COLORADO
Department of Revenue
Marijuana Enforcement Division

Initial Proposed Rules

Attachment to Notice of Rulemaking Filed August 31, 2022
Colorado Marijuana Rules
1 CCR 212-3

NOTES

Yellow highlighting designates that the proposed rule revision has been modified since the initial proposed rule was discussed at a stakeholder meeting.

Blue Highlighting designates additional context that may assist stakeholders in understanding the proposed rule revision and intent of the proposed rule revision.

Part 1 – General Applicability

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:

> "Accelerator Cultivator" means a Social Equity Licensee qualified to participate in the accelerator program established pursuant to the Marijuana Code and authorized to exercise the privileges of a Retail Marijuana Cultivation Facility on the premises of an Accelerator-Endorsed Retail Marijuana Cultivation Facility Licensee. The premises can be either the same premises or a separate Licensed Premises possessed by an Accelerator-Endorsed Licensee.
>
> "Accelerator-Endorsed Licensee" means a Retail Marijuana Cultivation Facility Licensee, Retail Marijuana Products Manufacturer Licensee, or a Retail Marijuana Store Licensee who has, pursuant to these rules, been endorsed to host and offer technical and capital support to a Social Equity Licensee pursuant to the requirements of the accelerator program established pursuant to the Code.
>
> "Accelerator Licensee" means an Accelerator Cultivator, Accelerator Manufacturer, or Accelerator Store.
>
> "Accelerator Manufacturer" means a Social Equity Licensee qualified to participate in the accelerator program established pursuant to the Marijuana Code and authorized to exercise the privileges of a Retail Marijuana Products Manufacturer on the premises of an Accelerator-

Endorsed Retail Marijuana Products Manufacturer Licensee. The premises can be either the same premises or a separate Licensed Premises possessed by an Accelerator-Endorsed Licensee.

"Accelerator Store" means a Social Equity Licensee qualified to participate in the accelerator program established pursuant to the Marijuana Code and authorized to exercise the privileges of a Retail Marijuana Store on the premises of an Accelerator-Endorsed Retail Marijuana Store Licensee. The premises can be either the same premises or a separate Licensed Premises possessed by an Accelerator-Endorsed Licensee.

"Acquire," when used in connection with the acquisition of an Owner's Interest of a Regulated Marijuana Business, means obtaining ownership, Control, power to vote, or sole power of disposition of the Owner's Interest, directly or indirectly through one or more transactions or subsidiaries, through purchase, assignment, transfer, exchange, succession or other means.

"Acting in Concert" means knowing participation in a joint activity or interdependent conscious parallel action toward a common goal, whether or not pursuant to an express agreement.

"Additive" means any non-marijuana derived substance added to Regulated Marijuana to achieve a specific technical and/or functional purpose during processing, storage, or packaging. Additives may be direct or indirect. Direct additives are used to impart specific technological or functional qualities. Indirect additives are not intentionally added but may be present in trace amounts as a result of processing, packaging, shipping, or storage. Botanically Derived Compounds which have been isolated or enriched and subsequently added back into cannabis products are additives.

"Adverse Health Event" means any untoward health condition or occurrence associated with the use of marijuana—this could include any unfavorable and unintended sign (including a hospitalization, emergency department visit, medical visit, abnormal laboratory finding, outbreak, death [non-motor vehicle]), symptom, or disease temporally associated with the use of a marijuana product, and may include concerns or reports on the quality, labeling, or possible adverse reactions to a specific marijuana (or hemp) product Transferred or manufactured at a Regulated Marijuana Business.

"Adverse Weather Event" means:

a. Damaging weather, which involves a drought, a freeze, hail, excessive moisture, excessive wind, or a tornado; or

b. An adverse natural occurrence, which involves an earthquake, wildfire, or flood.

"Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation, of visual, oral, or written communication, to directly induce any Person to patronize a particular Medical Marijuana Business or Retail Marijuana Business, or to purchase particular Regulated Marijuana. "Advertising" does not include packaging and labeling, Consumer Education Materials, or Branding.

"Affiliate" of, or Person affiliated with, a specified Person, means a Person that directly or indirectly through one or more intermediaries, Controls or is Controlled by, or is under common Control with, the Person specified.

"Alarm Installation Company" means a Person engaged in the business of selling, providing, maintaining, servicing, repairing, altering, replacing, moving or installing a Security Alarm System in a Licensed Premises.

"Alternative Use Designation" means a designation approved by the State Licensing Authority, permitting a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer to manufacture and Transfer Alternative Use Product.

"Alternative Use Product" means Regulated Marijuana that has at least one intended use that is not included in the list of intended uses in Rule 3-1015(B). Alternative Use Product may raise public health concerns that outweigh approval of the Alternative Use Product, or that require additional safeguards and oversight. Alternative Use Product cannot be Transferred except as permitted by Rule 5-325 or Rule 6-325 after obtaining an Alternative Use Designation. Rule 5-325 permits a Medical Marijuana Products Manufacturer to Transfer Alternative Use Product to a Medical Marijuana Testing Facility prior to receiving an Alternative Use Designation. Rule 6-325 permits a Retail Marijuana Products Manufacturer to Transfer Alternative Use Product to a Retail Marijuana Testing Facility prior to receiving an Alternative Use Designation. Except where the context otherwise clearly requires, rules applying to Regulated Marijuana Concentrate or Regulated Marijuana Product apply to Alternative Use Product.

"Applicant" means a Person that has submitted an application for licensure, permit, or registration, or for renewal of licensure, permit, or registration, pursuant to these rules that was accepted by the Division for review but has not been approved or denied by the State Licensing Authority.

"Approved Training Program" means a responsible vendor program that received approval from the Division prior to being offered to a Licensee.

"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 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, 4-115, 3-1010, and 3-1015 apply different requirements.

"Bad Actor" means a Person who:

a. Has been convicted, within the previous ten years (or five years, in the case of issuers, their predecessors and affiliated issuers), of any felony or misdemeanor:

   i. In connection with the purchase or sale of any Security;

   ii. Involving the making of any false filing with the Federal Securities Exchange Commission; or

   iii. Arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, or paid solicitor of purchasers of Securities;

b. Is subject to any order, judgment or decree of any court of competent jurisdiction, entered within the previous five years, that restrains or enjoins such Person from engaging or continuing to engage in any conduct or practice:

i. In connection with the purchase or sale of any Security;

ii. Involving the making of any false filings with the Federal Securities Exchange Commission; or

iii. Arising out of conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, or paid solicitor of purchasers of Securities:

c. Is subject to a final order of a state securities commission (or an agency or officer of a state performing like functions); a state authority that supervises or examines banks, savings associations, or credit unions; a state insurance commission (or an agency or officer of a state performing like functions); an appropriate federal banking agency; the U.S. Commodity Futures Trading Commission; or the National Credit Union Administration that:

i. Bars the Person from:

A. Association with an Entity regulated by such commission, authority, agency, or officer;

B. Engaging in the business of Securities, insurance, or banking; or

C. Engaging in savings association or credit union activities; or

ii. Constitutes a final order based on a violation of any law or regulation that prohibits fraudulent, manipulative, or deceptive conduct entered within the previous ten years;

d. Is subject to an order of the Federal Securities Exchange Commission entered pursuant to section 15(b) or 15B(c) of the Securities Exchange Act of 1934, or section 203(e) or (f) of the Investment Advisers Act of 1940 that:

i. Suspends or revokes such Person's registration as a broker, dealer, municipal securities dealer, or investment adviser;

ii. Places limitations on the activities, functions or operations of such Person; or

iii. Bars such Person from being associated with any Entity, or from participating in the offering of any Penny Stock;

e. Is subject to any order of the Federal Securities Exchange Commission entered within the previous five years that orders the Person to cease and desist from committing or causing a violation or future violation of:

i. Any scienter-based anti-fraud provision of the federal securities laws, including without limitations section 17(a)(1) of the Securities Act of 1933, section 10(b) of the Securities Exchange Act of 1934 and 17 C.F.R. 240.10b-5, section 15(c)(1) of the Securities Exchange Act of 1934 and section 206(1) of the Investment Advisers Act of 1940, or any other rule or regulation thereunder; or

ii. Section 5 of the Securities Act of 1933.

f. Is suspended or expelled from membership in, or suspended or barred from association with a member of, a registered national securities exchange or a registered national or affiliated securities association for any act or omission to act constituting conduct inconsistent with just and equitable principles of trade;

g. Has filed (as a registrant or issuer), or was named as an underwriter in, any registration statement or Regulation A offering statement filed with the federal Securities Exchange Commission that, within the previous five years, was the subject of a refusal order, stop order, or order suspending the Regulation A exemption, or is the subject of an investigation or proceeding to determine whether a stop order or suspension order should be issued; or

h. Is subject to a United States Postal Service false representation order entered with the previous five years, or is subject to a temporary restraining order or preliminary injunction with respect to conduct alleged by the United States Postal Service to constitute a scheme or device for obtaining money or property through the mail by means of false representations.

"Batch Number" means any distinct group of numbers, letters, or symbols, or any combination thereof, assigned by a Medical Marijuana Cultivation Facility or Medical Marijuana Products Manufacturer to a specific Harvest Batch or Production Batch of Medical Marijuana, or by a Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer to a specific Harvest Batch or Production Batch of Retail Marijuana.

"Beneficial Owner" includes the terms "beneficial ownership", or "beneficially owns" and means:

a. Any Person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares:

i. Voting power which includes the power to vote, or to direct the voting of, an Owner's Interest; and/or,

ii. Investment power which includes the power to dispose, or to direct the disposition of, an Owner's Interest.

b. Any Person who, directly or indirectly, creates or uses a trust, proxy, power of attorney, pooling arrangement or any other contract, arrangement, or device with the purpose of effect of divesting such Person of beneficial ownership of an Owner's Interest or preventing the vesting of such beneficial ownership as part of a plan or scheme to evade the reporting requirements of section 13(d) or (g) of the Securities Act of 1933 shall be deemed for purposes of such sections to be the beneficial owner of such Owner's Interest.

c. All Owner's Interests of the same class beneficially owned by a Person, regardless of the form which such beneficial ownership takes, shall be aggregated in calculating the number of shares beneficially owned by such Person.

d. Notwithstanding the provisions of paragraphs (a) and (c) of this rule:

i.

A. A Person shall be deemed to be the beneficial owner of an Owner's Interest, subject to the provisions of paragraph (b) of this rule, if that Person has the right to acquire beneficial

ownership of such Owner's Interest, as defined in Rule 13d-3(a) (§ 240.13d-3(a)) within sixty days, including but not limited to any right to acquire: (1) Through the exercise of any option, warrant or right; (2) through the conversion of an Owner's Interest; (3) pursuant to the power to revoke a trust, discretionary account, or similar arrangement; or (4) pursuant to the automatic termination of a trust, discretionary account or similar arrangement; provided, however, any person who acquires an Owner's Interest or power specified in paragraphs (d)(i)(A)(1), (2) or (3), of this section, with the purpose or effect of changing or influencing the control of the issuer, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon such acquisition shall be deemed to be the beneficial owner of the Owner's Interests which may be acquired through the exercise or conversion of such Owner's Interests or power. Any Owner's Interests not outstanding which are subject to such options, warrants, rights or conversion privileges shall be deemed to be outstanding for the purpose of computing the percentage of outstanding Owner's Interests of the class owned by such Person but shall not be deemed to be outstanding for the purpose of computing the percentage of the class by any other Person.

B. Paragraph (d)(i)(A) of this section remains applicable for the purpose of determining the obligation to file with respect to the underlying Owner's Interests even though the option, warrant, right or convertible Owner's Interests is of a class of equity Owner's Interest, as defined in § 240.13d-1(i), and may therefore give rise to a separate obligation to file.

ii. A member of a national securities exchange shall not be deemed to be a beneficial owner of an Owner's Interest held directly or indirectly by it on behalf of another Person solely because such member is the record holder of such Owner's Interests and, pursuant to the rules of such exchange, may direct the vote of such Owner's Interests, without instruction, on other than contested matters or matters that may affect substantially the rights or privileges of the holders of the Owner's Interests to be voted, but is otherwise precluded by the rules of such exchange from voting without instruction.

iii. A person who in the ordinary course of his business is a pledgee of Owner's Interests under a written pledge agreement shall not be deemed to be the beneficial owner of such pledged Owner's Interests until the pledgee has taken all formal steps necessary which are required to declare a default and determines that the power to vote or to direct the vote or to dispose or to direct the disposition of such pledged Owner's Interests will be exercised, provided, that:

A. The pledgee agreement is bona fide and was not entered into with the purpose nor with the effect of changing or influencing the control of the issuer, nor in connection with any transaction having such purpose or effect, including any transaction subject to Rule 13d-3(b);

B The pledgee is a Person specified in Rule 13d-1(b)(ii), including Persons meeting the conditions set forth in paragraph (G) thereof; and

C The pledgee agreement, prior to default, does not grant to the pledgee;

1. The power to vote or to direct the vote of the pledged Owner's Interests; or

2. The power to dispose or direct the disposition of the pledged Owner's Interests, other than the grant of such power(s) pursuant to a pledge agreement under which credit is extended subject to regulation T (12 CFR 220.1 to 220.8) and in which the pledgee is a broker or dealer registered under section 15 of the Securities Act of 1933.

iv. A Person engaged in business as an underwriter of Owner's Interests who acquires Owner's Interests through his participation in good faith in a firm commitment underwriting registered under the Securities Act of 1933 shall not be deemed to be the beneficial owner of such Owner's Interests until the expiration of forty days after the date of such acquisition.

"Blank Check Company" means an Entity that:

a. Is a development stage company that has no specific business plan or purpose or has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies, or other Entity or Person; and

b. Is issuing Penny Stock.

"Botanically Derived Compounds" are organic chemicals that typically have a high vapor pressure at room temperature and are likely to be dispersed into the air. Botanically Derived Compounds include, but are not limited to terpenes, terpenoids, ketones, esters, and other molecules which are naturally occurring in plants and are used to affect the flavor and aroma of Regulated Marijuana.

"Branding" means promotion of a Regulated Marijuana Business's brand through publicizing the Regulated Marijuana Business's name, logo, or distinct design feature of the brand.

"Cannabinoid" means any of the chemical compounds that are the active principles of marijuana.

"Centralized Distribution Permit" means a permit issued to a Medical Marijuana Cultivation Facility pursuant to section 44-10-502, C.R.S., or a Retail Marijuana Cultivation Facility pursuant to section 44-10-602, C.R.S., authorizing temporary storage of Medical Marijuana Concentrate and Medical Marijuana Product received from a Medical Marijuana Products Manufacturer or Retail Marijuana Concentrate and Retail Marijuana Product received from a Retail Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Medical Marijuana Stores or Retail Marijuana Stores. 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 Medical Marijuana Cultivation Facility possessing the Centralized Distribution Permit and the Medical Marijuana Store, or in both the Retail Marijuana Cultivation Facility possessing the Centralized Distribution Permit and the Retail Marijuana Store.

"Child-Resistant" means special packaging that is:

a. Designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as defined by 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995). 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 the applicable federal regulations, which is available to the public;

b. Opaque so that the packaging does not allow the product to be seen without opening the packaging material; and

c. Resealable for any product intended for more than a single use or containing multiple servings.

"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 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.

"Consumer Education Materials" means any informational materials that seek to educate consumers about Regulated Marijuana generally, including but not limited to education regarding the safe consumption of marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Products, provided it is not distributed or made available to individuals under twenty-one years of age.

"Consumption Area" means a designated and secured area within the Licensed Premises of a Licensed Hospitality Business where consumers can use and consume marijuana and where no one under the age of 21 is permitted. A Consumption Area may, but is not required to, be part of a Restricted Access Area.

"Container" means the receptacle directly containing Regulated Marijuana that is labeled according to the requirements in the 3-1000 Series Rules.

"Control" means the possession, direct or indirect, of the power to direct or cause the direction of the management or policies of a Person, whether through the ownership of voting Owner's Interests, by contract, or otherwise. This definition of Control includes Controls, Controlled, Controlling, Controlled by, and under common Control with.

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

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 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 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.

"Corrective Action" means a reactive action implemented to eliminate the root cause of a Nonconformance and to prevent recurrence.

"Court Appointee" means a Person appointed by a court as a receiver, personal representative, executor, administrator, guardian, conservator, trustee, or similarly situated Person; acting in accordance with section 44-10-401(3), C.R.S., and these rules; and authorized by court order to take possession of, operate, manage, or control a licensed Regulated Marijuana Business.

"Covered Securities" means:

a. A Security designated as qualified for trading in the national market system pursuant to section 78k-1(a)(2) of the Securities Act of 1933 that is listed, or authorized for listing, on a national securities exchange (or tier or segment thereof); or a Security of the same issuer that is equal in seniority or that is a senior Security to a Security designated as qualified for trading in the national market system.

b. A Security issued by an investment company that is registered, or that has filed a registration statement under the federal Investment Company Act of 1940.

c. A Security as defined by the Federal Securities Exchange Commission by rule pursuant to 15 U.S.C. §77r(b)(3).

d. A Security pursuant to 15 U.S.C. §77r(b)(4).

"Decontamination" means the process of neutralization or removal of dangerous substances or other contaminants from regulated marijuana without changing the product type of the Regulated Marijuana.

"Delivery Motor Vehicle" means any 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 that is used for delivery of Regulated Marijuana to patients or consumers; except that the term does not include electric assisted bicycles, wheelchairs, or vehicles moved solely by human power.

"Denied Applicant" means any Person whose application for licensure, permit, or registration pursuant to the Marijuana Code has been denied, any Person whose application for a responsible vendor program has been denied, or any Licensee whose application for any of the following non-exhaustive list has been denied: An initial license application pursuant to Rule 2-220, a renewal application pursuant to Rule 2-225, the request for a finding of suitability pursuant to Rule 2-235, a change of owner pursuant to Rule 2-245; a change of location of the Licensed Premises pursuant to Rule 2-255; a change, alteration, or modification of the Licensed Premises pursuant to Rule 2-260; or a production management tier increase request pursuant to Rule 5-225 or 6-220.

"Department" means the Colorado Department of Revenue.

"Designated Test Batch Collection Area" means an area that has been designated within the Limited Access Area of a Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Medical Marijuana Products Manufacturer that is under surveillance and used for purposes of organizing and combining Sample Increments

to create Test Batches, and which has been cleaned and sanitized prior to preparing Test Batches.

"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 4-110 to engage in Sample Increment Collection for the purpose of creating Test Batches.

"Director" means the Senior Director of the Marijuana Enforcement Division.

"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 High School; and

d. the percent of residents in the census tract who are unemployed.

"Division" means the Marijuana Enforcement Division.

"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 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.

"Employee License" means a license granted by the State Licensing Authority pursuant to section 44-10-401, C.R.S., to a natural person who is not a Controlling Beneficial Owner. Any person who possesses, cultivates, manufactures, tests, dispenses, sells, serves, transports, or delivers Regulated Marijuana, who is authorized to input data into a Regulated Marijuana Business's Inventory Tracking System or point-of-sale system, or who has unescorted access in the Restricted Access Area or Limited Access Area must hold an Employee License. Employee License includes both Key Licenses and Support Licenses.

