M 100 Series – General Applicability

Basis and Purpose – M 103

The statutory authority for this rule is found at subsection 12-43.3-202(1)(b)(I), C.R.S. 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 not intended to be a defined term, it is not capitalized.

With regard to the definition of Child-Resistant, the State Licensing Authority relied extensively upon written commentary provided by a public health agency within a Colorado hospital, which had conducted a health impact assessment of packaging regulations, looking at accidental ingestion of medical marijuana. The assessment was supported by others in the public, including industry representatives and a physician specializing in medical toxicology.

With regard to the definition of Restricted Access Area, the State Licensing Authority relied extensively upon written commentary provided by a consumer advocate.

M 103 – Definitions

Definitions. The following definitions of terms, in addition to those set forth in section 12-43.3-104, C.R.S., shall apply to all rules promulgated pursuant to the Medical Code, unless the context requires otherwise:

"Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation, visual, oral, or written, to induce directly or indirectly any Person to patronize a particular a Medical Marijuana Business, or to purchase particular Medical Marijuana or a Medical Marijuana-Infused Product. "Advertising" includes marketing, but does not include packaging and labeling. "Advertising" proposes a commercial transaction or otherwise constitutes commercial speech.

"Agreement" means any unsecured convertible debt option, option agreement, warrant, or at the Division's discretion, other document that establishes a right for a person to obtain a Permitted Economic Interest that might convert to an ownership interest in a Retail Marijuana Establishment or Medical Marijuana Business.

"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.

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

"Associated Key License" means an Occupational License for an individual who is an Owner of the Medical Marijuana Business.

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

"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. 1700.20 (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 regulation, 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;

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

"Container" means the sealed package in which Medical Marijuana or a Medical Marijuana-Infused Product is placed for sale to a patient and that has been labeled according to the requirements set forth in Rules M 1002 *et. seq.*

"Denied Applicant" means any Person whose application for licensure pursuant to the Medical Code has been denied.

"Department" means the Colorado Department of Revenue.

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

"Division" means the Marijuana Enforcement Division.

~~"Division Approved Sampler" means an individual who has completed all approval requirements, which may include but need not be limited to training, examination, and continuing education, and has a current approval from the Division to collect and transport Samples.~~

"Edible Medical Marijuana-Infused Product" means any Medical Marijuana-Infused Product that is intended to be consumed orally, including but not limited to, any type of food, drink, or pill.

"Executive Director" means the Executive Director of the Department of Revenue.

"Exit Package" means a sealed Container or package provided at the retail point of sale, in which any Medical Marijuana or Medical Marijuana-Infused Product already within a Container are placed.

"Final Agency Order" means an Order of the State Licensing Authority issued in accordance with the Medical 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 *Cannabis* in which the plant in in a light cycle intended to stimulate production of flowers, trichromes, and cannabinoids characteristic of marijuana.

"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.

"Good Cause" for purposes of denial of an initial, renewal or reinstatement license application or certification, or for purposes of discipline of a license or certification, 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 Medical Code, any rules promulgated pursuant it, 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 licensing authority; or

c. The Licensee's or the Applicant'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 an individual who has a personal history demonstrating honesty, fairness, and respect for the rights of others and for the law.

"Harvest Batch" means a specifically identified quantity of processed Medical Marijuana that is uniform in strain, cultivated utilizing the same Pesticide and other agricultural chemicals and harvested at the same time.

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

"Immature plant" means a nonflowering ~~Retail Marijuana or~~ Medical Marijuana plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping or seedling and that is in a growing container that is no larger than two inches wide and two inches tall that is sealed on the sides and bottom. Plants meeting these requirements are not attributable to a licensee's maximum allowable plant count, but must be fully accounted for in the Inventory Tracking System.

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

A. The special studies and training of such individuals shall be sufficient in the cognate sciences to provide the ability and competency to:

1. 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;

2. 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;

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

B. Any individual 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 individual 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.

"Initial Decision" means a decision of a hearing officer in the Department following a licensing, disciplinary, or other administrative hearing.

“Inventory Tracking System” means the required seed-to-sale tracking system that tracks Medical Marijuana from either the seed or immature plant stage until the Medical Marijuana or Medical Marijuana Infused-Product is sold to a customer at a Medical Marijuana Center or is destroyed.

"Inventory Tracking System Trained Administrator" means an Owner or an Occupational Licensed Licensee of a Medical Marijuana Business who has attended and successfully completed Inventory Tracking System training and who has completed any additional training required by the Division.

"Inventory Tracking System User" means an Owner or an occupationally licensed Medical Marijuana Business employee who is granted Inventory Tracking System User account access for the purposes of conducting inventory tracking functions in the Inventory Tracking System, who has been successfully trained by Inventory Tracking System Trained Administrator(s) in the proper and lawful use Inventory Tracking System, and who has completed any additional training required by the Division.

"Key License" means an Occupational License for an individual who performs duties that are key to the Medical Marijuana Business’ operation and have the highest level of responsibility. Examples of individuals who need this type of license include, but are not limited to, managers and bookkeepers but do not include an Owner.

"Licensed Premises" means the premises specified in an application for a license pursuant to the Medical Code that are owned or in possession of the Licensee and within which the Licensee is authorized to cultivate, manufacture, distribute, sell, or test Medical Marijuana in accordance with the provisions of the Medical Code and these rules.

"Licensee" means any Person licensed or registered pursuant to the Medical Code, including an Occupational Licensee.

"Limited Access Area" means a building, room, or other contiguous area upon the Licensed Premises where Medical Marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under control of the Licensee.

"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.

"Material Change" means any change that would require a substantive revision to a Medical Marijuana Business's standard operating procedures for the cultivation of Medical Marijuana or the production of a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

"Medical Code" means the Colorado Medical Marijuana Code found at sections 12-43.3-101 *et. seq*., C.R.S.

"Medical Marijuana" means marijuana that is grown and sold pursuant to the Medical Code and includes seeds and Immature Plants.

"Medical Marijuana Business" means a licensed Medical Marijuana Center, a Medical Marijuana-Infused Products Manufacturer, ~~or~~ an Optional Premises Cultivation Operation, or a Medical Marijuana Testing Facility.

"Medical Marijuana Center" means a Person that is licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-402, C.R.S., and that 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 Concentrate" means a specific subset of Medical Marijuana that was produced by extracting cannabinoids from Medical Marijuana. Categories of Medical Marijuana Concentrate include Water-Based Medical Marijuana Concentrate, Food-Based Medical Marijuana Concentrate and Solvent-Based Medical Marijuana Concentrate.

"Medical Marijuana-Infused Product" means a product infused with Medical Marijuana that is intended for use or consumption other than by smoking, including but not limited to edible products, ointments, and tinctures. Such products shall not be considered a food or drug for purposes of the "Colorado Food and Drug Act," part 4 of Article 5 of Title 25, C.R.S.

"Medical Marijuana-Infused Products Manufacturer" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-404, C.R.S.

"Medical Marijuana Testing Facility" means a public or private laboratory licensed and certified, or approved by the Division, to conduct research and analyze Medical Marijuana, Medical Marijuana-Infused Products, and Medical Marijuana Concentrate for contaminants and potency.

"Monitoring" means the continuous and uninterrupted attention to potential alarm signals that could be transmitted from a Security Alarm System located at a Medical 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 Monitoring services for a Medical Marijuana Business.

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

"Occupational License" means a license granted to an individual by the State Licensing Authority pursuant to section 12-43.3-401, C.R.S. An Occupational License may be an Associated Key License, a Key License or a Support License.

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

"Optional Premises Cultivation Operation" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-403, C.R.S.

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

"Owner" means the Person or Persons whose beneficial interest in the license is such that they bear risk of loss other than as an insurer, and have an opportunity to gain profit from the operation or sale of the establishment. Each individual Owner must have an Associated Key License. Owner includes any other Person that qualifies as an Owner pursuant to Rule M 204. The holder of a suitable Permitted Economic Interest is not an Owner.

"Permitted Economic Interest" means an Agreement to obtain an ownership interest in a Retail Marijuana Establishment or Medical Marijuana Business when the holder of such interest 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 and obtaining a license as an owner under the Retail Code or Medical Code.

"Person" means a natural person, partnership, association, company, corporation, limited liability company, or organization, or a manager, agent, owner, director, servant, officer, or employee thereof; except that "Person" does not include any governmental organization.

"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" shall not include any article that is a "new animal drug" as designated by the United States Food and Drug Administration."

"Production Batch" means (a) any amount of Medical 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 (b) any amount of Medical Marijuana Product of the same exact type, produced using the same ingredients, standard operating procedures and the same Production Batch(es) of Medical Marijuana Concentrate.

"Professional Engineer" means an individual who is licensed by the State of Colorado as a professional engineer pursuant to 12-25-101 et. seq., C.R.S.

"Proficiency Testing Samples" means performing the same analyses on the same Samples and comparing results to ensure the Samples are homogenous and stable, and also that the set of Samples analyzed are appropriate to test and display similarities and differences in results.

"Propagation" means the reproduction of Medical Marijuana plants by seeds, cuttings or grafting.

"RFID" means Radio Frequency Identification.

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

"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.

"Restricted Access Area" means a designated and secure area within a Licensed Premises in a Medical Marijuana Center where Medical Marijuana and Medical Marijuana-Infused Product are sold, possessed for sale, and displayed for sale, and where no one without a valid patient registry card is permitted.

"Retail Code" means the Colorado Retail Marijuana Code, found at sections 12-43.4-101 *et. seq* ~~,~~ 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 marijuana concentrate that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Establishment. "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.

"Retail Marijuana Concentrate" means a specific subset of Retail Marijuana that was produced by extracting cannabinoids from Retail Marijuana. Categories of Retail Marijuana Concentrate include Water-Based Retail Marijuana Concentrate, Food-Based Retail Marijuana Concentrate and Solvent-Based Retail Marijuana Concentrate.

"Retail Marijuana Cultivation Facility" means an entity licensed to cultivate, prepare, and package Retail Marijuana and sell Retail Marijuana Retail Marijuana Establishments, but not to consumers.

"Retail Marijuana Establishment" means a Retail Marijuana Store, a Retail Marijuana Cultivation Facility, a Retail Marijuana Products Manufacturing Facility, or a Retail Marijuana Testing Facility.

"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 Manufacturing Facility" means an entity licensed to purchase Retail Marijuana; manufacture, prepare, and package Retail Marijuana Product; and sell Retail Marijuana and Retail Marijuana Product to other Retail Marijuana Products Manufacturing Facilities and to Retail Marijuana Stores, but not to consumers.

"Retail Marijuana Store" means an entity licensed to purchase Retail Marijuana from a Retail Marijuana Cultivation Facility and to purchase Retail Marijuana Product from a Retail Marijuana Products Manufacturing Facility and to sell Retail Marijuana and Retail Marijuana Product to consumers.

