licensed Premises. An Accelerator Manufacturer may operate on a separate premises in the possession of a Retail Marijuana Products

Manufacturer that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.

3. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer Facility. However, a separate license is required for each specific business or business entity, regardless of geographical location. A Regulated Marijuana Business that is operating at the same premises as a commonly owned Medical Marijuana Business may become an Accelerator-Endorsed Licensee. An Accelerator Manufacturer may operate at the premises where the Accelerator-Endorsed Licensee operates along with the commonly owned Medical Marijuana Products Manufacturer.

B. Authorized Transfers. An Accelerator Manufacturer is authorized to Transfer Retail Marijuana as follows:

1. Retail Marijuana Concentrate and Retail Marijuana Product.
  - a. An Accelerator Manufacturer may Transfer Retail Marijuana Concentrate or Retail Marijuana Product to Retail Marijuana Stores, Accelerator Stores, other Accelerator Manufacturers, Retail Marijuana Products Manufacturers, Retail Marijuana Testing Facilities, Retail Marijuana Hospitality and Sales Businesses, and Pesticide Manufacturers.
  - b. An Accelerator Manufacturer may Transfer Retail Marijuana Product and Retail Marijuana Concentrate to a Retail Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit.
    - i. Prior to any Transfer pursuant to this Rule 6-805(B)(1)(b), an Accelerator Manufacturer shall verify the Retail Marijuana Cultivation Facility possesses a valid Centralized Distribution Permit. See Rule 6-205 – Retail Marijuana Cultivation Facility: License Privileges.
    - ii. For any Transfer pursuant to this Rule 6-805(B)(1)(b), an Accelerator Manufacturer shall only Transfer Retail Marijuana Product and Retail Marijuana Concentrate that is packaged and labeled for Transfer to a consumer. See 3-1000 Series Rules.
  - c. An Accelerator Manufacturer may Transfer Retail Marijuana Concentrate to a Medical Marijuana Products Manufacturer in compliance with Rule 6-335.
2. Retail Marijuana. An Accelerator Manufacturer may Transfer Retail Marijuana to other Accelerator Manufacturers, Retail Marijuana Products Manufacturer, Retail Marijuana Testing Facilities, Accelerator Stores, and Retail Marijuana Stores.
3. Sampling Units. An Accelerator Manufacturer may also Transfer Sampling Units of its own Retail Marijuana Concentrate or Retail Marijuana Product to a

designated Sampling Manager in accordance with the restrictions set forth in section 44-10-603(10), C.R.S., and Rule 6-820.

- C. Manufacture of Retail Marijuana Concentrate and Retail Marijuana Product and Production of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana Authorized. An Accelerator Manufacturer may manufacture, prepare, package, store, and label Retail Marijuana Concentrate and Retail Marijuana Product comprised of Retail Marijuana and other Ingredients intended for use or consumption, such as Edible Retail Marijuana Products, ointments, or tinctures. An Accelerator Manufacturer may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana.
1. Hemp Product Authorized. An Accelerator Manufacturer that uses Hemp Product as an Ingredient in the manufacture and preparation of Retail Marijuana Product must comply with this subparagraph (C)(1) of this Rule.
- a. Prior to accepting and taking possession of any Hemp Product for use as an Ingredient in a Retail Marijuana Product the Accelerator Manufacturer shall verify the following:
- i. That the Hemp Product has passed all required testing pursuant to the ~~4-2004-100~~ Series Rules at a Retail Marijuana Testing Facility; and
- ii. That the Person Transferring the Hemp Product to the Accelerator Manufacturer is registered with the Colorado Department of Public Health and Environment as a Hemp Product Manufacturer pursuant to section 25-5-42~~7~~6, C.R.S.
- D. Location Prohibited. An Accelerator Manufacturer may not manufacture, prepare, package, store, or label Retail Marijuana Concentrate or Retail Marijuana Product in a location that is operating as a retail food establishment.
- E. Test Batches Provided for Testing. An Accelerator Manufacturer may provide Test Batches of its Retail Marijuana Concentrate or Retail Marijuana Product to a Retail Marijuana Testing Facility for testing and research purposes. The Accelerator Manufacturer shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- F. Authorized Marijuana Transport. An Accelerator Manufacturer is authorized to utilize a Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken is a Retail Marijuana Business and the transportation order is delivered to a Retail Marijuana Business or Pesticide Manufacturer. Nothing in this Rule prevents an Accelerator Manufacturer from transporting its own Retail Marijuana.
- G. Performance-Based Incentives. An Accelerator Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, an Accelerator Manufacturer may not compensate a Sampling Manager using Sampling Units. See Rule 6-820 – Sampling Unit Protocols.

#### **Basis and Purpose – 6-810**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-203(2)(aa), 44-10-203(3)(d), 44-10-401(2)(b)(VIII), 44-10-603, 44-10-608 and 44-10-701(2)(a), C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by an Accelerator Manufacturer.

### **6-810 – Accelerator Manufacturer: General Limitations or Prohibited Acts**

- A. Packaging and Labeling Standards Required. An Accelerator Manufacturer is prohibited from Transferring Retail Marijuana Concentrate or Retail Marijuana Product that are not properly packaged and labeled. See 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
- B. THC Content Container Restriction. Each individually packaged Edible Retail Marijuana Product, even if comprised of multiple servings, may include no more than a total of 100 milligrams of active THC. See Rule 3-1010 – Packaging and Labeling – General Requirements Prior to Transfer to a Consumer.
1. Exception for Bulk Transfers to Retail Marijuana Hospitality and Sales Businesses. An individually packaged Edible Retail Marijuana Product comprised of multiple servings that is Transferred in bulk to a Retail Marijuana Hospitality and Sales Establishment may include more than a total of 100 milligrams of active THC.
- i. An Accelerator Manufacturer shall develop and maintain Standard Operating Procedures, and any additional equipment necessary, to ensure that a Retail Marijuana Hospitality and Sales Business receiving bulk Transfers of Edible Retail Marijuana Product can measure accurately the Edible Retail Marijuana Product in single serving sizes equal to or less than 10 milligrams of active THC per serving.
- C. Transfer to Consumer Prohibited. An Accelerator Manufacturer is prohibited from Transferring Retail Marijuana to a consumer. This prohibition does not apply to Transfers to a Sampling Manager that comply with section 44-10-603(10), C.R.S., and Rule 6-820.
- D. Adequate Care of Perishable Product. An Accelerator Manufacturer must provide adequate refrigeration for perishable Retail Marijuana Product that will be consumed and shall utilize adequate storage facilities and transport methods.
- E. Homogeneity of Edible Retail Marijuana Product. An Accelerator Manufacturer must ensure that its manufacturing processes are designed so that the Cannabinoid content of any Edible Retail Marijuana Product is homogenous.
- F. Use of Ingredients. An Accelerator Manufacturer must obtain and maintain certificates of analysis or other records demonstrating the full composition of each Ingredient used in the manufacture of Vaporizer Delivery Devices or Pressurized Metered Dose Inhalers.
- G. Corrective and Preventive Action. This paragraph G shall be effective January 1, 2021. An Accelerator Manufacturer shall establish and maintain written procedures for implementing Corrective Action and Preventive Action. The written procedures shall include the requirements listed below as determined by the Licensee. All activities

required under this Rule, and their results, shall be documented and kept as business records. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:

1. What constitutes a Nonconformance in the Licensee's business operation.
2. Analyzing processes, work operations, reports, records, service records, complaints, returned product, and/or other sources of data to identify existing and potential root causes of Nonconformances or other quality problems;
3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
7. Ensuring the information related to quality problems or Nonconformances is disseminated to those directly responsible for assuring the quality of products or the prevention of such problems; and
8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.

- H. Adverse Health Event Reporting. An Accelerator Manufacturer must report Adverse Health Events pursuant to Rule 3-920.

### **Basis and Purpose – 6-815**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-401(2)(b)(VIII), 44-10-203(2)(aa), 44-10-603, and 44-10-608, C.R.S. The purpose of this rule is to establish the categories of Retail Marijuana Concentrate that may be produced at an Accelerator Manufacturer and establish standards for the production of Retail Marijuana Concentrate. Nothing in this rule authorizes the unlicensed practice of engineering under Article 25 of Title 12, C.R.S.

### **6-815 – Accelerator Manufacturer: Retail Marijuana Concentrate Production**

- A. Permitted Categories of Retail Marijuana Concentrate Production.
1. An Accelerator Manufacturer may produce Physical Separation-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate and Heat/Pressure-Based Retail Marijuana Concentrate.
  2. An Accelerator Manufacturer may also produce Solvent-Based Retail Marijuana Concentrate using only the following solvents: butane, propane, CO<sub>2</sub>, ethanol,



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isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent is expressly prohibited unless it is approved by the Division.

3. An Accelerator Manufacturer may submit a request to the Division to consider the approval of solvents not permitted for use under this Rule during the next permanent rulemaking.

B. General Applicability. An Accelerator Manufacturer that engages in the production of Retail Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:

1. Ensure that the space in which any Retail Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule 3-905- Business Records Required.
2. Ensure that all applicable sanitary rules are followed. See 3-300 Series Rules.
3. Ensure that the ~~S~~standard ~~O~~perating ~~P~~procedure for each method used to produce a Retail Marijuana Concentrate includes, but need not be limited to, step-by-step instructions on how to safely and appropriately:
  - a. Conduct all necessary safety checks prior to commencing production;
  - b. Prepare Retail Marijuana for processing;
  - c. Extract Cannabinoids and other essential components of Retail Marijuana;
  - d. Purge any solvent or other unwanted components from a Retail Marijuana Concentrate,
  - e. Clean all equipment, counters and surfaces thoroughly; and
  - f. Dispose of any waste produced during the processing of Retail Marijuana in accordance with all applicable local, state and federal laws, rules and regulations. See Rule 3-230 – Waste Disposal.
4. Establish written and documentable quality control procedures designed to maximize safety for Owner Licensees and Employee Licensees and minimize potential product contamination.
5. Establish written emergency procedures to be followed by Owner Licensees or Employee Licensees in case of a fire, chemical spill or other emergency.
6. Have a comprehensive training manual that provides step-by-step instructions for each method used to produce a Retail Marijuana Concentrate. The training manual must include, but need not be limited to, the following topics:
  - a. All ~~S~~standard ~~O~~perating ~~P~~procedures for each method of concentrate production used;
  - b. The Accelerator Manufacturer's quality control procedures;
  - c. The emergency procedures;

- d. The appropriate use of any necessary safety or sanitary equipment;
  - e. The hazards presented by all solvents used as described in the safety data sheet for each solvent;
  - f. Clear instructions on the safe use of all equipment involved in each process and in accordance with manufacturer's instructions, where applicable; and
  - g. Any additional periodic cleaning required to comply with all applicable sanitary rules.
7. Provide adequate training to every Owner Licensee or Employee Licensee prior to that individual undertaking any step in the process of producing a Retail Marijuana Concentrate.
- a. Adequate training must include, but need not be limited to, providing a copy of the training manual for that Licensed Premises and live, in-person instruction detailing at least all of the topics required to be included in the training manual.
  - b. The individual training an Owner Licensee or Employee Licensee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner Licensee or Employee Licensee can safely produce a Retail Marijuana Concentrate. See Rule 3-905 – Business Records Required.
  - c. The Owner Licensee or Employee Licensee that received the training must sign and date a document attesting that he or she can safely implement all Standard Operating Procedures, quality control procedures, and emergency procedures, operate all closed-loop extraction systems, use all safety, sanitary and other equipment and understands all hazards presented by the solvents to be used within the Licensed Premises and any additional periodic cleaning required to maintain compliance with all applicable sanitary rules. See Rule 3-905 – Business Records Required.
8. Maintain clear and comprehensive records of the name, signature and Owner Licensee or Employee License number of every individual who engaged in any step related to the creation of a Production Batch of Retail Marijuana Concentrate and the step that individual performed. See Rule 3-905 – Business Records Required.
9. Accelerator Manufacturers Engaged in the Remediation of Retail Marijuana for elemental impurities. Retail Marijuana Products Manufacturers engaged in the Remediation of Retail Marijuana for elemental impurities shall:
- a. Implement effective cleaning procedures, additional testing plans, and other measures that will be performed to prevent cross contamination.
    - i. If potentially contaminated equipment, ingredients, or solvents used in the Remediation process are used for processing other

'non remediated' material, the subsequent Production Batch made using the equipment, ingredients, or solvent must then be tested for elemental impurities, and the Production Batch made using that equipment, ingredients, or solvents is not eligible for a Reduced Testing Allowance or otherwise exempt from required testing.

- ii. Manufacturers must document the equipment and lots of ingredients/solvents used in Remediation to ensure this requirement is met.
- b. Register as a hazardous waste generator, obtain a U.S. Environmental Protection Agency ID number for manifesting hazardous waste, and must have a disposal contract in place with a hazardous waste management company prior to attempting Remediation.
- c. Have a staff member who has received basic training in hazardous waste identification, storage, and disposal procedures, or hire a consultant who satisfies this criteria.
- d. Regardless of which type of analyte, if the Retail Marijuana flower, wet whole plant, or trim has failed testing for elemental impurities, the Licensee must implement Standard Operating Procedures to ensure:
  - i. That contaminated material is stored in a labelled container identifying the material as potentially hazardous, and that the container seals in such a way to prevent the risk of cross contamination or inhalation of dusts.
  - ii. That when material is removed from the sealed container and handled in any fashion (preparation, the extraction or other Remediation process, wasting, etc.), any workers exposed to dusts or particulates generated from the material must wear appropriate personal protective equipment (PPE), including at minimum: gloves, American National Standards Institute (ANSI) Z87.1 safety glasses, and a respirator rated to protect them from airborne dusts or particulates that may contain elemental impurities. Respirators should utilize National Institute for Occupational Safety and Health rated particulate filters of sufficient grade to prevent exposure to airborne dusts that could contain elemental impurities.
    - A. Workers utilizing a respirator must comply with applicable Occupational Safety and Health Administration regulations regarding respirator use before handling contaminated material. This includes receiving respirator clearance from a qualified professional and passing a respirator fit test before using a respirator.

- e. Additional forms of environmental airborne particulate control, such as industrial air filtration systems, handling material inside of enclosures, etc. must be implemented by the licensee to minimize the risk of exposure or cross contamination of contaminated dusts.
- f. These steps must be documented in the licensee's respiratory protection program that all employees exposed to elemental impurities contaminated plant material and waste products must be trained on.
- g. The Licensee must establish and train employees on SOPs designed to safely handle this contaminated material and prevent cross contamination.
- h. Mercury poses additional workplaces hazards since it is easily volatilized and since mercury vapor is highly toxic. Before attempting to remediate any Regulated Marijuana flower, wet whole plant, or trim that has failed elemental impurities testing and contains mercury, Licensees must additionally:
  - i. Work with a certified industrial hygienist to develop and implement some form of monitoring program that is capable of detecting mercury vapor concentrations in the areas where material contaminated with mercury will be processed and can be used to generate time weighted average exposures to mercury vapor. The monitoring system must be sufficient to ensure airborne concentrations of mercury do not exceed Occupational Safety and Health Administration Permissible Exposure Limits for Airborne Contaminants.
  - ii. Have a certified industrial hygienist approve the licensee's air handling system for managing mercury vapors in a fashion that is compliant with the Occupational Safety and Health Administration, and other applicable federal, state, and local regulations.
  - iii. Utilize a National Institute for Occupational Safety and Health rated half mask respirator with cartridges rated specifically for mercury vapor.
- i. A Licensee must ensure their processes and safety practices comply with applicable federal, state, and local environmental health and safety regulations.