"Entity" means a domestic or foreign corporation, cooperative, general partnership, limited liability partnership, limited liability company, limited partnership, limited liability limited partnership, limited partnership association, nonprofit association, nonprofit corporation, or any other organization or association that is formed under a statute or common law of the state of Colorado or any other jurisdiction as to which the laws of this state of Colorado or the laws of any other jurisdiction governs relations among owners and between the owners and the organization or association and that is recognized under the laws of the state of Colorado or the other jurisdiction as a separate legal entity.

"Executive Officer" means the president, any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function, or any other person who performs similar policy-making functions for the Regulated Marijuana Business.

"Exit Package" means an Opaque bag or other similar Opaque covering provided at the point of sale, in which Regulated Marijuana already in a Container is placed. If Regulated Marijuana flower, trim, or seeds are placed into a Container that is not Child-Resistant, then the Exit

Package must be Child-Resistant. The Exit Package is not required to be labeled in accordance with the 3-100 Series Rules.

"Fibrous Waste" means any roots, stalks, and stems from a Regulated Marijuana plant.

"Final Agency Order" means an Order of the State Licensing Authority issued in accordance with the Marijuana Code and the State Administrative Procedure Act. The State Licensing Authority will issue a Final Agency Order following review of the Initial Decision and any exceptions filed thereto or at the conclusion of the declaratory order process. A Final Agency Order is subject to judicial review.

"Flammable Solvent" means a liquid that has a flash point below 100 degrees Fahrenheit.

"Flowering" means the reproductive state of the cannabis plant in which there are physical signs of flower budding out of the nodes of the stem.

"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 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.

"Foreign Private Issuer" means any foreign issuer other than a foreign government except an issuer meeting the following conditions as of the last business day of its most recently completed second fiscal quarter:

a. More than 50 percent of the outstanding voting Securities of such issuer are directly or indirectly owned of record by residents of the United States; and

b. Any of the following:

    i. The majority of the executive officers or directors are United States citizens or residents;

    ii. More than 50 percent of the assets of the issuer are located in the United States; or

    iii. The business of the issuer is administered principally in the United States.

"Good Cause" for purposes of denial of an initial, renewal, or reinstatement of a license, registration, or permit application, means:

a. The Licensee or Applicant has violated, does not meet, or has failed to comply with any of the terms, conditions, or provisions of the Marijuana Code, any rules promulgated pursuant to the Marijuana Code, or any supplemental relevant state or local law, rule, or regulation;

b. The Licensee or Applicant has failed to comply with any special terms or conditions that were placed upon the license pursuant to an order of the State Licensing Authority or the relevant local jurisdiction; or

c. The Licensee's Licensed Premises have been operated in a manner that adversely affects the public health or welfare or the safety of the immediate neighborhood in which the establishment is located.

"Good Moral Character" means having a criminal history that demonstrates honesty, fairness, and respect for the rights of others and for the law.

"Greenhouse" means a hoop house or other structure with non-rigid walls that utilizes natural light, in whole or in part, for the cultivation of Regulated Marijuana.

"Harvest Batch" means a specifically identified quantity of processed Regulated Marijuana that is uniform in strain, cultivated utilizing the same Pesticide and other agricultural chemicals and harvested at the same time. A Harvest Batch may also include a Manicure Batch that was harvested prior to the creation of the Harvest Batch.

"Harvested Marijuana" means Regulated Marijuana flower reported as a package in the Inventory Tracking System or post-harvest Regulated Marijuana not including wet whole plant, trim, concentrate, waste, or Fibrous Waste that remains on the premises of the Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility or its off-premises storage location beyond 90 days from harvest.

"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 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.

"Identification Badge" means a physical badge issued by the Division to any 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.

"Identity Statement" means the name of the business as it is commonly known and used in any Advertising.

"Immature plant" means a nonflowering marijuana plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping or seedling and is in a cultivating container.

"Indirect Financial Interest Holder" means a Person that is not an Affiliate, a Controlling Beneficial Owner, or a Passive Beneficial Owner of a Regulated Marijuana Business and that:

a. Holds a Commercially Reasonable Royalty in exchange for a Regulated Marijuana Business's use of the Person's intellectual property;

b. Holds a Permitted Economic Interest that was issued prior to January 1, 2020, and that has not been converted into an Owner's Interest or holds any unsecured convertible debt option, option agreement or warrant that establishes a right for a

Person to obtain an interest that might convert to an ownership interest in a Regulated Marijuana Business obtained after January 1, 2020;

c. Is a contract counterparty with a Regulated Marijuana Business, other than a customary employment agreement, that has a direct nexus to the cultivation, manufacture, sale, or testing of Regulated Marijuana, including, but not limited to, a lease of real property on which the Regulated Marijuana Business operates, a lease of equipment used in the cultivation, manufacture, or testing of Regulated Marijuana, a secured or unsecured financing agreement with the Regulated Marijuana Business, a security contract with the Regulated Marijuana Business, or a management agreement with the Regulated Marijuana Business, provided that no such contract compensates the contract counterparty with a percentage of revenue for profits of the Regulated Marijuana Business.

i. Any secured interest in Regulated Marijuana must expressly provide that it is subject to all required suitability and application requirements.

d. Unless the context otherwise requires, the defined term Indirect Financial Interest Holder includes Indirect Beneficial Interest Owner.

"Industrial Fiber Products" means intermediate or finished products made from Fibrous Waste that are not intended for human or animal consumption and are not usable or recognizable as Regulated Marijuana. Industrial Fiber Products include, but are not limited to, cordage, paper, fuel, textiles, bedding, insulation, construction materials, compost materials, and industrial materials.

"Industrial Fiber Products Producer" means a Person who produces Industrial Fiber Products using Fibrous Waste.

"Industrial Hemp" means a plant of the genus Cannabis and any part of the plant, whether growing or not, containing a delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent (0.3%) on a dry weight basis.

"Industrial Hemp Product" means a finished product containing Industrial Hemp that:

a. Is a cosmetic, food, food additive, or herb;

b. Is for human use or consumption;

c. Contains any part of the hemp plant, including naturally occurring Cannabinoids, compounds, concentrates, extracts, isolates, resins, or derivatives; and

d. Contains a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent.

"Industrial Hygienist" means a natural person who has obtained a baccalaureate or graduate degree in industrial hygiene, biology, chemistry, engineering, physics, or a closely related physical or biological science from an accredited college or university.

a. The special studies and training of such persons must be sufficient in the cognate sciences to provide the ability and competency to:

i. Anticipate and recognize the environmental factors and stresses associated with work and work operations and to understand their effects on individuals and their well-being;

ii. Evaluate on the basis of training and experience and with the aid of quantitative measurement techniques the magnitude of such environmental factors and stresses in terms of their ability to impair human health and well-being;

iii. Prescribe methods to prevent, eliminate, control, or reduce such factors and stresses and their effects.

b. Any person who has practiced within the scope of the meaning of industrial hygiene for a period of not less than five years immediately prior to July 1, 1997, is exempt from the degree requirements set forth in the definition above.

c. Any person who has a two-year associate of applied science degree in environmental science from an accredited college or university and in addition not less than four years practice immediately prior to July 1, 1997, within the scope of the meaning of industrial hygiene is exempt from the degree requirements set forth in the definition above.

"Ineligible Issuer" means:

a. Any issuer that is required to file reports pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 that has not filed all reports and other materials required to be filed during the preceding 12 months, other than reports on Form 8-K required solely pursuant to an item specified in General Instruction I.A.3(b) of Form S-3;

b. The issuer is, or during the past three years the issuer or any of its predecessors was:

i. A Blank Check Company;

ii. A Shell Company;

iii. An issuer of an offering of Penny Stock;

c. The issuer is a limited partnership that is offering and selling its Securities other than through a firm commitment underwriting;

d. Within the past three years, a petition under the federal bankruptcy laws or any state insolvency law was filed by or against the issuer, or a court-appointed a receiver, fiscal agent, or similar officer with respect to the business or property of the issuer subject to the following:

i. In the case of an involuntary bankruptcy in which a petition was filed against the issuer, ineligibility will occur upon the earlier to occur of:

A. 90 days following the date of the filing of the involuntary petition (if the case has not been earlier dismissed); or

B. The conversion of the case to a voluntary proceeding under federal bankruptcy or state insolvency laws; and

ii. Ineligibility will terminate if an issuer has filed an annual report with audited financial statements subsequent to its emergence from that bankruptcy, insolvency, or receivership process;

e. Within the past three years, the issuer or any Entity that at the time was a subsidiary of the issuer was convicted of any felony or misdemeanor described in paragraphs (i) through (iv) of section 15(b)(4)(B) of the Securities Exchange Act of 1934;

f. Within the past three years, the issuer or any Entity that at the time was a subsidiary of the issuer was made the subject of any judicial or administrative decree or order arising out of a governmental action that:

i. Prohibits certain conduct or activities regarding, including future violations of, the anti-fraud provisions of the federal securities laws;

ii. Requires that the Person cease and desist from violating the anti-fraud provisions of the federal securities laws; or

iii. Determines that the Person violated the anti-fraud provisions of the federal securities laws;

g. The issuer has filed a registration statement that is the subject of any pending proceeding or examination under section 8 of the Securities Act of 1933 or has been the subject of any refusal order or stop order under section 8 of the Securities Act of 1933 within the past three years; or

h. The issuer is the subject of any pending proceeding under section 8A of the Securities Act of 1933 in connection with an offering.

"Infused Pre-Rolled Marijuana" means Regulated Marijuana that was produced by rolling, filling, or stuffing Harvested Marijuana flower, shake, and/or trim with Regulated Marijuana Concentrate(s) into paper, leaves, or an equivalent wrapper and is intended for consumption by inhalation.

"Ingredient" means any non-marijuana derived substance that is added to Regulated Marijuana to achieve a desired effect. The term Ingredient includes all Additives.

"Initial Decision" means a decision of a hearing officer in the Department following a licensing, disciplinary, or other administrative hearing. Either party may file exceptions to the Initial Decision. The State Licensing Authority will review the Initial Decision and any exceptions filed thereto, and will issue a Final Agency Order.

"Inventory Tracking System" means the required seed-to-sale tracking system that tracks Regulated Marijuana from either the seed or immature 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.

"Inventory Tracking System User" means an Owner Licensee of a Regulated Marijuana Business or an Employee Licensee employed by a Regulated Marijuana Business, who is granted Inventory Tracking System User account access for the purposes of performing inventory tracking

functions in the Inventory Tracking System. Each Inventory Tracking System User must have been successfully trained by an Inventory Tracking System Trained Administrator in the proper and lawful use of Inventory Tracking System.

"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 cannabinoids.

"License" means a license, permit, or registration pursuant to the Marijuana Code.

"Licensed Hospitality Business" means a Marijuana Hospitality Business or Retail Marijuana Hospitality and Sales Business.

"Licensed Premises" means the premises specified in an application for a license pursuant to the Marijuana Code that are owned or in possession of the Licensee and within which the Licensee is authorized to cultivate, manufacture, distribute, sell, store, transport, or test Medical Marijuana, or to cultivate, manufacture, distribute, sell, store, transport, test, or allow the use or consumption of Retail Marijuana, in accordance with the provisions of the Marijuana Code, and these rules. Not all areas of the Licensed Premises are Limited Access Areas or Restricted Access Areas.

"Licensee" means any Person licensed, registered, or permitted pursuant to the Marijuana Code including an Owner Licensee and an Employee Licensee.

"Limited Access Area" means a building, room, or other contiguous area upon the Licensed Premises where Regulated Marijuana and Regulated Marijuana Products are grown, cultivated, manufactured, stored, weighed, packaged, sold, possessed for sale, Transferred, or processed for Transfer, under control of the Licensee, with access limited to only those persons licensed by the State Licensing Authority and those visitors Escorted by a person licensed by the State Licensing Authority. All areas of ingress or egress to limited access areas must be clearly identified as such by a sign as designated by the State Licensing Authority.

"Limit of Detection" or "LOD" means the lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit (generally 1%).

"Limit of Quantitation" or "LOQ" means the lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

"Liquid Edible Medical Marijuana Product" means an Edible Medical Marijuana Product that is a liquid beverage or liquid food-based product for which the intended use is oral consumption, such as a soft drink or cooking sauce.

"Liquid Edible Retail Marijuana Product" means an Edible Retail Marijuana Product that is a liquid beverage or liquid food-based product for which the intended use is oral consumption, such as a soft drink or cooking sauce.

"Local Jurisdiction" means a locality as defined in section 16 (2)(e) of Article XVIII of the state constitution.

"Local Licensing Authority" means an authority designated by municipal, county, or city and county charter, ordinance, or resolution, or the governing body of a municipality or city and county, or the board of county commissioners of a county if no such authority is designated.

"Manager" means:

a. A member of a limited liability company in which management is not vested in managers rather than members;

b. A manager of a limited liability company in which management is vested in managers rather than members;

c. A member of a limited partnership association in which management is not vested in managers rather than members;

d. A manager of a limited partnership association in which management is vested in managers rather than members;

e. A general partner;

f. An officer or director of a corporation, a nonprofit corporation, a cooperative, or a limited partnership association; or

g. Any Person whose position with respect to an Entity, as determined under the constituent documents and organic statutes of the Entity, without regard to the Person's title, is the functional equivalent of any of the positions described in this definition.

"Manicure Batch" means a Harvest Batch or a part of a Harvest Batch of a specifically identified quantity of processed Regulated Marijuana that is uniform in strain, cultivated utilizing the same Pesticide and other agricultural chemicals and harvested at the same time. A Manicure Batch consists of Regulated Marijuana that has been harvested from plants that have not yet been cut down and/or used in a Harvest Batch. A Manicure Batch may be considered a Harvest Batch by itself, or it may be combined with a Harvest Batch containing the same plant from which the Manicure Batch was created.

"Marijuana Code" means the Colorado Marijuana Code found at sections 44-10-101 *et seq.*, C.R.S.

"Marijuana Consumer Waste" means any component left after the consumption of a Regulated Marijuana Product, including but not limited to Containers, packages, cartridges, pods, cups, batteries, all-in-one disposable devices, and any other waste component left after the Regulated Marijuana is consumed.

"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 licensee operates.

~~"Marketing Layer" means packaging in addition to the Container that is the outermost layer visible to the consumer at the point of sale. The Marketing Layer is optional, but if used by a Licensee in addition to the required Container, it must be labeled according to the requirements in the 3-1000 Series Rules.~~

"Marijuana Research and Development Facility" means a Person that is licensed pursuant to the Marijuana Code to grow, cultivate, manufacture, and possess Medical Marijuana, and to Transfer Medical Marijuana to another Marijuana Research and Development Facility all for limited research purposes authorized pursuant to section 44-10-507, C.R.S.

"Marketing Layer" means packaging in addition to the Container that is the outermost layer visible to the consumer at the point of sale. The Marketing Layer is optional, but if used by a Licensee in

addition to the required Container, it must be labeled according to the requirements in the 3-1000 Series Rules.

"Material Change" means ~~any change that would require a substantive revision to a Regulated Marijuana Business's standard operating procedures for the cultivation of Regulated Marijuana or the production of Regulated Marijuana Product~~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 standard operating procedures. *See* Rule 4-120(F)(1) for additional examples of Material Change.

"Medical Marijuana" means marijuana that is grown 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) or 39-26-717, or an over-the-counter medication for purposes of section 25.5-5-322. If the context requires, Medical Marijuana includes Medical Marijuana Concentrate and Medical Marijuana Products.

"Medical Marijuana Business" means any of the following entities licensed pursuant to article 10: A Medical Marijuana Store, a Medical Marijuana Cultivation Facility, a Medical Marijuana Product Manufacturer, a Medical Marijuana Testing Facility, a Marijuana Research and Development Licensee, a Medical Marijuana Business Operator, or a Medical Marijuana Transporter.

"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 Cultivation Facility" means a Person licensed pursuant to the Marijuana Code to operate a business as described in section 44-10-502, C.R.S.

"Medical Marijuana Product" means a product infused with Medical Marijuana and other Ingredients that is intended for use or consumption other than by smoking, including but not limited to edible product, ointments, and tinctures.

"Medical Marijuana Products Manufacturer" means a Person licensed pursuant to the Marijuana Code to operate a business as described in section 44-10-503, C.R.S.

"Medical Marijuana Store" means a Person licensed pursuant to the Marijuana Code to operate a business as described in section 44-10-501, C.R.S., and sells Medical Marijuana to registered patients or primary caregivers as defined in Article XVIII, Section 14 of the Colorado Constitution, but is not a primary caregiver.

"Medical Marijuana Testing Facility" means a public or private laboratory licensed and certified, or approved by the Division, to perform testing and research on Medical Marijuana.

"Medical Marijuana Transporter" means an entity 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.

"Mobile Premises" means a Licensed Premises operated by a Marijuana Hospitality Business in a motor vehicle, which includes any self-propelled vehicle that is designed primarily for travel on the public highways and that is generally and commonly used to transport persons and property over the public highways or a low-speed electric vehicle; but does not include electrical assisted bicycles, electric scooters, low-power scooters, wheelchairs, or vehicles moved solely by human power. A Marijuana Hospitality Business operating a Mobile Premises must comply with all requirements in Rule 6-940.

"Monitoring" means the continuous and uninterrupted attention to potential alarm signals that could be transmitted from a Security Alarm System located at a Regulated Marijuana Business Licensed Premises, for the purpose of summoning a law enforcement officer to the premises during alarm conditions.

"Monitoring Company" means a person in the business of providing security system Monitoring services for the Licensed Premises of a Regulated Marijuana Business.

"Multiple-Serving Edible Retail Marijuana Product" means an Edible Retail Marijuana Product unit for sale to consumers containing ~~no~~ more than 10 milligrams of active THC and no more than 100 milligrams of active THC. If the overall Edible Retail Marijuana Product unit for sale to the consumer consists of multiple pieces where each individual piece may contain less than 10 milligrams of active THC, yet in total all pieces combined within the unit for sale contain more than 10 milligrams of active THC, then the Edible Retail Marijuana Product shall be considered a Multiple-Serving Edible Retail Marijuana Product.

"Nonconformance" means a non-fulfillment of a requirement or departure from written procedures, work instructions, or quality system, as defined by the Licensee's written Corrective Action and Preventive Action procedures.

"Non-objecting Beneficial Owner" means a Beneficial Owner who gives permission to a financial intermediary to release their name and address to the company(ies) or issuer(s) in which they have bought Securities.

"Notice of Denial" means a written statement from the State Licensing Authority, articulating the reasons or basis for denial of a license application.

"Opaque" means that the packaging does not allow the product to be seen without opening the packaging material.

"Order to Show Cause" means a document from the State Licensing Authority alleging the grounds for imposing discipline against a Licensee's license.

"Owner Entity License" means a License issued to an Entity that is a Controlling Beneficial Owner of a Regulated Marijuana Business.