"Retail Marijuana Testing Facility" means a public or private laboratory licensed and certified, or approved by the Division, to conduct research and analyze Retail Marijuana, Retail Marijuana Products and Retail Marijuana Concentrate for contaminants and potency.

"Sample" means anything collected ~~by Division personnel or a Division Approved Sampler~~ from a Medical Marijuana Business that is provided for testing to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility in accordance with Rule M 701 – Vendor Registration and Occupational License for Medical Marijuana Testing and Research. The following is a non-exhaustive list of types of Samples: Medical Marijuana, Medical Marijuana-Infused Product, Medical Marijuana Concentrate, soil, growing medium, water, solvent or swab of a counter or equipment.

"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).

"Shipping Container" means any container or wrapping used solely for the transport of Medical Marijuana or Medical Marijuana-Infused Product in bulk, or in a quantity for other Medical Marijuana Businesses.

"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 M 605.

"State Licensing Authority" means the authority created for the purpose of regulating and controlling the licensing of the cultivation, manufacture, distribution, and sale of Medical Marijuana and Retail Marijuana in Colorado, pursuant to section 12-43.3-201, C.R.S.

"Support License" means a license for an individual who performs duties that support the Medical Marijuana Business' operations. While a Support Licensee must conduct himself or herself professionally, he or she has limited decision making authority and always fall under the supervision of an Associated Key Licensee. Examples of individuals who need this type of license include, but are not limited to, sales clerks or cooks.

"THC" means tetrahydrocannabinol.

"THCA" means tetrahydrocannabinolic acid.

"Test Batch" means a group of Samples that are collectively submitted to a Medical Marijuana Testing Facility or a Retail Marijuana Testing Facility for testing purposes in accordance with Rule M 701 – Vendor Registration and Occupational License for Medical Marijuana Testing and Research. A Test Batch may not be a combination of any two or three of the following: Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Product.

"Universal Symbol" means the image established by the Division and made available to Licensees through the Division's website indicating the Medical Marijuana or Medical Marijuana Infused-Product contains marijuana.

"Unrecognizable" means marijuana or *Cannabis* plant material rendered indistinguishable from any other plant material.

"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.

"Water-Based Medical Marijuana Concentrate" means a Medical Marijuana Concentrate that was produced by extracting cannabinoids from Medical Marijuana through the use of only water, ice or dry ice.

Basis and Purpose – M 104

The statutory authority for this rule exists in subsections 12-43.3-202(1)(b)(I) and 24-4-105(11), and section 12-43.3-201, C.R.S. The purpose of this rule is to establish a system by which a licensee may ~~petition~~ request the Division to ~~get~~ issue a formal statement of position and, subsequently, petition ~~by the~~ State Licensing Authority for a declaratory order. Typically, a positions tatement or declaratory order would address matters~~on issues~~ that are~~will~~ likely to be applicable to other licensees. ~~By utilizing this system, Licensees can ensure that their due process rights are protected because the Administrative Procedure Act will apply.~~ The approach is similar to that utilized by~~is system works for~~ other divisions within the Department of Revenue. ~~and helps the regulated community get clarity on yet-unknown issues.~~

M 104 – Declaratory Orders Concerning the Medical Code

A. Who May ~~Petition for~~ Request a Statement of Position. Any person as defined in section 24-4-102(12), C.R.S., may ~~petition~~ request the Division to issue~~for~~ a statement of position concerning the applicability to the petitioner of any provision of the Medical Code, or any regulation of the State Licensing Authority. ~~The Division shall respond with a written statement of position within 30 days of receiving a proper petition.~~

~~A.5~~B Division Response. The Division will determine, in its sound discretion, whether to respond with a written statement of position. Following receipt of a proper request, the Division will respond by issuing a written statement of position or by declining to issue such a statement.

~~B~~C. Petition for Declaratory Order. Any person who has properly ~~petitioned~~ requested ~~the Division for~~ a statement of position, and who is dissatisfied with the Division's response~~statement of position or who has not received a response within 30 days~~, may petition the State Licensing Authority for a declaratory order pursuant to section 24-4-105(11), C.R.S. The petition shall be filed within 30 days of the Division's response, or may be filed at any time before the Division's response if the Division has not responded within 60 days of receiving a proper request for a statement of position, and~~A petition~~ shall set forth the following:

1. The name and address of the petitioner.

2. Whether the petitioner is licensed pursuant to the Medical Code or Retail Code, and if so, the type of license and address of the Licensed Premises.

3. Whether the petitioner is involved in any pending administrative hearing with the State Licensing Authority or relevant local licensing authority.

4. The statute, rule, or order to which the petition relates.

5. A concise statement of all of the facts necessary to show the nature of the controversy or the uncertainty as to the applicability to the petitioner of the statue, rule or order to which the petition relates.

6. A concise statement of the legal authorities, if any, and such other reasons upon which petitioner relies.

7. A concise statement of the declaratory order sought by the petitioner.

~~C~~D. State Licensing Authority Retains Discretion Whether to Entertain Petition. The State Licensing Authority will determine, in its discretion and without prior notice to the petitioner, whether to entertain any petition. If the State Licensing Authority decides it will not entertain a petition, it shall ~~promptly~~ notify the petitioner in writing of its decision and the reasons for that decision. Any of the following grounds may be sufficient reason to refuse to entertain a petition:

1. The petitioner failed to properly ~~petition~~ request ~~the Division for~~ a statement of position from the Division, or ~~if a statement of position was issued,~~ the petition for declaratory order was filed with the State Licensing Authority more than 30 days after the Division's response to the request for statement of position was issued.

2. A ruling on the petition will not terminate the controversy nor remove uncertainties concerning the applicability to petitioner of the statute, rule or order in question.

3. The petition involves a subject, question or issue ~~which~~ that is currently ~~involved in~~relevant to a pending hearing before the state or any local licensing authority, ~~or which is involved in~~ an on-going investigation conducted by the Division, or ~~which is involved in~~ a written complaint ~~previously~~ filed with the State Licensing Authority.

4. The petition seeks a ruling on a moot or hypothetical question.

5. Petitioner has some other adequate legal remedy, other than an action for declaratory relief pursuant to Colo. R. Civ. Pro. 57, which will terminate the controversy or remove any uncertainty concerning applicability of the statute, rule or order.

~~C.5~~E State Licensing Authority May Adopt Division Position Statement. The State Licensing Authority may adopt the Division Position Statement as a Final Agency Action subject to judicial review pursuant to section 24-4-106, C.R.S.

~~D~~F. If State Licensing Authority Entertains Petition. If the State Licensing Authority determines that it will entertain the petition for declaratory order, it shall so notify the petitioner within 30 days, and any of the following procedures shall apply:

1. The State Licensing Authority may expedite the ~~hearing~~matter~~,~~ ~~where the interests of the petitioner will not be substantially prejudiced thereby,~~ by ruling on the basis of the facts and legal authority presented in the petition, or by requesting the petitioner or the Division to submit additional evidence and legal argument in writing.

2. In the event the State Licensing Authority determines that an evidentiary hearing ~~or legal argument~~ is necessary to a ruling on the petition, a hearing shall be conducted in accordance with Rules M 1304 – Administrative Hearings, M 1305 – Administrative Subpoenas, and M 1306 – Administrative Hearing Appeals. The petitioner will be identified as Respondent.

3. The parties to any proceeding pursuant to this rule shall be the petitioner/Respondent and the Division. Any other interested ~~person~~ Person may seek leave of the State Licensing Authority to intervene in the proceeding and such leave may be granted if the State Licensing Authority determines that such intervention will make unnecessary a separate petition for declaratory order by the interested Person.

4. The declaratory order shall constitute a Final Agency Order subject to judicial review pursuant to section 24-4-106, C.R.S.

~~E. Mailing Requirements. A copy of any petition for a statement of position to the Division and of any petition for a declaratory order to the State Licensing Authority shall be mailed, on the same day that the petition is filed with the Division or State Licensing Authority, to the relevant local licensing authority. Any petition filed with the Division or State Licensing Authority shall contain a certification that the mailing requirements of this paragraph have been met.~~

~~F~~G. Public Inspection. Files of all requests, petitions, ~~requests,~~ statements of position, and declaratory orders will be maintained by the Division. Except with respect to any material required by law to be kept confidential, such files shall be available for public inspection.

~~G~~H. Posted on Website. The Division shall post a copy of all statements of position~~s or~~ and all declaratory orders ~~constituting Final Agency Orders~~ on the Division's website.

Basis and Purpose – M 106

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-501(4), C.R.S. The purpose of this rule is to establish the basic fees that must be paid at the time of service of any subpoena (including a subpoena for testimony and/or a subpoena duces tecum) upon the State Licensing Authority, and for production of documents pursuant to any such subpoena. This rule also establishes additional fees for meals, mileage, and each day's testimony. The service fee is not applicable when a subpoena is served by a governmental agency.

M 106 – Subpoena Fees

A. Required Fees for Subpoenas. The following fees must be paid at the time of service of any subpoena on the Division or State Licensing Authority.:

1. Subpoenas for records only (subpoenas duces tecum):

a. Responsive records - $0.25/page. The Division and State Licensing Authority may use discretion when electronic copies are requested.

b. The Division or State Licensing Authority may charge $25/hour to retrieve and review voluminous records.

2. Subpoenas requiring any Division or State Licensing Authority employee to attend any proceeding:

a. $200/day attendance;

b. Current state mileage reimbursement fee; and

c. Current state meal reimbursement fee.

B. When Subpoena-Related Fees Are Due.

1. Subpoenas duces tecum fees must be paid before the Division or State Licensing Authority will release the records.

2. All other subpoena-related fees are due at the time of service of the subpoena.

C. Service Complete Only When Fees Are Paid. The Division or State Licensing Authority will not consider service to be complete unless and until all applicable fees are paid.

D. State Employees and Private Litigation. Division and State Licensing Authority employees will not serve as expert witnesses in private litigation. In addition, the Division and State Licensing Authority may move to quash any subpoena that seeks fact testimony from Division or State Licensing Authority employees in private litigation.

E. Not Applicable to Government-Issued Subpoenas. This rule does not apply to subpoenas issued by any governmental agency.

M 200 Series – Licensing

Basis and Purpose – M 201

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), and 12-43.3-310(7), and sections 12-43.3-305 and 12-43.3-306, C.R.S. The purpose of this rule is to establish that only materially complete applications for licenses, accompanied by all required fees, will be accepted and processed by the Division. The State Licensing Authority understands there may be instances where an application is materially complete, but further information is required before it can be fully processed. In such instances, the applicant must provide the additional requested information within the time frame given by the Division in order for the application to be acted on in a timely manner.

M 201 – Complete Applications Required: Medical Marijuana Businesses

A. General Requirements

1. All applications for licenses authorized pursuant to subsections 12-43.3-401(1)(a)-(c.5~~d~~), C.R.S., shall be made upon current forms prescribed by the Division. ~~Applications submitted to the Division may include, but not be limited to, new business premises, transfers of ownership, change of locations, premises modifications, and changes in trade name.~~ Such applications include, but are not limited to, Medical Marijuana Centers, Optional Premises Cultivation Operations, Medical Marijuana-Infused Products Manufacturers, and Medical Marijuana Testing Facilities.