C. Physical Separation-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate and Heat/Pressure-Based Retail Marijuana Concentrate. An Accelerator Manufacturer that engages in the production of a Retail Marijuana Concentrate must:

- 1. Ensure that all equipment, counters and surfaces used in the production of Retail Marijuana Concentrate is food-grade including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials, molds and fungi and can be easily cleaned.

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2. Ensure that all equipment, counters, and surfaces used in the production of a Retail Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.
3. Ensure that any room in which dry ice is stored or used in processing Retail Marijuana into a Retail Marijuana Concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO<sub>2</sub>.
4. Ensure that the appropriate safety or sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner Licensee or Employee Licensee engaged in the production of a Retail Marijuana Concentrate.
5. Ensure that only finished drinking water and ice made from finished drinking water is used in the production of a Physical Separation-Based Retail Marijuana Concentrate.
6. Ensure that if propylene glycol or glycerin is used in the production of a Food-Based Retail Marijuana Concentrate, then the propylene glycol or glycerin to be used is food-grade.
7. Follow all of the rules related to the production of a Solvent-Based Retail Marijuana Concentrate if a pressurized system is used in the production of a Retail Marijuana Concentrate.

D. Solvent-Based Retail Marijuana Concentrate. An Accelerator Manufacturer that engages in the production of Solvent-Based Retail Marijuana Concentrate must:

1. Obtain a report from an Industrial Hygienist or a Professional Engineer that certifies that the equipment, Licensed Premises and Standard Operating Procedures comply with these rules and all applicable local and state building codes, fire codes, electrical codes and other laws. If a Local Jurisdiction has not adopted a local building code or fire code or if local regulations do not address a specific issue, then the Industrial Hygienist or Professional Engineer shall certify compliance with the International Building Code of 2012 (<http://www.iccsafe.org>), the International Fire Code of 2012 (<http://www.iccsafe.org>) or the National Electric Code of 2014 (<http://www.nfpa.org>), as appropriate. Note that this Rule does not include any later amendments or editions to each Code. The Division has maintained a copy of each code, each of which is available to the public;
  - a. Flammable Solvent Determinations. If a Flammable Solvent is to be used in the processing of Retail Marijuana into a Retail Marijuana Concentrate, then the Industrial Hygienist or Professional Engineer must:
    - i. Establish a maximum amount of Flammable Solvents and other flammable materials that may be stored within that Licensed Premises in accordance with applicable laws, rules and regulations;
    - ii. Determine what type of electrical equipment, which may include but need not be limited to outlets, lights and junction boxes, must

- be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored in accordance with applicable laws, rules and regulations;
- iii. Determine whether a gas monitoring system must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations; and
  - iv. Determine whether fire suppression system must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
- b. CO<sub>2</sub> Solvent Determination. If CO<sub>2</sub> is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO<sub>2</sub> gas monitoring system must be installed within the room in which Retail Marijuana Concentrate is to be produced or CO<sub>2</sub> is stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
  - c. Exhaust System Determination. The Industrial Hygienist or Professional Engineer must determine whether a fume vent hood or exhaust system must be installed within the room in which Retail Marijuana Concentrate is to be produced, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
  - d. Material Change. If an Accelerator Manufacturer makes a Material Change to its equipment or a concentrate production procedure, in addition to all other requirements, it must obtain a report from an Industrial Hygienist or Professional Engineer re-certifying its ~~S~~standard ~~O~~perating ~~P~~rocedures and, if changed, its equipment as well.
  - e. Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Accelerator Manufacturer by the designer or manufacturer of any equipment used in the processing of Retail Marijuana into a Retail Marijuana Concentrate.
  - f. Records Retention. An Accelerator Manufacturer must maintain copy of all reports received from an Industrial Hygienist and Professional Engineer on its Licensed Premises. Notwithstanding any other law, rule, or regulation, compliance with this Rule is not satisfied by storing these reports outside of the Licensed Premises. Instead the reports must be maintained on the Licensed Premises until the Licensee ceases production of Retail Marijuana Concentrate on the Licensed Premises.

2. Ensure that all equipment, counters and surfaces used in the production of a Solvent-Based Retail Marijuana Concentrate are food-grade and do not react adversely with any of the solvents to be used in the Licensed Premises. Additionally, all counters and surface areas must be constructed in a manner that reduces the potential development of microbials, molds and fungi and can be easily cleaned;
3. Ensure that the room in which Solvent-Based Retail Marijuana Concentrate shall be produced must contain an emergency eye-wash station;
4. Ensure that only a professional grade, closed-loop extraction system capable of recovering the solvent is used to produce Solvent-Based Retail Marijuana Concentrate;
  - a. UL or ETL Listing.
    - i. If the system is UL or ETL listed, then an Accelerator Manufacturer may use the system in accordance with the manufacturer's instructions.
    - ii. If the system is UL or ETL listed but the Accelerator Manufacturer intends to use a solvent in the system that is not listed in the manufacturer's instructions for use in the system, then, prior to using the unlisted solvent within the system, the Accelerator Manufacturer must obtain written approval for use of the non-listed solvent in the system from either the system's manufacturer or a Professional Engineer after the Professional Engineer has conducted a peer review of the system. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
    - iii. If the system is not UL or ETL listed, then there must a designer of record. If the designer of record is not a Professional Engineer, then the system must be peer reviewed by a Professional Engineer. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.
  - b. Ethanol or Isopropanol. An Accelerator Manufacturer need not use a professional grade, closed-loop system extraction system capable of recovering the solvent for the production of a Solvent-Based Retail Marijuana Concentrate if ethanol or isopropanol are the only solvents being used in the production process.
5. Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;
  - a. An Accelerator Manufacturer must obtain a safety data sheet for each solvent used or stored on the Licensed Premises. An Accelerator Manufacturer must maintain a current copy of the safety data sheet and a

receipt of purchase for all solvents used or to be used in an extraction process. See Rule 3-905 – Business Records Required.

- b. An Accelerator Manufacturer is prohibited from using denatured alcohol to produce a Retail Marijuana Concentrate, unless the denaturant is an approved solvent listed in Rule 6-815(A)(2) and the alcohol and the denaturant meet all other requirements set forth in this Rule.
- 6. Ensure that all Flammable Solvents or other flammable materials, chemicals and waste are stored in accordance with all applicable laws, rules and regulations. At no time may an Accelerator Manufacturer store more Flammable Solvent on its Licensed Premises than the maximum amount established for that Licensed Premises by the Industrial Hygienist or Professional Engineer;
- 7. Ensure that the appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each Owner Licensee or Employee Licensee engaged in the production of a Solvent-Based Retail Marijuana Concentrate; and
- 8. Ensure that a trained Owner Licensee or Employee Licensee is present at all times during the production of a Solvent-Based Retail Marijuana Concentrate whenever an extraction process requires the use of pressurized equipment.
- E. Ethanol and Isopropanol. If an Accelerator Manufacturer only produces Solvent-Based Retail Marijuana Concentrate using ethanol or isopropanol at its Licensed Premises and no other solvent, then it shall be considered exempt from paragraph D of this Rule and instead must follow the requirements in paragraph C of this Rule. Regardless of which rule is followed, the ethanol or isopropanol must be food grade or at least 99% pure and denatured alcohol cannot be used. The Accelerator Manufacturer shall comply with contaminant testing required in Rule 4-2154-120(C)(4).
- F. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

### **Basis and Purpose – 6-820**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(2)(d), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-401(2)(b)(VIII), 44-10-603(10), and 44-10-608 C.R.S. The purpose of this rule is to establish the circumstances under which an Accelerator Manufacturer may provide Sampling Units to a designated Sampling Manager for quality control or product development purposes. In order to maintain the integrity of Colorado's regulated Retail Marijuana Businesses, this rule establishes limits on the amount of Sampling Units a Sampling Manager may receive in a calendar month and imposes inventory tracking, reporting and recordkeeping requirements on an Accelerator Manufacturer that Transfer Sampling Units.

### **6-820 – Accelerator Manufacturer: Sampling Unit Protocols**

- A. Designation of Sampling Manager(s). In any calendar month, an Accelerator Manufacturer may designate no more than five Sampling Managers in the Inventory Tracking System.



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1. Only management personnel of the Accelerator Manufacturer who holds an Owner License or an Employee License may be designated as a Sampling Manager.
  2. An individual may be designated as a Sampling Manager by more than one Retail Marijuana Business.
  3. By virtue of the decision to be designated as a Sampling Manager, the Sampling Manager expressly consents to being identified in the Inventory Tracking System and makes a voluntary decision that any Sampling Units Transferred to the Sampling Manager will be identified in the Inventory Tracking System.
  4. An Accelerator Manufacturer who wishes to provide Sampling Units to a Sampling Manager shall first establish and provide to each Sampling Manager ~~S~~standard ~~O~~perating ~~P~~rocedures that explain the requirements of section 44-10-603(10), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements of this Rule 6-820. *See also* Rule 3-905 – Business Records Required. An Accelerator Marijuana Products Manufacturer shall maintain and update such ~~S~~standard ~~O~~perating ~~P~~rocedures as necessary to reflect accurately any changes in the relevant statutes and rules.
- B. Sampling Unit Limits. Only one Sampling Unit may be designated per Production Batch. A Sampling Unit shall not be designated until the Production Batch has satisfied the testing requirements in the ~~4-2004-100~~ Series Rules – Regulated Marijuana Testing Program.
1. A Sampling Unit of Retail Marijuana Product shall not exceed one Standardized Serving of Marijuana.
  2. A Sampling Unit of Retail Marijuana Concentrate shall not exceed one quarter of one gram; except that a Sampling Unit of Retail Marijuana Concentrate which has the intended use of being delivered in a vaporized form shall not exceed one-half of one gram.
- C. Transfer Restrictions.
1. No Sampling Unit shall be Transferred unless it is packaged and labeled in accordance with the requirements in the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
  2. No Sampling Unit shall be Transferred to any individual who is not currently designated in the Inventory Tracking System by the Accelerator Manufacturer as a Sampling Manger for the calendar month in which the Transfer occurs.
  3. In any calendar month, a Sampling Manager shall not receive Sampling Units totaling more than:
    - a. With respect to Retail Marijuana Product, fourteen Standardized Servings of Marijuana; and
    - b. Eight grams of Retail Marijuana Concentrate.

4. The monthly limit established in subparagraph (C)(3) applies to each Sampling Manager, regardless of the number of Retail Marijuana Businesses with which the Sampling Manager is associated.
  5. A Sampling Manager shall not accept Sampling Units in excess of the monthly limit established in subparagraph (C)(3). Before Transferring any Sampling Units, an Accelerator Manufacturer shall verify with the recipient Sampling Manager that the Sampling Manager will not exceed the monthly limit established in subparagraph (C)(3).
  6. A Sampling Manager shall not Transfer any Sampling Unit to any other Person, including but not limited to any other Person designated as a Sampling Manager.
- D. Compensation Prohibited. An Accelerator Manufacturer may not use Sampling Units to compensate a Sampling Manager.
- E. On-Premises Consumption Prohibited. A Sampling Manager shall not consume any Sampling Unit on any Licensed Premises.
- F. Acceptable Purposes. Sampling Units shall only be designated and Transferred for purposes of quality control and product development in accordance with section 44-10-603(10), C.R.S.
- G. Record keeping requirements. An Accelerator Manufacturer shall maintain copies of any material documents created regarding the quality control and product development purpose(s) of each Sampling Unit. Such documents shall constitute business records under Rule 3-905 – Business Records Required. At a minimum, an Accelerator Manufacturer shall maintain records that show whether a Sampling Unit Transferred to a Sampling Manager is for the purpose of either quality control or product development. An Accelerator Manufacturer shall also maintain copies of the Accelerator Manufacturer's Sstandard Operating Procedures provided to Sampling Managers.
- H. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

### **Basis and Purpose – 6-825**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-203(3)(b), 44-10-203(3)(e), 44-10-401(2)(b)(VIII), 44-10-603, 44-10-701(3)(c) and 44-10-608, C.R.S. The purpose of this rule is to define requirements for manufacture of Audited Product for administration by: (1) metered dose nasal spray, (2) vaginal administration, or (3) rectal administration which may raise public health concerns. This rule defines audit, insurance, minimum product requirements, minimum production process requirements, and pre-production testing requirements for Accelerator Manufacturers that manufacture Audited Products. The purpose of this rule further recognizes that Alternative Use Product not within an intended use identified in Rule 3-1015 may raise public health concerns that outweigh its manufacture or Transfer entirely or that require additional safeguards to protect public health and safety prior to manufacturer or Transfer. This rule identifies general requirements for an Accelerator Manufacturer to seek an Alternative Use Designation from the

State Licensing Authority to manufacture any type of Retail Marijuana Product that is not within an intended use identified in Rule 3-1015.