"Owner's Interest" means the shares of stock in a corporation, a membership in a nonprofit corporation, a membership interest in a limited liability company, the interest of a member in a

cooperative or in a limited cooperative association, a partnership interest in a limited partnership, a partnership interest in a partnership, and the interest of a member in a limited partnership association.

"Owner License" means a license issued to a natural person who is a Controlling Beneficial Owner of a Regulated Marijuana Business or who is a Passive Beneficial Owner electing to be subject to licensure.

"Passive Beneficial Owner" means any Person Acquiring any Owner's Interest in a Regulated Marijuana Business that is not otherwise a Controlling Beneficial Owner or in Control.

"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 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);

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.

~~"Permitted Economic Interest" means any unsecured convertible debt option, option agreement or warrant that establishes a right for a Person to obtain an interest that might convert to an ownership interest in a Regulated Marijuana Business issued prior to January 1, 2020 where the holder is a natural person who is a lawful United States resident and whose right to convert into an ownership interest is contingent on the holder qualifying as a Controlling Beneficial Owner or Passive Beneficial Owner under the Retail Code or Medical Code. This definition is repealed effective January 1, 2020.~~

"Person" means a natural person, an estate, a trust, an Entity, or a state or other jurisdiction.

"Pesticide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest or any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant; except that the term "pesticide" does not include any article that is a "new animal drug" as designated by the United States Food and Drug Administration.

"Pesticide Manufacturer" means a Person who (1) manufactures, prepares, compounds, propagates, or processes any Pesticide or device or active ingredient used in producing a Pesticide; (2) who possesses an establishment registration number with the U.S. Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.*; (3) who conducts research to establish safe and effective protocols, including but not limited to establishing efficacy and toxicity, for the use of Pesticides on Regulated Marijuana; (4) who has applied for and received any necessary license, registration, certifications, or permits 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.; (5) who is authorized to conduct business in the State of Colorado; and (6) who has physical possession of the location in the State of Colorado where its research activities occur. A Pesticide Manufacturer is neither a Regulated Marijuana Business, nor a Licensee.

"Physical Separation-Based Medical Marijuana Concentrate" means a Medical Marijuana Concentrate that was produced by separating Cannabinoids from Medical Marijuana through the use of physical separation by grinding, sifting, or a similar process and may use water, ice, or dry ice. Physical Separation-Based Medical Marijuana Concentrate does not include Solvent-Based Medical Marijuana Concentrate or Heat/Pressure-Based Medical Marijuana Concentrate.

"Physical Separation-Based Retail Marijuana Concentrate" means a Retail Marijuana Concentrate that was produced by separating Cannabinoids from Retail Marijuana through the use of physical separation by grinding, sifting, or a similar process and may use water, ice, or dry ice. Physical Separation-Based Retail Marijuana Concentrate does not include Solvent-Based Retail Marijuana Concentrate or Heat/Pressure-Based Retail Marijuana Concentrate.

"Pre-Rolled Marijuana" means Regulated Marijuana that was produced by rolling, filling, or stuffing Harvested Marijuana flower, shake, and/or trim into paper, leaves or an equivalent wrapper and is intended for consumption by inhalation.

"Pressurized Metered Dose Inhaler" means inhalable Regulated Marijuana Concentrate, which may be comprised of other Ingredients, and a pressurized propellant inside a device that administers a dose of an aerosolized composition.

"Preventive Action" means a proactive action implemented to eliminate the cause of a potential Nonconformance or other quality problem before it occurs.

"Processing Aid" means any non-marijuana derived substance used in the production of Regulated Marijuana to assist in extraction or manufacturing processes.

"Production Batch" means (a) any amount of Regulated Marijuana Concentrate of the same category and produced using the same extraction methods, standard operating procedures 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, standard operating procedures, 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, standard operating procedures, 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 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.

"Public Institution," for purposes of the 5-700 Series Rules, means any entity established or controlled by the federal government, a state government, or a local government or municipality, including but not limited to an institution of higher education or a public higher education research institution.

"Public Money," for purposes of the 5-700 Serie Rules, means any funds or money obtained by the holder from any governmental entity, including but not limited to research grants.

"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 licensee or an intermediary or holding company licensee which directly or indirectly owns ten percent or more of a 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.

"Qualified Private Fund" means an issuer that would be an investment company, as defined in section 3 of the Federal Investment Company Act of 1940, but for the exclusions provided under sections 3(c)(1) or 3(c)(7) of that Act, and that:

a. Is advised or managed by an investment adviser as defined and registered pursuant to 15 U.S.C. sec. 80b-1 et seq., and for which the registered investment adviser is current in all applicable reporting and record-keeping requirements under such act and rules promulgated thereunder; and

b. Satisfies one or more of the following:

i. Is organized under the law of a state or the United States;

ii. Is organized, operated, or sponsored by a U.S. person, as defined under subsection 17 CFR 230.902(k), as amended; or

iii. Sells Securities to a U.S. person, as defined under subsection 17 CFR 230.902(k), as amended.

"Reduced Testing Allowance" means the allowance for a Regulated Marijuana Business to conduct less testing than otherwise required by Rules 4-120 and 4-125 upon demonstrating that standard operating procedures and production practices result in consistent passing test results over a time frame established in Rules 4-120 and 4-125.

"R&D Co-Location Permit" means a permit issued to a Marijuana Research and Development Facility authorizing it to co-locate with a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility pursuant to Rule 5-705. A separate R&D Co-Location Permit is required for each location at which a Marijuana Research and Development Facility seeks to share a single Licensed Premises.

"Reasonable Cause" means just or legitimate grounds based in law and in fact to believe that the particular requested action furthers the purposes of the Marijuana Code or protects the public safety.

"Regulated Marijuana" means Medical Marijuana and Retail Marijuana. If the context requires, Regulated Marijuana includes Medical Marijuana Concentrate, Medical Marijuana Product, Retail Marijuana Concentrate, and Retail Marijuana Product.

"Regulated Marijuana Business" means Medical Marijuana Businesses and Retail Marijuana Businesses.

"Regulated Marijuana Concentrate" means Medical Marijuana Concentrate and Retail Marijuana Concentrate.

"Regulated Marijuana Cultivation Facility" means a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, and Accelerator Cultivator.

"Regulated Marijuana Products Manufacturer" means a Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, and Accelerator Manufacturer.

"Regulated Marijuana Product" means Medical Marijuana Product and Retail Marijuana Product.

"Regulated Marijuana Store" means a Medical Marijuana Store, Retail Marijuana Store, and Accelerator Store.

"Regulated Marijuana Testing Facility" means a Medical Marijuana Testing Facility and Retail Marijuana Testing Facility.

"Remediation" means the process of neutralization or removal of dangerous substances or other contaminants from regulated marijuana while changing the product type of the regulated marijuana.

"Resealable" means that the Container maintains its Child-Resistant effectiveness for multiple openings.

"Research Project" means a discrete scientific endeavor to answer a research question or a set of research questions. A Research Project must include a description of a defined protocol, clearly articulated goal(s), defined methods and outputs, and a defined start and end date. The description must demonstrate that the Research Project will comply with all requirements in the 5-700 Series Rules – Marijuana Research and Development Facility. All research and development conducted by a Marijuana Research and Development Facility must be conducted in furtherance of an approved Research Project.

"Respondent" means a Person who has filed a petition for declaratory order that the State Licensing Authority has determined needs a hearing or legal argument, or a Licensee who is subject to an Order to Show Cause.

"Responsible Vendor Program Provider" means a Person offering an Approved Training Program, in accordance with section 44-10-1201, C.R.S., to Licensees seeking to be designated a responsible vendor.

"Restricted Access Area" means a designated and secure area within a Licensed Premises in a Medical Marijuana Store where Medical Marijuana is sold to patients or their caregiver, possessed for sale, and displayed for sale, and where no one without a valid patient registry card or that patient's caregiver is permitted, and 2) in a Retail Marijuana Store or a Retail Marijuana Hospitality and Sales Business where Retail Marijuana is sold to consumers, possessed for sale, and displayed for sale, and where no one under the age of 21 is permitted.

"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;

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” means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including but not limited to Retail Marijuana Concentrate, that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Business. “Retail Marijuana” does not include industrial hemp, nor does it include fiber produced from stalks, oil, or cake made from the seeds of the plant, sterilized seed

of the plant which is incapable of germination, or the weight of any other Ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other product. If the context requires, Retail Marijuana includes Retail Marijuana Concentrate and Retail Marijuana Product.

"Retail Marijuana Business" means a Retail Marijuana Store, a Retail Marijuana Cultivation Facility, a Retail Marijuana Products Manufacturer, a Marijuana Hospitality Business, a Retail Marijuana Hospitality and Sales Business, a Retail Marijuana Testing Facility, a Retail Marijuana Business Operator, and a Retail Marijuana Transporter.

"Retail Marijuana Business Operator" means an entity or person 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 retail marijuana plant and results in matter with a higher concentration of cannabinoids than naturally occur in the plant. Retail Marijuana Concentrate contains 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 ingredients 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.

"Retail Marijuana Cultivation Facility" means an entity 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 retail marijuana or retail marijuana products it has sold pursuant to the provisions of an enacted, initiated, or referred ordinance or resolution of the local jurisdiction in which the licensee operates.

"Retail Marijuana Product" means a product that is comprised of Retail Marijuana and other Ingredients and is intended for use or consumption, such as, but not limited to, edible product, ointments and tinctures.

"Retail Marijuana Products Manufacturer" means an entity licensed to purchase Retail Marijuana; manufacture, prepare, and package Retail Marijuana Product; and Transfer Retail Marijuana, Retail Marijuana Concentrate, and Retail Marijuana Product only to other Retail Marijuana Products Manufacturers, Retail Marijuana Stores, Retail Marijuana Hospitality and Sales Businesses and Pesticide Manufacturers.

"Retail Marijuana Store" means an entity licensed to purchase Retail Marijuana and Retail Marijuana Concentrate from a Retail Marijuana Cultivation Facility and to purchase Retail Marijuana Product and Retail Marijuana Concentrate from a Retail Marijuana Products Manufacturer, and to Transfer Retail Marijuana to Retail Marijuana Hospitality and Sales Businesses and to consumers.

"Retail Marijuana Testing Facility" means an entity licensed to analyze and certify the safety and potency of marijuana.

"Retail Marijuana Transporter" means a Person licensed to transport Retail Marijuana from one Retail Marijuana Business to another Retail Marijuana Business or to a Pesticide Manufacturer,

and to temporarily store the transported Retail Marijuana at its Licensed Premises, but is not authorized to sell, give away, buy, or receive complimentary Retail Marijuana under any circumstances. A Retail Marijuana Transporter does not include a Licensee that transports and distributes its own Retail Marijuana.

"RFID" means Radio Frequency Identification.

"Sample Increment" means a single portion or unit that is removed from a Harvest Batch or Production Batch by a Designated Test Batch Collector for the creation of a Test Batch. For Harvest Batches, a Sample Increment shall be 500 milligrams of flower or trim. For Regulated Marijuana Products, Audited Products, and Alternative Use Products, a Sample Increment shall be a single serving of the product as defined by the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer, but shall contain no more than 10 milligrams of active THC per serving for Edible Retail Marijuana Products. For Regulated Marijuana Concentrate, a Sample Increment shall be 250 milligrams of concentrate.

"Sample Increment Collection" means the gathering of Sample Increments to combine into a larger, composite Test Batch.

"Sampling Manager" means an Owner Licensee or management personnel holding an Employee Licensee designated by a Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, Retail Marijuana Cultivation Facility, or Retail Marijuana Products Manufacturer to receive Transfers of Sampling Units pursuant to Rules 5-230, 5-320, 6-225, and 6-320.

"Sample Plan" means a written, documented plan generated by Designated Test Batch Collector(s) in line with the Regulated Marijuana Business' Standard Operating Procedure for Sample Increment Collection.

"Sampling Unit" means a unit of Regulated Marijuana Transferred to a Sampling Manager for purposes of quality control and product development pursuant to Rules 5-230 and 5-320, sections 44-10-502(4) and 44-10-503(10), C.R.S., and Rules 6-225 and 6-320, and sections 44-10-602(6) and 44-10-603(10), C.R.S.

"Security(ies)" means any note, stock, treasury stock, security future, security-based swap, bond, debenture, evidence of indebtedness, certificate of interest or participation in any profit-sharing agreement, collateral-trust certificate, preorganization certificate or subscription, transferable share, investment contract, voting-trust certificate, certificate of deposit for a security, fractional undivided interest in oil, gas, or other mineral rights, any put, call, straddle, option, or privilege on any security, certificate of deposit, or group index of securities (including any interest therein or based on the value thereof), or any put, call, straddle, option, or privilege entered into on a national securities exchange relating to foreign currency, or, in general, any interest or instrument commonly known as a "security," or any certificate of interest or participation in, temporary or interim certificate for, receipt for, guarantee of, or warrant or right to subscribe to or purchase, any of the foregoing.

"Security Alarm System" means a device or series of devices, intended to summon law enforcement personnel during, or as a result of, an alarm condition. Devices may include hard-wired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audible, visual, or electronic signal; motion detectors, pressure switches, duress alarms (a silent system signal generated by the entry of a designated code into the arming station to indicate that the user is disarming under duress); panic alarms (an audible system signal to indicate an emergency situation); and hold-up alarms (a silent system signal to indicate that a robbery is in progress).

"Shell Company" means a registrant, other than an asset-backed issuer as defined in Item 1101(b) of Regulation AB, that has:

a. No or nominal operations; and

b. Either:

i. No or nominal operations;

ii. Assets consisting solely of cash and cash equivalents; or

iii. Assets consisting of any amount of cash and cash equivalents and nominal other assets.

"Shipping Container" means a hard-sided container with a lid or other enclosure that can be secured in place. A Shipping Container is used solely for the transport of Regulated Marijuana between Regulated Marijuana Businesses or a Pesticide Manufacturer.

"Single-Serving Edible Retail Marijuana Product" means an Edible Retail Marijuana Product unit for sale to consumers containing no more than 10mg of active THC.

"Social Equity Licensee" means a natural person who meets the criteria established pursuant to section 44-10-308(4), 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 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.

"Standardized Graphic Symbol" means a graphic image or small design adopted by a Licensee to identify its business.

"Standardized Serving of Marijuana" means a standardized single serving of active THC in Retail Marijuana. The size of a Standardized Serving of Marijuana shall be no more than 10mg of active THC.

"State Licensing Authority" means the authority created for the purpose of regulating and controlling the licensing of the cultivation, manufacture, distribution, sale, and testing of Regulated Marijuana in Colorado, pursuant to section 44-10-201, C.R.S.

"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 standard operating procedures.

"Temporary Appointee Registration" means a registration issued to a Court Appointee pursuant to section 44-10-401(3)(a), C.R.S.

"THCA" means tetrahydrocannabinolic acid.

"THC" means tetrahydrocannabinol.

~~"THCA" means tetrahydrocannabinolic acid.~~

"Test Batch" means a group of Sample Increments that are derived from a single Harvest Batch, Production Batch, or Inventory Tracking System package, and that are collectively submitted to a Regulated Marijuana Testing Facility for testing purposes.

"Total THC" means the following:

The sum of the percentage by weight of Delta-9-tetrahydrocannabinolic acid (D9-THCA) multiplied by 0.877,

Plus the percentage by weight of Delta-8-tetrahydrocannabinol (D8-THC),

Plus the percentage by weight of Delta-9-tetrahydrocannabinol (D9-THC),

Plus the percentage by weight of Exo-tetrahydrocannabinol (Exo-THC),

Plus the percentage by weight of Delta-10-tetrahydrocannabinol (D10-THC).

i.e. Total THC = (% D9-THCA * 0.877) + % D8-THC + % D9-THC + % Exo-THC + % D10-THC.

"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. 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.

"Universal Symbol" means the image established by the Division and made available to Licensees through the Division's website indicating the Regulated Marijuana contains marijuana.

"Unrecognizable" means Regulated Marijuana that has been rendered indistinguishable from any other plant material.

"U.S. Person" means:

a. Any natural person resident in the United States;

b. Any partnership or corporation organized or incorporated under the laws of the United States;

c. Any estate of which any executor or administrator is a U.S. natural person;

d. Any trust of which any trustee is a U.S. natural person;

e. Any agency or branch of a foreign entity located in the United States;

f. Any non-discretionary account or similar account (other than an estate or trust) held by a dealer or other fiduciary for the benefit or account of a U.S. natural person;

g. Any discretionary account or similar account (other than an estate or trust) held by a dealer or other fiduciary organized, incorporated, or (if a natural person) resident in the United States; and

h. Any partnership or corporation if:

i. Organized or incorporated under the laws of any foreign jurisdiction; and

ii. Formed by a U.S. natural person principally for the purpose of investing in Owner's Interests not registered under the Securities Act of 1933, unless it is organized or incorporated, and owned, by accredited investors (as defined in § 230.501(a)) who are not natural persons, estates or trusts.

"Vaporizer Delivery Device" means inhalable Regulated Marijuana Concentrate, which may be comprised of other Ingredients inside a device that uses a heating element to create a vapor including, but not limited to, vaporizer cartridges and vaporizer pens.

"Vegetative" means the state of the *Cannabis* plant during which plants do not produce resin or flowers and are bulking up to a desired production size for Flowering.

Part 2 – Applications and Licenses

2-200 Series – Applications and Licenses Rules

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. *See* Rule 2-205.

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.

Please Note*: The MED proposes this change in light of SB 21-199, which does not impose requirements on MED, but MED sees the opportunity to honor the spirit of the bill in our rules here.*

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. ~~Each natural person required to obtain an Owner License or an Employee License must provide proof of lawful presence or citizenship, and Colorado residency, if required.~~

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 Application 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 – 2-225

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), 44-10-307, 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 one year from the date of issuance.

2. Medical Marijuana Transporters, Retail Marijuana Transporters, and Employee Licenses are valid for two years from the date of issuance.

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 physical address of record.

2. Failure to receive the Division notification does not relieve the Licensee of the obligation to timely renew the license.

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 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 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 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 2-205; 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. If 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 the Licensee may be subject to administrative action as authorized by the Marijuana Code or these Rules.

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;

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. ~~Tax documents and f~~Financial statements required by Rule 2-220(A)(10) ~~and (11)~~;

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 agreement, or security contract 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 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 year.

2. Accelerator-Endorsed Licensee Additional Renewal Requirements.

a. An endorsement issued to an Accelerator-Endorsed Licensee is required to be renewed 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 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 – 2-235

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), 44-10-309, 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

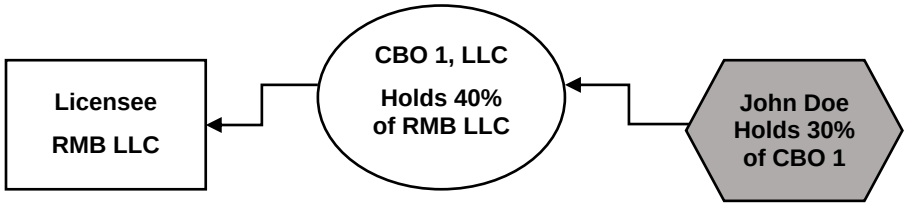
A. Persons Subject to a Mandatory Finding of Suitability for Regulated Marijuana Businesses That Are Not Publicly Traded Corporations.