2. A license issued by the Division to a Medical Marijuana Business constitutes a revocable privilege. The burden of proving an Applicant's qualifications for licensure rests at all times with the Applicant.

3. If required by the forms supplied by the Division, each application shall identify the relevant local jurisdiction.

4. Applicants must submit a complete application to the Division before it will be accepted or considered.

   a. All applications must be complete in every material detail.

   b. All applications must include all attachments or supplemental information required by the current forms supplied by the Division.

   c. All applications must be accompanied by a full remittance for the whole amount of the application and license fees.

   d. The Applicant or its authorized agent must provide a surety bond, if applicable, and prove that all tax returns related to the Medical Marijuana Business have been timely filed;

5. The Division may refuse to accept an incomplete application.

B. Additional Information May Be Required

1. Each Applicant shall provide any additional information required that the Division may request to process and fully investigate the application. The additional

information must be provided to the Division no later than seven days of the request unless otherwise specified by the Division.

2. An Applicant's failure to provide the requested evidence or information by the Division deadline may be grounds for denial of the application.

C. Information Must Be Provided Truthfully. All Applicants shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where the Applicant made intentional or purposeful misstatements, omissions, misrepresentations, or untruths in the application or in connection with the Applicant's background investigation. This type of conduct may be considered as the basis for additional administrative action against the Applicant and it may also be the basis for criminal charges against the Applicant.

D. Application Forms Accessible. All application forms supplied by the Division and filed by an Applicant for a license, including attachments and any other documents associated with the investigation, shall be accessible by the State Licensing Authority, local licensing authorities, and any state or local law enforcement agency for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose.

E. Other Considerations Regarding Medical Marijuana Business Applications. The Applicant, if not an individual, must be comprised of individuals. If the Applicant is not an individual, each of the Applicant's individual Owners, as defined in rule M 103, including without limitation the shareholders, officers and directors of a corporation, the general, limited and managing partners of a partnership, the members and managers of a limited liability company, and any Person contracted to manage the overall operation of a Licensed Premises, must establish that:

1. ~~Whose criminal history background checks establish they~~ He or she is~~are all~~ of Good Moral Character based upon his or her criminal history background check; and

2. He or she has~~Who have~~ met all other licensing requirements.

Basis and Purpose – M 201.5

The statutory authority for this rule is found at subsections 12-43.3-104(12.3) and (12.4), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), and 12-43.3-310(7), and sections 12-43.3-305 and 12-43.3-306, C.R.S. The purpose of this rule is to establish that only materially complete applications for Permitted Economic Interests, accompanied by all required fees, will be accepted and processed by the Division. The State Licensing Authority understands there may be instances where an application is materially complete and accepted, but further information is required before it can be fully processed. In such instances, the applicant must provide the additional requested information within the time frame given by the Division in order for the application to be acted on in a timely manner.

M 201.5 – Complete Applications Required for Permitted Economic Interests: Medical Marijuana Businesses

A. Medical Marijuana Business Initiates Process. The Medical Marijuana Business seeking to obtain financing from a Permitted Economic Interest must file all required documents with the Division.

B. Agreement Requirements. The Medical Marijuana Business seeking to obtain financing from a Permitted Economic Interest must submit a copy of the Agreement between the Medical

Marijuana Business and the person seeking to hold a Permitted Economic Interest. The following requirements apply to all Agreements:

1. The Agreement must be complete.

2. The Agreement must be fully incorporated.

3. The following provisions must be included in the Agreement:

a. The [business entity][Medical Marijuana Business] shall not issue any Agreement or other interests except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the rules promulgated thereunder. The issuance of any Agreement or other interest in violation thereof shall be void and such Agreement or other interest shall be deemed not to be issued and outstanding until (a) the [business entity][Medical Marijuana Business] shall cease to be subject to the jurisdiction of the State Licensing Authority, or (b) the State Licensing Authority or its designee shall, in writing, validate said issuance or waive any defect in issuance.

b. No Agreement or other interest issued by the [business entity][Medical Marijuana Business] and no claim or charge therein or thereto shall be transferred in any manner whatsoever except in accordance with the provisions of the Medical Code and/or Retail Code as applicable, and the regulations promulgated thereunder. Any transfer in violation thereof shall be void until (a) the [business entity][Medical Marijuana Business] shall cease to be subject to the jurisdiction of the State Licensing Authority, or (b) the State Licensing Authority or its designee shall, in writing, validate said transfer or waive any defect in said transfer.

c. The [business entity][Medical Marijuana Business] must initiate the process to convert a Permitted Economic Interest to an ownership interest. The holder of the Permitted Economic Interest must meet all qualifications for licensure and ownership pursuant to the Medical Code and/or Retail Code and any rules promulgated thereunder prior to conversion of the Permitted Economic Interest to an ownership interest.

d. At the election of the Medical Marijuana Business, if the holder of the Permitted Economic Interest is unsuitable for licensure and/or ownership but is suitable as a holder of the Permitted Economic Interest, and the Permitted Economic Interest is also suitable, then the Permitted Economic Interest may remain in force and effect for as long as it maintains suitability under the Medical Code and/or Retail Code and any rules promulgated thereunder.

e. The Permitted Economic Interest holder shall disclose in writing to the Division and to the [business entity][Medical Marijuana Business] any and all disqualifying events, within ten days after occurrence of the event, that would lead to a finding of unsuitability to hold the Permitted Economic Interest and/or a denial of licensure pursuant to the Medical Code and/or Retail Code and any rules promulgated thereunder.

f. The Licensee shall disclose in writing to the Division any and all disqualifying events, within ten days after receiving notice of the event, which would lead to a finding of unsuitability the Permitted Economic Interest and/or a denial of licensure pursuant to the Medical Code and/or Retail Code and any rules promulgated thereunder.

g. Failure to make required discloses by a Permitted Economic Interest holder or a Licensee may be grounds for denial of the change of ownership.

C. General Requirements. The Medical Marijuana Business seeking to obtain financing from a Permitted Economic Interest must meet the following requirements:

1. All applications for Permitted Economic Interests shall be made upon current forms prescribed by the Division.

2. The burden of proving that an applicant for a Permitted Economic Interest is qualified to hold such an interest rests at all times with the applicant for a Permitted Economic Interest.

3. The Medical Marijuana Business seeking to obtain financing from a Permitted Economic Interest must submit a complete application to the Division before it will be accepted or considered.

4. All applications must be complete in every material detail.

5. All applications must include all attachments or supplemental information required by the current forms supplied by the Division.

6. All applications must be accompanied by a full remittance of the required fees.

7. The Division may refuse to accept an incomplete application.

8. Additional Information May Be Required

a. Upon request by the Division, either a Medical Marijuana Business that is seeking to obtain financing from a Permitted Economic Interest or the person seeking to hold a Permitted Economic Interest, or both, shall provide any additional information required to process and fully investigate the application. The additional information must be provided to the Division no later than seven days after of the request is made unless otherwise specified by the Division.

b. Failure to provide the requested information by the Division's deadline may be grounds for denial of the application.

9. Information Must Be Provided Truthfully. A Medical Marijuana Business seeking to obtain financing from a Permitted Economic Interest and the person seeking to hold a Permitted Economic Interest shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where either party made intentional or purposeful misstatements, omissions, misrepresentations or untruths in the application or in connection with the background investigation of the person seeking to hold a Permitted Economic Interest. This type of conduct may be considered as the basis for additional administrative action against the Retail Marijuana Establishment or the person seeking to hold a Permitted Economic Interest and it may also be the basis for criminal charges against either party.

10. Application Forms Accessible. All application forms supplied by the Division and filed by the Medical Marijuana Business seeking to obtain financing from a Permitted Economic Interest, including attachments and any other documents

associated with the investigation, shall be accessible by the State Licensing Authority, local jurisdictions, and any state or local law enforcement agency for a purpose authorized by the Medical Code, Retail Code, or for any other state or local law enforcement purpose.

Basis and Purpose – M 202

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), and 12-43.3-310(7), and sections 12-43.3-308, 24-4-104, and 24-76.5-101 *et. seq.,* C.R.S. The purpose of this rule is to establish basic requirements for all Division applications for new Medical Marijuana Business licenses. It helps the regulated community understand the procedural licensing requirements.

M 202 – Process for Issuing a New License: Medical Marijuana Businesses

A. General Requirements

1. All applications for state licenses authorized pursuant to subsections 12-43.3-401(1)(a)-(d), C.R.S., shall be made upon current forms prescribed by the Division. Each application for a new license shall identify the relevant local licensing authority.

2. All applications for new Medical Marijuana Businesses must include application and licensing fees for each premises. *See* Rules M 207 - Schedule of Application Fees: Medical Marijuana Businesses and M 208 - Schedule of Business License Fees: Medical Marijuana Businesses.

3. Each Applicant for a new license shall provide, at the time of application, the following information:

a. Suitable evidence of proof of lawful presence, residence, if applicable, and Good Moral Character and reputation as required by the current forms prescribed by the Division;

b. All requested information concerning financial and management associations and interests of other Persons in the business;

i. If the Applicant for any license pursuant to the Medical Code is a corporation or limited liability company, it shall submit with the application the names, mailing addresses, and Owner's background forms of all of its ~~principal~~ officers, directors, and Owners; a copy of its articles of incorporation or articles of organization; and evidence of authorization to do business within this State. In addition, each Applicant shall submit the names, mailing addresses, and Owner's background applications of all Persons owning any of the outstanding or issued capital stock, or of any Persons holding a membership interest.

ii. If the Applicant for any license pursuant to this section is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, it shall submit with the application the names, mailing addresses, and Owner's background forms of all of its partners and a copy of its partnership agreement.

c. Department of Revenue tax payment information;

d. Proof of good and sufficient surety bond, if applicable;

e. Accurate floor plans for the premises to be licensed; and

f. The deed, lease, contract, or other document governing the terms and conditions of occupancy of the premises licensed or proposed to be licensed.

Nothing in this section is intended to limit the Division's ability to request additional information it deems necessary or relevant to determining an Applicant's suitability for licensure.

4. Failure to provide such additional information by the requested deadline may result in denial of the application.

5. All applications to reinstate a license will be deemed applications for new licenses. This includes, but is not limited to, licenses that have been expired for more than 90 days, licenses that have been voluntarily surrendered, and licenses that have been revoked.

B. Other Factors

1. If the Division grants a state license before the relevant local licensing authority approves the application or grants a local license, the state license will be conditioned upon local approval. Such a condition will not be viewed as a denial pursuant to the Administrative Procedure Act. If the local licensing authority fails to approve or denies the application, the state license will be revoked.

2. An Applicant is prohibited from operating a Medical Marijuana Business prior to obtaining all necessary licenses or approvals from both the State Licensing Authority and the relevant local licensing authority.