### **6-825 – Accelerator Manufacturer: Audited Product and Alternative Use Product**

- A. General Rule. An Accelerator Manufacturer shall not Transfer Audited Product to a Retail Marijuana Store, an Accelerator Store, a Retail Marijuana Products Manufacturer, another Accelerator Manufacturer, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator that has obtained a Centralized Distribution Permit except in accordance with all requirements of this Rule 6-825. The requirements of this Rule 6-825 are in addition to all other Rules that apply to Accelerator Manufacturers; except where the context otherwise clearly requires this Rule 6-825 controls.
- B. Audited Products – Mandatory Audit Prior to Transfer. Following submission of an independent third-party audit to the Division and, if applicable, to the Local Jurisdiction as required by this Rule, an Accelerator Manufacturer may Transfer Audited Product with an intended use of: (1) metered dose nasal spray, (2) vaginal administration, or (3) rectal administration.
1. A written audit report from an independent third-party auditor that was completed within the last 24 months shall be submitted to the Division and, if applicable to the Local Licensing Authority: (i) before the first Transfer of Audited Product to any Retail Marijuana Store, (ii) prior to Transfer of any Audited Product following a Material Change to any ~~S~~standard ~~O~~perating ~~P~~rocedure or master formulation record regarding the Audited Product, and (iii) with the Accelerator Manufacturer's renewal application if the Accelerator Manufacturer will Transfer Audited Product after renewal.
  2. The independent third-party audit shall be performed by either a certified quality auditor or a certified GMP auditor. The Accelerator Manufacturer shall be responsible for all costs associated with obtaining the independent third-party audit.
  3. The independent third-party written audit report shall include the following minimum requirements:
    - a. The independent third-party auditor's qualifications and an attestation that the certified quality auditor or certified GMP auditor has no conflict of interest;
    - b. Establish that the Accelerator Manufacturer and the Audited Product meet all requirements of this Rule 6-825, including but not limited to the specific requirements of this Rule 6-825(C), 6-825(D), 6-825(E), 6-825(G), and 6-825(H);
    - c. Verify the written ~~S~~standard ~~O~~perating ~~P~~rocedure(s) for Audited Product include sufficient and detailed step-by-step instructions on how to produce the Audited Product in a manner that prevents contamination and protects the public health and safety;

- d. Verify, based upon a physical inspection, the manufacture of Audited Product by the Accelerator Manufacturer adheres to all applicable ~~S~~standard ~~O~~perating ~~P~~rocedures;
  - e. Verify, based upon a physical inspection, of any Licensed Premises that such Licensed Premises complies with the requirements of this Rule 6-825(E), including any Limited Access Area where the Audited Product is to be manufactured;
  - f. Include the independent third-party auditor's findings;
  - g. Include the plan of correction identifying any corrective actions and/or preventative actions implemented as a result of the findings of the independent third-party audit; and
  - h. Include the independent third-party auditor's assessment that the Accelerator Manufacturer demonstrated compliance with all requirements of Rule 6-825 and with the requirements of all ~~S~~standard ~~O~~perating ~~P~~rocedures, master formulation records, and Batch manufacturing records that apply to the Audited Product.
- C. Products Liability Insurance. Any Accelerator Manufacturer that intends to Transfer Audited Product shall first obtain products liability insurance providing coverage for liability arising from manufacture or Transfer of Audited Product and shall provide an unredacted certificate of product liability insurance to the Division and the independent third-party auditor.
- D. Audited Product Requirements. Audited Product shall meet the following minimum product requirements:
  - 1. Inactive Ingredients. Audited Product must meet the requirements in Rule 3-335 – Production of Regulated Marijuana Products.
    - a. If the Audited Product contains a fungicidal or bactericidal Ingredient listed in, and with a concentration that is at or below the maximum concentration permitted in, the Federal Food and Drug Administration Inactive Ingredients Database, <https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>, the Audited Product is not required to undergo microbial contaminant testing required by Rules ~~4-115 and 4-1204-215~~.
  - 2. Required Product Development Testing. The Accelerator Manufacturer must establish the Audited Product meets the following through independent third-party testing:
    - a. The Audited Product must deliver the amount of each ~~e~~Cannabinoid identified on the label throughout the entire volume of the Audited Product using the intended delivery device and in accordance with the instructions provided by the Accelerator Manufacturer, as demonstrated by testing at a Retail Marijuana Testing Facility.

- i. For Audited Product with an intended use of metered dose nasal spray, compliance with this requirement shall be established by test results verifying the delivered dose of each **eC**annabinoid identified on the label using the methods described in The United States Pharmacopeia Physical Test and Determination Chapter 601, *Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers*.
    - ii. For Audited Product with an intended use of either vaginal administration or rectal administration, compliance with this testing requirement shall be established by test results demonstrating that each **eC**annabinoid identified on the label is within +/- 15% of the amount identified on the label.
  - b. The expiration date identified on the label of the Audited Product is appropriate when the Audited Product is stored at room temperature, as demonstrated by testing from a Retail Marijuana Testing Facility.
  - c. Identification of all non-cannabis derived Ingredients and constituents in the Audited Product at concentrations of 1%, which verification is obtained from one or more of the following:
    - i. Testing by a Retail Marijuana Testing Facility;
    - ii. Testing by a laboratory that is ISO 17025 accredited but is not a Retail Marijuana Testing Facility, except that no Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product may be Transferred to such a laboratory; and/or
    - iii. One or more certificate(s) of analysis from the manufacturer of any Ingredient or constituent included in the Audited Product.
- E. Additional Production Requirements for Audited Product. In addition to all other requirements applicable to Accelerator Manufacturer, an Accelerator Manufacturer that manufactures and Transfers Audited Product shall meet the following additional requirements:
  - 1. Personnel Training. All personnel directly involved in the manufacture and handling of Audited Product must be trained, must demonstrate competency, and must undergo annual refresher training, which shall be documented and maintained at the Accelerator Marijuana Products Manufacturer's Licensed Premises. Personnel directly involved in the manufacture and handling of Audited Product must be trained and demonstrate proficiency in hand hygiene, cleaning and sanitizing, performing necessary calculations, measuring and mixing, and documenting the manufacturing process including master formulation records and batch manufacturing records.
  - 2. Facility Requirements. An Accelerator Manufacturer must have a space that is specifically designated for the manufacture of Audited Products that is designed and operated to prevent cross contamination from other areas of the Licensed

Premises. The surfaces, walls, floors, fixtures, shelving, work surfaces, and cabinets in this designated area must be non-porous and cleanable.

3. Cleaning and Sanitizing. An Accelerator Manufacturer must clean and sanitize surfaces where Audited Product is manufactured and handled on a regular basis and at a minimum, work surfaces and floors must be cleaned and sanitized daily. All other surfaces must be cleaned and sanitized at least every three months. An Accelerator Manufacturer must clean and sanitize all surfaces when a spill occurs and when surfaces, floors, and walls are visibly soiled.
4. Hand Hygiene. Hand hygiene is required when entering and re-entering any area where Audited Product is manufactured and handled. Hand hygiene includes washing hands and forearms up to the elbows with soap and water for at least 30 seconds followed by drying completely with disposable towels. Alcohol hand sanitizers alone are not sufficient.
  - a. Gloves are required to be worn for all mixing activities. Other garb such as shoe covers, head and facial hair covers, face masks, and gowns must be worn as appropriate to protect Licensees and/or prevent contamination of the Audited Product.
5. Equipment. Mechanical, electronic, and other types of equipment used in mixing, measuring, or testing of Audited Product must be inspected prior to use and verified for accuracy at the frequency recommended by the manufacturer, and at least annually.
6. Ingredient Quality. All Ingredients used to manufacture Audited Product must be handled and stored in accordance with the manufacturer's instructions. Ingredients that lack a manufacturer's expiration date shall not be used if a reasonable manufacturer would not use the Ingredient or after 1 year from the date of receipt, whichever period is shorter.
7. Master Formulation Record. A master formulation record must be prepared and maintained for each unique Audited Product an Accelerator Manufacturer manufactures. A master formulation record must include at least the following information:
  - a. Name of the Audited Product;
  - b. Ingredient identities and amounts;
  - c. Specifications on the delivery device (if applicable);
  - d. Complete instructions for preparing the Audited Product, including equipment, supplies, and description of the manufacturing steps;
  - e. Quality control procedures; and
  - f. Any other information needed to describe the Retail Marijuana Products Manufacturer's production and ensure its repeatability.

8. Batch Manufacturing Records. A batch manufacturing record shall be created for each Production Batch of Audited Product. This record shall include at the least the following information:
- a. Name of the Audited Product;
  - b. Master formulation record reference for the Audited Product;
  - c. Date and time of preparation of the Audited Product;
  - d. Production Batch number;
  - e. Signature or initials of individuals involved in each manufacturing step;
  - f. Name, vendor, or manufacturer, Production Batch number, and expiration date of each Ingredient;
  - g. Weight or measurement of each Ingredient;
  - h. Documentation of quality control procedures;
  - i. Any deviations from the master formulation record, and any problems or errors experienced during the manufacture; and
  - j. Total quantity of the Audited Product manufactured.
- F. Audited Product Testing. For each Production Batch, the Audited Product shall undergo all required testing in the ~~4-2004-100~~ Series Rules for Retail Marijuana Product and/or Audited Product. ~~See also Rule 4-115—Regulated Marijuana Testing Program: Sampling and Testing Program.~~
- G. Packaging and Labeling of Audited Product. Audited Product must be packaged and labeled in accordance with all requirements of the 3-1000 Series Rules regarding packaging and labeling for Transfer to a consumer prior to any Transfer.
- H. Adverse Event Reporting. An Accelerator Manufacturer must report Adverse Health Events pursuant to Rule 3-920.
- I. Alternative Use Designation – Any Other Method of Consumption or Administration. An Accelerator Manufacturer shall not Transfer to a Retail Marijuana Store, an Accelerator Store, a Retail Marijuana Products Manufacturer, another Accelerator Manufacturer, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator that has obtained a Centralized Distribution Permit any Retail Marijuana Concentrate or Retail Marijuana Product that is not within any intended use identified in Rule 3-1015(B) until it applies for and receives an Alternative Use Designation from the State Licensing Authority in consultation with the Colorado Department of Public Health and Environment. In the process of applying for an Alternative Use Designation, the Accelerator Manufacturer shall work with the Division and the Colorado Department of Public Health and Environment to determine whether the proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when particular independent review factors, safeguards, and tests are in place. The following are minimum requirements for any application for an Alternative Use Designation:

1. The Accelerator Manufacturer shall identify provisions of this Rule 6-825 that apply to its Alternative Use Product, any proposed additional or alternative requirements, and how any proposed alternatives protect public health and safety. The Accelerator Manufacturer shall also provide any additional information as may be requested by the Division, in consultation with the Colorado Department of Public Health and Environment.
  2. The Accelerator Manufacturer bears the burden of proving its proposed Alternative Use Product may be manufactured in a manner that does not pose a threat to public health and safety when the identified independent review factors, safeguards, and tests are in place.
  3. An Accelerator Manufacturer seeking an Alternative Use Designation shall cooperate with the Division. Failure to cooperate with the Division is grounds for denial of an Alternative Use Designation.
  4. The granting of an Alternative Use Designation shall rest in the discretion of the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment. The State Licensing Authority may in his or her discretion deny an Alternative Use Designation where the Accelerator Manufacturer does not meet the burden established in this Rule 6-825.
- J. Alternative Use Designation – Packaging and Labeling Requirements. If the Division recommends, and the State Licensing Authority grants, an Alternative Use Designation, the State Licensing Authority, in consultation with the Colorado Department of Public Health and Environment shall provide the Accelerator Manufacturer the appropriate statement of intended use label to be affixed to the Alternative Use Product, and any additional or distinct packaging and labeling requirements applicable to the Alternative Use Product. See Rules 3-1010 and 3-1015.
- K. Required Records. An Accelerator Manufacturer manufacturing or Transferring Audited Product and/or Alternative Use Product shall maintain accurate and comprehensive records on the Licensed Premises regarding the manufacturing process, a list of all active and inactive Ingredients used in the Audited Product and/or Alternative Use Product, and such other documentation as required by this Rule 6-825. See Rule 3-905 – Business Records Required.

## **6-900 Series – Licensed Hospitality Businesses**

### **Basis and Purpose – 6-905**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to establish general provisions for Licensed Hospitality Businesses.

### **6-905 – Licensed Hospitality Businesses: General Provisions**

- A. Privileges Granted. A Licensed Hospitality Business shall only exercise those privileges granted pursuant to the Marijuana Code and these Rules.
- B. Local Approval Required. No Licensed Hospitality Business may operate in a Local Jurisdiction that does not have an ordinance or resolution authorizing the operation of



that type of Licensed Hospitality Business within the Local Jurisdiction. A Licensed Hospitality Business must comply with any requirements or restrictions on its operations imposed by the Local Jurisdiction's ordinance or resolution.

- C. Liability Insurance Required. Licensed Hospitality Businesses are required to carry general liability insurance. If a Licensed Hospitality Business has not obtained general liability insurance at the time of its initial license application, it must obtain general liability insurance prior to submitting the Licensee's first renewal application.
- D. Responsible Vendor Training Required. All Controlling Beneficial Owners and employees of a Licensed Hospitality Business shall have a valid responsible vendor designation as required in section 44-10-609, C.R.S., and described in the 3-500 Series Rules.
- E. No Visible Consumption of Regulated Marijuana. A Licensed Hospitality Business shall ensure that the display and consumption of any marijuana is not visible from outside of its Licensed Premises. The requirement in this paragraph (E) also applies to Licensed Hospitality Businesses that operate in an isolated portion of a Retail Food Establishment. See Rule 6-915 – Licensed Hospitality Businesses: Operation Within A Retail Food Establishment.
1. Outdoor Consumption Areas Permitted. A Licensed Hospitality Business may have a Consumption Area outdoors under the following conditions:
- a. The Licensed Hospitality Business shall ensure that all marijuana is kept out of plain sight and is not visible from a public place without the use of optical aids, such as telescopes or binoculars, or aircraft; and
  - b. The Licensed Hospitality Business shall ensure that the Consumption Area is surrounded by a sight-obscuring wall, fence, hedge, or other opaque or translucent barrier.
- F. Required Signage.
1. Identification of Consumption Area. A Licensed Hospitality Business shall ensure all areas ingress and egress to the Consumption Area(s) be clearly identified by the posting of a sign which shall not be less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, "Consumption Area – No One Under 21 Years of Age Allowed."
2. Required Warning. Licensed Hospitality Businesses must post, at all times and in a prominent place inside the Consumption Area, a warning that is at minimum twelve inches high and twelve inches wide that reads as follows:
- "Must be 21 or older to enter
- Marijuana may only be consumed in designated areas out of public view
- No consumption of alcohol or tobacco products on site
- We reserve the right to refuse entry or service for reasons including visible intoxication
- It is against the law to drive while impaired by marijuana"

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- G. Entry By A Person Under 21 Years Prohibited. A Licensed Hospitality Business shall not allow any individual under 21 years of age to enter its Licensed Premises. A Licensed Hospitality Business shall verify that every individual entering the Licensed Premises has a valid government-issued photo identification showing that the individual is 21 years of age or older. See Rule 3-405 – Acceptable Forms of Identification.
- H. Customers in Consumption Area. The Consumption Area must be reasonably monitored by a Licensee at all times when consumers are present to ensure that only persons who are 21 years of age or older are permitted to enter. A Licensed Hospitality Business shall reasonably monitor consumers in the Consumption Area to ensure compliance with these 6-900 Series Rules.
- I. Conduct on the Licensed Premises.
1. Consumption By Intoxicated Patrons Prohibited. A Licensed Hospitality Business shall not permit the Transfer, the use, or consumption of marijuana by any person displaying any visible signs of intoxication.
  2. Alcohol Consumption Prohibited. No consumption of alcohol is permitted in a Licensed Hospitality Business. A Licensed Hospitality Business is responsible for preventing the consumption of alcohol within its Licensed Premises.
  3. Tobacco Consumption Prohibited. No smoking of tobacco or tobacco products is permitted in a Licensed Hospitality Business. A Licensed Hospitality Business is responsible for preventing the smoking of tobacco and tobacco products within its Licensed Premises.
  4. Employee Consumption Prohibited. No employee of a Licensed Hospitality Business who is on duty may use or consume marijuana. A Licensed Hospitality Business is responsible for preventing the use or consumption of marijuana by on-duty employees within its Licensed Premises.
  5. Flammable Instrument Restrictions. A Licensed Hospitality Business shall not allow the use of the following devices in the Licensed Premises if prohibited by a local ordinance or resolution:
    - a. Any device using liquid petroleum gas;
    - b. A butane torch;
    - c. A butane lighter; or
    - d. Matches.
  6. Orderliness. A Licensed Hospitality Business shall operate the business in a decent, orderly, and respectable manner. A Licensed Hospitality Business shall not knowingly permit any activity or acts of disorderly conduct as defined by and provided for in section 18-9-106, C.R.S., nor shall a Licensed Hospitality Business permit rowdiness, undue noise, or other disturbances or activity offensive to the senses of the average citizen, or to the residents of the neighborhood in which the Licensed Hospitality Business is located.