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 an Entity.

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).

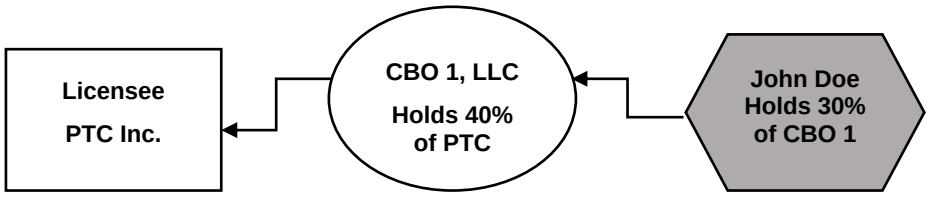
4. For a Controlling Beneficial Owner that is a trust, the trust's request for a finding of suitability must include all documents and information required or requested by the State Licensing Authority to permit a determination of whether or not the trustee and any beneficiary who may exercise control 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.

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. 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 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(C)(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.

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.

Please Note: *MED proposes the following change in order to clarify that an applicant's financial character may be evaluated either at the time of the request for a finding of suitability (if financing is known) or at the time of the business license application. Additionally, financial character my be reevaluated at the time of business license application if financing has changed since the request for finding and approval of suitability.*

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 ~~the~~ a Person~~'s~~ is submitting a request for a finding of suitability ~~is to~~ ~~for purposes of~~ acquir~~e~~~~ing~~ ten percent or more of the Owner's Interest in ~~the~~ 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 subsection (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. Title is not dispositive, however, the Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, president, the General Counsel, 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.

Please Note: *The following proposed rule revision was recommended by the Social Equity Program Advisory Work Group, where the proposed revision was discussed.*

H. Findings of Suitability ~~Valid for One Year~~.

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.

2. Finding of Suitability for Social Equity Licensees. A finding of suitability for Social Equity Licensee 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.

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, ~~and~~ 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 regarding a Controlling Beneficial Owner of a Regulated Marijuana Business that does not involve a Publicly Traded Corporation must include the following documents:

   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; and

   e. Copy of current Medical Marijuana or Retail Marijuana State Sales Tax or Wholesale license and any other documents necessary to verify tax compliance.

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 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 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. Reallocation of Owner's Interests Among 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 reallocation to the Division with its next application submission as long as there are no new Controlling Beneficial Owners. Reallocations 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). A reallocation under this R~~r~~ule is subject to the following requirements:

a. All Owner's Interests of a Controlling Beneficial Owner may be reallocated to other existing Controlling Beneficial Owners;

b. Only consensual reallocations where all Controlling Beneficial Owners whose ownership percentages will change agree to the reallocation are permitted under this Rule. Proof that the transfer was consensual may include affirmation from all Controlling Beneficial Owners for which the Owner's Interests were reallocated in the required disclosure at the next application submission.

c. If any Controlling Beneficial Owner will not hold any Owner's Interest in a Regulated Marijuana Business following the reallocation, that Controlling Beneficial Owner shall voluntarily surrender his or her Owner's License and identification badge within 30 days of the reallocation;

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 reallocation; and

e. Disclosure and submission of the fee required by Rule 2-205(F)(2)(b) 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 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) 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 Entity Controlling Beneficial Owner~~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. 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 ~~235-1~~2-235(A)(1)(a) unless exempt under subparagraph (b) of this Rule 2-245(C)(4); or,

   b. ~~i~~If exempt from a finding of suitability pursuant to Rule ~~235-1(E)~~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 days.

   ~~b~~c. The fee required by Rule 2-205(F)(2)(b).

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 whose Owner's Interests are proposed to change and any Person proposed to become a Controlling Beneficial Owner(s). 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 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 thirty days of the 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

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. ~~Medical Marijuana Transporters and Retail Marijuana Transporters Not Eligible for Change of Owner. Medical Marijuana Transporters and Retail Marijuana Transporters are not eligible to transfer the entire Beneficial Ownership of their Regulated Marijuana Business~~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 – 2-260

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)(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. Application Required to Change, Alter, or Modify 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. Changes to the Licensed

Premises which do not require an application must be disclosed on a floorplan submitted with the Licensee's renewal application.

~~1. Emergency Exemption. A Regulated Marijuana Business making temporary modifications to its Licensed Premises to effectuate social distancing measures in response to COVID-19 and applicable executive orders and public health orders in effect at the time of the temporary modifications, is exempt from State Licensing Authority application and prior-approval requirements in this Rule. The exemption provided under this subparagraph (A)(1) shall remain effective until repealed by the State Licensing Authority upon notice to the Secretary of State.~~

B. What Constitutes a Significant Change. This Rule does not exempt Licensees 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. Any increase or decrease in the total physical size or capacity of the Licensed Premises;

2. 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. Any physical modification of the Licensed Premises which would require the installation of additional video surveillance cameras. *See* Rule 3-225 – Video Surveillance.

C. 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.

Please Note: *MED proposes this change in order to allow licensees similar flexibility to change their mobile premises without having to go through the licensure process to obtain a new license in the event a vehicle needs to be replaced after the Mobile Hospitality License is issued.*

D. 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;

f. A copy of a valid permit issued by the Public Utilities Commission to the Marijuana Hospitality Business; and

g. Information demonstrating the proposed Mobile Premises meets the requirements in Rule 6-940(E).

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. ~~Associated Key Licenses. Associated Key licenses remain valid until the first renewal following August 1, 2019, after which such licenses will be renewed as an Owner License.~~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.

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 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;

2. 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:

i. 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 2-205.

ii. 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.

iii. 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 least once every two years, and may be fingerprinted more often at the Division's discretion.

      i. [Emergency rule expired 05/11/2021]

   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.

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.

   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.

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 ~~sections~~ 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; ~~or~~

d. A conviction of a criminal offense in which a court issued an order of collateral relief specific to the application for state licensure;

Please Note: *On July 14, 2022, Governor Polis signed Executive Order D2022-034 Protecting Colorado's Workforce and Expanding Licensing Opportunities, giving rise to the following proposed rule amendment and proposed revision in subparagraph (L)(2)(a), below.*

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

Please Note: *HB 22-1383, Concering increasing the workforce by removing barriers to employment opportunities for juveniles, minimizes hudles to employment for juveniles in the justice system with amendments to section 24-5-101, C.R.S., giving rise to the revised rule below.*

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~~, and~~ Voluntary Withdrawal, and Effect of License Surrender or Revocation on Related Applications

A. Applicant Bears the Burden of Proving It Meets Licensure Requirements. A L~~l~~icense~~, registration, or permit~~ 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 ~~l~~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 on Related Applications. If a License is voluntarily surrendered or revoked, 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 action, the related applications become moot and those moot applications will be closed by the Division without further action or notification to the Applicant.

Part 3 – Regulated Marijuana Business Operations

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, and with the photo of the Licensee visible. 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 personnel of the Licensee 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. 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. 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 subsection 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 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, 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 – 3-230

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 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:

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

ii. Tested for elemental impurities content.

a. 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.

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.

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 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.

J. Non-Marijuana Waste – Hardware and Other Manufactured Product Waste. A Licensee may Transfer solid, non-marijuana waste, such as vaporizer cartridges and hardware, to another Regulated Marijuana Business for the purpose of destruction in accordance the following requirements:

1. The waste must be clearly marked or otherwise labeled as "WASTE" prior to Transfer and must remain marked "WASTE" until destruction is complete;

2. The waste must remain separated from other Regulated Marijuana and Regulated Marijuana waste at all times;

3. The waste must be destroyed by the receiving Licensee within two weeks of receipt; and

4. Any non-marijuana waste Transferred for the purpose of destruction must be tracked in the Inventory Tracking System until destroyed.

3-300 Series – Health and Safety Regulations

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. The Division and State Licensing Authority intend to monitor data regarding Regulated Marijuana expiration dates following effectiveness and implementation of these rules, and will make any necessary changes, including but not limited to, reducing the amount of time a test result is valid prior to expiration if Licensees choose not conduct stabilization studies.

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_2.

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 standard 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 standard operating procedures must be maintained on the Licensed Premises of the Regulated Marijuana Cultivation Facility.

a. The standard operating procedures must include when, and the manner in which, all Pesticide and other agricultural chemicals are to be applied during its cultivation process.

b. The standard operating procedures must also include any methods and processes related to Decontamination of Harvest Batches.

c. If a Regulated Marijuana Cultivation Facility produces Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana made from Physical Separation-Based Concentrate, the standard 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 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.

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 standard operating procedures 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 ~~or other agricultural chemical~~ to any portion of a Regulated Marijuana plant~~, water, or feed used~~ 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 ~~or other agricultural chemical~~;

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 ~~or CAS number of any other agricultural chemical(s)~~ applied;

e. Any of the active ingredients of the Pesticide ~~or other agricultural chemical(s)~~ applied;

f. Brand name and product name of the Pesticide ~~or other agricultural chemical(s)~~ applied;

g. The restricted entry interval from the product label of any Pesticide ~~or other agricultural chemical(s)~~ applied;

h. The RFID tag number of the Regulated Marijuana plant(s) that the ~~Pesticide or other agricultural chemical(s)~~ was applied to or if applied to all plants, a statement to that effect; and

i. The total amount of each Pesticide ~~or other agricultural chemical~~ 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.

F. Expiration Date for Regulated Marijuana. Effective January 1, 2024, a Regulated Marijuana Business that produces Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, or Physical Separation-Based Marijuana Concentrate shall establish an expiration date for each type of Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, or Physical Separation-Based Marijuana Concentrate that it produces upon which the Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, or Physical Separation-Based Marijuana Concentrate will no longer be fit for consumption.

1. In the absence of testing data establishing an expiration date, the expiration date for any Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, or Physical Separation-Based Marijuana Concentrate will be 6 months from the date the Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, or Physical Separation-Based Marijuana Concentrate last passed required testing.

2. If the Regulated Marijuana Business establishes an expiration date required in this subparagraph (F), then the Regulated Marijuana Business shall determine the expiration date by conducting potency and contaminant testing pursuant to Rules 4-120 and 4-125 on the final Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, or Physical Separation-Based Marijuana Concentrate to ensure the Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, or Physical Separation-Based Marijuana Concentrate can pass potency, microbial contaminant, and water activity testing prior to the established expiration date based on testing data collected by the Regulated Marijuana Business. The Regulated Marijuana Business shall also establish ideal storage conditions used to support the expiration date.

2. If the Regulated Marijuana Business chooses not to conduct testing to support the expiration date required in this subparagraph (F), the expiration date will be 12 months from the date the Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, or Physical Separation-Based Marijuana Concentrate was last tested.

3. The Regulated Marijuana Business must enter all expiration dates for Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, or Physical Separation-Based Marijuana Concentrate into the Inventory Tracking System.

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 ~~ServSafe~~ 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 ¼ inch by ¼ 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 ¼ inch by ¼ 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.

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 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 required to be provided to a patient 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 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.

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:

   i. The distinct shape of a human, animal, or fruit; or

   ii. 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.

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 4-115(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:

~~1~~a. Polyethylene glycol (PEG);

~~2~~b. Vitamin E Acetate;

~~3~~c. Medium Chain Triglycerides (MCT Oil);

~~4~~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. Standard Operating Procedures.

1. A Regulated Marijuana Products Manufacturer must have written standard operating procedures for each category and type of Medical Marijuana Product or Retail Marijuana Product that it produces.

a. All standard operating procedures 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 standard operating procedures 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 standard 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 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.

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 standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

M. Expiration Date for Regulated Marijuana Concentrate and Regulated Marijuana Products. ~~Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers. Effective July 1, 2022, a~~A Regulated Marijuana Business~~Products Manufacturer that produces a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler~~ shall establish an expiration date for each type of Regulated Marijuana Concentrate or Regulated Marijuana Product that it produces upon which the Regulated Marijuana Concentrate or Regulated Marijuana Product ~~Vaporized Delivery Device or Pressurized Metered Dose Inhaler~~ will no longer be fit for consumption. The ~~Licensee~~ Regulated Marijuana Business shall determine the expiration date by conducting potency and contaminant testing pursuant to Rules 4-120 and 4-125 on the final Regulated Marijuana Concentrate or Regulated Marijuana Product~~Vaporizer Delivery Device or Pressurized Metered Dose Inhaler~~ prior to Transfer to ensure the Regulated Marijuana Concentrate or Regulated Marijuana Product~~Vaporizer Delivery Device or Pressurized Metered Dose Inhaler~~ can pass potency and contaminant testing prior to the established expiration date. These requirements are effective July 1, 2022 for Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers, and July 1, 2023 for all other Regulated Marijuana Concentrates and Regulated Marijuana Products.

1. When determining the expiration date for Regulated Marijuana Concentrate or Regulated Marijuana Product~~a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler~~ pursuant to this R~~r~~ule, the ~~Licensee~~ Regulated Marijuana Business shall also consider the following:

i. Any expiration dates of additives used to produce the ~~Vaporizer Delivery Device or Pressurized Metered Dose Inhaler~~Regulated Marijuana Product and Regulated Marijuana Concentrate;

ii. The interaction of the Regulated Marijuana Product and Regulated Marijuana Concentrate with any processing equipment, containers, packaging, or~~with~~ hardware; and

iii. ~~The final formulation within the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler; and~~

~~iv.~~ The ideal storage conditions for the Regulated Marijuana Concentrate or Regulated Marijuana Product Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.

2. The ~~License~~ Regulated Marijuana Business 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 and Rule 3-905.

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.

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, and proof of identification to confirm the information contained on the documents and also to judge the authenticity of the documents presented.

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;

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.

3-500 Series – Responsible Vendor Program

Basis and Purpose – 3-505

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-12-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(v), 44-203(2)(dd)(II), 44-10-609(3)(b), 44-10-1201, and 44-10-1202, C.R.S. The purpose of this rule is to establish the standards for a person, employee, manager, or Controlling Beneficial Owner, Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, Retail Marijuana Transporter, Marijuana Hospitality Businesses, and Retail Marijuana Hospitality and Sales Businesses to obtain and maintain a "responsible vendor" designation. This rule identifies Licensees required to attend the Approved Training Program and requirements to maintain a "responsible vendor" designation after initially being designated a "responsible vendor." This Rule 3-505 was previously Rules M 408, 1 CCR 212-1, and R 407, 1 CCR 212-2.

3-505 – General Standards for ~~a Regulated Marijuana Business Designated A~~ Responsible Vendor Designations

A. Pursuant to section 44-10-1202, C.R.S., a Regulated Marijuana Business Licensee, Owner Licensee, or Employee Licensee ~~Medical Marijuana Store, Accelerator Store, Retail Marijuana Store, Medical Marijuana Transporter, Retail Marijuana Transporter, or Licensed Hospitality Business~~ shall comply with these 3-500 Series Rules to be designated a "responsible vendor" of Regulated Marijuana.

B. Regulated Marijuana Business Responsible Vendor Designation. To be designated a "responsible vendor" as a Regulated Marijuana Business all Controlling Beneficial Owners with day-to-day operational control of the Licensed Premises, management personnel with responsibility over sales or training of employees who engage in sales or other consumer, primary caregiver, or patient interactions, and Employee Licensees involved in the handling and Transfer of Regulated Marijuana ~~shall attend and~~must have successfully completed an Approved Training Program.

C. Individual Responsible Vendor Designation. A person, Employee Licensee, manager, or Controlling Beneficial Owner may receive a "responsible vendor" designation upon successful completion of an Approved Training Program~~Once a Licensee is designated a "responsible vendor," all new employees involved in the handling and Transfer of Regulated Marijuana shall successfully complete the training described in these 3-500 Series Rules within 90 days of hire~~.

D. Maintaining Responsible Vendor Designation.

1. After initial successful completion of a responsible vendor program, each Controlling Beneficial Owner with day-to-day operational control of the Licensed Premises, management personnel, and Employee Licensee of a Regulated Marijuana Business, as described in subparagraph (B) of this Rule, shall successfully complete ~~the~~an Approved Training ~~p~~Program once every two years thereafter for the Regulated Marijuana Business to maintain its designation as a "responsible vendor."

2. Once a Regulated Marijuana Business License is designated a "responsible vendor," all new Controlling Beneficial Owners with day-to-day operational control, new managers, or employees with responsibility over sales or training of employees who engage in sales or other consumer, primary caregiver, or patient interactions shall successfully complete the training described in these 3-500 Series Rules within 90 days of becoming employed or an owner.

3. If an Employee Licensee with a "responsible vendor" designation leaves the employment of a Regulated Marijuana Business and is employed by another Regulated Marijuana Business, the Employee Licensee does not have to receive a new "responsible vendor" designation until the Employee Licensee's current "responsible vendor" designation expires.

4. If an Employee Licensee or Controlling Beneficial Owner has a valid "responsible vendor" designation upon hiring or becoming a Controlling Beneficial Owner, then the Regulated Marijuana Business must verify the designation within 90 days to maintain the Regulated Marijuana Business's "responsible vendor" designation.

E. Documentation Required. Information or documentation related to a "responsible vendor" designation must be maintained in accordance with Rule 3-905 of these Rules.

1. An Employee Licensee or Controlling Beneficial Owner with a valid "responsible vendor" designation is responsible for maintaining information related to the designation, including but not limited to the date(s) the Employee Licensee or Controlling Beneficial Owner took the Approved Training Program and the Responsible Vendor Training Program Provider's information.

2. A Regulated Marijuana Business is responsible for maintaining information related to a "responsible vendor" designation, including but not limited to the Employee Licensee(s) or Controlling Beneficial Owner(s) who have passed an Approved Training Program and the date(s) of such training.

F. Failure to Complete Approved Training Program or Verify Valid Responsible Vendor Designation. If within 90 days of hire an Employee Licensee or Controlling Beneficial Owner either fails to successfully complete an Approved Training Program, or the Regulated Marijuana Business fails to verify the new employee, manager, or Controlling Beneficial Owner has a valid "responsible vendor" designation, then the Regulated Marijuana Business will lose its "responsible vendor" designation.

3-600 Series – Transport and Storage

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, 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 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, 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 must be renewed annually with the Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter license it accompanies. A Medical Marijuana Store or Retail Marijuana Store must disclose to the Division any online platform provider that the Licensee has utilized during the previous year at the time of renewal.

    b. Length of Delivery Permit.

        i. A delivery permit issued with an initial or renewal license application is valid for one year and will expire at the same time as the license for the associated Medical Marijuana Store, Retail Marijuana Store, Medical Marijuana Transporter, or Retail Marijuana Transporter.

        ii. A delivery permit 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, Medical Marijuana Transporter, or Retail Marijuana Transporter. In all years after the first year, such a delivery permit will be valid for 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 or Retail Marijuana 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 or Retail Marijuana Store is located, or to the county if the Medical Marijuana Store or Retail Marijuana 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, Medical Marijuana Transporter, or Retail Marijuana Transporter must obtain a valid responsible vendor designation pursuant to section~~s 44-10-1201 or~~ 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, 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, 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

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 40 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 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 or a Retail Marijuana Store that utilizes an online platform provider:

a. The online platform provider must require that the patient or consumer choose a Medical Marijuana Store or Retail Marijuana Store before displaying the price of Regulated Marijuana to the patient or consumer; and

b. The Medical Marijuana Store or Retail Marijuana 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.