Basis and Purpose – M 202.5

The statutory authority for this rule is found at subsections 12-43.3-104(12.3) and (12.4), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), and 12-43.3-310(7), and sections 12-43.3-308, 24-4-104, and 24-76.5-101 *et. seq,* C.R.S. The purpose of this rule is to establish basic requirements for Medical Marijuana Businesses that are seeking to obtain financing from a Permitted Economic Interest. In addition, the rule clarifies what information is required for a person seeking to hold a Permitted Economic Interest to establish he or she has lawful residency in the United States. This rule clarifies that such lawful residency must be maintained throughout the duration of holding a Permitted Economic Interest in order for a person to be a suitable holder of a Permitted Economic Interest.

M 202.5 – Process for Obtaining a Permitted Economic Interest: Medical Marijuana BUsinesses

A. General Requirements

1. All applications for Permitted Economic Interests shall be made upon current forms prescribed by the Division.

2. All applications for new Permitted Economic Interests must include the required administrative service fee. *See* M 210 – Schedule of Licensing Administrative Service Fees: All Licensees.

3. A Permitted Economic Interest approved by the Division constitutes a revocable privilege. The burden of proving the suitability of the Permitted Economic Interest rests at all times with the applicant.

B. Agreement Required. All applications for Permitted Economic Interests must include a copy of the Agreement between the Medical Marijuana Business and the person seeking to hold a Permitted Economic Interest.

1. The Agreement must be complete.

2. The Agreement must be fully incorporated.

C. Lawful Residency Required. At the time of application, a Medical Marijuana Business seeking to obtain financing from a Permitted Economic Interest shall provide suitable evidence that the person seeking to hold a Permitted Economic Interest is a lawful resident of the United States. Such evidence can be established by the following:

1. A valid Colorado driver's license;

2. U.S. military card or military dependent's identification card;

3. Certificate verifying naturalized status issued by an authorized agency of the United States bearing Applicant's intact photographs impressed with the raised embossed seal of the issuing agency;

4. Certificate verifying United States citizenship issued by an authorized agency of the United States bearing Applicant's intact photograph impressed with the raised embossed seal of the issuing agency;

5. Valid driver's license or ID card bearing Applicant's photograph issued by a lawful presence state, including the District of Columbia;

6. Valid immigration documents demonstrating lawful presence and verified through the Systematic Alien Verification for Entitlements, administered by the United States Citizenship and Immigration Services of the Department of Homeland Security Valid immigration documents are as follows:

a. Unexpired foreign passport bearing an unexpired "Processed for I-551" stamp or with an attached unexpired "Temporary I-551" visa;

b. Unexpired foreign passport accompanied by an "I-94" indicating a specific future "until" date;

c. "I-94" with refugee or asylum status; or

d. Unexpired "Resident Alien" card, "Permanent Resident" card, "Temporary Resident" card, or "Employment Authorization" card.

D. Good Moral Character. At the time of application, a Medical Marijuana Business seeking to obtain financing from a Permitted Economic Interest shall provide suitable evidence

that the person seeking the Permitted Economic Interest is of Good Moral Character as required by the current forms prescribed by the Division.

E. Additional Information. Nothing in this section is intended to limit the Division's ability to request additional information it deems necessary or relevant to determining one's suitability for holding a Permitted Economic Interest.

F. Failure to Provide Additional Information When Requested. Failure to provide such additional information by the requested deadline may result in denial of the application.

Basis and Purpose – M 203

The statutory authority for this rule is found at subsections 12-43.3-104(12.3) and (12.4),12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), and 12.43.3-307(2)(c), and section 12-43.3-311, C.R.S. The purpose of this rule is to establish how licenses can be renewed.

M 203 – Process for Renewing a License: Medical Marijuana Businesses

A. General Process for License Renewal

1. The Division will send a notice for license renewal 90 days prior to the expiration of an existing license by first class mail to the Licensee's mailing address of record.

2. A Licensee may apply for the renewal of an existing license not less than 30 days prior to the license's expiration date. If a Licensee timely applies for the renewal of an existing license, the Division may administratively continue the license beyond the expiration date while it completes the renewal licensing process.

3. If the Licensee files a renewal application within 30 days prior to expiration, the Licensee must provide a written explanation detailing the circumstances surrounding the late filing. If the Division accepts the application, then the Division ~~it~~ may elect to administratively continue the license beyond the expiration date while it completes the renewal licensing process.

~~3~~4. An application for renewal will only be accepted if it is accompanied by the requisite licensing fees. *See* Rule M 209 - Schedule of Business License Renewal Fees: Medical Marijuana Businesses.

~~4~~5. Each Owner must be fingerprinted ~~each year at renewal~~ at the Division's discretion.

B. Failure to Receive a Notice for License Renewal. Failure to receive a notice for license renewal does not relieve a Licensee of the obligation to renew all licenses as required.

C. If License Not Renewed Before Expiration. A license is immediately invalid upon expiration if the Licensee has not filed a late renewal application and remitted all of the required fees.

1. In the event the license is not renewed prior to expiration, a Medical Marijuana Business may not operate.

2. If a former Licensee files a late application and the requisite fees with the Division within 90 days of expiration of the license, the Division may

administratively continue the license from the date the late application was received until it can complete its renewal application process and investigate the extent to which the Licensee operated with an expired license.

3. If a former Licensee files a renewal application after 90 days from date of expiration, the application will be treated as a new license application.

D. Licenses Subject to Ongoing Discipline and/or Summary Suspension. Licenses that are the subject of a summary suspension, a disciplinary action, and/or any other administrative action are subject to the requirements of this rule. Licenses that are not timely renewed will expire. *See* Rules M 1301 – Disciplinary Process: Non-Summary Suspension and M 1302 – Disciplinary Process: Summary Suspensions.

E. Permitted Economic Interests. At the time of renewal, a Medical Marijuana Business shall disclose any and all Permitted Economic Interests that it is a party to. If a Medical Marijuana Business is financed by a Permitted Economic Interest, the following must accompany all renewal materials and be submitted at the time the Medical Marijuana Business submits its renewal materials:

1. Current Division Permitted Economic Interest renewal forms;

2. Current Division form, signed by the Owner(s) of the Medical Marijuana Business and the person holding the Permitted Economic Interest, allowing the holder of the Permitted Economic Interest to be investigated by the Division if the Division deems it necessary;

3. At the discretion of the Division, the holder of the Permitted Economic Interest may need to submit new fingerprints; and

4. Current Division certification form, signed by the holder of the Permitted Economic Interest, certifying that he or she:

a. Has maintained, and currently maintains, lawful residence in the United States; and

b. Has met, and currently meets, the requirements of M 231.5 – Qualifications for Permitted Economic Interests: Individuals.

Basis and Purpose – M 204

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), and 12-43.3-310(7) and section 12-43.3-310, C.R.S. The purpose of this rule is to clarify what elements the State Licensing Authority considers when determining who has a beneficial interest in a license to such an extent that one is considered an Owner.

M 204 – Factors Considered When Evaluating Ownership of a License: Medical Marijuana Businesses

A. Licenses Held By Owners. Each Medical Marijuana Business License must be held by the Owner or Owners of the licensed establishment. The Division may consider the following non-exhaustive list of elements when determining who is an Owner:

1. Who bears risk of loss and opportunity for profit;

2. Who is entitled to possession of the Licensed Premises or premises to be licensed;

3. Who has final decision making authority over the operation of the licensed Medical Marijuana Business;

4. Who guarantees the Medical Marijuana Business' debts or production levels;

5. Who is a beneficiary of the Medical Marijuana Business' insurance policies;

6. Who acknowledges liability for the Medical Marijuana Business' federal, state, or local taxes; or

7. Who is an officer or director of a Medical Marijuana Business.

B. Businesses Must Have 100% Ownership To Operate.

a. The sum of the percentages of ownership of all Owners of a Medical Marijuana Business must equal 100%, and a Medical Marijuana Business must maintain 100% ownership, held by Owners who possess current and valid Occupational Licenses. *See* Rule M 233 – Medical Code or Retail Code Occupational Licenses Required.

b. In the event of an Owner's death or Occupational License revocation, a Medical Marijuana Business shall have 45 days to submit a change of ownership application to the Division detailing how the Licensee intends to redistribute ownership among the remaining Owners.

C. Loss Of Occupational License As An Owner Of Multiple Businesses. If an Owner's Occupational License is suspended or revoked as to one Medical Marijuana Business or Retail Marijuana Establishment, that Owner's Occupational License shall be suspended or revoked as to any other Medical Marijuana Business or Retail Marijuana Establishment in which that Owner possesses an ownership interest. *See* Rule M 233 – Medical Code or Retail Code Occupational Licenses Required.

D. Management Companies. Any Person contracted to manage the overall operation of a Licensed Premises may be considered an Owner.

~~C~~E. Role of Managers. Owners may hire managers, and managers may be compensated on the basis of profits made, gross or net. A Medical Marijuana Business license may not be held in the name of the manager.

~~D~~F. Entities and Interests~~.~~

1. A partnership interest, limited or general, a joint venture interest, a licensing agreement, ownership of a share or shares in a corporation, or a limited liability company which is licensed, or having a secured interest in inventory constitutes ownership and a direct financial interest.

2. Having a secured interest in furniture, fixtures, or equipment used directly in the manufacture or cultivation of Medical Marijuana or Medical Marijuana-Infused Product~~, equipment or inventory~~ may constitute~~s~~ ownership and a direct financial interest.

~~1.~~3. Secured or unsecured notes or loans ~~shall~~ constitute a~~n indirect~~ financial interest. It shall be unlawful to fail to completely report all financial interests in each license issued.

Basis and Purpose – M 205

The statutory authority for this rule is found at subsections 12-43.3-104(12.3) and (12.4), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), ~~and~~ 12-43.3-310(7), 12-43.3-310(11), and sections 12-43.3-305, 12-43.3-306, 12-43.3-309, and 24-76.5-101 *et. seq.,* C.R.S. The purpose of this rule is to establish protocol for ownership transfers. In addition, the rule clarifies that a business cannot use the transfer of ownership process in order to circumvent the administrative disciplinary process and that an ongoing investigation or disciplinary action may: (1) constitute grounds to deny a transfer of ownership request; (2) constitute grounds to delay a transfer of ownership request, or (3) mandate that the new business owner is responsible for any imposed sanction.

M 205 – Transfer of Ownership and Changes in Licensed Entities: Medical Marijuana Businesses

A. General Requirements

1. All applications for transfers of ownership or changes in corporate entities by licensed Medical Marijuana Businesses authorized pursuant to section 12-43.3-401, C.R.S., shall be made upon current forms prescribed by the Division. Each application shall identify the relevant local licensing authority.

2. All applications for transfers of ownerships and changes in licensed entities by Medical Marijuana Businesses must include application fees, ~~and~~ be complete in every material detail, and be filled out truthfully.

3. All applications for transfers of ownership and changes in licensed entities by Medical Marijuana Businesses must be submitted to the State Licensing Authority or its designee and relevant local licensing authority 30 days prior to any requested transfer or change.