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- J. Free Marijuana Prohibited. A Licensed Hospitality Business may not give away marijuana to a consumer for any reason.
- K. Food Products Permitted. A Licensed Hospitality Business is permitted to sell or give away consumable products that do not contain marijuana under the following circumstances:
1. The Licensed Hospitality Business operates in an isolated portion of a Retail Food Establishment;
  2. A Licensed Hospitality Business that is not a Retail Food Establishment may prepare and serve hot coffee, hot tea, instant hot beverages, and nonpotentially hazardous doughnuts or pastries obtained from sources complying with all laws related to food and food labeling; or
  3. A Licensed Hospitality Business that is not a Retail Food Establishment may sell or give away nonpotentially hazardous prepackaged food and commercially prepared, prepackaged foods requiring no preparation other than the heating of food within its original container or package.
- L. Emergency Entry by Public Safety Personnel. If an emergency requires law enforcement, firefighters, emergency medical service providers, or other public safety personnel to enter the Licensed Premises of a Licensed Hospitality Business, the Licensed Hospitality Business is responsible for ensuring that all consumption and other activities, including sales, if applicable, cease until such personnel have completed their investigation or services and have left the Licensed Premises.
- M. Criminal Activity Reporting Requirements. In addition to other reporting requirements set forth in these Rules, a Licensed Hospitality Business must report directly to the Division any criminal activity requiring an in-person response from law enforcement. Any report required under this Rule must be submitted within 48 hours after an Owner Licensee or Employee Licensee of the Licensed Hospitality Business learns of the event.
- N. Removal of Persons from the Licensed Premises. A Licensed Hospitality Business may remove a person from the Licensed Premises for any reason, including but not limited to, any consumer showing any visible signs of intoxication.
- O. Control and Disposal of Marijuana Left by a Consumer. A Licensed Hospitality Business is responsible for the collection and disposal of any marijuana left on the Licensed Premises by a consumer. When a consumer leaves any marijuana on the Licensed Premises, a Licensed Hospitality Business must promptly collect and remove the marijuana from the Restricted Access Area or Consumption Area and either immediately destroy or store and secure the marijuana in a Limited Access Area or an area inaccessible to consumers in accordance with Rule 6-920(A).
1. Marijuana Consumer Waste. In conjunction with the collecting and securing of any remaining marijuana, a Licensed Hospitality Business may segregate any Marijuana Consumer Waste in order to Transfer the Marijuana Consumer Waste for purposes of recycling in accordance with Rule 3-240 – Collection of Marijuana Consumer Waste.

2. Destruction Required. At, or before, the end of each business day, a Licensed Hospitality Business shall destroy any marijuana left on its Licensed Premises by a consumer in conformance with Rule 3-230 – Waste Disposal. The Licensed Hospitality Business shall document any destruction of Regulated Marijuana in a waste log. See Rule 3-905 – Business Records Required.
- P. Consumer Education Materials. A Licensed Hospitality Business must provide Consumer Education Materials regarding the safe consumption of marijuana. Consumer Education Materials may be made available in print or digital form, may never make claims regarding health or physical benefits of marijuana, and must be prominently displayed. Consumer Education Materials shall at a minimum include the following statement:
- “**WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.
- Create a transportation plan ahead of time. Don’t operate a vehicle impaired.
- Impairing effects of marijuana may be delayed.”
- Q. Licensees shall provide consumers with information regarding safe transportation, which must be reflected in the Licensee’s Sstandard Operating Procedures and posted on the Licensed Premises.
- R. Noncompliance Severity. In addition to any mitigating or aggravating factors in Rule 8-235(C), a Licensee’s lack of internal controls to effectively monitor conduct on the Licensed Premises, including prevention of underage access, compliance with sales limits, and preventing consumption of alcohol will be considered as aggravating factors when determining the appropriate recommendation for disciplinary action and the State Licensing Authority’s appropriate determination of a penalty.

### **Basis and Purpose – 6-910**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to establish additional health and safety regulations for Licensed Hospitality Businesses.

### **6-910 – Licensed Hospitality Businesses: Additional Health and Safety Regulations**

- A. Local Safety Requirements and Inspections. A Licensed Hospitality Business must comply with any safety requirements or required inspections imposed by the Local Jurisdiction’s ordinance or resolution which authorizes the Licensed Hospitality Business’s operation.
- B. Sanitation of Consumption Equipment. If a Licensed Hospitality Business provides consumers with reusable equipment or devices to aid in the use or consumption of marijuana, the Licensed Hospitality Business shall ensure the equipment or device is sanitized properly. A Licensed Hospitality Business shall maintain Sstandard Operating Procedures regarding reusable equipment and device sanitation practices. ~~Failure to maintain records and/or sanitize reusable equipment may constitute a license violation affecting public safety.~~

**Basis and Purpose – 6-920**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), and 44-10-610, C.R.S. The purpose of this rule is to establish requirements for the display of Retail Marijuana on the Licensed Premises of a Retail Marijuana Hospitality and Sales Business, and to establish that a Retail Marijuana Hospitality and Sales Business must control and safeguard access to certain areas where Retail Marijuana will be sold.

**6-920 – Retail Marijuana Hospitality and Sales Businesses Point of Sale: Restricted Access Area**

A. Display of Retail Marijuana. The display of Retail Marijuana for sale is allowed only in Restricted Access Areas. Any product displays that are readily accessible to the consumer must be supervised by the Owner Licensee or Employee Licensees at all times when consumers are present.

B. Pregnancy Warning. Retail Marijuana Hospitality and Sales Business must post, at all times and in a prominent place at every point of sale inside the Restricted Access Area, a warning that is at minimum three inches high and six inches wide that reads:

**WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.

**Basis and Purpose – 6-925**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(1)(k), 44-10-203(2)(v), 44-10-203(2)(z), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to clarify additional license privileges and restrictions for Retail Marijuana Hospitality and Sales Businesses that do not apply to Marijuana Hospitality Businesses.

**6-925 – Retail Marijuana Hospitality and Sales Businesses: Additional License Privileges and Restrictions**

- A. Authorized Sources of Retail Marijuana. A Retail Marijuana Hospitality and Sales Business may only Transfer Retail Marijuana that it obtained from another Retail Marijuana Business.
- B. Restriction on Transfers to Consumers. A Retail Marijuana Hospitality and Sales Business and its employees are prohibited from Transferring Retail Marijuana to a consumer if the Retail Marijuana Hospitality and Sales Business' employee knows or reasonably should know that the consumer does not intend to consume at least a portion of the Transferred Retail Marijuana on the Licensed Premises of the Retail Marijuana Hospitality and Sales Business or previously during the same business day the consumer already received the relevant quantity limitation in this Rule. In determining the imposition of any penalty for violation of this Rule 6-925, the State Licensing Authority will consider any mitigating and aggravating factors set forth in Rule 8-235(C).
- B.5. Educational Resource. When completing a sale of Retail Marijuana Concentrate, a Retail Marijuana Hospitality and Sales Business shall physically attach to the

~~consumer's receipt of sale, product container, or exit package~~ provide the consumer with the tangible educational resource created by the State Licensing Authority regarding the use of Regulated Marijuana Concentrate.

- C. Inventory Tracking System Requirements. A Retail Marijuana Hospitality and Sales Business must use the Inventory Tracking System in accordance with the requirements of the 3-800 Series Rules.
- D. Test Batches Provided for Testing. A Retail Marijuana Hospitality and Sales Business may provide Test Batches of Retail Marijuana for testing purposes to a Retail Marijuana Testing Facility. The Retail Marijuana Hospitality and Sales Business shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.
- E. Authorized On-Premises Storage. A Retail Marijuana Hospitality and Sales Business may store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules. See Rule 3-800 Series Rules – Regulated Marijuana Business: Inventory Tracking System.
- F. Authorized Marijuana Transport. A Retail Marijuana Hospitality and Sales Business is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where the transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents a Retail Marijuana Hospitality and Sales Business from transporting its own Retail Marijuana to the Licensed Premises of its Retail Marijuana Hospitality and Sales Business.
- G. Quantity Limitations on Sales. All Transfers of Retail Marijuana by a Retail Marijuana Hospitality and Sales Business to a consumer shall not exceed the following sales limits established in this Rule.
1. Daily Sales Limits. A Retail Marijuana Hospitality and Sales Business shall not Transfer more than the following to a single customer in a single day
    - a. More than one ounce of Retail Marijuana flower;
    - b. More than eight grams of Retail Marijuana Concentrate;
    - c. A Retail Marijuana Product intended for oral consumption containing more than 100 milligrams of active THC. For any Transfer of Retail Marijuana Product containing more than 10 milligrams of active THC, the Retail Marijuana Product must be Transferred to a consumer in separate serving sizes containing no more than 10 milligrams of active THC per serving; or
    - d. A Retail Marijuana Product that is a non-edible and non-psychoactive, such as a skin and body product, is exempt from the daily sales limit in subparagraph (G)(1)(c) of this Rule.
  2. Consumers are limited to one transaction per day of no more than the sales limit set forth in subparagraph (G)(1). A transaction may consist of multiple Transfers of Retail Marijuana within a single visit to a Retail Marijuana Hospitality and Sales

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Business. The transaction occurs when the consumer completes their purchase and remits payment to the Retail Marijuana Hospitality and Sales Business.

- a. Retail Marijuana Hospitality and Sales Business may not make multiple Transfers of Retail Marijuana to the same consumer during separate visits in the same day.
  - b. Each Transfer must be entered in the Inventory Tracking System pursuant Rule 3-805(E)(1).
  - c. A Retail Marijuana Hospitality and Sales Business Licensee must establish ~~S~~standard ~~O~~perating ~~P~~rocedures that include processes to prevent overconsumption and to prevent the Transfer, use, or consumption of Retail Marijuana by any person displaying visible signs of intoxication. For example, policies that establish specific Transfer increments to individual customers as part of monitoring and preventing instances of overconsumption.
3. Sales limits shall apply on an individual basis per consumer.
- a. A Retail Marijuana Hospitality and Sales Business establishment shall identify an individual consumer for each Transfer and apply the amount of Retail Marijuana ordered and Transferred to that individual's sales limit.
  - b. A Retail Hospitality and Sales Business shall include in their ~~S~~standard ~~O~~perating ~~P~~rocedures how Employee Licensees will monitor daily sales limits, and how the Licensee will provide consumers with information regarding safe transportation.

H. Measurement Procedures and Equipment.

1. A Retail Marijuana Hospitality and Sales Business shall develop and maintain ~~S~~standard ~~O~~perating ~~P~~rocedures, and any additional equipment necessary, to ensure any Retail Marijuana Product Transferred to a consumer does not exceed the sales limitation and provisions for sharing of Retail Marijuana set forth in subparagraph G(3).
2. A Retail Marijuana Hospitality and Sales Business Transferring Multiple-Serving Edible Retail Marijuana Product or Multiple-Serving Liquid Edible Retail Marijuana Product to a consumer shall provide a measurement device necessary for the consumer to achieve accurate measurements of each serving in increments equal to or less than 10 milligrams of active THC per serving.

I. Packaging and Labeling.

1. Packaging and Labeling Not Required at Time of Transfer. A Retail Marijuana Hospitality and Sales Business may Transfer Retail Marijuana to a consumer without packaging and labeling so long as the Retail Marijuana Hospitality and Sales Business complies with the requirements of Rule 3-1020. See Rule 3-1020 – Packaging and Labeling: Requirements Prior to Transfer to a Consumer at a Retail Marijuana Hospitality and Sales Business.

2. Packaging and Labeling Required Before Retail Marijuana Removed from Licensed Premises. A Retail Marijuana Hospitality and Sales Business shall not permit a consumer to leave the Licensed Premises with any unconsumed marijuana unless the Retail Marijuana Hospitality and Sales Business has ensured unconsumed marijuana is packaged and labeled in accordance with the requirements of Rule 3-1020. See Rule 3-1020 – Packaging and Labeling: Requirements Prior to Transfer to a Consumer at a Retail Marijuana Hospitality and Sales Business.
- J. Licenses May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to Transfer Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product to a consumer.

**Basis and Purpose – 6-926**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to clarify additional license privileges and restrictions for Retail Marijuana Hospitality and Sales Businesses that are specific to commercial spa businesses, where Regulated Marijuana Products or non-Regulated Marijuana products are provided to a consumer in a service offered by the commercial spa business.

**6-926 – Licensed Marijuana Hospitality Businesses: Spa Businesses**

- A. All privileges, restrictions on, and requirements of Licensed Marijuana Hospitality Businesses apply in addition to the requirements below.
- B. Massage Therapist. In addition to holding an Employee License, a massage therapist employed by a Licensed Marijuana Hospitality Business must also be licensed pursuant to section 12-235-101 et seq., C.R.S., and rules promulgated therewith, including 3 CCR 722-1.
- C. Employee Consumption Prohibited. A Licensed Marijuana Hospitality Business must have Sstandard Operating Procedures that include protocols Employee Licensees must follow when providing massage services to prevent employees from consuming Regulated Marijuana on the Licensed Premises.
- D. Consumption Area for Massage Services. The massage therapist may only apply topical Retail Marijuana Product in a Consumption Area of a Licensed Hospitality Business. The massage therapist may also apply non-Regulated Marijuana spa products. No other consumption of Regulated Marijuana is permitted in a Consumption Area for massage services, other than the application of topical Regulated Marijuana Product by the massage therapist to the consumer. The Consumption Area of a spa business where a consumer receives massage services shall not overlap with the Restricted Access Area and is not required to be under video surveillance, except all points of ingress and egress must be under video surveillance.
- E. Misconduct Reporting. A Licensed Hospitality Business must notify the Division of any misconduct conducted by its employees, including reports of misconduct to the Colorado Department of Regulatory Agencies.



- F. Daily Sales Limits. A Retail Marijuana Hospitality and Sales Business must comply with sales limits in 6-925(G).

**Basis and Purpose – 6-930**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), 44-10-609, and 44-10-610, C.R.S. The purpose of this rule is to establish general limitations and prohibited acts for Retail Marijuana Hospitality and Sales Businesses.

**6-930 – Retail Marijuana Hospitality and Sales Businesses: General Limitations and Prohibited Acts**

- A. Age Verification. Prior to Initiating the Transfer of Retail Marijuana a Licensee must verify that the purchaser has a valid government-issued photo identification showing that the purchaser is 21 years of age or older. See Rule 3-405 – Acceptable Forms of Identification.
- B. Purchases Only Within Restricted Access Area. A consumer must be physically present within the Restricted Access Area of the Retail Marijuana Hospitality and Sales Business's Licensed Premises to purchase Retail Marijuana.
1. Application to Retail Marijuana Hospitality and Sales Businesses Operating in a Retail Food Establishment. The requirement of paragraph (B) also applies to all Retail Marijuana Hospitality and Sales Businesses operating in an isolated portion of the Retail Food Establishment. All Transfers of Retail Marijuana may occur only in the Retail Marijuana Hospitality and Sales Business' Restricted Access Area, and not in any other area of the Retail Food Establishment.
  2. Application to Retail Marijuana Hospitality and Sales Businesses operating as Spa Business. A Licensed Massage Therapist may apply topical Retail Marijuana Product in a Consumption Area of the Retail Marijuana Hospitality and Sales Business.
- C. Prohibited Sales and Activity.
1. Sales to Persons Under 21 Years. A Retail Marijuana Hospitality and Sales Business is prohibited from Transferring, giving, or distributing Regulated Marijuana to persons under 21 years of age.
  2. Alternative Use Products. A Retail Marijuana Hospitality and Sales Business shall not Transfer, or permit the use or consumption of, any Alternative Use Product.
  3. Marijuana Not Transferred by the Retail Marijuana Hospitality and Sales Business. A Retail Marijuana Hospitality and Sales Business shall not permit the purchase, use or consumption of any marijuana other than the Retail Marijuana it Transfers pursuant to these rules.
  4. Nicotine or Alcohol. A Retail Marijuana Hospitality and Sales Business is prohibited from Transferring Retail Marijuana that contain nicotine or alcohol, if the sale of alcohol would require a license pursuant to articles 3, 4, or 5 of Title 44, C.R.S.