3. All delivery orders must document the following information which must be maintained pursuant to Rule 3-905 by the Medical Marijuana Store or the Retail Marijuana 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 or a Retail Marijuana 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 or Retail Marijuana 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 or Retail Marijuana 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 or Retail Marijuana 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 and Retail Marijuana Stores pursuant to a contract with the Medical Marijuana Store or Retail Marijuana 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 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, 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, 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 or Retail Marijuana 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 or Retail Marijuana 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 that also hold valid delivery permits

using the same Delivery Motor Vehicle and without returning to a Retail Marijuana 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 or Retail Marijuana Store.

4. A Medical Marijuana Store or Retail Marijuana 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, 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 (~~F~~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.

   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~~F~~)(~~5~~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 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 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, 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, 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, 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.

3-900 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), 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.

Please Note: *The following revisions reflect only one new record keeping requirement (see subparagraph (B)(24) – internal security controls) and otherwise seek to consolidate all record-keeping requirements that are in the rules in this Rule 3-905. Where applicable, internal rule cross-references have also been added for cohesion and consistency.*

The new requirement in subparagraph (B)(24) to maintain Internal Security Controls is intended to encourage licensees to consider how they can best prevent theft and burglary at their premises. Through documentation of a security plan, businesses will be better positioned to prevent significant losses to the business.

Additionally, the Science & Policy Work Group made recommendations to update record keeping requirements for Reduced Testing Allowances.

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.

2. Each Regulated Marijuana Business shall retain all books and records necessary to fully account for the business transactions conducted under its license for the current year and three preceding calendar years.

   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.

   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 must fully account for the transactions of the business and must include, but shall not be limited to:

   ~~a. 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 a 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.~~

~~i. 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.~~

~~b~~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).

~~c~~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.

~~d~~5. Diagram for the Licensed Premises – Diagram of all approved Limited Access Areas, Restricted Access Areas, and any permitted off-premises storage facilities.

~~e~~6. Visitor Log – List of all visitors entering Limited Access Areas or Restricted Access Areas.

~~f~~7. All records normally retained for tax purposes.

~~g~~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, standard operating procedures, and receipts relating to collection and Transfer of Marijuana Consumer Waste as required by Rule 3-240.

~~h~~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.

~~i~~11. Every Licensee shall maintain a record of its identity statement and Standardized Graphic Symbol ~~which shall be available upon request by the State Licensing Authority or Division~~. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule.

~~j~~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 as permitted by Rule 5-240(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 4-110(C)(3).

    b. Records regarding wet whole plant that was not tested for microbials pursuant to Rule 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.

~~k~~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, standard operating procedures 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.

~~l~~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.

~~m~~16. Standard Operating Procedures – All standard operating procedures as required by these Rules, including 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 standard operating procedures.

~~n~~17. Audited Product and/or Alternative Use Product Records – All records required to demonstrate compliance with Rule 5-325 and 6-325.

~~o. All records required by Rule 3-240 regarding collection and Transfers of Marijuana Consumer Waste.~~

~~p~~18. Corrective Action and Preventive Action records required by Rules 5-115, 5-210, 5-310, 6-110, 6-210, 6-310.

~~q~~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).

~~r~~20. Records required to be maintained by Delivery Permit holders including delivery order requirements and contracts for delivery pursuant to Rule 3-615.

~~s. Records required to be maintained by Licensed Hospitality Businesses.~~

~~t~~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.

~~u~~22. All records related to Material Changes as required by Rules 3-330(D) and 3-335(L).

~~v~~23. Records related to Adverse Health Events as required by Rule 3-920.

~~w~~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 5-115(D).

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 documents required by Rules 3-330(F) and 3-335(M).

30. 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. Documentation required to demonstrate valid responsible vendor designation(s).

~~x~~33. All other records required by these Rules.

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 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.

~~B~~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.

~~C~~E. Violation Affecting Public Safety. Violation of this Rule may constitute a license violation affecting public safety.

~~D. 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 until the Regulated Marijuana is destroyed or Transferred to another Regulated Marijuana Business, a consumer, a patient, or a Pesticide Manufacturer.~~

~~E. 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.~~

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 – 3-920

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. 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. A Regulated Marijuana Business must also maintain a copy of this written report with its business records as required in Rule 3-905.

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

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.

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. The expiration date and storage conditions as determined by Rules 3-330(F) or 3-335(M).

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. 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;

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.

vi. The expiration date and storage conditions as determined by Rules 3-330(F) or 3-335(M).

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 and Immature Plants 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 or Immature plants to another Regulated Marijuana Business:

1. 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. Prior to Transfer to a Regulated Marijuana Business, Immature plants shall be placed into a receptacle. The receptacle may but is not required to be Child-Resistant.

3. 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.

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 ½ of an inch by ½ 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. RFID Tag Required. Licensees shall ensure that either the multiple Containers placed within a Shipping Container each have an RFID tag, or the Shipping Container itself must have an RFID tag. If the Licensee elects to place the RFID 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 RFID 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 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. 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, Trim, and Seeds. Any Regulated Marijuana flower, 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.

12. Expiration Date. All Regulated Marijuana shall include an expiration date on the label pursuant to Rules 3-330(F) or 3-335(M).

13. Storage Conditions. All Regulated Marijuana shall include storage conditions determined by Rules 3-330(F) or 3-335(M) on the label.

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 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. 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 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 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).~~Repealed.

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).~~Repealed.

l. Expiration Date and Recommended Storage Condition. The label must also include the expiration date and storage conditions required by Rules 3-330(F) and 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 ¼ of an inch by ¼ 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 ~~as follows~~:

i. ~~Single-Serving Liquid Edible Medical Marijuana Product Liquid Edible Retail Marijuana Product. Each Liquid Edible Medical Marijuana Product and Liquid Edible Retail Marijuana Product that is a Single-Serving must be packaged in a Child-Resistant Container~~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:

a. 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

b. 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:

a. Packaged in a structure that uses a single mechanism to achieve both Child-Resistant properties and accurate pouring measurement of each liquid serving; and

b. 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. 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.**"

k. Expiration Date and Recommended Storage Condition. The label must also include the expiration date and storage conditions required by Rules 3-330(F) and 3-335(M).

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; 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 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 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."**

j. Expiration Date and Recommended Storage Condition. The label must also include the expiration date and storage conditions required by Rules 3-330(F) and 3-335(M).

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 plants 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 plant 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 plant was grown, the Retail Marijuana Cultivation Facility where the Retail Marijuana that produced the seeds or the Immature plant was grown, or the Accelerator Cultivator where the Retail Marijuana that produced the seeds or the Immature plant was grown; and

        ii. The Medical Marijuana Store that sold the seeds or Immature plant to the patient, the Retail Marijuana Store that sold the seeds or Immature plant to the consumer, or the Accelerator Store that sold the seeds or Immature plant to the consumer.

    b. Universal Symbol. The Universal Symbol on the front of the Container holding seeds and the receptacle containing each Immature plant, 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 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.

Part 4 – Regulated Marijuana Testing Program

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 Sample Submission. A Regulated Marijuana Business may be required by the Division to submit a Sample(s) 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. Samples 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 Sample(s) 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 Sample was taken, until it passes all required testing.

B. Methods for Determining Required Testing.

1. Random Testing. The Division may require Samples 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 Samples 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 4-100 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 Sample Types. The Division may also require a Regulated Marijuana Business to submit Samples comprised of items other than Regulated Marijuana to be tested for contaminants which may include, but may not be limited to, Pesticide, microbials, molds, elemental impurities, residual solvents, biological contaminants, and chemical contaminants. The following is a non-exhaustive list of the types of Samples 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 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. 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.

b. Failed~~ing~~ R&D Test Results. If a Harvest or Production Batch fails an R&D test ~~that is a contaminant or potency test required by these rules~~, it does not require compliance with failed test procedures. *See* Rule 4-135~~. A Licensee cannot achieve a Reduced Testing Allowance if a Harvest or Production Batch fails an R&D test that is required by contaminant and potency testing rules. *See* Rules 4-120 and 4-125. If a Licensee has a Reduced Testing Allowance, and fails an R&D test that is required by contaminant and potency testing rules, the Licensee must comply with Rules 4-120(F)(2) and 4-125(H)(2)~~.

c. Failed R&D Test Results – Reduced Testing Allowance. A failing R&D test that is a contaminant or potency test required by these Rules shall be considered a failing result for the purposes of achieving or maintaining a Reduced Testing Allowance.

i. If a Regulated Marijuana Business that is actively working to achieve a Reduced Testing Allowance fails a R&D test, it must restart the process of achieving Reduced Testing Allowance.

ii. If a Regulated Marijuana Business that has achieved and maintained a Reduced Testing Allowance fails a R&D test for a test type required by these Rules, I t must follow the appropriate Reduced Testing Allowance re-authorization procedure for the failed test type to maintain that Reduced Testing Allowance. *See* Rules 4-120(F)(2)(b), 4-121(H), and 4-125(H)(2)(b).

F. 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;

    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 Samples 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. *See* Rule 4-110(A)(5) -Test Batch Container and Packaging.

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 ~~may~~ shall not accept a Test Batch that is smaller than its standard minimum amount.

2. A Regulated Marijuana Testing Facility ~~may~~ shall not accept a Test Batch that does not contain the minimum number and weight of Sample Increments, or the Regulated Marijuana Testing Facility ~~it has reason to believe knows~~ was not collected ~~taken~~ in accordance with Test Batch collection requirements in ~~these r~~Rule 4-110~~s or proceed with testing of a Test Batch for which adulteration is suspected, unless otherwise permitted by Rule 4-105(E), and except a Regulated Marijuana Testing Facility may~~

~~accept a Test Batch that was collected by Division representatives or that was collected by a Licensee pursuant to Division direction~~.

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)

Substance	**Acceptable Limits**	**Product to be Tested**
–Shiga-toxin producing *Escherichia coli* (STEC)*- Bacteria	Absent in 1 g	• Regulated Marijuana flower, shake, and trim (other than wet whole plant allocated for extraction); • Regulated Marijuana Products
Salmonella species* – Bacteria	Absent in 1 g	
Aspergillus (A. fumigatus, A. flavus, A. niger, A. terreus)	Absent in 1 g	

Total Yeast and Mold	< 1.0 x 10^4 Colony Forming Unit (CFU) per 1 ml or 1 g	(other than Audited Product); • Pre-Rolled Marijuana; • Infused Pre-Rolled Marijuana; • Physical Separation-Based, Heat/Pressure-Based, and Food-Based Medical Marijuana Concentrate; • Physical Separation-Based, Heat/Pressure-Based, and Food-Based Retail Marijuana Concentrate; • Industrial Hemp Products; • Pressurized Metered Dose Inhalers; • Vaporizer Delivery Device; • Solvent-Based Medical Marijuana Concentrate produced through Remediation; • Solvent-Based Retail Marijuana Concentrate produced through Remediation; • Solvent-Based Medical Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials; • Solvent-Based Retail Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials; • Re-testing of Regulated Marijuana flower, shake, and trim that has undergone Decontamination.
	≤ 1.0 x 10^1 CFU/ml or ≤ 1.0 x 10^1 CFU/g	Audited Product: administration by metered dose nasal spray or vaginal administration
	≤ 1.0 x 10^2 CFU/ml or ≤ 1.0 x 10^2 CFU/g	Audited Product: rectal administration
Total aerobic microbial count	≤ 1.0 x 10^2 CFU/ml or ≤ 1.0 x 10^2 CFU/g	Audited Product: administration by metered dose nasal spray or vaginal administration
	≤ 1.0 x 10^3 CFU/ml or ≤ 1.0 x 10^3 CFU/g	Audited Product: rectal administration
Staphylococcus aureus	Absent in 1 ml or 1 g	Audited Product: administration by metered dose nasal spray or vaginal administration

Pseudomonas aeruginosa	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
Candida albicans	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.

1.5 Water Activity

Substance	**Acceptable Limits**	**Product to be Tested**
Water Activity	0.65 aW	• Regulated Marijuana flower shake, and trim (other than wet whole plant); • Retesting of Regulated Marijuana flower, shake, and trim that has undergone Decontamination; • Pre-Rolled Marijuana; • Infused Pre-Rolled Marijuana.

2. Mycotoxins

Substance	**Acceptable Limits**	**Product to be Tested**
Aflatoxins (B1, B2, G1, and G2)	< 20 Parts Per Billion (PPB) (total of B1 + B2 + G1 + G2)	• Solvent-Based Medical Marijuana Concentrate manufactured from Medical Marijuana flower or trim that failed microbial testing; • Solvent-Based Retail Marijuana Concentrate manufactured from Retail Marijuana flower or trim that failed microbial testing; • Solvent-Based Medical Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials; • Solvent-Based Retail Marijuana Concentrate produced from Regulated Marijuana wet whole plant that was not tested for microbials; • Regulated Marijuana flower, shake, and trim that has
Ochratoxin A	< 20 PPB	

		undergone Decontamination.

3. Residual Solvents

Substance	**Acceptable Limits**	**Product to be Tested**
Acetone	< 1,000 Parts Per Million (PPM)	• Solvent-Based Medical Marijuana Concentrate; • Solvent-Based Retail Marijuana Concentrate; • Industrial Hemp Product (if a solvent was used)
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	
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

Substance	**Acceptable Limits Based on Intended Use**	**Product to be Tested**
Elemental Impurities (Arsenic, Cadmium, Lead and Mercury)	**Inhaled Product or Audited Product: administration by metered dose nasal spray** Lead – Max Limit: < .5 PPM Arsenic – Max Limit: < 0.2 PPM Cadmium – Max Limit: < 0.2 PPM Mercury – Max Limit: < 0.1 PPM	• Regulated Marijuana flower, shake, trim, and wet whole plant; • Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate; • Physical Separation-Based, Food-Based,
	Topical and/or Transdermal Lead – Max Limit: < 10 PPM Arsenic – Max Limit: < 3 PPM Cadmium – Max Limit: < 3 PPM Mercury – Max Limit: < 1 PPM	

	Oral Consumption or Audited Product: rectal or vaginal administration Lead – Max Limit: < 1 PPM Arsenic – Max Limit: < 1.5 PPM Cadmium – Max Limit: < 0.5 PPM Mercury – Max Limit: < 1.5 PPM	Heat/Pressure-Based and Solvent Based Retail Marijuana Concentrate; • Regulated Marijuana Product; • Pre-Rolled Marijuana; • Infused Pre-Rolled Marijuana; • Pressurized Metered Dose Inhaler; • Vaporizer Delivery Device; • Audited Product; • Industrial Hemp Product

5. Pesticides.

a. Effective January 1, 2023, the following pesticides are currently subject to required testing, at the associated action limits:

Substance	**Action Limit**	**Product to be Tested**
Abamectin (Avermectins: B1a & B1b)	< 0.0~~7~~1 PPM	• Regulated Marijuana flower, shake, trim, and wet whole plant; • Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate; • Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Retail Marijuana Concentrate; • Pre-Rolled Marijuana; • Infused Pre-Rolled Marijuana. • Industrial Hemp Product
Azoxystrobin	< 0.02 PPM	
Bifenazate	< 0.02 PPM	
Etoxazole	< 0.02~~1~~ PPM	
Imazalil	< 0.05~~4~~ PPM	
Imidacloprid	< 0.02 PPM	
Malathion	< 0.02~~5~~ PPM	
Myclobutanil	< 0.02~~4~~ PPM	
Permethrin (mix of isomers)	< 0.5~~04~~ PPM	
Spinosad (Mixture of A and D)	< 0.1~~06~~ PPM	
Spiromesifen	< 3.0~~.03~~ PPM	
Spirotetramat	< 0.02 PPM	
Tebuconazole	< 0.05~~1~~ PPM	

b. Effective July 1, 2023, the following pesticides will be subject to required testing, at the associated action limits:

Substance	**Action Limit**	**Product To Be Tested**

Abamectin (Avermectins B1a & B1b)	< 0.1 PPM	• Regulated Marijuana flower, shake, trim, and wet whole plant; • Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate; • Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Retail Marijuana Concentrate; • Pre-Rolled Marijuana; • Infused Pre-Rolled Marijuana. • Industrial Hemp Product
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	
Etoxazole	< 0.02 PPM	
Imazalil	< 0.05 PPM	
Imidacloprid	< 0.02 PPM	
Malathion	< 0.02 PPM	
Metalaxyl	< 0.02 PPM	
Myclobutanil	< 0.02 PPM	
Permethrins	< 0.5 PPM	
Propiconazole	< 0.1 PPM	
Pyriproxyfen	< 0.01 PPM	
Spinosad	< 0.1 PPM	
Spriomesifen	< 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:

Substance	**Action Limit**	**Product To Be Tested**
Abamectin (Avermectins B1a & B1b)	< 0.1 PPM	• Regulated Marijuana flower, shake, trim, and
Acephate	< 0.02 PPM	

Acequinocyl	< 0.03 PPM	wet whole plant; • Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate; • Physical Separation-Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Retail Marijuana Concentrate; • Pre-Rolled Marijuana; • Infused Pre-Rolled Marijuana. • Industrial Hemp Product
Acetamiprid	< 0.1 PPM	
Aldicarb	< 1.0 PPM	
Allethrin	< 0.2 PPM	
Atrazine	< 0.025 PPM	
Azoxystrobin	< 0.02 PPM	
Benzovindiflupyr	< 0.02 PPM	
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	<.01 PPM	
Dimethoate	< 0.02 PPM	
Dimethomorph	< 0.05 PPM	
Dinotefuran	< 0.1 PPM	
Diuron	< 0.125 PPM	
Dodemorph	< 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	
Imidacloprid	< 0.02 PPM	
Iprodione	< 1.0 PPM	
Kinoprene	< 0.5 PPM	
Krosoxim-methyl	< 0.02 PPM	
Malathion	< 0.02 PPM	
Metalaxyl	< 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	
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	
Spriomesifen	< 3.0 PPM	
Spirotetramat	< 0.02 PPM	
Spiroxamine	< 0.1 PPM	
Tebuconazole	< 0.05 PPM	
Tebuenozide	< 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	

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.

~~Pesticide~~	~~If the Test Batch is found to contain banned prohibited Pesticide not listed in paragraph (5) above, or the improper application of a permitted Pesticide, then that Test Batch shall be considered to have failed contaminant testing.~~
~~Chemicals~~	~~If the Test Batch is found to contain levels of any chemical that could be toxic if consumed or as applied, then the Division may determine that the Test Batch has failed contaminant testing.~~
~~Microbials~~	~~If the Test Batch is found to contain levels of any microbial that could be toxic if~~

	~~consumed or present, then the Division may determine that the Test Batch has failed contaminant testing.~~
~~Elemental Impurities~~	~~If the Test Batch is found to contain levels of any elemental impurities that could be toxic if consumed or present then the Division may determine that the Test Batch has failed contaminant testing.~~

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 Samples 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.