~~3~~4. Each Applicant for a transfer of ownership shall provide suitable evidence of a Person's proof of lawful presence, residence and good character and reputation that the Division may request. Each Applicant shall also provide all requested information concerning financial and management associations and interests of other Persons in the business, Department of Revenue tax payment information, proof of good and sufficient surety bond and the deed, lease, contract, or other document governing the terms and conditions of occupancy of the Licensed Premises. Nothing in this section is intended to limit the Division's ability to request additional information it deems necessary relevant to determining an Applicant's suitability for licensure.

~~4~~5. Failure to provide such additional evidence by the requested deadline may result in denial of the application.

~~5~~6. The Division will not approve a transfer of ownership application without first receiving written notification ~~and approval from the relevant local licensing authority~~that the Applicant disclosed the transfer of ownership to the relevant local licensing authority. *See* Rule M 1401 - Instructions for Local Licensing Authorities and Law Enforcement Officers.

7.~~8.~~ The Applicant(s), or proposed transferee(s), for any license shall not operate the Medical Marijuana Business identified in the transfer of ownership application until the transfer of ownership request is approved in writing by the Division. A violation of this requirement shall constitute grounds to deny the transfer of ownership request and may result in disciplinary action against the Applicant's existing license(s), if applicable.

8. The current Owner(s), or proposed transferor(s), of the license(s) at issue retain full responsibility for the Medical Marijuana Business identified in the transfer of ownership application until the transfer of ownership request is approved in writing by the Division. A violation of this requirement shall constitute grounds to deny the transfer of ownership request and may result in disciplinary action against the license(s) of the current Owner(s) and/or the Medical Marijuana Business.

9. If a Medical Marijuana Business or any Licensees affiliated or associated with the business are applying to transfer ownership and are involved in an administrative investigation or administrative disciplinary action, the following may apply:

   a. The transfer of ownership may be delayed or denied until the administrative action is resolved; or

   b. If the transfer of ownership request is approved in writing by the Division, the transferee may be responsible for the actions of the Medical Marijuana Business and its prior owners, and subject to discipline based upon the same.

10. All individuals holding a suitable Permitted Economic Interest who are converting to an ownership interest are subject to this rule M 205. The Licensee that is a party to the Permitted Economic Interest must initiate the change of ownership process for an individual holding a suitable Permitted Economic Interest who is converting its interest to ownership. Unsuitable Permitted Economic Interests and holders thereof shall not be allowed to convert to an ownership interest.

B. As It Relates to Corporations and Limited Liability Companies

1. If the Applicant ~~for any license pursuant the Medical Code~~ is a corporation or limited liability company, it shall submit with the application the names, mailing addresses, and Owner's background forms of all of its ~~principal~~ officers, directors, and Owners; a copy of its articles of incorporation or articles of organization; and evidence of its authorization to do business within this State. In addition, each Applicant shall submit the names, mailing addresses of all Persons owning any of the outstanding or issued capital stock, or of any Persons holding a membership interest.

2. Any proposed transfer of capital stock, regardless of the number of shares of capital stock transferred, ~~or any change in principal officers or directors of a corporation~~ shall be reported and approved by the State Licensing Authority or its designee and the local licensing authority at least 30 days prior to such transfer or change.

~~3. Any proposed transfer of membership interest or any change in members of any limited liability company holding a license shall be reported and approved by the State Licensing Authority and the local licensing authority prior to such transfer or change.~~

C. As It Relates to Partnerships.

~~1.~~ If the Applicant ~~for any license pursuant to the Medical Code~~ is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, it shall submit with the application the names, mailing addresses, and Owner's background forms of all of its partners and a copy of its partnership agreement.

~~2. Any proposed transfer of partnership interest or any change in general or managing partners of any partnership holding a license shall be reported and approved by the State Licensing Authority and local licensing authority prior to such transfer or change.~~

D. As It Relates to Entity Conversions. Any Licensee that qualifies for an entity conversion pursuant to sections 7-90-201, C.R.S., *et. seq*., shall not be required to file a transfer of ownership application pursuant to section 12-43.3-309, C.R.S., upon statutory conversion, but shall submit a report containing suitable evidence of its intent to convert at least 30 days prior to such conversion. Such evidence shall include, but not be limited to, any conversion documents or agreements for conversion at least ten days prior to the date of recognition of conversion by the Colorado Secretary of State. The Licensee shall submit to the Division the names and mailing addresses of any officers, directors, general or managing partners, and all Persons having an ownership interest.

E. Approval Required. It may be considered a license violation affecting public safety if a Licensee engages in any transfer of ownership without prior approval from the Division and the relevant local licensing authority.

F. Applications for Reinstatements Deemed New Applications. The Division will not accept an application for transfer of ownership if the license to be transferred is expired for more than 90 days, is voluntarily surrendered, or is revoked. *See* Rule M 202 - Process for Issuing a New License: Medical Marijuana Businesses.

Basis and Purpose – M 206

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-305, 12-43.3-310(7), and 12-43.3-310(13), and section 12-43.3-305, C.R.S. The purpose of this rule is to clarify the application process for changing location of a Licensed Premises.

M 206 – Changing Location of the Licensed Premises: Medical Marijuana Businesses

A. Application Required to Change Location of Licensed Premises

1. An Owner or other authorized representative of a Medical Marijuana Business must make application to the Division for permission to change location of its Licensed Premises.

2. Such application shall:

a. Be made upon current forms prescribed by the Division;

b. Be complete in every material detail and include remittance of all applicable fees;

c. Be submitted at least 30 days prior to the proposed change~~.~~;

~~c~~d. Explain the reason for requesting such change;

~~d~~e. Be supported by evidence that the application complies with any local licensing authority requirements; and

~~e~~f. Contain a report of the relevant local licensing authority(-ies) in which the Medical Marijuana Business is to be situated, which report shall demonstrate the approval of the local licensing authority(-ies) with respect to the new location.

B. Permit Required Before Changing Location

1. No change of location shall be permitted until after the Division considers the application, and such additional information as it may require, and issues to the Applicant a permit for such change.

2. The permit shall be effective on the date of issuance, and the Licensee shall, within 120 days, change the location of its business to the place specified therein and at the same time cease to operate a Medical Marijuana Business at the former location. At no time may a Medical Marijuana Business operate or exercise any of the privileges granted pursuant to the license in both locations. For good cause shown, the 120 day deadline may be extended for an additional 90 days.

3. The permit shall be conspicuously displayed at the new location, immediately adjacent to the license to which it pertains.

4. No change of location will be allowed except to another place within the same city, town, county or city and county in which the license as originally issued was to be exercised.

C. General Requirements

1. An application for change of location to a different local licensing authority shall follow the same procedures as an application for a new Medical Marijuana Business license. See Rule M 202 - Process for Issuing a New License: Medical Marijuana Businesses.

2. An Applicant for change of location shall file a change of location application with the Division and pay the requisite change of location fee. See Rule M 207 - Schedule of Application Fees: Medical Marijuana Businesses.

Basis and Purpose – M 210

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), and 12-43.3-202(2)(a)(XX), and sections 12-43.3-310, 12-43.3-501, and 12-43.3-502, C.R.S. The purpose of this rule is to establish basic requirements for all Division applications and help the regulated community understand procedural licensing requirements.

M 210 – Schedule of Licensing Administrative Service Fees: All Licensees

A. Administrative Service Fees. The following administrative service fees apply:

1. Transfer of Ownership - New Owners - $2,000.00

2. Transfer of Ownership - Reallocation of Ownership - $800.00

3. Change of Corporation or LLC Structure - $800.00/Person

4. Change of Trade Name - $40.00

5. Change of Location Application Fee - Same Local Jurisdiction Only - $500.00

6. Modification of Licensed Premises - $120.00

7. Duplicate Business License - $40.00

8. Duplicate Occupational License - $10.00

~~9. Duplicate Vendor Registration - $40.00~~

~~10~~9. Indirect Financial Interest Background Investigations - $150.00

10. Off Premises Storage Permit - $2,200.00

11. Subpoena Fee ~~- *$200.00*~~*See* Rule M 106 – Subpoena Fees

B. When Administrative Service Fees Are Due. All administrative service fees are due at the time each applicable request is made.

Basis and Purpose – M 211

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XVI), and 12-43.4-202(4)(b)(I)(a), 12-43.4-104, and 12-43.3-501, C.R.S. The purpose of this rule is to clarify that, with the exception of Medical Marijuana Testing Facilities, existing Medical Marijuana Businesses may apply to convert a Medical Marijuana Business License to a Retail Marijuana Establishment License or may apply to obtain one additional license to operate a Retail Marijuana Establishment. It is important to note that the State Licensing Authority considers each license issued as separate and distinct. Each license, whether it is in the same location or not, is fully responsible to maintain compliance with all statutes and rules promulgated regardless of whether or not they are located in a shared address.

A Medical Marijuana Business may only obtain one Retail Marijuana Establishment License, whether it converts the Medical Business License or obtains a Retail Marijuana Establishment License, for each Medical Marijuana Business License it holds. In order to ensure all Retail Marijuana and Retail Marijuana Product are tracked in the Inventory Tracking System and as a condition of licensure, a Medical Marijuana Business must declare in the Inventory Tracking System all Medical Marijuana and Medical Marijuana Infused-Product that are converted for sale as Retail Marijuana or Retail Marijuana Product prior to initiating or allowing any sales. This declaration may be made only once. Beginning July 1, 2016, the only allowed transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Establishment is the transfer of Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility. The marijuana subject to the one-time transfer is subject to the excise tax upon the first transfer from the Retail Marijuana Cultivation Facility to another Retail Marijuana Establishment.

The State Licensing Authority received several comments from stakeholders who requested lower fees for Medical Marijuana Businesses that were either converting a Medical Marijuana Business license to a Retail Marijuana Establishment license or obtaining an additional Retail Marijuana Establishment license while retaining the existing Medical Marijuana Business license. The adopted permanent regulations reflect changes to address this concern. Under the rules as adopted, Medical Marijuana Businesses that apply to convert to a Retail Marijuana Establishment license will be required to pay an application fee, but no license fees will be charged until such time as the renewal fees would have been due under the Medical Marijuana Business license term. The Retail Marijuana Establishment license, if approved, would assume the balance of the license term from the Medical Marijuana Business license and have the same expiration date.

M 211 –Conversion - Medical Marijuana Business to Retail Marijuana Establishment

A. Retail Marijuana Establishment Expiration Date

1. A Medical Marijuana Business converting its license to a Retail Marijuana Establishment license shall not be required to pay a license fee at the time of application for conversion.

2. If a Medical Marijuana Business licensee is scheduled to renew its license during the processing of its conversion to a Retail Marijuana Establishment license, the Medical Marijuana Business must complete all renewal applications and pay the requisite renewal licensing fees.

3. A Retail Marijuana Establishment license that was fully converted from a Medical Marijuana Business license will assume the balance of licensing term previously held by the surrendered Medical Marijuana Business license.