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5. Transfer of Expired Product. A Retail Marijuana Hospitality and Sales Business shall not Transfer any expired Retail Marijuana Product to a consumer.
  6. Transporter Transfer Restrictions. A Retail Marijuana Hospitality and Sales Business shall not Transfer Retail Marijuana to a Retail Marijuana Transporter, and shall not buy or receive complimentary Retail Marijuana from a Retail Marijuana Transporter.
  7. Possession and Transfer of Sampling Units. A Retail Marijuana Hospitality and Sales Business may not possess or Transfer Sampling Units.
  8. Research Transfers. A Retail Marijuana Hospitality and Sales Business shall not Transfer any Retail Marijuana to a Pesticide Manufacturer or a Marijuana Research and Development Facility.
- D. Storage and Display Limitations.
1. A Retail Marijuana Hospitality and Sales Business shall not display Retail Marijuana outside of a designated Restricted Access Area or in a manner in which Retail Marijuana can be seen from outside the Licensed Premises. Storage of Retail Marijuana shall otherwise be maintained in Limited Access Area or Restricted Access Area.
  2. Any product displays that are readily accessible to the customer must be supervised by the Owner Licensee or Employee Licensee at all times when consumers are present.
- E. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~
- F. Adverse Health Event Reporting. A Retail Hospitality and Sales Business must report Adverse Health Events pursuant to Rule 3-920.

**Basis and Purpose – 6-940**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1), 44-10-203(2)(ff), 44-10-305(2)(b), and 44-10-609, C.R.S. The purpose of this rule is to establish requirements for Marijuana Hospitality Businesses with a Mobile Premises.

**6-940 – Marijuana Hospitality Business: Requirements for Mobile Premises**

- A. Separate License Required for Each Mobile Premises. Each Mobile Premises requires a separate Marijuana Hospitality Business License.
- B. Consumption Area of the Mobile Premises. The Consumption Area of the Mobile Premises shall exclude the area designed to seat the driver and front seat passenger.
- C. Requirements for Motor Vehicles Designated as Mobile Premises. A Marijuana Hospitality Business must ensure that the motor vehicle serving as the Mobile Premises of a Marijuana Hospitality Business complies with all state and local registration and permitting requirements. At each initial and renewal application, a Marijuana Hospitality Business must provide the Division with the following information regarding its Mobile Premises:

- a. Documentation that the Mobile Premises is owned or leased by the Marijuana Hospitality Business;
  - b. The vehicle manufacturer/make, model, and model year associated with the Mobile Premises;
  - c. The vehicle identification number (VIN) associated with the Mobile Premises;
  - d. The Colorado license plate number and copy of the registration associated with the Mobile Premises; and
  - e. If applicable, the automatic vehicle identification tag associated with the Mobile Premises.
- C.5 Valid Public Utilities Commission Permit Required. Prior to operating a Mobile Premises, the Licensee must obtain a valid permit issued by the Public Utilities Commission to the Marijuana Hospitality Business.
- D. Local Approval Required. A Marijuana Hospitality Business with a Mobile Premises may only operate in Local Jurisdictions that have an ordinance or resolution authorizing the operation of Mobile Premises and for which it holds any required valid local license(s). A Mobile Premises' operation includes, but is not limited to, allowing passengers to consume marijuana and boarding or disembarking the Mobile Premises.
- E. Additional Requirements for Mobile Premises. Before receiving a License for a Mobile Premises, a Marijuana Hospitality Business must establish that the Mobile Premises will be able to meet the following requirements:
1. Global position system tracking of the Mobile Premises;
  2. Written Standard Operating Procedures that address the logging of the route(s) of each Mobile Premises;
  3. Video surveillance inside of the Mobile Premises, including the entry and exit points to the Mobile Premises and driver's area of the vehicle;
  4. Proper ventilation within the vehicle, which includes, if marijuana is smoked or vaped in the Licensed Premises, that air is not circulated into the driver's area of the Licensed Premises;
  5. Policies and procedures to ensure that no marijuana is possessed or consumed in the area designed to seat the driver and front seat passenger in a motor vehicle designed, maintained, or used primarily for the transportation of persons for compensation;
  6. Methods to ensure consumption activity is not visible outside the vehicle;
  7. Policies, procedures or other measures to ensure that consumers are prohibited from entering the driver's area of the Mobile Premises; and
  8. Display of the Marijuana Hospitality Business license on the dashboard of the Mobile Premises.

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- F. Separate Place of Business. A Marijuana Hospitality Business with a Mobile Premises shall designate and maintain a fixed place of business in Colorado that is separate from the Mobile Premises. The fixed place of business does not need to be a Licensed Premises. However, if the Marijuana Hospitality Business will transport any marijuana to the separate place of business for purposes of destruction, the separate place of business shall also be a Licensed Premises and is subject to any applicable state and local licensing requirements or restrictions.
1. Shared Places of Business. Multiple Marijuana Hospitality Business Licensees with Mobile Premises may share a single separate place of business so long as the Marijuana Hospitality Businesses are identically owned.
  2. Shared Premises with Another Licensed Hospitality Business. A Marijuana Hospitality Business with a Mobile Premises may designate the location of another Marijuana Hospitality Business's Licensed Premises as its separate place of business subject to the following conditions:
    - a. The relevant Local Licensing Authority or Local Jurisdiction permit a Marijuana Hospitality Business with a Mobile Premises to designate the location of another Marijuana Hospitality Business's Licensed Premises as its separate place of business;
    - b. The Marijuana Hospitality Businesses are identically owned; and
    - c. Record-keeping shall enable the Division and the Local Licensing Authority or Local Jurisdiction to distinguish clearly the business transactions and operations of each Marijuana Hospitality Business.
- G. Business Records. All records required to be maintained by these rules must be maintained at the Marijuana Hospitality Business's separate place of business, and not at the Mobile Premises, except that when the Mobile Premises is in operation it must maintain its current route log on the Mobile Premises.
1. A Marijuana Hospitality Business is not required to maintain records related to inventory tracking because a Marijuana Hospitality Business is prohibited from engaging in Transfers of marijuana.
- H. Health and Safety Requirements. A Marijuana Hospitality Business' Mobile Premises shall comply with all relevant requirements in the 3-300 Series Rules. Hand-washing facilities, however, need not be in the Mobile Premises, but may be located in the Marijuana Hospitality Business's separate place of business.
- I. Operating Restrictions. A Marijuana Hospitality Business shall ensure that its Mobile Premises does not operate outside of the state of Colorado.
- J. Change of Mobile Premises. A Marijuana Hospitality Business may change its Mobile Premises in accordance with the change of Mobile Premises application requirements in Rule ~~2-255(F)2-260(D)~~.

**6-1100 Series – Accelerator Store Licenses****Basis and Purpose – 6-1105**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(aa), 44-10-203(2)(dd), 44-10-401(2)(b)(l), 44-10-601, 44-10-605, and 44-10-611, C.R.S. The purpose of this rule is to establish the license privileges of an Accelerator Store.

### **6-1105 – Accelerator Store: License Privileges**

A. Licensed Premises.

1. Shared Licensed Premises. An Accelerator Store may operate on the same Licensed Premises as a Retail Marijuana Store that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.
2. Separate Licensed Premises. An Accelerator Store may operate on a separate premises in the possession of a Retail Marijuana Store that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.
3. To the extent authorized by Rule 3-215 – Regulated Marijuana Business– Shared Licensed Premises and Operational Separation, an Accelerator Store may share, and operate at, the same Licensed Premises as an Accelerator-Endorsed Licensee’s Retail Marijuana Store that shares a Licensed Premises with a Medical Marijuana Store.

B. Authorized Sources of Retail Marijuana. An Accelerator Store may only Transfer Retail Marijuana that was obtained from another Retail Marijuana Business.

C. Test Batches Provided for Testing. An Accelerator Store may provide Test Batches of its products for testing and research purposes to a Retail Marijuana Testing Facility. The Accelerator Store shall maintain the testing results as part of its business books and records. See Rule 3-905 – Business Records Required.

D. Authorized On-Premises Storage. An Accelerator Store is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules.

E. Authorized Marijuana Transport. An Accelerator Store is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents an Accelerator Store from transporting its own Retail Marijuana.

F. Performance-Based Incentives. An Accelerator Store may compensate its employees using performance-based incentives, including sales-based performance-based incentives.

G. Authorized Transfers of Hemp Products. An Accelerator Store may Transfer Hemp Product to a consumer only after it has confirmed:

1. That the Hemp Product has passed all required testing pursuant to the ~~4-2004-~~ ~~100~~ Series Rules at a Retail Marijuana Testing Facility; and

2. That the Person Transferring the Hemp Product to the Retail Marijuana Store is registered with the Colorado Department of Public Health and Environment as a Hemp Product Manufacturer pursuant to section 25-5-427~~6~~, C.R.S.

G.2. Authorized Food Transfers. An Accelerator Store may sell any food that is not infused with marijuana if the annual gross revenues from the sale of food does not exceed twenty (20) percent of the Accelerator Store's total annual gross revenues.

G.5. Accelerator Store Delivery Permit.

1. An Accelerator Store with a valid delivery permit may accept delivery orders to deliver Retail Marijuana to consumers pursuant to Rule 3-615.
2. An Accelerator Store that does not possess a valid delivery permit cannot deliver Retail Marijuana.

H. Automated Vending Machine. An Accelerator Store may use an automated machine in the Restricted Access Area of its Licensed Premises to dispense Regulated Marijuana to consumers without interaction with an Owner Licensee or Employee Licensee if the automated machine is reasonably monitored and complies with all requirements of these rules including but not limited to:

1. Health and safety standards,
2. Testing,
3. Packaging and labeling requirements,
4. Inventory tracking,
5. Identification requirements, and
6. Transfer limits to consumers.

I. Walk-up Window or Drive-up Window. An Accelerator Store may serve customers through a walk-up window or drive-up window pursuant to the requirements of this rule.

1. ~~Repealed. Modification of Premises Required. Before accepting orders for sales of Retail Marijuana to a customer through either a walk-up window or drive-up window, an Accelerator Store shall apply for, and obtain approval of, an application for a modification of its Licensed Premises for the addition of a walk-up window or drive-up window.~~
2. The area immediately outside the walk-up window or drive-up window must be under the Licensee's possession and control and cannot include any public property such as public streets, public sidewalks, or public parking lots.
3. Order and Identification Requirements.
  - a. Prior to accepting an order or Transferring Retail Marijuana to a customer, the Employee Licensee or Owner Licensee must physically view and inspect the consumer's identification and ensure that the consumer is 21 years of age or older.

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- b. The Accelerator Store may accept telephone orders or may accept orders from the customer at the walk-up window or drive-up window.
    - c. All orders received through a walk-up window or a drive-up window must be placed by the customer from a menu. The Accelerator Store may not display Retail Marijuana at the walk-up or drive-up window.
  - 4. Payment Requirements. Cash, credit, debit, cashless ATM, or other payment methods, including online payments, are permitted for Retail Marijuana at the walk-up window or drive-up window.
  - 5. Video Surveillance Requirements. For every Transfer of Regulated Marijuana through either a walk-up window or drive-up window, the Accelerator Store's video surveillance must enable the recording of the consumer's identity (and consumer's vehicle in the event of drive-up window), and must enable the recording of the Licensee verifying the consumer's identification and completion of the transaction through the Transfer of Regulated Marijuana.
  - 6. Packaging and Labeling Requirements. An Accelerator Store utilizing a walk-up window or drive-up window must ensure that all Retail Marijuana is packaged and labeled in accordance with Rule 3-1010 and Rule 3-1015 prior to Transfer to the consumer.
  - 7. Local Restrictions. Transfers of Regulated Marijuana using a walk-up window or drive-up window are subject to requirements and restrictions imposed by the relevant Local Jurisdiction.
- J. Sales over the Internet. An Accelerator Store may accept orders and payment for Retail Marijuana over the internet.
  - 1. Online Order Requirements.
    - a. Online orders must include the customer's name and date of birth.
    - b. Prior to accepting the order, the store must provide and the customer must acknowledge receipt of:
      - i. A digital copy of the pregnancy warning required in Rule 6-1115; and
      - ii. If accepting an order for Retail Marijuana Concentrate, the Accelerator Store must also provide the educational resource required in Rule 6-1110(C.5).
    - c. Licensees must maintain Sstandard Operating Procedures documenting their compliance with the requirements of this subparagraph (L).
  - 2. Transfer of Retail Marijuana to a customer.
    - a. A customer must be physically present on the Licensed Premises to take possession of Retail Marijuana.

- b. The Accelerator Store must verify the customer's physical identification matches the name and date of birth the customer provided at the time of the order, and verify that the customer is twenty-one years of age or older, in accordance with these Rules.
- 3. Delivery. An Accelerator Marijuana Store that holds a valid delivery permit may make sales of Retail Marijuana over the internet in accordance with Rule 3-615.
- 4. Approved Sources of Payment. An Accelerator store may accept payment using any legal method of payment, gift card pre-payments, or pre-payment accounts established with an Accelerator Marijuana Store except that any payment with an Electronic Benefits Transfer Services Card is not permitted.
  - a. A Local Licensing Authority or Local Jurisdiction may further restrict legal methods of payment not expressly permitted by section 44-10-203(2)(dd)(XV), C.R.S.

### **Basis and Purpose – 6-1110**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(4)(b), 44-10-203(1)(k), 44-10-203(2)(aa), 44-10-401(2)(b)(I), 44-10-601, 44-10-611, 44-10-701(1)(a), and 44-10-701(3)(d) and (f), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsections 16(3)(a), 16(5)(a)(V) and 16(5)(a)(VIII). The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by an Accelerator Store. Such limitations include, but are not limited to, quantity limitations on sales and equivalencies for Retail Marijuana Concentrate and Retail Marijuana Product to Retail Marijuana flower. The establishment of equivalencies also provides information to stakeholders including Licensees, the general public, and law enforcement to aid in the enforcement of and compliance with the lawful personal possession limit of one ounce or less of marijuana. Setting these equivalencies provides Accelerator Stores and their employees with necessary information to avoid being complicit in a patron acquiring more marijuana than is lawful to possess under the Colorado Constitution pursuant to Article XVIII, Subsection 16(3)(a).