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.

G. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Please Note: *The following redlines addressing Reduced Testing Allowance were presented at the August 12th Science & Policy Stakeholder meeting. The Division continues to evaluate available data and the proposed revisions and may make additional revisions to the proposed rules ahead of the permanent rulemaking hearing.*

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 (42 days) but no longer than a 12-week period (84 days) passed all contaminant tests required by Paragraph (C) of this Rule. If the Licensee produces at least four Harvest Batches per week during this period, then the Licensee may achieve Reduced Testing Allowance in a three-week period (21 days) but no longer than a 12-week period (84 days). This must include at least six Test Batches. The period begins from the date of the creation of the first Harvest Batch that passed process validation 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. 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).

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 (28 days) but no longer than an eight-week period (56 days) passed all contaminant tests required by Paragraph (C) of this Rule. If the Licensee produces at least four Production Batches per week during this period, then the Licensee may achieve a Reduced Testing Allowance in a two-week period (14 days), but no longer than an eight-week period (56 days). This must include Test Batches from at least four Production Batches. This period begins from the date of the creation of the first Production Bach that passed process validation 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 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, once every 30 days a Regulated Marijuana Business shall subject at least one Harvest Batch to all contaminant testing required by Paragraph (C) of this Rule. If a Licensee produces more than six Harvest Batches subject to the allowance during that 30-day period, they shall subject at least two Harvest Batches 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 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 Samples.

   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 a Licensee produces more than four Production Batches subject to the allowance during that 30-day period, they shall subject at least two Production Batches 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.

C. 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, Industrial 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(E)(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.

    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 Pesticide, chemical contaminants, biological contaminants, or other types of microbials, 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(B) 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.

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 ~~six~~three-week (21 days) period but no longer than a 12-week (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 36 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 Samples.

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 appliable.

d. Origin Verification. Verification of the Regulated Marijuana Business that cultivated the wet whole plant used to manufacture the Regulated Marijuana Concentrate.

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).

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 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.

Please Note: *The following proposed rule revisions in subsection E.1(2) reorganize the paragraph for additional clarity and do not make any substantive change to what the rule already requires.*

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~~a Regulated Marijuana Business shall have potency tests conducted according to paragraph (~~F~~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 ~~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. 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.

~~i. If the Licensee fails to comply with Paragraph (F)(2) of this Rule, the Regulated Marijuana Business is no longer granted a Reduced Testing Allowance for the ongoing potency testing requirement.~~

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-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 Samples.

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. ~~Notification. A Regulated Marijuana Products Manufacturer must notify the Regulated Marijuana Testing Facility of a Material Change~~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.

Part 5 – Medical Marijuana Business License Types

5-100 Series – Medical Marijuana Stores

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

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, ~~T~~the new primary Medical Marijuana Store shall maintain:

1. ~~w~~Written authorization from the patient;~~,~~

2. ~~any relative plant count waiver to support the number of ounces of Medical Marijuana (excluding Medical Marijuana Products and Medical Marijuana Concentrate) included in its on-hand inventory for that patient, a~~A hard or electronic copy of the patient's registry card;~~, and~~

3. ~~a~~A copy of the patient's proof of identification; and.~~ *See also* Rule 3-905 – Business Records Required.~~

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. 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 provide the patient with the tangible educational resource created by the State Licensing Authority regarding the use of Regulated Marijuana Concentrate

D. Repealed.

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 Medical Marijuana 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. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

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 ~~over~~ 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.

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 (C)(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. The patient is homebound;

B. The uniform certification form specifically states that the patient needs more than eight grams of Medical Marijuana Concentrate if a patient is ~~over~~ 21 years or 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.

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 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. Violation Affecting Public Safety. Violation of this Rule may be considered a license violation affecting public safety

5-200 Series – Medical Marijuana Cultivation Facility: License Privileges

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~~(5)~~, 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.

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 to another Medical Marijuana Cultivation Facility prior to testing if such Transfer is for the purpose of Decontamination and only after all other steps outlined in the Medical Marijuana Cultivation Facility's standard 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 standard 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;

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 standard 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.

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.

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, and Immature Plants. A Medical Marijuana Cultivation Facility shall only 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.

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 – 5-235

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), ~~and~~ 44-10-502(9)(a)-(c), 44-10-502(9.5), and 3~~9~~8-28.8-~~302(2)(b)~~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 ~~from Retail~~of Regulated Marijuana ~~to Medical 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 RFID 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 4-100 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. Bothe 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 Medial 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.

5-300 Series – Medical Marijuana Products Manufacturers

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~~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;

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 Manufactures.

   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.

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. Industrial Hemp Product Authorized. This subparagraph (C)(1) is effective July 1, 2020. A Medical Marijuana Products Manufacturer that uses Industrial 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 Industrial Hemp Product for use as an Ingredient in a Medical Marijuana Product the Medical Marijuana Products Manufacturer shall verify the following:

i. That the Industrial Hemp Product has passed all required testing pursuant to the 4-100 Series Rules at a Medical Marijuana Testing Facility; and

ii. That the Person Transferring the Industrial Hemp Product to the Medical Marijuana Products Manufacturer is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, 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. Samples Provided for Testing.

1. A Medical Marijuana Products Manufacturer may provide samples 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.

Please Note: *MED proposes the following rule revision as clarification and clean up pursuant to HB 21-1216 allowing the transfer of Retail Marijuana Concentrate to a Medical Marijuana Products Manufacturer.*

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_2, 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 standard 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 standard operating procedures 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 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 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_2.

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_2 Solvent Determination. If CO_2 is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO_2 gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or CO_2 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 standard operating procedures 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 standard operating procedures 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.

Please Note: *The following proposed rule revision was submitted as a written comment by a stakeholder to address worker safety with similar protections that are already in place for remediating metals*.

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.

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 4-120(C)(3).

F. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose – 5-335

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)(III), and 44-10-503, 44-10-503(12)(a)-(b), and 3~~8~~9-28.8-~~302(2)(b)~~297, C.R.S. The purpose of this rule is to allow a Medical Marijuana Products Manufacturer to receive Transfers of Retail Marijuana Concentrate from a Retail Marijuana Products Manufacturer in order to change its designation from "Retail" to "Medical."

5-335 – Medical Marijuana Products Manufacturer: Ability to Change Designation from Retail Marijuana Concentrate to Medical Marijuana Concentrate.

A. Changing Designation: Beginning July 1, 2022, a Medical Marijuana Products Manufacturer may accept Retail Marijuana Concentrate from a Retail Marijuana Products Manufacturer in order to change its designation from Retail Marijuana Concentrate to Medical Marijuana Concentrate pursuant to the following requirements:

1. The Medical Marijuana Products Manufacturer may only accept Retail Marijuana Concentrate that has passed all required testing;

2. The Medical Marijuana Products Manufacturer and the Retail Marijuana Products Manufacturer ~~are co-located~~share a Licensed Premises in accordance with Rule 3-215;

3. The Medical Marijuana Products Manufacturer and Retail Marijuana Products Manufacturer have at least one identical Controlling Beneficial Owner;

4. The Medical Marijuana Products Manufacturer must receive the Transfer and designate the inventory as Medical Marijuana Concentrate in the Inventory Tracking System the same day. The Medical Marijuana Products Manufacturer must assign and attach an RFID tag reflecting its Medical Marijuana Products Manufacturer license number to the Medical Marijuana Concentrate following completion of the Transfer in the Inventory Tracking System;

5. After the designation change, the Medical Marijuana Concentrate 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; and

6. 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.

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 Samples of Medical Marijuana from Medical Marijuana Businesses for testing and research purposes only, which purposes may include the provision of testing services for Samples submitted by a Medical Marijuana Business for the purpose of product development. The Division may require a Medical Marijuana Business to submit a Sample of Medical Marijuana to a Medical Marijuana Testing Facility upon demand.

C. Testing of Industrial Hemp Product Authorized.

1. A Medical Marijuana Testing Facility may accept and test samples of Industrial Hemp Products.

2. Before a Medical Marijuana Testing Facility accepts a sample of Industrial 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 pursuant to section 25-5-426, C.R.S.

3. A Medical Marijuana Testing Facility is responsible for entering and tracking samples of Industrial 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 Industrial 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 Industrial Hemp Product to the Person submitting the sample of Industrial Hemp Product.

6. Nothing in these rules shall be construed to require a Medical Marijuana Testing Facility to accept and/or test samples of Industrial Hemp Product.

D. Testing Medical Marijuana for Patients in Research Project. A Medical Marijuana Testing Facility is authorized to accept 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 Samples to Another Licensed and Certified Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility may Transfer Samples 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.

G. Authorized Medical Marijuana Transport. A Medical Marijuana Testing Facility is authorized to utilize a licensed Medical Marijuana Transporter to transport Samples 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 Samples of Medical Marijuana for testing.

H. 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 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 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 Sample to another Medical Marijuana Testing Facility.

D. Destruction of Received Samples. A Medical Marijuana Testing Facility shall properly dispose of all Samples it receives, that are not Transferred to another Medical Marijuana Testing Facility, after all necessary tests have been conducted and any required period of storage. *See* Rule 3-230 – Waste Disposal.

E. 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 or Samples 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 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. Industrial Hemp Testing Prohibited. A Medical Marijuana Testing Facility shall not perform testing on Industrial Hemp.

I. Testing of Unregistered or Untracked Industrial Hemp Products Prohibited. A Medical Marijuana Testing Facility is authorized to accept or test Industrial Hemp Product only if (1) the entity providing the Samples of Industrial Hemp Product is registered and regulated pursuant to Article 4 or Title 25, C.R.S., and (2) the Industrial Hemp Product being submitted for testing is tracked in the Inventory Tracking System.

J. Violation Affecting Public Safety. Failure to comply with this Rule may constitute 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 or testing analyst, or both, for a Medical Marijuana Testing Facility.

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, 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 standard 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 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 Samples, perform test procedures and report test results promptly and 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 standard 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.

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 ~~three~~ 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 ~~three~~ 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. ~~h~~Have at least a bachelor's degree in one of the natural sciences and one year of full-time experience in laboratory testing;

a. Have a least a bachelor's degree in one of the natural sciences;

b. Have earned an associated 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 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. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

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 standard operating procedures manual standards 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 standard operating procedure manual must include, but need not be limited to, procedures for:

1. ~~Sample~~ Test Batch receiving;

2. Test Batch ~~Sample~~ accessioning;

3. Test Batch ~~Sample~~ storage;

4. Identifying, ~~and~~ rejecting, and reporting unacceptable Test Batches~~Samples~~;

5. Recording and reporting discrepancies during Test Batch receiving and accessioning;

6. Security of Test Batches~~Samples~~, aliquots and extracts and records;

7. Validating a new or revised method prior to testing of Test Batches ~~Samples~~ 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 ~~A~~aliquoting ~~Samples~~ Test Batches to avoid contamination and carry-over;

9. ~~Sample~~ Test Batch archive retention to assure stability, as follows:

   a. For ~~Samples~~ Test Batches~~that comprise Test Batches~~ submitted for testing other than Pesticide contaminant testing, ~~Sample~~ Test Batch archive retention for 14 days;

   b. For ~~Samples~~ Test Batches~~that comprise Test Batches~~ submitted for Pesticide contaminant testing, ~~Sample~~ Test Batch retention for 90 days.

10. Disposal of ~~Samples~~Test Batches;

11. The theory and principles behind each assay;

12. Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to National Institute of Standards of Technology (“NIST”);

13. Special requirements and safety precautions involved in performing assays;

14. Frequency and number of control and calibration materials;

15. Recording and reporting assay results;

16. Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;

17. Pertinent literature references for each method;

18. 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. Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns;

20. ~~A documented system for r~~Reviewing the results of testing calibrators, controls, standards, and ~~subject tests~~Test Batch results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results~~. Are corrective actions implemented and documented, and does the laboratory contact the requesting entity~~; ~~and~~

21. Policies and procedures to follow when ~~Samples~~ 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 ne 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 4-135(D) and 4-135(D.1)).

B. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Please Note*:* *Redline rules in subparagraphs (G) through (J) are proposed to add analytical sections for the testing categories of Microbials and Water Activity - currently nothing in the rule outlines analytical requirements for these two categories in which labs already seek certification. In contrast to chemistry which has several analytical method requirements outlined, Water Activity and Microbials do not. The recommended redlines add the most important items from the CDPHE checklists to MED Rule in order to codify their necessity. The redline also adds a requirement for microbial methods to allow adequate time and nutrient media in order to achieve exponential growth to assure pathogen detection as required in 4-115 (D)(1) is met. The intent of the rule was also further clarified by including a decimal in 10^4 (1.0x10^4) to mean <10,000 instead of <10,000 – 99,999. In addition, a rule recommendation was put forward to add matrix categories and laboratory validation/verification requirements in order to encompass the endless variety of matrices tested but not always necessarily verified as part of daily laboratory activities.*

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;

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.

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;

2. Document the changes of septa as specified in the standard operating procedure;

3. Document liners being cleaned or replaced as specified in the standard operating procedure;

4. Ensure that records are maintained and readily available to the staff operating the equipment;

5. Maintain records of mass spectrometric tuning;

6. Establish written criteria for an acceptable mass-spectrometric tune;

7. Document corrective actions if a 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 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.

C. Immunoassays. A Medical Marijuana Testing Facility using Immunoassays must:

1. Perform and document preventive maintenance as required by the manufacturer;

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 Sample is not included within the 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. 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 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 Medical Marijuana Testing Facility using HPLC must:

1. Perform and document preventive maintenance as required by the manufacturer;

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.

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;

2. Ensure that records are maintained and readily available to the staff operating the equipment;

3. Maintain records of mass spectrometric tuning;

4. Document corrective actions if a 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 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.

G. Microbial Assays. A Medical Marijuana Testing Facility using microbial assays must:

1. Perform and document preventive maintenance as required by the manufacturer and standard operating 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 sample submitted for testing is not included within the types of Test Batches approved by the manufacturer;

4. Verify the method at the action levels 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 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 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. Qualitative microbial methods must include an enrichment in which test samples are diluted with an appropriate nutritive growth media and incubated at an appropriate time/temperature to achieve exponential growth of the target analyte(s), if present. Enrichment broth and incubation times/temperatures must be validated or, if vendor validated and approved, verified prior to implementation;

9. 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.

H. Water Activity. A Medical Marijuana Testing Facility analyzing water activity must:

1. Perform and document preventive maintenance as required by the manufacturer and standard operating 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;

5. Establish criteria for acceptable instrument performance.

I. ~~Other~~ Analytical Methodology. A Medical Marijuana Testing Facility must validate new ~~using other~~ methodology and revalidate any changes to approved~~or new~~ methodology prior to testing Test Batches. A Medical Marijuana Testing Facility must:

1. 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

   b. Verification of Precision

   c. Verification of Analytical Sensitivity

   d. Verification of Analytical Specificity

   e. Verification of the LOD

   f. Verification of the LOQ

   g. Verification of the Reportable Range

   h. Identification of Interfering Substances

2. Validation of the other or new methodology must be documented.

3. Prior to use, other or new methodology must have a standard operating procedure approved and signed by the laboratory director.

4. Testing analysts must have documentation of competency assessment prior to testing Samples.

5. Any changes to the approved other or new methodology must be revalidated and documented prior to testing Samples.

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 4-115(D). The laboratory shall independently determine the category of matrix a product falls within; properties to consider include fat content, 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 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 Industrial Hemp Product must be tested as received, must not be manipulated, and tested in a manner that ensures results are representative of sample as received.

L. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose – 5-435

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.

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 standard operating procedures.

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 Samples 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.

J. 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 and must include, but is not limited to:

1. Review of instrument preventive maintenance, repair, troubleshooting and corrective actions documentation must be performed by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of actions taken over time;

2. Review by the laboratory director or designated 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 standard operating procedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.

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 standard 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 corrective 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 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 standard 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 calibrators throughout the reporting range;

9. For qualitative analyses, analyzing, at minimum, a negative and a positive control with each 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 acceptability criteria as defined in the Standard Operating 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 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 standard operating procedures manual for the test or tests to be performed.

C. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

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 Samples 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 chain of custody and ~~Sample~~ Test Batch requirement instructions that must include, but not be limited to;

1. Issue instructions for the minimum Test Batch ~~Sample~~ 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~~Sample~~;

3. Document the condition and amount of Test Batch ~~Sample~~ provided at the time of receipt;

4. Document all persons handling the original Test Batches~~Samples~~, aliquots, and extracts;

5. Document all Transfers of Test Batches~~Samples~~, aliquots, and extracts referred to another certified Medical 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~~Samples~~;

10. Ensure Test Batches~~Samples~~ are stored appropriately; ~~and~~

11. Document the disposal of Test Batches~~Samples~~, 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.

B. 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 accession numbers, ~~Sample~~ Test Batch type, and acceptable reference range parameters;

3. Standard Operating Procedures;

4. Personnel Records;

5. Chain of Custody Records, including documentation of rejected Test Batches;

6. Proficiency Testing Records; and

7. Analytical Data to include data generated by the instrumentation, raw data calibration standards, and curves.

C. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

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 44-10-604, 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. If a Medical Marijuana Testing Facility is not compliant with the certification requirements in Rule 5-415, the Division identifies errors or deviations in testing results or procedures, or the Division discovers a risk to public health or safety that could result from any testing processes for any certified testing category, the Division may immediately suspend the Licensees' testing category certification in accordance with section 24-4-104, C.R.S., and the 8-200 Series Rules.

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 Licensee 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~~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 receivesd directly from ~~the a originating~~ 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. 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. 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.

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 ~~the receiving~~ 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 ~~originating~~ 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 plants.

5-600 Series – Medical Marijuana Business Operators

Basis and Purpose – 5-620

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 establish records retention standards for a Medical Marijuana Business Operators. This Rule 5-620 was previously Rule M 1704, 1 CCR 212-1.

5-620 – Medical Marijuana Business Operators: Business Records Required

A. General Requirement. A Medical Marijuana Business Operator must maintain all required business records as set forth in Rule 3-905 - Business Records Required, except that:

1. A Medical Marijuana Business Operator is not required to maintain secure facility information, diagrams of its designated place of business, or a visitor log for its separate place of business, because a Medical Marijuana Business Operator will not come into contact with Medical Marijuana at its separate place of business; and

2. A Medical Marijuana Business Operator is not required to maintain records related to inventory tracking, or transport, because a Medical Marijuana Business Operator is prohibited from engaging in activities on its own behalf that would require inventory tracking or transport. All records relating to inventory tracking activities and records related to transport pertaining to the Medical Marijuana Business(es) operated by the Medical Marijuana Business Operator shall be maintained at the Licensed Premises of such Medical Marijuana Business(es).