B. Medical Marijuana Licensees Applying for Retail Marijuana Establishments. Except for a Medical Marijuana Testing Facility, a~~A~~ Medical Marijuana Business Licensee in good standing or who had a pending application as of December 10, 2012 that has not yet been denied, and who has paid all applicable fees, may apply for a Retail Marijuana Establishment license in accordance with the Retail Code and these rules on or after October 1, 2013. A Medical Marijuana Business meeting these conditions may apply to convert a Medical Marijuana Business license to a Retail Marijuana Establishment license or may apply for a single Retail Marijuana Establishment of the requisite class of license in the Medical Marijuana Code for each Medical Marijuana Business License not converted.

C. Retail Marijuana Establishment Licenses Conditioned

1. It shall be unlawful for a Retail Marijuana Establishment to operate without being issued a Retail Marijuana Establishment license by the State Licensing Authority and receiving all relevant local jurisdiction approvals. Each Retail Marijuana Establishment license issued shall be conditioned on the Licensee's receipt of all required local jurisdiction approvals and licensing, if required.

2. Each Retail Marijuana Establishment license issued shall be conditioned on the Medical Marijuana Business Licensee's declaration of the amount of Medical Marijuana or Medical Marijuana-Infused Product it intends to transfer from the requisite Medical Marijuana Business for sale as Retail Marijuana or Retail Marijuana Product. A Retail Marijuana Establishment shall not exercise any of the rights or privileges of a Retail Marijuana Establishment Licensee until such time as all such Medical Marijuana and Medical Marijuana-Infused Product are fully transferred and declared in the Inventory Tracking System. *See also*, Rule R

309 – Inventory Tracking System. Beginning July 1, 2016, the only allowed transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Establishment is the transfer of Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility.

D. One-Time Transfer.

1. This rule M 211(D)(1) is repealed effective July 1, 2016. Prior to July 1, 2016, ~~O~~once a Retail Marijuana Establishment has declared Medical Marijuana and/or Medical Marijuana-Infused Product as Retail Marijuana or Retail Marijuana Product in the Inventory Tracking System and begun exercising the rights and privileges of the license, no additional Medical Marijuana or Medical Marijuana-Infused Product can be transferred from the Medical Marijuana Business to the relevant Retail Marijuana Establishment at any time.

2. Beginning July 1, 2016, the only allowed transfer of marijuana between a Medical Marijuana Business and a Retail Marijuana Establishment is the transfer of Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility. All other transfers are prohibited, including but not limited to transfers from a Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer to any Retail Marijuana Establishment. Once a Retail Marijuana Establishment has declared Medical Marijuana and Medical Marijuana Concentrate as Retail Marijuana or Retail Marijuana Concentrate in the Inventory Tracking System and begun exercising the rights and privileges of the license, no additional Medical Marijuana or Medical Marijuana Concentrate can be transferred from the Medical Marijuana Business to the relevant Retail Marijuana Establishment at any time.

Basis and Purpose – M 231

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), ~~and~~ 12-43.3-310(4), and 24-18-105(3), and sections 12-43.3-306, 12-43.3-401, 24-76.5-101 *et. seq,.* and 12-43.3-307, C.R.S. The purpose of this rule is clarify the qualifications for licensure, including, but not limited to, the requirement for a fingerprint-based criminal history record check for all Owners, officers, managers, contractors, employees, and other Support, Associated Key and Key Licensees.

M 231 – Qualifications for Licensure: Individuals

A. General Requirements

1. All Applicants shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where the Applicant made intentional misstatements, purposeful omissions, misrepresentations, or untruths in the application or in connection with the Applicant's background investigation. This type of conduct may be considered as the basis of additional administrative action against the Applicant and it may also be the basis for criminal charges against the Applicant.

2. The Division may deny the application of an Applicant who fails to provide the requested evidence or information by the Division deadline.

B. Other Licensing Requirements

1. Fingerprints Required

a. All Applicants for initial licensure shall be fingerprinted for a fingerprint-based criminal history record check.

b. A renewal Applicant shall be fingerprinted at the Director's discretion.

c. An Applicant shall also be fingerprinted at the Division's discretion if the Director has required the Applicant to submit a new application. The Director may require a new application for the following non-exhaustive list of reasons:

i. An Applicant is re-applying after more than one year since the expiration of his or her most recent license;

ii. If an Applicant's previous license was denied or revoked by the State Licensing Authority; or

iii. When the Division needs additional information in order to proceed with a background investigation.

2. Other Documents May Be Required. Any Applicant may be required to establish his or her identity and age by any document required for a determination of lawful presence.

3. Maintaining Ongoing Suitability For Licensing: Duty to Report Offenses. An Applicant or Licensee shall notify the Division in writing of any felony criminal charge and felony conviction against such person within ten days of such person's arrest, felony summons, and within ten days of the disposition of any arrest or summons. Failure to make proper notification to the Division may be grounds for disciplinary action. Licensees shall cooperate in any investigation conducted by the Division. This duty to report includes, but is not limited to, deferred sentences or judgments that are not sealed. If the Division lawfully finds a disqualifying event and an Applicant asserts that the record was sealed, the Division may require the Applicant to provide proof from a court evidencing the sealing of the case.

4. Application Forms Accessible to Law Enforcement and Licensing Authorities. All application forms supplied by the Division and filed by an Applicant for license shall be accessible by the State Licensing Authority, local jurisdictions, and any state or local law enforcement agent.

C. Associated Key Licenses/Owners. An Owner Applicant for an Associated Key License must meet the following criteria before receiving a license:

1. The Applicant must pay the annual application and licensing fees;

2. The Applicant's criminal history must indicate that he or she is of Good Moral Character;

3. The Applicant is not employing, or financed in whole or in party by any other Person whose criminal history indicates that he or she is not of Good Moral Character;

4. The Applicant is at least 21 years of age;

5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business or Retail Marijuana Establishment, if applicable;

6. The Applicant establishes~~can prove~~ that he or she is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;

7. The Applicant meets qualifications for licensure that directly and demonstrably relate to the operation of a Medical Marijuana Business.

~~7~~8. ~~The Applicant can prove that he or she has not discharged a sentence in the five years immediately preceding the application date for a conviction of a felony not related to possession, distribution, manufacturing, cultivation, or use of a controlled substance;~~

~~8. The Applicant can prove that he or she has not been convicted at any time of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance;~~The Applicant establishes that he or she is not currently subject to and has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer; except that the State Licensing Authority may grant a license to a person if the Applicant has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony of the Applicant were convicted of the offense on the date he or she applied for licensure'

9. The Applicant establishes ~~can establish~~ that he or she does not employ another person who does not have a valid Occupational License issued pursuant to either the Medical Code or Retail Code;

10. The Applicant establishes ~~can establishes~~ that he or she is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority;

11. The Applicant establishes that he or she was not a State Licensing Authority employee with regulatory oversight responsibilities for individuals, Retail Marijuana Establishments and/or Medical Marijuana Businesses licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application; and

~~11~~12. The Applicant establishes ~~can establish~~ that the premises he or she~~its premises proposed~~ proposes to be licensed is not currently licensed as a retail food establishment or wholesale food registrant; and

~~12~~13. The Applicant has been a resident of Colorado for at least two years prior to the date of the Application. *See* Rule M 232 – Factors Considered When Determining Residency: Individuals.

D. Support and Key Licenses~~ and Vendor Registrations~~. Beginning July 1, 2016, a Retail Marijuana Testing Facility cannot obtain an Occupational License. Prior to July 1, 2016,

anAn Occupational License Applicant for a Support License and a Retail Marijuana Testing Facility must meet the following criteria before receiving a license or vendor registration:

1. The Applicant must pay the annual application and licensing fees;

2. The Applicant's criminal history must indicate that he or she is of Good Moral Character;

3. The Applicant is at least 21 years of age;

4. An Applicant establishescan establish that he or she is currently a resident of Colorado.*See* Rule M 232 – Factors Considered When Determining Residency: Individuals;

5. The Applicant has paid all taxes, interest, or penalties due the Department of Revenue relating to a Medical Marijuana Business;

6. The Applicant establishes can prove that he or she is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;

7. The Applicant meets qualifications for licensure that directly and demonstrably relate to the operation of a medical marijuana business.

8. The Applicant can prove that he or she is not currently subject to and has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer; except that the State Licensing Authority may grant a license to a person if the person has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony of the person were convicted of the offense on the date he or she applied for licensure.

7. The Applicant can prove that he or she has not discharged a sentence in the five years immediately preceding the application date for a conviction of a felony not related to possession, distribution, manufacturing, cultivation, or use of a controlled substance;

8. The Applicant can prove that he or she has not been convicted at any time of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance, except that the State Licensing Authority may grant a license to an Applicant if the Applicant has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony if the employee were convicted of the offense on the date he or she applied for a license; and

9. The Applicant can establishes that he or she is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local licensing authority; and.

10. The Applicant establishes that he or she was not a State Licensing Authority employee with regulatory oversight responsibilities for individuals and/or Medical Marijuana Businesses licensed by the State Licensing Authority in the six months immediately preceding the date of the Applicant's application.

E. Current Medical Marijuana Occupational Licensees.

~~1.~~ An individual who holds a current, valid Occupational License issued pursuant to the Medical Code may also work in a Retail Marijuana Establishment; no separate Occupational License is required.

2. An individual who holds a current, valid Occupational License issued pursuant to the Retail Code after July 1, 2015 may also work in a Medical Marijuana Business; no separate Occupational License is required.

2~~. An individual who holds a current, valid Occupational License issued pursuant to the Retail Code shall not work at a Medical Marijuana Business unless he or she also holds a current, valid Occupational License issued pursuant to the Medical Code.~~

Basis and Purpose – M 231.5

The statutory authority for this rule is found at subsections 12-43.3-104(12.3) and (12.4), 12-43.3-201(4), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XVIII.5), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), ~~and~~ 12-43.3-310(4), and 24-18-105(3), and sections 12-43.3-306, 12-43.3-401, 24-76.5-101 *et. seq,* and 12-43.3-307, C.R.S. The purpose of this rule is to clarify the qualifications for holding a Permitted Economic Interest, including, but not limited to, the requirement for a fingerprint-based criminal history record check and that the applicant is a natural person who is a lawful United States resident.

M 231.5 – Qualifications for Permitted Economic Interests: Individuals

A. General Requirements

1. All individuals applying for a Permitted Economic Interest shall submit information to the Division in a full, faithful, truthful, and fair manner. The Division may recommend denial of an application where the individual made intentional misstatements, purposeful omissions, misrepresentations, or untruths in the application or in connection with the individual's background investigation. This type of conduct may be considered as the basis of additional administrative action against the individual and it may also be the basis for criminal charges against the individual.

2. The Division may deny the individual's application when the individual fails to provide any requested evidence or information by the Division's deadline.