### **6-1110 – Accelerator Store: General Limitations or Prohibited Acts**

- A. Sales to Persons Under 21 Years. Licensees are prohibited from Transferring, giving, or distributing Retail Marijuana to persons under 21 years of age. Licensees are prohibited from permitting a person under the age of 21 years of age from entering the Restricted Access Area.
- B. Age Verification. Prior to initiating the Transfer of Retail Marijuana, a Licensee must verify that the purchaser has a valid government-issued photo identification showing that the purchaser is 21 years of age or older.
- C. Quantity Limitations On Sales.
  - 1. An Accelerator Store and its employees are prohibited from Transferring more than one ounce of Retail Marijuana flower or its equivalent in Retail Marijuana Concentrate or Retail Marijuana Product or more than six Retail Marijuana seeds in a single transaction to a consumer. A single transaction includes multiple Transfers to the same consumer during the same business day where the



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Accelerator Store employee knows or reasonably should know that such Transfer would result in that consumer possessing more than one ounce of marijuana. In determining the imposition of any penalty for violation of this Rule 6-1110(C), the State Licensing Authority will consider any mitigating and aggravating factors set forth in Rule 8-235(C).

2. Equivalency. Non-edible, non-psychoactive Retail Marijuana Products including ointments, lotions, balms, and other non-transdermal topical products are exempt from the one-ounce quantity limit on Transfers. For all other Retail Marijuana Products or Retail Marijuana Concentrate, the following equivalency applies for the one ounce quantity Transfer limit:
  - a. One ounce of Retail Marijuana flower shall be equivalent to eight grams of Retail Marijuana Concentrate.
  - b. One ounce of Retail Marijuana flower shall be equivalent to 80 ten-milligram servings of THC in Retail Marijuana Product.
- C.5. Educational Resource. When completing a sale of Retail Marijuana Concentrate, an Accelerator Store shall ~~provide the consumer with~~physically attach to the consumer's receipt of sale, product container, or exit packaging the tangible educational resource created by the State Licensing Authority regarding the use of Regulated Marijuana Concentrate.
- D. Licensees May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to Transfer Retail Marijuana to a consumer.
- E. Repealed.
- F. Delivery Outside Colorado Prohibited. An Accelerator Store holding a valid delivery permit shall not deliver Retail Marijuana to an address that is outside the state of Colorado.
- G. Prohibited Items. An Accelerator Store is prohibited from selling or giving away ~~any consumable product that is not a Retail Marijuana Product or a Hemp Product including, but not limited to,~~ cigarettes or tobacco products, and alcohol beverages, ~~and food products or non-alcohol beverages that are not Retail Marijuana Product.~~
- H. Free Product Prohibited. An Accelerator Store may not give away Retail Marijuana to a consumer for any reason.
- I. Nicotine or Alcohol Prohibited. An Accelerator Store is prohibited from Transferring Retail Marijuana that contain nicotine or alcohol, if the sale of the alcohol would require a license pursuant to Articles 3, 4, or 5 of Title 44, C.R.S.
- J. Storage and Display Limitations.
  1. An Accelerator Store shall not display Retail Marijuana outside of a designated Restricted Access Area or in a manner in which Retail Marijuana can be seen from outside the Licensed Premises. Storage of Retail Marijuana shall otherwise be maintained in Limited Access Areas or Restricted Access Area.

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2. Any Retail Marijuana Concentrate displayed in an Accelerator Store must include the potency of the concentrate on a sign next to the name of the product.
  - a. The font on the sign must be large enough for a consumer to reasonably see from the location where a consumer would usually view the concentrate.
  - b. The potency displayed on the sign must be within plus or minus fifteen percent of the concentrate's actual potency.
- K. Transfer of Expired Product Prohibited. An Accelerator Store shall not Transfer any expired Retail Marijuana Product to a consumer.
- L. Transfer Restriction.
  1. Sampling Units. An Accelerator Store may not possess or Transfer Sampling Units.
  2. Research Transfers Prohibited. An Accelerator Store shall not Transfer any Retail Marijuana to a Pesticide Manufacturer or a Marijuana Research and Development Facility.
- L.5. Standard Operating Procedures. An Accelerator Store must establish written Sstandard Operating Procedures for the management and storage of Retail Marijuana inventory and the sale of Retail Marijuana to consumers. A written copy of the Sstandard Operating Procedures must be maintained on the Licensed Premises.
  1. An Accelerator Store must provide adequate training to every Owner Licensee and Employee Licensee who performs a task or set of tasks that are referenced in the Sstandard Operating Procedures. Adequate training must include, but need not be limited to, providing a copy of the Sstandard Operating Procedures for that Licensed Premises detailing at least all of the topics required to be included in the Sstandard Operating Procedures.
- M. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit.
  1. The sale of Edible Retail Marijuana Products in the following shapes is prohibited:
    - a. The distinct shape of a human, animal, or fruit; or
    - b. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
  2. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Retail Marijuana Business. Nothing in this subparagraph (M)(2) alters or eliminates a Licensee's obligation to comply with the requirements of the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.
  3. Edible Retail Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and

4. Edible Retail Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible.
- N. Adverse Health Event Reporting. An Accelerator Store must report Adverse Health Events pursuant to Rule 3-920.
- O. Corrective and Preventive Action. An Accelerator Store shall establish and maintain written procedures for implementing Corrective Action and Preventive Action. The written procedures shall include the requirements listed below as determined by the Licensee. All activities required under this Rule, and their results, shall be documented and kept as business records. See Rule 3-905. The written procedures shall include requirements, as appropriate, for:
1. What constitutes a Nonconformance in the Licensee's business operation;
  2. Analyzing processes, work operations, reports, records, service records, complaints, returned product, and/or other sources of data to identify existing and potential root causes of Nonconformances or other quality problems;
  3. Investigating the root cause of Nonconformances relating to product, processes, and the quality system;
  4. Identifying the action(s) needed to correct and prevent recurrence of Nonconformance and other quality problems;
  5. Verifying the Corrective Action or Preventive Action to ensure that such action is effective and does not adversely affect finished products;
  6. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
  7. Ensuring the information related to quality problems or Nonconformances is disseminated to those directly responsible for assuring the quality of products or the prevention of such problems; and
  8. Submitting relevant information on identified quality problems and Corrective Action and Preventive Action documentation, and confirming the result of the evaluation, for management review.
- P. ~~Repealed. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**Basis and Purpose – 6-1115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(z), 44-10-203(2)(aa), 44-10-202(3)(h), 44-10-401(2)(b)(I), and 44-10-611, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsections 16(5)(a)(V) and 16(5)(a)(VIII). The purpose of this rule is to establish that an Accelerator Store must control and safeguard access to certain areas where Retail Marijuana and Retail Marijuana Product will be sold to the general public and prevent the diversion of Retail Marijuana and Retail Marijuana Product to people under 21 years of age.

**6-1115 – Point of Sale: Restricted Access Area**

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- A. Identification of Restricted Access Area. All areas where Retail Marijuana are sold, possessed for sale, displayed, or dispensed for sale shall be identified as a Restricted Access Area and shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state, "Restricted Access Area – No One Under 21 Years of Age Allowed."
- B. Consumers in Restricted Access Area. The Restricted Access Area must be supervised by a Licensee at all times when consumers are present to ensure that only persons who are 21 years of age or older are permitted to enter. When allowing a customer access to a Restricted Access Area, Owner Licensees and Employee Licensees shall make reasonable efforts to limit the number of consumers in relation to the number of Owners Licensees and Employee Licensees in the Restricted Access Area at any time.
- C. Display of Retail Marijuana. The display of Retail Marijuana for sale is allowed only in Restricted Access Areas. Any product displays that are readily accessible to the consumer must be supervised by the Owner Licensee or Employee Licensees at all times when consumers are present.
- D. Pregnancy Warning. Accelerator Stores must post, at all times and in a prominent place at every point-of-sale inside the Restricted Access Area, a warning that is at minimum three inches high and six inches wide that reads:

**WARNING:** Using marijuana, in any form, while you are pregnant or breastfeeding passes THC to your baby and may be harmful to your baby. There is no known safe amount of marijuana use during pregnancy or breastfeeding.

**Part 7 – Regulated Marijuana Transfers to Unlicensed Pesticide Manufacturers****Basis and Purpose – 7-115**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a)(II), 44-10-202(1)(c), 44-10-203(1)(c), and 44-10-203(1)(k), C.R.S. The purpose of this rule is to establish requirements associated with the Transfer of Regulated Marijuana and Regulated Marijuana Product to Pesticide Manufacturers, including requirements for the possession and disposition of Regulated Marijuana and Regulated Marijuana Products by Pesticide Manufacturers. This Rule 7-115 was previously Rules M and R 1802, 1 CCR 212-1 and 1 CCR 212-2.

**7-115 – Pesticide Manufacturers**

- A. Transfers to Pesticide Manufacturers. A Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, Retail Marijuana Cultivation Facility, and Retail Marijuana Products Manufacturer may Transfer Regulated Marijuana to a Pesticide Manufacturer solely for the purpose of conducting research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Regulated Marijuana. See Rules 5-205, 5-305, 6-205, 6-305.
- B. Written Documentation Required. A Licensee shall require, and shall not Transfer Regulated Marijuana prior to receiving, written proof under oath, as evidenced by an affidavit entered into by an authorized person on behalf of the Pesticide Manufacturer,

affirming that the Pesticide Manufacturer meets the requirements set forth in subparagraph (C)(4) of this Rule. This documentation shall constitute a business record under Rule 3-905 – Business Records Required.

- C. Agreement with Pesticide Manufacturer. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer that Transfers Regulated Marijuana to a Pesticide Manufacturer shall enter into a written agreement with the Pesticide Manufacturer prior to Transferring any Regulated Marijuana to the Pesticide Manufacturer. The written agreement, which shall constitute a business record under Rule 3-905, shall include:

1. The identity of the Pesticide Manufacturer;
2. The quantity of Regulated Marijuana that will be Transferred to the Pesticide Manufacturer;
3. The date(s) upon which Transfer of the Regulated Marijuana will occur;
4. An affirmation by the Pesticide Manufacturer that it:
  - ai. Has an establishment number with the U.S. Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*;
  - bii. Is authorized to do business in Colorado;
  - ciii. Is in possession of a physical location in the State of Colorado where its research activities will occur;
  - diii. Has applied for and received any necessary license, registration, certification, or permit from the Colorado Department of Agriculture pursuant to the Pesticide Act, sections 35-9-101 *et seq.*, C.R.S. and/or the Pesticide Applicators' Act, sections 35-10-101 *et seq.*, C.R.S.;
  - ev. Remains authorized to receive the quantity of Regulated Marijuana that will be Transferred to the Pesticide Manufacturer; and
  - fvi. Will only use the Transferred Regulated Marijuana for the purpose of research to establish safe and effective protocols for the use of Pesticides on Regulated Marijuana, which protocols may include but not be limited to establishing efficacy and toxicity; and
5. An affirmation by the Licensee that it has received written proof the Pesticide Manufacturer meets the requirements set forth in subparagraph (C)(4) of this Rule.

- D. Inventory Tracking Requirements. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, and Retail Marijuana Products Manufacturer shall track all Regulated Marijuana in the Inventory Tracking System until it is delivered to a Pesticide Manufacturer.

1. Transport Manifest. A Licensee shall not deliver or permit the delivery of Regulated Marijuana unless a manifest is generated from the Inventory Tracking System.
  2. Complete Manifest. A Licensee shall not relinquish possession or control of Regulated Marijuana to a Pesticide Manufacturer until a natural person authorized by the Pesticide Manufacturer acknowledges receipt of the Regulated Marijuana by signing the transport manifest.
  3. No Inventory Tracking Following Delivery. Once Regulated Marijuana has been Transferred by a Licensee to a Pesticide Manufacturer, no further inventory tracking is required.
  4. Licensee Delivery Responsibility. The originating Licensee is responsible for confirming delivery of all Regulated Marijuana in the Inventory Tracking System.
- E. Packaging, Labeling, and Testing. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer that Transfers Regulated Marijuana to a Pesticide Manufacturer shall package, label, and test all Regulated Marijuana in conformance with these rules prior to Transferring the Regulated Marijuana. See – Labeling, Packaging, and Product Safety; – Regulated Marijuana Testing Program.
- F. Business Records. A Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or Retail Marijuana Products Manufacturer that Transfers Regulated Marijuana to a Pesticide Manufacturer shall keep all documents concerning the relationship and Transfer of any Regulated Marijuana in accordance with Rules 3-605 and 3-905.
- G. Pesticide Manufacturer Authorized Activities. A Pesticide Manufacturer is only authorized to possess Transferred Regulated Marijuana in order to conduct research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Regulated Marijuana.
- H. Quantity Limitations for Pesticide Manufacturer. In no event shall a Pesticide Manufacturer possess at any given time more than (i) 12 Medical Marijuana plants and (ii) four pounds of Medical Marijuana or its equivalency in Medical Marijuana Concentrate (512 grams) or Medical Marijuana Product (5,120 Medical Marijuana Products), and (i) 12 Retail Marijuana plants and (ii) four pounds of Retail Marijuana or its equivalency in Retail Marijuana Concentrate (512 grams) or Retail Marijuana Products (5,120 ten-milligram servings of Retail Marijuana Product).
- I. Disposition of Transferred Regulated Marijuana. A Pesticide Manufacturer shall destroy all Transferred Regulated Marijuana received from a Licensee following completion of research activities.
1. A Pesticide Manufacturer shall destroy Transferred Regulated Marijuana in conformance with Rule 3-230 – Waste Disposal.
  2. A Pesticide Manufacturer shall document the destruction of Transferred Regulated Marijuana, which documentation shall include:

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- a.i. Whether the destroyed material was Transferred Regulated Marijuana;
    - b.ii. The date of destruction;
    - c.iii. The location of the destruction;
    - d.iv. The manner in which the Transferred Regulated Marijuana was rendered unusable and Unrecognizable;
    - e.v. The method of final disposition pursuant to Rule 3-230; and
    - f.vi. The identity(ies) and contact information of all Person(s) involved in the destruction.
  3. A Pesticide Manufacturer shall keep all documentation regarding destruction of Transferred Regulated Marijuana for the current year and three preceding calendar years.
- J. No Pesticide on Licensed Premises. Under no circumstance may a Pesticide Manufacturer apply Pesticide(s) for research purposes on the Licensed Premises of a Regulated Marijuana Business.
1. Licenses Shall Not Permit Pesticide on Licensed Premises. Under no circumstance may a Licensee allow or permit the application of Pesticide(s) by a Pesticide Manufacturer for research purposes on the Licensed Premises of a Regulated Marijuana Business.
  2. ~~Repealed. Violation Affecting Public Safety. A violation of this prohibition shall be considered a violation affecting public safety.~~
- K. No Human or Animal Subjects. Under no circumstance shall a Pesticide Manufacturer receiving Regulated Marijuana from a Licensee engage in research involving human subjects. Additionally, under no circumstance shall a Pesticide Manufacturer receiving Regulated Marijuana from a Licensee engage in research involving animal subjects, as defined in the Animal Welfare Act, 7 U.S.C. § 2132(g).
1. Licenses Shall Not Permit Human or Animal Subject Research. If a Licensee knows or reasonably should know that a Pesticide Manufacturer intends to engage in or has engaged in marijuana-related research involving human and/or animal subjects, the Licensee shall not Transfer any Regulated Marijuana to the Pesticide Manufacturer.
  2. ~~Repealed. Violation Affecting Public Safety. A violation of this Rule shall be considered a violation affecting public safety.~~
- L. No Transfer to Licensees. Under no circumstance may a Licensee receive or obtain for any purposes any Transferred Regulated Marijuana from a Pesticide Manufacturer.