B. All records required to be maintained shall be maintained ~~at the Medical Marijuana Business Operator's separate place of business, and not~~ at the Licensed Premises of the Medical Marijuana Business(es) it operates.

Part 6 – Retail Marijuana Business License Types

6-100 Series – Retail Marijuana Stores

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:

    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 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. Sales over the Internet. ~~A Licensee is prohibited from selling Retail Marijuana over the internet. Any Transfer of Retail Marijuana must occur within the Retail Marijuana Store's Restricted Access Area.~~ Only a ~~Licensee~~ Retail Marijuana Store holding a valid delivery permit taking orders for delivery may make sales over the internet or deliver to a private residence.

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 an Industrial Hemp Product including, but not limited to, cigarettes or tobacco products, 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 ~~46 or 47~~3, 4, or 5 of Title ~~12~~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 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 Retail Marijuana 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 standard operating procedures for the management and storage of Retail Marijuana inventory and the sale of Retail Marijuana to consumers. A written copy of the standard operating procedures must be maintained on the Licensed Premises.

1. 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.

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

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.

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 to another Retail Marijuana Cultivation Facility prior to testing if such Transfer is for the purpose of Decontamination and only after all other steps outlined in the Retail Marijuana Cultivation Facility's standard 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 standard 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 standard operating procedures 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.

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. Samples Provided for Testing. A Retail Marijuana Cultivation Facility may provide Samples 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.

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 and Immature Plants. A Retail Marijuana Cultivation Facility shall only 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.

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 – 6-230

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), and 3~~98~~-28.8-~~302(2)(b)~~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 ~~from Retail~~of Regulated Marijuana ~~to Medical 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 ~~are co-located~~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 4-100 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 RFID 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.

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~~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.

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. Industrial Hemp Product Authorized. This subparagraph (C)(1) is effective July 1, 2020. A Retail Marijuana Products Manufacturer that uses Industrial 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 Industrial Hemp Product for use as an Ingredient in a Retail Marijuana Product the Retail Marijuana Products Manufacturer shall verify the following:

        i. That the Industrial Hemp Product has passed all required testing pursuant to the 4-100 Series Rules at a Retail Marijuana Testing Facility; and

        ii. That the Person Transferring the Industrial Hemp Product to the Retail Marijuana Products Manufacturer is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

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. Samples Provided for Testing. A Retail Marijuana Products Manufacturer may provide samples 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 – 6-315

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_2, 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 standard operating 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 standard operating 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 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.

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_2.

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 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_2 Solvent Determination. If CO_2 is used as solvent at the Licensed Premises, then the Industrial Hygienist or Professional Engineer must determine whether a CO_2 gas monitoring system must be installed within the room in which Retail Marijuana Concentrate is to be produced or CO_2 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 standard operating procedures 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.

Please Note: *The following proposed rule revision was submitted as a written comment by a stakeholder to address worker safety with similar protections that are already in place for remediating metals*.

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.

f. The Licensee must establish and train employees on standard operating procedures 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 4-120(C)(4).

F. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Basis and Purpose – 6-335

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)(b)(III), and 44-10-603, 44-10-603(15)(a)-(b), and 3~~9~~8-28.8-30~~2(2)(b)~~0 C.R.S. The purpose of this rule is to allow a Medical Marijuana Products Manufacturer to receive Transfers of Retail Marijuana Concentrate from a Retail Marijuana Products Manufacturer in order to change its designation from "Retail" to "Medical."

6-335 – Retail Marijuana Products Manufacturer: Ability to Change Designation from Retail Marijuana Concentrate to Medical Marijuana Concentrate.

A. Changing Designation: Beginning July 1, 2022, a Retail Marijuana Products Manufacturer may Transfer Retail Marijuana Concentrate to a Medical Marijuana Products Manufacturer in order to change its designation from Retail Marijuana Concentrate to Medical Marijuana Concentrate pursuant to the following requirements:

1. The Retail Marijuana Products Manufacturer may only Transfer Retail Marijuana Concentrate that has passed all required testing;

2. The Medical Marijuana Products Manufacturer and the Retail Marijuana Products Manufacturer ~~are co-located~~share a Licensed Premises in accordance with Rule 3-215;

3. The Medical Marijuana Products Manufacturer and Retail Marijuana Products Manufacturer have at least one identical Controlling Beneficial Owner;

4. The Retail Marijuana Products Manufacturer must report the Transfer in the Inventory Tracking System the same day that the change in designation from Retail Marijuana Concentrate to Medical Marijuana Concentrate occurs;

5. After the designation change, the Medical Marijuana Concentrate 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; and

6. The Transfer and change in designation does not create a right to a refund of any Retail Marijuana excise tax incurred or paid prior to the Transfer and change in designation.

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.

B. Testing of Retail Marijuana Authorized. A Retail Marijuana Testing Facility may accept Samples of Retail Marijuana from Retail Marijuana Businesses for testing and research purposes only. The Division may require a Retail Marijuana Business to submit a Sample 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 Samples to Another Licensed and Certified Retail Marijuana Testing Facility. A Retail Marijuana Testing Facility may Transfer Samples 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 Industrial Hemp Authorized.

1. A Retail Marijuana Testing Facility may accept and test Industrial Hemp as regulated by Article 61 of Title 35, C.R.S.

2. Before a Retail Marijuana Testing Facility accepts a sample of Industrial 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 ~~may only accept samples that are tracked through the radio frequency identification-based inventory tracking system approved by the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-105.5, C.R.S.~~is responsible for entering tracking samples of Industrial Hemp in the Inventory Tracking System pursuant to the 3-800 Series Rules.

4. A Retail Marijuana Testing Facility shall be permitted to test Industrial 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 Industrial Hemp to the Person submitting the sample of Industrial Hemp and to the Colorado Department of Agriculture.

6. Nothing in these rules shall be construed to require a Retail Marijuana Testing Facility to accept and/or test Samples of Industrial Hemp.

F. Testing of Industrial Hemp Product Authorized.

1. A Retail Marijuana Testing Facility may accept and test samples of Industrial Hemp Products.

2. Before a Retail Marijuana Testing Facility accepts a sample of Industrial 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 pursuant to section 25-5-426, C.R.S.

3. A Retail Marijuana Testing Facility is responsible for entering and tracking samples of Industrial 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 Industrial 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 Industrial Hemp Product to the Person submitting the sample of Industrial Hemp Product.

6. Nothing in these rules shall be construed to require a Retail Marijuana Testing Facility to accept and/or test samples of Industrial Hemp Product.

G. Authorized Retail Marijuana Transport. A Retail Marijuana Testing Facility is authorized to utilize a licensed Retail Marijuana Transporter to transport Samples 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 Samples of Retail Marijuana for testing.

H. 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

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.

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 to another Retail Marijuana Testing Facility.

D. Destruction of Received Samples. A Retail Marijuana Testing Facility shall properly dispose of all Samples 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. 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 or Samples 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 Industrial Hemp must use the Inventory Tracking System to ensure all samples of Industrial 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 Industrial 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 Sample records with the Inventory 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 Industrial Hemp or Industrial Hemp Products Prohibited.

1. A Retail Marijuana Testing Facility is authorized to accept or test Industrial Hemp only if (1) the entity providing the Samples of Industrial Hemp is regulated by Article 61 of Title 35, C.R.S., (2) the Industrial Hemp is submitted by a registered cultivator, and (3) the Industrial Hemp is tracked ~~through the radio frequency identification-based inventory tracking system approved by the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-105.5, C.R.S~~in the Inventory Tracking System.

2. A Retail Marijuana Testing Facility is authorized to accept or test Industrial Hemp Product only if (1) the entity providing the Samples of Industrial Hemp Product is registered and regulated pursuant to Article 4 or Title 25, C.R.S., and (2) the Industrial Hemp Product being submitted for testing is tracked in the Inventory Tracking System.

I. Violation Affecting Public Safety. Failure to comply with this Rule may constitute 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 or testing analyst, or both, for a Retail Marijuana Testing Facility.

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, 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 standard 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 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 Samples, 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 standard 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.

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 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. A combination of education and experience may substitute for the three 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 have at least a bachelor's degree in one of the natural sciences and one year of full-time experience in laboratory 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. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

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 standard operating procedure manual standards 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 standard operating procedure manual must include, but need not be limited to, procedures for:

1. ~~Sample~~ Test Batch receiving;

2. Test Batch ~~Sample~~ accessioning;

3. Test Batch ~~Sample~~ storage;

4. Identifying, ~~and~~ rejecting, and reporting unacceptable Test Batches~~Samples~~;

5. Recording and reporting discrepancies during Test Batch receiving an accessioning;

6. Security of Test Batches~~Samples~~, aliquots and extracts and records;

7. Validating a new or revised method prior to testing of Test Batches ~~Samples~~ 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 ~~A~~aliquoting Test Batches ~~Samples~~ to avoid contamination and carry-over;

9. Test Batch archive~~Sample~~ retention to assure stability, as follows:

a. For Test Batches ~~Samples that comprise Test Batches~~ submitted for testing other than Pesticide contaminant testing, Test Batch ~~Sample~~ retention for 14 days;

b. For Test Batch ~~Samples that comprise Test Batches~~ submitted for Pesticide contaminant testing, Test Batch ~~Sample~~ retention for 90 days.

10. Disposal of Test Batches~~Samples~~;

11. The theory and principles behind each assay;

12. Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to National Institute of Standards of Technology ("NIST");

13. Special requirements and safety precautions involved in performing assays;

14. Frequency and number of control and calibration materials;

15. Recording and reporting assay results;

16. Protocol and criteria for accepting or rejecting analytical Procedure to verify the accuracy of the final report;

17. Pertinent literature references for each method;

18. 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. Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns;

20. ~~A documented system for r~~Reviewing the results of testing calibrators, controls, standards, and Test Batch ~~subject tests~~ 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; and~~

21. Policies and procedures to follow when Test Batch ~~Samples~~ are requested for referral and testing by another certified Retail Marijuana Testing Facility or an approved local or state agency's laboratory; ~~.~~

22. Testing Industrial Hemp, if the Retail Marijuana Testing Facility tests Industrial 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 4-135(d) and 4-135(D.1));

B. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

Please Note: *Redline rules (G) through (J) are proposed to add analytical sections for the testing categories of Microbials and Water Activity - currently nothing in the rule outlines analytical requirements*

for these two categories in which labs already seek certification. In contrast to chemistry which has several analytical method requirements outlined, Water Activity and Microbials do not. The recommended redlines add the most important items from the CDPHE checklists to MED Rule in order to codify their necessity. The redline also adds a requirement for microbial methods to allow adequate time and nutrient media in order to achieve exponential growth to assure pathogen detection as required in 4-115 (D)(1) is met. The intent of the rule was also further clarified by including a decimal in 10^4 (1.0x10^4) to mean <10,000 instead of <10,000 – 99,999. In addition, a rule recommendation was put forward to add matrix categories and laboratory validation/verification requirements in order to encompass the endless variety of matrices tested but not always necessarily verified as part of daily laboratory activities.

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;

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.

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;

2. Document the changes of septa as specified in the standard operating procedure;

3. Document liners being cleaned or replaced as specified in the standard operating procedure;

4. Ensure that records are maintained and readily available to the staff operating the equipment;

5. Maintain records of mass spectrometric tuning;

6. Establish written criteria for an acceptable mass-spectrometric tune;

7. Document corrective actions if a 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 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.

C. Immunoassays. A Retail Marijuana Testing Facility using Immunoassays must:

1. Perform and document preventive maintenance as required by the manufacturer;

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 Sample is not included within the 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. 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;

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.

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;

2. Ensure that records are maintained and readily available to the staff operating the equipment;

3. Maintain records of mass spectrometric tuning;

4. Document corrective actions if a 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 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.

G. Microbial Assays. A Retail Marijuana Testing Facility using microbial assays must:

1. Perform and document preventive maintenance as required by the manufacturer and standard operating 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 sample is not included within the types of Test Batches approved by the manufacturer;

4. Verify the method at the action levels 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 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. Qualitative microbial methods must include an enrichment in which test samples are diluted with an appropriate nutritive growth media and incubated at an appropriate time/temperature to achieve exponential growth of the target analyte(s), if present. Enrichment broth and incubation times/temperatures must be validated or, if vendor validated and approved, verified prior to implementation;

9. 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.

H. Water Activity. A Retail Marijuana Testing Facility analyzing water activity must:

1. Perform and document preventive maintenance as required by the manufacturer and standard operating 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;

5. Establish criteria for acceptable instrument performance.

I. ~~Other~~ Analytical Methodology. A Retail Marijuana Testing Facility ~~using other~~must validate new methodology ~~or new~~and revalidate any changes to approved methodology prior to testing Test Batches. A Retail Marijuana Testing Facility must:

1. 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

   b. Verification of Precision

   c. Verification of Analytical Sensitivity

   d. Verification of Analytical Specificity

   e. Verification of the LOD

   f. Verification of the LOQ

   g. Verification of the Reportable Range

   h. Identification of Interfering Substances

2. Validation of the other or new methodology must be documented.

3. Prior to use, other or new methodology must have a standard operating procedure approved and signed by the laboratory director.

4. Testing analysts must have documentation of competency assessment prior to testing Samples.

5. Any changes to the approved other or new methodology must be revalidated and documented prior to testing Samples.

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 4-115(D). The laboratory shall independently determine the category of matrix a product falls within; properties to consider include fat content, 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 Industrial Hemp Product must be tested as received, must not be manipulated, and tested in a manner that ensures results are representative of sample as received.

L. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

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.

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 standard operating procedures.

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 Samples 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.

J. 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 and must include, but is not limited to:

1. Review of instrument preventive maintenance, repair, troubleshooting and corrective actions documentation must be performed by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of actions taken over time;

2. Review by the laboratory director or designated supervisory analyst 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 standard operating procedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.

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 standard 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 corrective 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 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 standard 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 calibrators throughout the reporting range;

9. For qualitative analyses, analyzing, at minimum, a negative and a positive control with each 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 acceptability criteria as defined in the standard operating 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 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 Standard Operating Procedures Manual for the test or tests to be performed.

C. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

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 Samples 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 and Test Batch ~~Sample~~ requirement instructions that must include, but not limited to:

1. Issue instructions for the minimum Test Batch ~~Sample~~ 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~~Sample~~;

3. Document the condition and amount of Test Batch ~~Sample~~ provided at the time of receipt;

4. Document all persons handling the original Test Batches~~Samples~~, aliquots, and extracts;

5. Document all Transfers of Test Batches~~Samples~~, 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~~Samples~~;

10. Ensure Test Batches~~Samples~~ are stored appropriately; ~~and~~

11. Document the disposal of Test Batches~~Samples~~, 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~~.~~

B. 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 Records, including accession numbers, ~~Sample~~ Test Batch type, and acceptable reference range parameters;

3. Standard Operating Procedures;

4. Personnel Records;

5. Chain of Custody Records, including documentation of rejected Test Batches;

6. Proficiency Testing Records; and

7. Analytical Data to include data generated by the instrumentation, raw data of calibration standards and curves.

C. Violation Affecting Public Safety. Failure to comply with this Rule may constitute a license violation affecting public safety.

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. If a Retail Marijuana Testing Facility is not compliant with the certification requirements in Rule 5-415, the Division identifies errors or deviations in testing results or procedures, or the Division discovers a risk to public health or safety that could result from any testing processes for any certified testing category, the Division may immediately suspend the Licensees' testing category certification in accordance with section 24-4-104, C.R.S., and the 8-200 Series Rules.

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 Licensee 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~~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 receive~~d~~s directly from ~~the originating~~a Retail Marijuana Business in accordance with the 3-600 Series Rules.

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. 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. If a Retail Marijuana Transporter Licensed Premises ~~is co-located~~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.

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.

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 ~~the receiving~~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 ~~originating~~ 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 delivery 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 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.

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.

6-600 Series – Retail Marijuana Business Operators

Basis and Purpose – 6-620

The statutory authority for this rule includes but is not limited to 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 records retention standards for a Retail Marijuana Business Operators. This Rule 6-620 was previously Rule R 1704, 1 CCR 212-2.

6-620 – Retail Marijuana Business Operators: Business Records Required

A. General Requirement. A Retail Marijuana Business Operator must maintain all required business records as set forth in Rule 3-905 - Business Records Required, except that:

1. A Retail Marijuana Business Operator is not required to maintain secure facility information, diagrams of its designated place of business, or a visitor log for its separate place of business, because a Retail Marijuana Business Operator will not come into contact with Retail Marijuana at its separate place of business; and

2. A Retail Marijuana Business Operator is not required to maintain records related to inventory tracking, or transport, because a Retail Marijuana Business Operator is prohibited from engaging in activities on its own behalf that would require inventory tracking or transport. All records relating to inventory tracking activities and records related to transport pertaining to the Retail Marijuana Business(es) operated by the Retail Marijuana Business Operator shall be maintained at the Licensed Premises of such Retail Marijuana Business(es).

B. All records required to be maintained shall be maintained ~~at the Retail Marijuana Business Operator's separate place of business, and not~~ at the Licensed Premises of the Retail Marijuana Business(es) it operates.

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 ~~and~~ 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.

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 for the purpose of Decontamination 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.

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. Samples Provided for Testing. An Accelerator Cultivator may provide Samples 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 and Immature Plants. An Accelerator Cultivator shall only 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 ~~t~~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.

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 – 6-730

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 398-28.8-3012(2)(b), 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 ~~from Retail~~of Regulated Marijuana ~~to Medical Marijuana~~

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 ~~are co-located~~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 4-100 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 RFID 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.

6-800 Series – Accelerator Manufacturer Licenses

Basis and Purpose – 6-830

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)(b)(III), and 44-10-603, 44-10-603(15)(a)-(b), 44-10-608, and 3~~8~~9-28.8-302,~~(2)(b)~~ C.R.S. The purpose of this rule is to allow a Medical Marijuana Products Manufacturer to receive Transfers of Retail Marijuana Concentrate from a Retail Marijuana Products Manufacturer in order to change its designation from “Retail” to “Medical.”

6-830 – Accelerator Manufacturer: Ability to Change Designation from Retail Marijuana Concentrate to Medical Marijuana Concentrate.

A. Changing Designation: Beginning July 1, 2022, an Accelerator Manufacturer may Transfer Retail Marijuana Concentrate to a Medical Marijuana Products Manufacturer in order to change its designation from Retail Marijuana Concentrate to Medical Marijuana Concentrate pursuant to the following requirements:

1. The Accelerator Manufacturer may only Transfer Retail Marijuana Concentrate that has passed all required testing;

2. The Medical Marijuana Products Manufacturer and the Accelerator Manufacturer ~~are co-located~~share a Licensed Premises in accordance with Rule 3-215;

3. The Medical Marijuana Products Manufacturer and Accelerator Manufacturer have at least one identical Controlling Beneficial Owner;

4. The Accelerator Manufacturer must report the Transfer in the Inventory Tracking System the same day that the change in designation from Retail Marijuana Concentrate to Medical Marijuana Concentrate occurs;

5. After the designation change, the Medical Marijuana Concentrate cannot be Transferred to the originating Accelerator Manufacturer 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; and

6. The Transfer and change in designation does not create a right to a refund of any Retail Marijuana excise tax incurred or paid prior to the Transfer and change in designation.