3. A Permitted Economic Interest approved by the Division constitutes a revocable privilege. The burden of proving the qualifications for suitability to hold a Permitted Economic Interest rests at all times with the applicant.

B. Other Requirements

1. Fingerprints Required. Any individual applying for a Permitted Economic Interest shall be fingerprinted for a fingerprint-based criminal history record check at the Division's discretion.

2. Other Documents May Be Required. Any individual applying for a Permitted Economic Interest may be required to establish his or her identity and age by any document required for a determination of lawful United States residence.

C. Maintaining Ongoing Suitability:

1. An individual seeking or holding a Permitted Economic Interest shall notify the Division in writing of any felony criminal charge and felony conviction against such person within ten days of such person's arrest or felony summons, and within ten days of the disposition of any arrest or summons. Failure to make proper notification to the Division may be grounds for disciplinary action. This duty to report includes, but is not limited to, deferred sentences, prosecutions, or judgments that are not sealed. If the Division lawfully finds a disqualifying event and the individual asserts that the record was sealed, the Division may require the individual to provide proof from a court evidencing the sealing of the case.

2. An individual seeking or holding a Permitted Economic Interest shall cooperate in any investigation conducted by the Division.

D. Application Forms Accessible to Law Enforcement and Licensing Authorities. All application forms supplied by the Division and filed by an individual for a Permitted Economic Interest shall be accessible by the State Licensing Authority, local jurisdictions, and any state or local law enforcement agent.

E. Permitted Economic Interest Applicants. An individual seeking to hold a Permitted Economic Interest must meet the following criteria before holding the interest:

1. The individual shall establish that he or she is a natural person with lawful United States residency, and that he or she can maintain such residency throughout the duration of holding the Permitted Economic Interest;

2. The application fee must be paid;

3. The individual's criminal history must indicate that he or she is of Good Moral Character;

4. The money used to finance the Agreement was not obtained by or through any Person whose criminal history indicates that he or she is not of Good Moral Character;

5. The individual is at least 21 years of age;

6. The individual establishes that he or she is not currently subject to and has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;

7. The individual can prove that he or she is not currently subject to or has not discharged a sentence for a conviction of a felony pursuant to any state or federal law regarding the possession, distribution, manufacturing, cultivation, or use of a controlled substance in the ten years immediately preceding his or her application date or five years from May 28, 2013, whichever is longer, except that

the State Licensing Authority or its designee may grant a Permitted Economic Interest to a person if the person has a state felony conviction based on possession or use of marijuana or marijuana concentrate that would not be a felony if the person were convicted of the offense on the date he or she applied for a Permitted Economic Interest;

8. The individual establishes that he or she is not a sheriff, deputy sheriff, police officer, or prosecuting officer, or an officer or employee of the State Licensing Authority or a local jurisdiction; and

9. The individual establishes that he or she was not a State Licensing Authority employee with regulatory oversight responsibilities for individuals, Medical Marijuana Businesses and/or Retail Marijuana Establishments licensed by the State Licensing Authority in the six months immediately preceding the date of the individual's application.

Basis and Purpose – M 233

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(VIII), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), and 12-43.3-401, C.R.S. The purpose of this rule is to clarify when an individual must be licensed or registered with the Division before commencing any work activity at a Medical Marijuana Business. The rule also sets forth the process for obtaining a license or registration and explains what information may be required before obtaining such license or registration.

M 233 – Medical Code or Retail Code Occupational Licenses Required

A. Medical Code or Retail Code Occupational Licenses~~, Vendor Registrations,~~ and Identification Badges

1. Any person who possesses, cultivates, manufactures, tests, dispenses, sells, serves, transports or delivers Medical Marijuana or Medical Marijuana-Infused Product as permitted by privileges granted under a Medical Marijuana Business license~~License~~ must have a valid Occupational License.

2. Any person who has the authority to access or input data into the Inventory Tracking System or a Medical Marijuana Business point of sale system must have a valid Occupational License.

3. Any person within a Restricted Access Area or Limited Access Area that does not have a valid Occupational License shall be considered a visitor and must be escorted at all times by a person who holds a valid ~~Owner or~~ Occupational License. Failure by a Medical Marijuana Business to continuously escort a person who does not have a valid Occupational License within a Limited Access Area may be considered a license violation affecting the public safety. See Rule M 1307 – Penalties. *See also* Rule M 301 – Limited Access Areas. Nothing in this provision alters or eliminates a Medical Marijuana Business's obligation to comply with the Occupational License requirements of paragraph (A) of this rule M 233.

B. Occupational License~~es~~ Required to Commenc~~eing~~ or Continue Employment. Any person required to be licensed pursuant to ~~this rule~~these rules shall obtain all required~~Division~~ approvals and obtain a Division-issued identification badge before

commencing activities permitted by ~~the~~ his or her Medical Code or Retail Code Occupational License. *See* ~~*also*~~ Rules M 231 – Qualifications for Licensure: Individuals, M 204 – Factors Considered When Evaluating Ownership of a License: Medical Marijuana Businesses, and M 301 – Limited Access Areas.

C. Identification Badges Are Property of State Licensing Authority. All identification badges shall remain the property of the State Licensing Authority, and all identification badges shall be returned to the Division upon demand of the State Licensing Authority or the Division.

Basis and Purpose – M 235

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), and 12-43.3-401(1)(d), and sections 12-43.3-310, 12-43.3-501, and 12-43.3-502, C.R.S. The purpose of this rule is to establish licensing fees for individuals.

M 235 – Schedule of License Fees: Individuals

A. Individual License Fees

1. Occupational Key License - $300.00

2. Associated Key~~/Associated Person~~ License Fee - $1,300.00

3. Occupational Support License - $150.00

B. When Fees Are Due. License fees are due at the time Applicant submits application.

Basis and Purpose – M 236

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), and 12-43.3-401(1)(d), and sections 12-43.3-310, 12-43.3-501, and 12-43.3-502, C.R.S. The purpose of this rule is to establish license renewal fees for individuals.

M 236 – Schedule of Renewal License Fees: Individuals

A. Individual Renewal License Fees

1. Occupational Key License Fee - $200.00

2. Associated Key~~/Associated Person~~ License Fee - $200.00

3. Occupational Support License - $75.00

B. When Fees Are Due. Renewal License fees are due at the time applicant submits application for renewal.

M 300 Series – The Licensed Premises

Basis and Purpose – M 301

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2)(a)(XX), and section 12-43.3-105, C.R.S. The purpose of this rule is to establish regulations governing Limited Access Areas for inside a Licensed Premises. 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 Occupational License.

M 301 – Limited Access Areas

A. Proper Display of License Badge. All persons in a Limited Access Area as provided for in section 12-43.3-105, C.R.S., shall be required to hold and properly display a current license badge issued by the Division at all times. Proper display of the license 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 and individuals without a valid Occupational License, including outside vendors, and contractors, must obtain a visitor identification badge from management personnel of the Licensee that shall remain visible, as required by part A of this rule, while in the Limited Access Area.~~ 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 ~~Licensee personnel~~the Medical Marijuana Business's licensed personnel at all times. No more than five visitors may be escorted by a single employee.

3. 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 or relevant local licensing authority.

4. 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 M 405 – Acceptable Forms of Identification for Medical Sales.

5. The Licensee shall check an acceptable form of identification for all visitors to verify that the name on the identification matches the name in the visitor log. *See* Rule M 405 – Acceptable Forms of Identification for Medical Sales

6. A Licensee may not receive consideration or compensation for permitting a visitor to enter a Limited Access Area.

7. Use of a visitor badge to circumvent the Occupational License requirements of rule M 233 – Medical Code or Retail Code Occupational Licenses Required 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".

D. Diagram for Licensing Licensed Premises. All Limited Access Areas shall be clearly identified to the Division or relevant local licensing authority and described by the filing of 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, and Restricted Access Areas. *See* Rule M 901 – Business Records Required.

E. Modification of a Limited Access Area. A Licensee's proposed modification of designated Limited Access Areas shall be approved by Division or local licensing authorities. *See* Rule M 303 – 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 local licensing authority or any state or local law enforcement agency, for a purpose authorized by the Medical 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.

Basis and Purpose – M 302

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), and 12-43.3-308(1)(b), C.R.S. The purpose of this rule is to establish and clarify the means by which the Licensee ~~has~~ can establish lawful possession of the Licensed Premises.

M 302 – Possession of Licensed Premises

A. Evidence of Lawful Possession. Persons licensed pursuant to sections 12-43.3-402, 12-43.3-403, or 12-43.3-404, C.R.S., or those making application for such licenses, must demonstrate proof of lawful possession of the premises to be licensed or Licensed Premises. Evidence of lawful possession consists of properly executed deeds of trust, leases, or other written documents acceptable to the State Licensing Authority and local licensing authorities.

B. Relocation Prohibited. The Licensed Premises shall only be those geographical areas that are specifically and accurately described in executed documents verifying lawful possession. Licensees are not authorized to relocate to other areas or units within a building structure without first filing a change of location application and obtaining approval from the Division and the local licensing authority. Licensees shall not add additional contiguous units or areas, thereby altering the initially-approved premises, without filing an Application to modify the Licensed Premises on current forms prepared by the Division, including any applicable processing fee. *See* Rule M 303 - Changing, Altering, or Modifying Licensed Premises.

C. Subletting Not Authorized. Licensees are not authorized to sublet any portion of a Licensed Premises for any purpose, unless all necessary applications to modify the existing Licensed Premises to accomplish any subletting have been approved by the Division and local licensing authority.

Basis and Purpose – M 304

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A)-(F), 12-43.4-104(1)(a)(V), 12-43.4-202(2)(b), 12-43.4-401(2), and 12-43.4-404(2), C.R.S. The purpose of this rule is to establish guidelines for the manner in which a Medical Marijuana Business may share its existing Licensed Premises with a Licensed Retail Marijuana Establishment, and to ensure the proper separation of a Medical Marijuana Business operation from Retail Marijuana Establishment operation.

M 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation

A. Licensed Premises – General Requirements

1. A Medical Marijuana Center that prohibits patients under the age of 21 years to be on the Licensed Premises may also hold a Retail Marijuana Store license and operate a dual retail business operation on the same Licensed Premises if the relevant local licensing authority permits a dual operation at the same location and the two are commonly owned.

2. A Medical Marijuana Center that authorizes medical marijuana patients under the age of 21 years to be on the premises is prohibited from sharing its Licensed Premises with a Retail Marijuana Establishment. Even when the two are commonly owned, the two shall maintain distinctly separate Licensed Premises; including, but not limited to, separate sales and storage areas, separate entrances and exits, separate inventories, separate point-of-sale operations, and separate record-keeping.

3. An Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility may share a single Licensed Premises in order to operate a dual cultivation business operation, if the relevant licensing authority permits a dual operation at the same location and the two are commonly owned.

4. A Medical Marijuana-Infused Products Manufacturer Business Licensee and a Retail Marijuana Products Manufacturing Facility may share a single Licensed Premises to operate a dual manufacturing business operation, if the relevant local licensing authority permits a dual operation at the same location and the two are commonly owned.