## Part 8 – Enforcement and Discipline

## 8-100 Series - Enforcement

## Basis and Purpose – 8-110



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The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(f), 44-10-202(1)(g), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-207, 44-10-203(1)(k), and 44-10-902, C.R.S. This rule explains that Licensees must cooperate with Division employees when they are acting within the normal scope of their duties and that failure to do so may result in sanctions. It also explains the administrative hold process, the handling of inventory subject to administrative hold and under investigation and the process for voluntary surrender of Regulated Marijuana. This Rule 8-110 was previously Rules M and R 1202, 1 CCR 212-1 and 1 CCR 212-2.

**8-110 – Requirement for Inspections and Investigations, Searches, Administrative Holds, Embargos, Voluntary Surrenders****A. Applicants and Licensees Shall Cooperate with Division Employees.**

1. Applicants and Licensees must cooperate with employees of the Division who are conducting inspections or investigations relevant to the enforcement of laws and regulations related to the Marijuana Code.
2. No Applicant or Licensee shall by any means interfere with, obstruct, or impede the State Licensing Authority or any employee of the Division from exercising their duties pursuant to the provisions of the Marijuana Code and all rules promulgated pursuant to it. This would include, but is not limited to:
  - a. Threatening force or violence against an employee or investigator of the Division, or otherwise endeavoring to intimidate, obstruct, or impede employees or investigators of the Division, their supervisors, or any peace officers from exercising their duties. The term “threatening force” includes the threat of bodily harm to such individual or to a member of his or her family;
  - b. Denying investigators of the Division access to premises where the Licensee’s Regulated Marijuana are grown, stored, cultivated, manufactured, tested, distributed, or Transferred during business hours or times of apparent activity;
  - c. Providing false or misleading statements;
  - d. Providing false or misleading documents and records;
  - e. Failing to timely produce requested books and records required to be maintained by the Licensee; or
  - f. Failing to timely respond to any other request for information made by a Division employee or investigator in connection with an investigation of the qualifications, conduct or compliance of an Applicant or Licensee.
3. ~~Repealed. License Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.~~

**B. Administrative Hold.**



1. Notice of Administrative Hold. To prevent destruction of evidence, diversion, or other threats to public safety, while permitting a Licensee to retain its inventory pending further investigation of an alleged violation of the Marijuana Code or Marijuana Rules, a Division investigator may order an administrative hold of Regulated Marijuana pursuant to the following procedure:
  - a. If during an investigation or inspection of a Licensee, a Division investigator develops objective and reasonable grounds to believe certain Regulated Marijuana constitute evidence of acts in violation of the Marijuana Code or Marijuana Rules, or constitute a threat to the public safety, the Division investigator may issue a notice of administrative hold of any such Regulated Marijuana pending further investigation of an alleged violation of the Marijuana Code or Marijuana Rules. The notice of administrative hold shall provide a documented description of the Regulated Marijuana to be subject to the administrative hold . Following the issuance of a notice of administrative hold, the Division will identify the Regulated Marijuana subject to the administrative hold in the Inventory Tracking System. The Licensee shall continue to comply with all tracking requirements. See Rule 3-805 – Regulated Marijuana Businesses: Inventory Tracking System.
  - b. The Senior Director, or their designee, shall promptly approve and issue a concise statement regarding the reasons for issuing the administrative hold and outlining the estimated time required to complete the investigation. The estimated time required to complete the investigation is not binding and may be adjusted at any time. If the estimated time is adjusted, the Division will provide the Licensee written notice.
2. The Licensee shall completely and physically segregate the Regulated Marijuana subject to the administrative hold in a Limited Access Area of the Licensed Premises under investigation, where it shall be safeguarded by the Licensee.
  - a. While the administrative hold is in effect, the Licensee is prohibited from, giving away, Transferring, transporting, or destroying the Regulated Marijuana subject to the administrative hold, except as otherwise authorized by these rules.
  - b. While the administrative hold is in effect, the Licensee must safeguard the Regulated Marijuana subject to the administrative hold, must maintain the Licensed Premises in reasonable condition according to health, safety, and sanitary standards, and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements as set forth in the Marijuana Code and the Marijuana Rules .
  - c. Nothing herein shall prevent a Licensee from voluntarily surrendering Regulated Marijuana that is subject to an administrative hold, except that the Licensee must follow the procedures set forth in paragraph (C) for voluntary surrender of Regulated Marijuana.

- d. Nothing herein shall prevent a Licensee from the continued possession, cultivation or harvesting of the Regulated Marijuana subject to the administrative hold. All Regulated Marijuana subject to an administrative hold must be put into separate Harvest Batches.
  - e. If the Division determines that the need to preserve evidence has subsided, the Licensee may destroy the Regulated Marijuana subject to an administrative hold at its expense, with advance approval from and in coordination with the Division, and in accordance with Rule 3-230 – Waste Disposal.
- 3. Lift, Expiration, or Extension of Administrative Hold.
  - a. At any time after the initiation of the administrative hold, the administrative hold may be lifted by order of the State Licensing Authority or a Division Investigator, or by agreement between the State Licensing Authority and the Licensee subject to the administrative hold. If a Division investigator determines to lift the administrative hold, the investigator will send the Licensee written notification of the reason the administrative hold is being lifted.
  - b. At any time after the initiation of the administrative hold, the State Licensing Authority may lift, revise, or extend the administrative hold.
  - c. An administrative hold expires after 120 days unless an administrative action has been initiated concerning the Regulated Marijuana subject to the administrative hold, or the State Licensing Authority extends the administrative hold.
  - d. The State Licensing Authority's order to extend the administrative hold will identify the reasons for extending the administrative hold. The State Licensing Authority will only consider the following factors when deciding whether to extend an administrative hold:
    - i. The need to preserve evidence for a pending administrative action;
    - ii. The existence of a new or continued threat of diversion;
    - iii. The existence of a new or continued threat of public safety;
    - iv. The Licensee's failure to cooperate with Division investigators;
    - v. The Licensee's failure to maintain security and inventory controls, including record keeping and inventory tracking requirements, video surveillance, Security Alarm System, or lock requirements;
    - vi. The Licensee's failure to maintain all required state or local licenses; or
    - vii. The Licensee's current tax noncompliance.

B.5. Embargo.

1. Notice of Embargo.
  - a. The Division may embargo Regulated Marijuana when there are objective and reasonable grounds to believe the Regulated Marijuana poses a risk to health, safety, or welfare of the public that imperatively requires emergency action.
  - b. A Division investigator will issue a Notice of Embargo to only the Licensee from which the Regulated Marijuana originated including a description of the Regulated Marijuana and identifying any permitted activities regarding the Regulated Marijuana subject to the embargo. Following the issuance of a Notice of Embargo, the Division will identify the Regulated Marijuana subject to embargo in the Inventory Tracking System. The Licensee shall issue a recall pursuant to Rule 3-336 for Regulated Marijuana subject to an embargo. The recall can only be terminated with approval of the Division. With approval from the Division, a Licensee subject to the Notice of Embargo may instruct other Licensees to destroy the affected Regulated Marijuana as part of the recall. The Division may also notify Licensees that received the embargoed Regulated Marijuana of the embargo and requirement that the Regulated Marijuana be physically segregated. The Licensee shall continue to comply with all tracking requirements. See Rule 3-805 – Regulated Marijuana Businesses: Inventory Tracking System.
  - c. The Senior Director, or their designee, shall promptly approve and issue a concise statement regarding the reasons for issuing the embargo.
2. The Effect of Embargo.
  - a. The Licensee shall completely and physically segregate the Regulated Marijuana subject to the embargo in a Limited Access Area of the Licensed Premises.
  - b. While the embargo is in effect, the Licensee is prohibited from Transferring, or transporting the Regulated Marijuana subject to the embargo, except as otherwise authorized by this Rule 8-110. The Licensee can choose to destroy the Regulated Marijuana that is the subject of the embargo at its expense, with advance approval from and in coordination with the Division and in accordance with Rule 3-230 – Waste Disposal.
  - c. While the embargo is in effect, the Licensee must safeguard the Regulated Marijuana subject to the embargo, must maintain the Licensed Premises in reasonable condition according to health, safety, and sanitary standards, and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements as set forth in the Marijuana Rules.
3. Release, Destruction, and Opportunity for Hearing.

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- a. At any time after service of a Notice of Embargo, the Division or the State Licensing Authority may lift, revise, or extend the embargo by agreement between the Division or the State Licensing Authority and the Licensee subject to the embargo.
  - b. If a Notice of Destruction has not been issued after 120 days of the Notice of Embargo, the Licensee that received the Notice of Embargo from the Division investigator may submit a written request for a hearing before a Department of Revenue Hearing Officer. The issue at the hearing will be whether there are reasonable grounds to support that the Regulated Marijuana poses a risk to public health or safety and should be subject to destruction, should be subject to continued embargo, or does not pose a risk to public health and safety and should be released from the embargo.
  - c. Within 60 days of receiving a Notice of Destruction, the Licensee receiving the Notice of Destruction ~~from the Division~~ may request a hearing pursuant to Rule 8-220(B). Failure to request a hearing within the 60-day time period automatically results in the Notice of Destruction becoming an order of destruction.
  - d. If the Licensee receiving the Notice of Destruction ~~from the Division~~ requests a hearing, the hearing will be conducted by a Department of Revenue Hearing Officer pursuant to section 24-4-105, C.R.S. The sole issue at the hearing will be whether the Regulated Marijuana subject to the embargo poses a threat to the health, safety, or welfare of the public and therefore should be destroyed. Following the hearing, the Hearing Officer will issue an Initial Decision that is subject to exceptions and judicial review.
  - e. If a destruction is ordered pursuant to this Rule 8-110(B.5)(3), the Licensee that received the Notice of Destruction ~~from the Division~~ is responsible for completing the destruction in coordination with the Division and in accordance with the Marijuana Rules. The Licensee receiving the Notice of Destruction ~~from the Division~~ is also responsible for all expenses related to the embargo and destruction of Regulated Marijuana.
4. The Division may seek the assistance of the Department of Public Health and Environment in connection with an embargo or a hearing seeking destruction of Regulated Marijuana.

C. Voluntary Surrender of Regulated Marijuana.

1. A Licensee, prior to a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any Regulated Marijuana to the Division.
  - a. Such voluntary surrender may require destruction of any Regulated Marijuana in the presence of a Division investigator and at the Licensee's expense.

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- b. The individual signing the Division's voluntary surrender form on behalf of the Licensee must certify that the individual has authority to represent and bind the Licensee.
2. The voluntary surrender form may be utilized in connection with a stipulated agency order through which the Licensee waives the right to hearing and any associated rights.
3. The voluntary surrender form may be utilized even if the Licensee does not waive the right to hearing and any associated rights, with the understanding that the outcome of the hearing does not impact the validity of the voluntary surrender.
4. A Licensee, after a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any Regulated Marijuana to the Division.
  - a. The Licensee must complete and return the Division's voluntary surrender form within 15 calendar days of the date of the Final Agency Order.
  - b. Such voluntary surrender may require destruction of any Regulated Marijuana in the presence of a Division investigator and at the Licensee's expense.
  - c. The individual signing the Division's voluntary surrender form on behalf of the Licensee must certify that the individual has authority to represent and bind the Licensee.

**Basis and Purpose – 8-120**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(f), 44-10-203(1)(g), 44-10-203(1)(k), and 44-10-203(2)(w), C.R.S. This rule explains that Division investigators may exercise discretion in issuing written warning when, during the course of a compliance check or investigation, the Division investigator identifies a violation(s) of the Marijuana Code or the rules promulgated thereunder. This rule also explains that the Director of the Division may exercise discretion to accept an assurance of voluntary compliance. It also explains the evidentiary value of a written warning or an assurance of voluntary compliance. This Rule 8-120 was previously Rules M and R 1204, 1 CCR 212-1 and 1 CCR 212-2.

**8-120 – Written Warnings and Assurances of Voluntary Compliance**

- A. Written Warnings. ~~During an investigation, if~~ a Division investigator identifies a violation(s) of the Marijuana Code or the rules promulgated thereunder that is not identified as ineligible for a written warning pursuant to subpart (D) of this Rule, the Division investigator may issue a written warning in lieu of recommending immediate disciplinary administrative action.
  1. The written warning shall identify the alleged violation(s).
  2. The written warning shall not constitute an admission of a violation(s) for any purpose or finding of a violation(s) by the State Licensing Authority, and shall not be evidence that Licensee violated the Marijuana Code, or the rules promulgated thereunder.

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3. A written warning shall constitute evidence in any subsequent administrative proceeding, if relevant, that the Licensee was previously warned of the violation(s).
  4. The Division may in its discretion initiate a subsequent administrative action and prove the violation(s) that was the subject of the written warning
- B. Assurances of Voluntary Compliance. The Director of the Division may accept an assurance of voluntary compliance regarding any act or practice alleged to violate the Marijuana Code, or the rules promulgated thereunder that is not identified as ineligible for an assurance of voluntary compliance pursuant to subpart (D) of this Rule.
1. The assurance must be in writing and may include a stipulation for the voluntary payment of the cost commensurate with the acts or practices and an amount necessary to restore money or property which may have been acquired by the alleged violator because of the acts or practices. It may include stipulations for other terms such as the completion of training, submission of Standard Operating Procedures, or other agreed-upon terms.
  2. An assurance of voluntary compliance may not be considered an admission of a violation(s) for any purpose or a finding of a violation(s) by the State Licensing Authority; however, the assurance of voluntary compliance shall constitute evidence in any subsequent administrative proceeding that Licensee entered into an agreement to comply with the Marijuana Code, and/or the rules promulgated thereunder.
  3. The State Licensing Authority may approve or review an assurance of voluntary compliance.
- C. Not a Disciplinary Action. Neither a written warning nor an assurance of voluntary compliance constitutes a disciplinary action.
- D. Not Eligible for Written Warning or Assurance of Voluntary Compliance. If a Division investigator identifies a violation(s) of the Marijuana Code or rules promulgated thereunder, the following conduct is not eligible for a Written Warning or Assurance of Voluntary Compliance.
1. Any disqualifying event prohibiting an Applicant or Licensee from holding a license pursuant to section 44-10-307, C.R.S.;
  2. Knowingly adulterating or altering a Sample Increment or Test Batch;
  3. Violations of Medical or Retail Marijuana Sales limits established by Rules 5-125 and 6-110(C);
  4. Any sale by a Retail Marijuana Store to an individual under the age of 21 years;
  5. Any sale by a Medical Marijuana Store to a person who is not a patient or caregiver;

6. Permitting the diversion of Regulated Marijuana outside the regulated distribution system, possessing marijuana obtained from outside the regulated distribution system or from an authorized source; and
7. Violation(s) for which the State Licensing Authority issued an Order of Summary Suspension or an Order of Show Cause to the Licensee.