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~~complete annual~~ responsible vendor ~~training that~~

~~satisfies the requirements of the responsible vendor program established~~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”

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 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. 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 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.

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."

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;

   e. If applicable, the automatic vehicle identification tag associated with the Mobile Premises; and

   f. A copy of 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.

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 2-260(D).

6-1100 Series – Accelerator Store Licenses

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 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 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. Sales over the Internet. A Licensee is prohibited from selling Retail Marijuana over the internet. Any Transfer of Retail Marijuana must occur within the Accelerator Store's Restricted Access Area. Only a Licensee holding a valid delivery permit may make sales over the internet or deliver to a private residence.

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 an Industrial Hemp Product including, but not limited to, cigarettes or tobacco products, 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 ~~46 or 47~~ 3, 4, or 5 of Title ~~12~~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.

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 standard operating procedures for the management and storage of Retail Marijuana inventory and the sale of Retail Marijuana to consumers. A written copy of the standard operating procedures must be maintained on the Licensed Premises.

1. 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.

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

Part 8 – Enforcement and Discipline

8-200 Series ~~–~~ Discipline and Administrative Hearings

Basis and Purpose – 8-205

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(d), 44-10-203(1)(k), 44-10-203(2)(a), 44-10-203(2)(l), 44-10-701, 44-10-901, and 24-4-105 C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(I). The purpose of this rule is to clarify how the disciplinary process for non-summary license suspensions and license revocations is initiated. This Rule 8-205 was previously Rules M and R 1301, 1 CCR 212-1 and 1 CCR 212-2.

8-205 – ~~Disciplinary Process:~~ Non-Summary Suspensions

A. How a Disciplinary Action is Initiated.

1. If the State Licensing Authority, on its own initiative or based on a complaint, has reasonable cause to believe that a Licensee has violated the Marijuana Code, any rule promulgated pursuant to it, or any of its orders, the State Licensing Authority shall issue and serve upon the Licensee an Order to Show Cause (administrative citation) as to why its license should not be suspended, revoked, restricted, fined, or subject to other disciplinary sanction.

2. The Order to Show Cause shall identify the statute, rule, regulation, or order allegedly violated, and the facts alleged to constitute the violation. The order shall also provide an advisement that the license could be suspended, revoked, restricted, fined, or subject to other disciplinary sanction should the charges contained in the notice be sustained upon final hearing.

B. Disciplinary Hearings. Disciplinary hearings will be conducted in accordance with Rule 8-220 – Administrative Hearings.

C. Renewal. The issuance of an Order to Show Cause does not relieve the Licensee of the obligation to timely comply with all license renewal requirements.

Basis and Purpose – 8-215

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(d), 44-10-203(1)(k), 44-10-203(2)(a), 44-10-203(2)(l), 44-10-701, 44-10-901, 24-4-104(4)(a), and 24-4-105, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(I). The State Licensing Authority recognizes that if Licensees are not able to care for their products during a period of active suspension, then their plants could die, their edible products could deteriorate, and their on-hand inventory may not be properly maintained. Accordingly, this rule was written to clarify that Licensees whose licenses are summarily suspended may care for on-hand inventory, manufactured products, and plants during the suspension (unless the State Licensing Authority does not allow such activity), provided the Licensed Premises and all Regulated Marijuana is adequately secured. In addition, the rule clarifies what activity is always prohibited during such suspension. This Rule 8-215 was previously Rules M and R 1303, 1 CCR 212-1 and 1 CCR 212-2.

8-215 – Suspension Process: Regular and Summary Suspensions

A. Signs Required During Suspension. Every Licensee whose license has been suspended, whether summarily or after an administrative hearing, shall post two notices in conspicuous places, one on the exterior and one on the interior of its premises, for the duration of the suspension. The notices shall be at least 17 inches in length and 11 inches in width containing lettering not less than 1/2'' in height.

1. For suspension following issuance of a Final Agency Order, the sign shall be in the following form:

   NOTICE OF SUSPENSION

   REGULATED MARIJUANA LICENSES ISSUED

   FOR THESE PREMISES HAVE BEEN

   SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY

   FOR VIOLATION OF THE COLORADO MARIJUANA CODE

2. For a summary suspension pending issuance of a Final Agency Order, the sign shall be in the following form:

   NOTICE OF SUSPENSION

   REGULATED MARIJUANA LICENSES ISSUED

   FOR THESE PREMISES HAVE BEEN

   SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY

   FOR ALLEGED VIOLATION OF THE COLORADO MARIJUANA CODE

Any advertisement or posted signs that indicate that the premises have been closed or business suspended for any reason other than by the manner described in this Rule shall be deemed a violation of these rules.

B. Prohibited Activity During Active Suspension.

1. Unless otherwise ordered by the State Licensing Authority, during any period of active license suspension the Licensee shall not permit the serving, giving away, distribution, manufacture, sampling, acquisition, purchase, testing, Transfer, or transport of Regulated Marijuana on or from the Licensed Premises, nor allow patients or consumers to enter the Licensed Premises.

2. Unless otherwise ordered by the State Licensing Authority, during any period of suspension the Licensee may continue to possess, maintain, cultivate, or harvest Regulated Marijuana on the Licensed Premises. The Licensee must fully account for all such Regulated Marijuana in the Inventory Tracking System. The Licensee must safeguard any Regulated Marijuana in its possession or control. The Licensee must possess and 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 set forth in the Marijuana Code and the rules of the State Licensing Authority.

C. Removal and Destruction of Regulated Marijuana. Regulated Marijuana shall not be removed from the Licensed Premises or destroyed unless:

1. The provisions described in section 44-10-902, C.R.S., related to the proper destruction of unauthorized marijuana are met, and the State Licensing Authority orders forfeiture and destruction. *See also* Rule 8-115 – Disposition of Unauthorized Regulated Marijuana;

2. The Licensee has voluntarily surrendered the Regulated Marijuana in accordance with Rule 8-110(C) – Voluntary Surrender; or

3. The State Licensing Authority has seized the Regulated Marijuana pursuant to an Administrative Warrant. *See* Rule 8-130 – Administrative Warrant.

D. Renewal. The issuance of an Order to Show Cause ~~suspension~~ or an Order of Summary Suspension does not relieve the Licensee of the obligation to timely comply with all license renewal requirements. The Division's approval of any renewal application filed by a Licensee while subject to an Order to Show Cause or an Order of Summary Suspension shall not constitute a Final Agency Order or an agreement to a settlement of the administrative action. The Licensee shall continue to comply with the requirements of this Rule pending a Final Agency Order resolving the Order of Summary Suspension and any related Order to Show Cause.

Basis and Purpose – 8-220

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(d), 44-10-203(1)(k), 44-10-203(2)(a), 44-10-203(2)(l), 44-10-204(1)(a), 44-10-701, 44-10-901, 24-4-104, and 24-4-105, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(I). The purpose of this rule is to establish what entity conducts the administrative hearings, the procedures governing administrative hearings, and other general hearings issues. The purpose of the modifications to this rule is to clarify that the hearing following the Order of Summary Suspension concerns the allegations set forth in the Order to Show Cause, and to clarify that an answer is required only for two types of administrative notices: an Order to Show Cause and a Notice of Grounds for Denial. This Rule 8-220 was previously Rules M and R 1304, 1 CCR 212-1 and 1 CCR 212-2.

8-220 – Administrative Hearings

A. General Procedures.

1. Hearing Location. Hearings will generally be conducted by the Department's Hearings Division. Hearings will be held virtually unless otherwise ordered by the hearing officer for

good cause. "Good cause" for an in-person hearing means that there are unusual circumstances where justice, judicial economy, and convenience of the parties would be served by holding a hearing in person. The Division, Respondent or Denied Applicant may request a hearing officer order an in-person hearing upon a showing of good cause. If the hearing officer orders an in-person hearing, the hearing will be conducted at a location in the greater Denver metropolitan area to be determined by the hearing officer.

2. Scope of Hearing Rules. This Rule shall be construed to promote the just and efficient determination of all matters presented.

3. Right to Legal Counsel. Any Denied Applicant or Respondent has a right to legal counsel throughout all processes described in rules associated with the denial of an application and disciplinary action. Such counsel shall be provided solely at the Denied Applicant's or Respondent's expense. Unless a Denied Applicant or Respondent that is an entity ~~or Respondent that is an entity~~ satisfies the exception in section 13-1-127(2), C.R.S., the Denied Applicant or Respondent must be represented by an attorney admitted to practice law in the state of Colorado.

4. Service. Service of pleadings or other papers on a Denied Applicant, Respondent, or any attorney representing a party, may be made by hand delivery, by mail to the party's last known address, or by electronic mail. Service of pleadings or other papers on the Division in an administrative hearing may be made to the attorney(s) of record, as identified on the Certificate of Service to the Order to Show Cause, Order of Summary Suspension, or Notice of Denial, by electronic mail or first-class mail.

B. Requesting a Hearing.

1. A Denied Applicant that has been served with a Notice of Denial may request a hearing within 60 days of the service of the Notice of Denial by making a written request for a hearing to the Division. The request must be submitted by United States mail or by hand delivery. Email or fax requests will not be considered. The request must be sent to the mailing address of the Division's headquarters, as listed on the Division's website. Include "Attn: Hearing Request" in the mailing address. The written request for a hearing must be received by the Division within the time stated in the Notice of Denial. An untimely request for hearing will not be considered.

2. A Denied Applicant that timely requests a hearing following issuance of a Notice of Denial shall be served with a Notice of Grounds for Denial, and shall be entitled to a hearing regarding the matters addressed therein.

3. A Respondent that has been served with an Order to Show Cause shall be entitled to a hearing regarding the matters addressed therein.

C. When a Responsive Pleading is Required.

1. A Respondent shall file a written answer with the Hearings Division and the Division within 30 days after the date of mailing of any Order to Show Cause. The written answer shall comply with the requirements of Rule 8 of the Colorado Rules of Civil Procedure. If a Respondent fails to file a required answer, the ~~H~~hearing ~~O~~officer, upon motion, may enter a default against that Person pursuant to section 24-4-105(2)(b), C.R.S. For good cause, as described in this Rule, shown, the hearing officer may set aside the entry of default within ten days after the date of such entry.

2. A Denied Applicant shall file a written answer with the Hearings Division and the Division within 30 days after the date of mailing of any Notice of Grounds for Denial. The written

answer shall comply with the requirements of Rule 8 of the Colorado Rules of Civil Procedure. If a Denied Applicant fails to file a required answer, the hearing officer, upon motion, may enter a default against that Person pursuant to section 24-4-105(2)(b), C.R.S. For good cause, as described in this Rule, shown, the hearing officer may set aside the entry of default within ten days after the date of such entry.

D. Hearing Notices.

1. Notice to Set. The Division shall send a notice to set a hearing to the Denied Applicant or Respondent in writing by electronic mail or by first-class mail to the last mailing address of record if an electronic mail address is unknown.

2. Notice of Hearing. The Hearings Division shall notify the Division and Denied Applicant or Respondent of the date, place, time, and nature of the hearing regarding denial of the license application or whether discipline should be imposed against the Respondent's license at least 30 days prior to the date of such hearing, unless otherwise agreed to by both parties. This notice shall be sent to the Denied Applicant or Respondent in writing by first-class mail to the last mailing address of record. Hearings shall be scheduled and held as soon as is practicable.

   a. If an Order of Summary Suspension has issued, the hearing on the Order to Show Cause will be scheduled and held promptly.

   b. Continuances may be granted for good cause, as described in this Rule, shown. A motion for a continuance must be timely.

   c. "Good cause" for a continuance may include but is not limited to: death or incapacitation of a party or an attorney for a party; a court order staying proceedings or otherwise necessitating a continuance; entry or substitution of an attorney for a party a reasonable time prior to the hearing, if the entry or substitution reasonably requires a postponement of the hearing; a change in the parties or pleadings sufficiently significant to require a postponement; a showing that more time is clearly necessary to complete authorized discovery or other mandatory preparation for the hearing; or agreement of the parties to a settlement of the case which has been or will likely be approved by the final decision maker. Good cause normally will not include the following: unavailability of counsel because of engagement in another judicial or administrative proceeding, unless the other proceeding was involuntarily set subsequent to the setting in the present case; unavailability of a necessary witness, if the witness' testimony can be taken by telephone or by deposition; or failure of an attorney or a party timely to prepare for the hearing.

E. Prehearing Matters Generally.

1. Prehearing Conferences Once a Hearing is Set. Prehearing conferences may be held at the discretion of the hearing officer upon request of any party, or upon the ~~H~~hearing ~~O~~officer's own motion. If a prehearing conference is held and a prehearing order is issued by the ~~H~~hearing ~~O~~officer, the prehearing order will control the course of the proceedings. ~~Such prehearing conferences may occur by telephone.~~

2. Depositions. Depositions are generally not allowed; however, a hearing officer has discretion to allow a deposition if a party files a written motion and can show why such deposition is necessary to prove its case. When a hearing officer grants a motion for a deposition, C.R.C.P. 30 controls. Hearings will not be continued because a deposition is allowed unless (a) both parties stipulate to a continuance and the hearing officer grants

the continuance, or (b) the hearing officer grants a continuance over the objection of any party in accordance with subsections (D)(2)(b) and (c) of this Rule.

3. Prehearing Statements Once a Hearing is Set. Prehearing Statements are required and unless otherwise ordered by the hearing officer, each party shall file with the hearing officer and serve on each party a prehearing statement no later than seven calendar days prior to the hearing. Parties shall also exchange exhibits at that time. Parties shall not file exhibits with the ~~H~~hearing ~~O~~officer. Parties shall exchange exhibits by the date on which prehearing statements are to be filed. Prehearing statements shall include the following information:

   a. Witnesses. The name, mailing address, and telephone number of any witness whom the party may call at hearing, together with a detailed statement of the expected testimony.

   b. Experts. The name, mailing address, and brief summary of the qualifications of any expert witness a party may call at hearing, together with a statement that details the opinions to which each expert is expected to testify. These requirements may be satisfied by the incorporation of an expert's resume or report containing the required information.

   c. Exhibits. A description of any physical or documentary evidence to be offered into evidence at the hearing. Exhibits should be identified as follows: Division using numbers and Denied Applicant or Respondent using letters.

   d. Stipulations. A list of all stipulations of fact or law reached, as well as a list of any additional stipulations requested or offered to facilitate disposition of the case.

4. Prehearing Statements Binding. The information provided in a party's prehearing statement shall be binding on that party throughout the course of the hearing unless modified to prevent manifest injustice. New witnesses or exhibits may be added only if: (1) the need to do so was not reasonably foreseeable at the time of filing of the prehearing statement; (2) it would not prejudice other parties; and (3) it would not necessitate a delay of the hearing.

5. Consequence of Not Filing a Prehearing Statement Once a Hearing is Set. If a party does not timely file a prehearing statement, the hearing officer may impose appropriate sanctions including, but not limited to, striking proposed witnesses and exhibits.

F. Conduct of Hearings.

1. The hearing officer shall cause all hearings to be electronically recorded.

2. The hearing officer may allow a hearing, or any portion of the hearing, to be conducted in real time by telephone or other electronic means. If a party is appearing by telephone, the party must provide actual copies of the exhibits to be offered into evidence at the hearing to the hearing officer when the prehearing statement is filed. Electronic filings will be accepted at: dor_regulatoryhearings@state.co.us.

3. The hearing officer shall administer oaths or affirmations to all witnesses at hearing. The hearing officer may question any witness.

4. The hearing, including testimony and exhibits, shall be open to the public unless otherwise ordered by the hearing officer in accordance with a specific provision of law.

a. Reports and other information that would otherwise be confidential pursuant to subsection 44-10-204(1)(a), C.R.S., may be introduced as exhibits at hearing.

b. Any party may move the hearing officer to seal an exhibit or order other appropriate relief if necessary to safeguard the confidentiality of evidence.

5. Court Rules.

a. To the extent practicable, the Colorado Rules of Evidence apply. Unless the context requires otherwise, whenever the word "court," "judge," or "jury" appears in the Colorado Rules of Evidence, such word shall be construed to mean a ~~H~~hearing ~~O~~officer. A hearing officer has discretion to consider evidence not admissible under such rules, including but not limited to hearsay evidence, pursuant to section 24-4-105(7), C.R.S.

b. To the extent practicable, the Colorado Rules of Civil Procedure apply. However, Colorado Rules of Civil Procedure 16 and 26-37 do not apply, although parties are encouraged to voluntarily work together to resolve the case, simplify issues, and exchange information relevant to the case prior to a hearing. Unless the context otherwise requires, whenever the word "court" appears in a rule of civil procedure, that word shall be construed to mean a ~~H~~hearing ~~O~~officer.

6. Exhibits.

a. All documentary exhibits must be paginated by the party offering the exhibit into evidence.

b. The Division shall use numbers to mark its exhibits.

c. The Denied Applicant or Respondent shall use letters to mark its exhibits.

7. The hearing officer may proceed with the hearing or enter default judgment if any party fails to appear at hearing after proper notice.

G. Post Hearing. After considering all the evidence, the hearing officer shall determine whether the proponent of the order has proven its case by a preponderance of the evidence, and shall make written findings of evidentiary fact, ultimate conclusions of fact, conclusions of law, and a recommendation. These written findings shall constitute an Initial Decision subject to review by the State Licensing Authority pursuant to the Colorado Administrative Procedure Act and as set forth in Rule 8-230 – Administrative Hearing Appeals/Exceptions to Initial Decision.

H. No Ex Parte Communication. Ex parte communication shall not be allowed at any point following the formal initiation of the hearing process. A party or counsel for a party shall not initiate any communication with a hearing officer or the State Licensing Authority, or with conflicts counsel representing the hearing officer or State Licensing Authority, pertaining to any pending matter unless all other parties participate in the communication or unless prior consent of all other parties (and any pro se parties) has been obtained. Parties shall provide all other parties with copies of any pleading or other paper submitted to the hearing officer or the State Licensing Authority in connection with a hearing or with the exceptions process.

I. Marijuana Enforcement Division representation. The Division shall be represented by the Colorado Department of Law.

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. 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 Samples of Regulated Marijuana, violations related to ~~co-located~~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, or packaging or labeling violations that directly impact patient or consumer safety. 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. 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. 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.

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. Any prior violations that the Licensee has admitted to or was found to have engaged in.

2. 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;

   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; and

   ~~d. Previously established and maintained responsible vendor designation pursuant to the 3-500 Series Rules.~~

3. Licensee's past history of success or failure with compliance checks.

4. Corrective action(s) taken by the Licensee related to the current violation or prior violations.

5. Willfulness and deliberateness of the violation.

6. Likelihood of reoccurrence of the violation.

7. 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. Owner or management personnel is the violator or has directed an employee or other individual to violate the law.

D. 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.