### **Basis and Purpose – 8-130**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(e), 44-10-203(2)(l), 44-10-203(1)(e), 44-10-203(1)(g), and 44-10-203(2)(w), C.R.S. The purpose of this rule is to establish the circumstances under which the Division may seek from a district court an administrative warrant to search and/or seize marijuana and marijuana products, or other evidence indicating a violation of the Marijuana Code or rules. The Division has encountered circumstances that would have justified such a warrant. Establishing the criteria under which the Division may seek an administrative warrant will give fair notice to the regulated community regarding the types of violations that would lead to a request for an administrative warrant. This Rule 8-130 was previously Rules M and R 1309, 1 CCR 212-1 and 1 CCR 212-2.

### **8-130 – Administrative Warrants**

- A. Criteria. The Division may seek from a district court an administrative search warrant authorizing search and seizure in circumstances in which the Division makes a proper showing that:
  1. A Licensee has refused entry of Division investigators during business hours or times of apparent activity;
  2. A Licensee subject to an administrative hold or summary suspension has failed to comply with applicable rules; or
  3. A Licensee otherwise has acted in a manner demonstrating disregard for the Marijuana Code and the State Licensing Authority's rules or that threatens the public health, safety, and welfare.
4. A sole Controlling Beneficial Owner is deceased and a Temporary Appointee Registration is not timely filed.
- B. Affidavit. When seeking an administrative search warrant, the Division will supply the district court with a sworn affidavit explaining the bases for seeking the warrant.
- C. Seized Property. If the Division seizes marijuana, neither the Division nor the State Licensing Authority shall cultivate or care for any seized marijuana or marijuana products. The Division may seek from the district court an order to destroy any such marijuana or marijuana products.

### **8-200 Series – Discipline and Administrative Hearings**

#### **Basis and Purpose – 8-235**

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(l), 44-10-701, and 44-10-901(3)(b), C.R.S. Authority also exists in the

Colorado Constitution at Article XVIII, Subsection 16(5)(a)(IX). The purpose of this rule is to establish guidelines for enforcement and penalties that will be imposed by the State Licensing Authority for non-compliance with Marijuana Code, section 18-18-406.3(7), or any other applicable rule. The State Licensing Authority may pursue a violation in any of the categories described in this Rule and is not required to prove harm from any of the alleged violation types. This Rule 8-235 was previously Rules M and R 1307, 1 CCR 212-1 and 1 CCR 212-2.

### 8-235 – Penalties

A. Penalty Schedule. The State Licensing Authority will make determinations regarding the type of penalty to impose based on the severity of the violation in the following categories:

1. ~~Repealed License Violations Affecting Public Safety. This category of violation is the most severe and may include, but is not limited to, Retail Marijuana sales to persons under the age of 21 years, Medical Marijuana sales to non-patients, consuming marijuana on the Licensed Premises, Regulated Marijuana sales in excess of the relevant sales limitations, permitting the diversion of Regulated Marijuana outside the regulated distribution system, possessing marijuana obtained from outside the regulated distribution system or from an unauthorized source, making misstatements or omissions in the Inventory Tracking System, failure to report any transfer required by section 44-10-313(11), knowingly adulterating or altering or attempting to adulterate or alter any Test Batches of Regulated Marijuana, violations related to sharing Licensed Premises between Medical Marijuana Businesses and Retail Marijuana Businesses, violations related to R&D Co-Location Permits, failure to maintain books and records to fully account for all transactions of the business, failure to cooperate with Division investigators during the course of a Division investigation, failure to comply with any requirement related to the Transfer of Sampling Units, utilizing advertising material that is misleading, deceptive, or false, advertising violations directly targeting minors, packaging or labeling violations that directly impact patient or consumer safety, or violations related to the mandatory testing program. Violations of this nature generally have an immediate or potential negative impact on the health, safety, and welfare of the public at large. The range of penalties for this category of violation may include license suspension, a fine per individual violation, a fine in lieu of suspension of up to \$100,000, and/or license revocation depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.~~
2. ~~Repealed License Violations. This category of violation is more severe than a license infraction but generally does not have an immediate or potential negative impact on the health, safety, and welfare of the public at large. License violations may include but are not limited to, advertising and/or marketing violations, packaging or labeling violations that do not directly impact patient or consumer safety, failing to continuously escort a visitor in a Limited Access Area, failure to maintain minimum security requirements, failure to keep and maintain adequate business books and records, or minor or clerical errors in the Inventory Tracking System. The range of penalties for this category of violation may include license suspension, a fine per individual violation, a fine in lieu of suspension of up to~~



~~\$50,000, and/or license revocation depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.~~

3. ~~Repealed. License Infractions. This category of violation is the least severe and may include, but is not limited to, failure to display required Identification Badges, visitor badges, unauthorized modifications of the Licensed Premises of a minor nature, or failure to notify the State Licensing Authority of a minor change in ownership. The range of penalties for this category of violation may include license suspension, a fine per individual violation, and/or a fine in lieu of suspension of up to \$10,000 depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license.~~
4. Level I Violation(s). This category of violation is the most severe and may include deliberate and willful violations or violations that harm or have the potential to harm the public health, safety, or welfare. The range of penalties for this category of violation may include license suspension, a fine per individual violation, a fine in lieu of suspension of up to \$100,000, and/or license revocation depending on the mitigating and aggravating circumstances. Sanctions may also include restrictions on the license. Level I violations may include, but are not limited to:
  - a. Retail Marijuana sales to persons under the age of twenty-one (21) years;
  - b. Medical Marijuana sales to non-patients;
  - c. Any conduct that constitutes an unlawful act under section 44-10-701, C.R.S.;
  - d. Any disqualifying event prohibiting an Applicant or Licensee from holding a license pursuant to section 44-10-307, C.R.S.;
  - e. Violations of Medical Marijuana or Retail Marijuana Sales limits established by Rules 5-125 and 6-110(C);
  - f. Permitting the diversion of Regulated Marijuana outside the regulated distribution system;
  - g. Possessing marijuana obtained from outside the regulated distribution system or from an unauthorized source;
  - h. Making misstatements or omissions in the Inventory Tracking System, including failure to report any transfer required by section 44-10-313(11);
  - i. Knowingly adulterating or altering or attempting to adulterate or alter any Sample Increment or Test Batches of Regulated Marijuana;
  - j. Substantial failure to maintain required books and records;
  - k. Deliberately providing misleading information to Division investigators;
  - l. Falsifying or destroying records, or failing to respond to Division requests for records or information;

m. Failure to comply with requirements of an Administrative Hold or Embargo;

n. Utilizing advertising material that is misleading, deceptive, or false, or advertising violations directly targeting minors;

o. Packaging or labeling violations that directly impact patient or consumer safety including, but not limited to, child-proof packaging violations, not including required labels, or failing to include the Universal Symbol;

p. Violations related to the mandatory testing program; or

q. Failure to make any payment required in connection with biennial licensure.

5. Other Violation(s). The range of available penalties for other violations include one or more of the following: license suspension, a fine of up to \$25,000.00 per individual violation, a fine in lieu of suspension, and/or license revocation. Sanctions may also include restrictions on the license.

B. Other Factors.

1. The State Licensing Authority may take into consideration any aggravating and mitigating factors surrounding the violation which could impact the type or severity of penalty imposed.
2. The penalty structure is a framework providing guidance as to the range of violations, suspension description, fines, and mitigating and aggravating factors. The circumstances surrounding any penalty imposed will be determined on a case-by-case basis.
3. For all administrative offenses involving a proposed suspension, a Licensee may petition the State Licensing Authority for permission to pay a monetary fine, within the provisions of section 44-10-901, C.R.S., in lieu of having its license suspended for all or part of the suspension.

C. Mitigating and Aggravating Factors. The State Licensing Authority may consider mitigating and aggravating factors when considering the imposition of a penalty. These factors may include, but are not limited to:

1. ~~Repealed. Any prior violations that the Licensee has admitted to or was found to have engaged in.~~
2. ~~Repealed. Good faith measures by the Licensee to prevent the violation, including the following:~~
  - a. ~~Proper supervision;~~
  - b. ~~Regularly provided and documented employee training, provided the Licensee demonstrates all reasonable training measures were delivered prior to the Division's investigation; and~~

- ~~c. Standard operating procedures established prior to the Division's investigation, and which include procedures directly addressing the conduct for which imposition of a penalty is being considered.~~
- 3. Repealed. Licensee's past history of success or failure with compliance checks.
- 4. Repealed. Corrective action(s) taken by the Licensee related to the current violation or prior violations.
- 5. Repealed. Willfulness and deliberateness of the violation.
- 6. Repealed. Likelihood of reoccurrence of the violation.
- 7. Repealed. Circumstances surrounding the violation, which may include, but are not limited to:
  - ~~a. Prior notification letter to the Licensee that an underage compliance check would be forthcoming.~~
  - ~~b. The dress or appearance of an underage operative used during an underage compliance check (e.g., the operative was wearing a high school letter jacket).~~
  - ~~c. Licensee self-reported violation(s) of the Marijuana Code or rules promulgated pursuant to the Marijuana Code.~~
- 8. Repealed. Owner or management personnel is the violator or has directed an employee or other individual to violate the law.
- 9. Mitigating Factors:
  - a. No prior written warning(s), assurance(s) of voluntary compliance, or disciplinary action against the Licensee in the preceding twenty-four (24) months;
  - b. Corrective action(s) taken by the Licensee related to the violation(s);
  - c. Good faith efforts taken by the Licensee to comply with the rules;
  - d. Good faith measures by the Licensee to prevent the violation(s) prior to the Division's investigation, including Standard Operating Procedures which comply with the rules and directly address the conduct leading to the violation, proper supervision, and regularly provided and documented employee training;
  - e. Licensee self-reported the violation(s);
  - f. Licensee obtained and was current with a responsible vendor designation pursuant to the 3-500 Series Rules prior to the Division's investigation and the violation; and
  - g. Any other relevant circumstances which mitigate the violation(s).
- 10. Aggravating Factors:

- a. Licensee Transferred unsafe or potentially unsafe Regulated Marijuana;
  - b. Conduct or violation(s) resulting in a recall pursuant to Rule 3-336, an Embargo or Administrative Hold pursuant to Rule 8-110, or a health and safety advisory;
  - c. Willful or deliberate nature of actions by Licensee;
  - d. Duration of conduct and violation(s) by Licensee;
  - e. The quantity of Regulated Marijuana involved in the conduct or violation(s) by Licensee;
  - f. The quantity of statutory or rules violations related to investigation;
  - g. Licensee received verbal or written warning(s) or signed assurance(s) of voluntary compliance pursuant to Rule 8-120 for the same conduct or violation(s) in the previous twenty-four (24) months;
  - h. Prior disciplinary action against Licensee in the previous twenty-four (24) months for the same conduct or violation(s);
  - i. Licensee subject to a summary suspension for any conduct or violation(s) in the previous 24 months;
  - j. Owner or manager involvement in the conduct or violation(s);
  - k. Involvement by a person unlicensed to work for a Regulated Marijuana Business acting in a capacity that requires a license by these Rules;
  - l. Substantial risk for diversion of Regulated Marijuana as a result of the Licensee's conduct or violation(s); and
  - m. Any other relevant circumstances which aggravate the violation(s).
- D. Repealed. Responsible Vendor Designation. The State Licensing Authority shall consider responsible vendor designation pursuant to the 3-500 Series Rules as a mitigating factor when considering the imposition of sanctions or penalties.

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**Editor's Notes****History**

New rule eff. 01/01/2020.

Rules 2-205, 2-225 emer. rules eff. 02/07/2020.

Rules 1-105, 2-260 A.1, 2-265 H.1.d.i, 3-345, 3-605 B.1.a emer. rules eff. 03/20/2020.

Rules 1-105, 1-115, 2-225 C.3, 2-260 A.1, 2-265 E.5, 2-265 H.1.d.i, 2-265.I.2, 3-205 A.1, 3-345, 3-605 B.1.a.ii emer. rules eff. 04/02/2020.

Rules 1-105, 1-115, 2-225 C.3, 2-260 A.1, 2-265 E.5, 2-265 H.1.d.i, 2-265.I.2, 3-205 A.1, 3-345, 3-605 B.1.a emer. rules eff. 05/01/2020. Rules 1-115, 3-205 A.1 expired 08/29/2020.

Rules 1-105, 2-205 F.5, 2-225, 2-260 A.1, 2-265 H.1.d.i, 3-345, 3-605 B.1.a emer. rules eff. 06/05/2020. Rule 3-605 B.1.a expired 10/03/2020.

Rule 2-225 C.3 emer. rule eff. 06/26/2020.

Rules 1-105, 2-205 F.5, 2-225, 2-260 A.1, 2-265, 3-345 emer. rules eff. 09/15/2020.

Rule 4-136 emer. rule eff. 12/17/2020; expired 04/16/2021.

Entire rule eff. 01/01/2021.

Rules 2-265 I.1.d.i, 3-345 emer. rules eff. 01/11/2021; expired 05/11/2021.

Rules 1-115, 4-120 C.1.b, 4-135 C.2-3, 5-205 C.3, 6-205 C.3 eff. 05/01/2021.

Rule 2-205 emer. rule eff. 06/30/2021.

Rule 2-205 eff. 08/01/2021.

Entire rule eff. 01/01/2022.

Rules 2-245 B&P, 2-245 D.6 repealed, 2-265 L.1.e-f, 2-265 L.2.a emer. rules eff. 08/09/2022.

Entire rule eff. 12/01/2022.

Rules 2-205, 2-206 emer. rules eff. 07/01/2023.

Rules 2-220, 2-225, 6-105, 6-110, 6-1105, 6-1110 emer. rules eff. 08/08/2023.

Rules 2-205, 2-206, 2-220, 2-225, 6-105, 6-110, 6-1105, 6-1110 emer. rules eff. 10/27/2023.

Rules 1-115, 2-205, 2-206, 2-215, 2-220, 2-225, 2-235, 2-245, 2-260, 2-265, 2-275, 2-280, 3-110, 3-205, 3-215, 3-225, 3-305, 3-320, 3-325, 3-330, 3-335, 3-336, 3-605, 3-610, 3-615, 3-805, 3-810, 3-825, 3-905, 3-920, 3-1005, 3-1015, 3-1025, 3-1105, 3-1110, 3-1115, 4-105, 4-110, 4-115, 4-120, 4-121, 4-125, 4-135, 5-105, 5-205, 5-215, 5-235, 5-305, 5-335, 5-405, 5-410, 5-415, 5-420, 5-430, 5-435, 5-445, 5-455, 5-510, 5-705, 5-725, 6-105, 6-110, 6-205, 6-230, 6-305, 6-405, 6-410, 6-415, 6-420, 6-425, 6-430, 6-435, 6-440, 6-445, 6-455, 6-510, 6-705, 6-730, 6-805, 6-905, 6-925, 6-926, 6-930, 6-940, 6-1105, 6-1110, 8-110, 8-220, 8-235 eff. 01/08/2024.