5. A Medical Marijuana Testing Facility Licensee and a Retail Marijuana Testing Facility Licensee may share a single Licensed Premises to operate a dual testing business operation at the same location if the relevant local licensing authority permits dual operation at the same location and the two are identically owned.

B. Separation of Co-located Licensed Operations

1. Cultivation Operations. A Person operating an Optional Premises Cultivation Operation and a Retail Marijuana Cultivation Facility shall maintain either physical or virtual separation of the facilities, marijuana plants, and marijuana inventory. Record keeping for the business operations and labeling of products must enable the Division and relevant local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana Business from the Retail Marijuana Establishment.

2. Manufacturing Operations. A Person operating a Medical Marijuana-Infused Products Manufacturer Business and Retail Marijuana Products Manufacturing Facility shall maintain either physical or virtual separation of the facilities, product ingredients, product manufacturing, and final product inventory. Record keeping for the business operations and labeling of products must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana-Infused Product from Retail Marijuana Product.

3. Raw Ingredients May Be Shared. Nothing in this rule prohibits a co-located Retail Marijuana Establishment and Medical Marijuana Business from sharing raw ingredients in bulk, for example flour or sugar, except that Retail Marijuana and Medical Marijuana may not be shared under any circumstances.

4. Retail Store and Medical Center Operations: No Patients Under The Age of 21 Years. Persons operating a Medical Marijuana Center that specifically prohibits the admittance of patients under the age of 21 years and a Retail Marijuana Store may share their Licensed Premises. Such a Medical Marijuana Center Licensee must post signage that clearly conveys that persons under the age of 21 years may not enter. Under these circumstances and upon approval of the State Licensing Authority, the Medical Marijuana Center and the Retail Marijuana Store may share the same entrances and exits. Also under these circumstances, Medical Marijuana and Retail Marijuana and Medical Marijuana-Infused Product and Retail Marijuana Product must be separately displayed on the same sale floor. Record keeping for the business operations of both must allow the Division and relevant local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana and Medical Marijuana-Infused Product from Retail Marijuana and Retail Marijuana Product. Violation of the restrictions in this rule by co-located Medical Marijuana Centers and Retail Marijuana Establishments may be considered a license violation affecting public safety.

5. Retail Stores and Medical Marijuana Centers: Patients Under The Age of 21 Years. A co-located Medical Marijuana Center and Retail Marijuana Store shall maintain separate Licensed Premises, including entrances and exits, inventory, point of sale operations, and record keeping if the Medical Marijuana Center serves patients under the age of 21 years or permits admission of patients under the age of 21 years on its premises.

~~5.5~~6 Testing Facilities. A co-located Medical Marijuana Testing Facility and Retail Marijuana Testing Facility shall maintain either physical or virtual separation of the facilities and marijuana and products being tested. Record keeping for the business operations and labeling of products must enable the Division and local licensing authority to clearly distinguish the inventories and business transactions of Medical Marijuana and Medical Marijuana-Infused Product and Retail Marijuana and Retail Marijuana Product.

~~6~~7. Clear Separation of Inventory. A Person who operates both a Medical Marijuana Business and Retail Marijuana Establishment within one location is required to maintain separate and distinct inventory tracking processes for Medical and Retail Marijuana inventories. The inventories must be clearly tagged or labeled so that the products can be reconciled to a particular Medical Marijuana Business or a Retail Marijuana Establishment.

Basis and Purpose – M 307

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(1)(b)(XV), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish sanitary requirements for Medical Marijuana Businesses.

M 307 – Waste Disposal

A. All Applicable Laws Apply. Medical Marijuana and Medical Marijuana-Infused Product waste must be stored, secured and managed in accordance with all applicable state and local statutes, regulations, ordinances or other requirements.

B. Liquid Waste. Liquid waste from Medical Marijuana Businesses shall be disposed of in compliance all applicable federal, state and local laws, regulations, rules and other requirements.

C. Chemical, Dangerous and Hazardous Waste. Disposal of chemical, dangerous or hazardous waste must be conducted in a manner consistent with federal, state and local laws, regulations, rules or other requirements. This may include, but is not limited to, the disposal of all Pesticide or other chemicals used in the cultivation process, certain solvents or other chemicals used in the production of Medical Marijuana Concentrate or any Medical Marijuana soaked in a Flammable Solvent for purposes of producing a Medical Marijuana Concentrate.

D. Waste Must Be Made Unusable and Unrecognizable. Medical Marijuana and Medical Marijuana-Infused Product waste must be made unusable and Unrecognizable prior to leaving the Licensed Premises.

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

1. Grinding 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:

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. Other wastes approved by the State Licensing Authority that will render the Medical Marijuana and Medical Marijuana-Infused Product waste unusable and Unrecognizable as marijuana; and

h. Soil.

F. After Waste is Made Unusable and Unrecognizable. After the Medical Marijuana and Medical Marijuana-Infused Product waste is made unusable and Unrecognizable, then the rendered waste shall be:

1. Disposed of at a solid waste site and disposal facility that has a Certificate of Designation from the local governing body;

2. Deposited at a compost facility that has a Certificate of Designation from the Department of Public Health and Environment; or

3. Composted on-site at a facility owned by the generator of the waste and operated in compliance with the Regulations Pertaining to Solid Waste Sites and Facilities (6 CCR 1007-2, Part 1) in the Department of Public Health and Environment.

G. Proper Disposal of Waste. A Licensee shall not dispose of Medical Marijuana and Medical Marijuana-Infused Product waste in an unsecured waste receptacle not in possession and control of the Licensee.

H. 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 materials are identified, weighed and tracked while on the Licensed Premises until disposed of.

2. All Medical Marijuana waste must be weighed before leaving any Medical Marijuana Business. A scale used to weigh Medical Marijuana waste prior to entry into the Inventory Tracking System shall be ~~certified~~ tested and approved in accordance with ~~measurement standards established in Article 14 of Title 35, C.R.S.~~ 35-14-127, C.R.S. *See* Rule M 309 – Medical Marijuana Business: Inventory Tracking System.

3. A Licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of Marijuana. *See* Rule M 901 – 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 Medical Marijuana plant prior to harvest, which must include weighing and documenting all waste. Unless required by an Inventory Tracking System procedure, records of waste produced prior to harvest must be maintained on the Licensed Premises. All waste, whether produced prior or subsequent to harvest, must be disposed of in accordance with this rule and be made unusable and unrecognizable.

Basis and Purpose – M 308

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2)(a)(XX), and C.R.S. The purpose of this rule is to establish hours of operation requirements for Medical Marijuana Businesses. The State Licensing Authority modeled this rule after the Retail Marijuana Establishment Hours of Operation rule, Rule R 308 located in 1 CCR 212-2, and the Colorado Department of Revenue's liquor rules.

M 308 – Selling, Serving, Distributing, and Transporting Medical Marijuana and Medical Marijuana-Infused Product: Hours of Operation

A. Hours of Operation. Medical Marijuana Businesses shall not sell, serve, distribute, or initiate the transport of Medical Marijuana or Medical Marijuana-Infused Product at any time other than between the hours of 8:00 am and 12:00 am, Mountain Time, Monday through Sunday.

B. Local Jurisdictions May Further Restrict Hours. Nothing in this rule shall prohibit a local jurisdiction from further restricting hours of operation within its jurisdiction.

Basis and Purpose – M 309

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XX), 12-43.3-403(2), and 12-43.4-104(1)(a)(III) C.R.S. The purpose of this rule is to establish a system that will allow the State Licensing Authority and the industry to jointly track Medical Marijuana and Medical Marijuana-Infused Product from either seed or immature plant stage until the Medical Marijuana or Medical Marijuana-Infused Product is sold to the patient or destroyed.

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

The State Licensing Authority finds it essential to regulate, monitor, and track all Medical Marijuana and Medical Marijuana-Infused Product to eliminate diversion, inside and outside of the state, and to ensure that all marijuana grown, processed, sold and disposed of in the Medical Marijuana market is transparently accounted for. An existing Medical Marijuana Business must have an active and functional Inventory Tracking System account on or before December 31, 2013 or it may not excise the privileges of its license.

The State Licensing Authority will engage the industry and provide training opportunities and continue to evaluate the Inventory Tracking System to promote an effective means for this industry to account for and monitor its Medical Marijuana inventory.

M 309 – Medical Marijuana Business: Inventory Tracking System

A. Inventory Tracking System Required. A Medical Marijuana Business is required to use the Inventory Tracking System as the primary inventory tracking system of record. A ~~Medical Marijuana Business must have an Inventory Tracking System account activated and functional on or before December 31, 2013. After December 31, 2013, a~~ Medical Marijuana Business without an Inventory Tracking System account that is activated and functional shall not operate or exercise any privileges of a license. Medical Marijuana Businesses converting to or adding a Retail Marijuana Establishment must follow the inventory transfer guidelines detailed in Rule R 309 (D) below.

B. Inventory Tracking System Access - Inventory Tracking System Administrator

1. Inventory Tracking System Administrator Required. A Medical Marijuana Business must have at least one individual Owner who is an Inventory Tracking

System Administrator. A Medical Marijuana Business may also designate additional Owners and occupationally licensed employees to obtain Inventory Tracking System Administrator accounts.

2. Training for Inventory Tracking System Administrator Account. In order to obtain an Inventory Tracking System Administrator account, a person must attend and successfully complete all required Inventory Tracking System training. The Division may also require additional ongoing, continuing education for an individual to retain his or her Inventory Tracking System Administrator account.

C. Inventory Tracking System Access - Inventory Tracking System User Accounts. A Medical Marijuana Business may designate licensed Owners and employees who hold a valid Occupational License as an Inventory Tracking System User. A Medical Marijuana Business shall ensure that all Owners and Occupational Licensees who are granted Inventory Tracking System User account access for the purposes of conducting inventory tracking functions in the system are trained by Inventory Tracking System Administrators in the proper and lawful use of Inventory Tracking System.

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

1. Medical Marijuana Inventory Transfer to Retail Marijuana Establishments.

a. This rule M 309(D)(1)(a) is repealed effective July 1, 2016. Prior to July 1, 2016, each~~Each~~ Medical Marijuana Business that is either converting to or adding a Retail Marijuana Establishment license must create a Retail Marijuana Inventory Tracking System account for each license it is converting or adding. A Medical Marijuana Business must transfer all relevant Medical Marijuana inventory into the Retail Marijuana Establishment's Inventory Tracking System account and affirmatively declare those items as Retail Marijuana and Retail Marijuana Product.

b. Beginning July 1, 2016:

i. The the only allowed transfer of marijuana between a Medical Marijuana Business and Retail Marijuana Establishment is Medical Marijuana and Medical Marijuana Concentrate that was produced at the Optional Premises Cultivation Operation, from the Optional Premises Cultivation Operation to a Retail Marijuana Cultivation Facility.

ii. Each Optional Premises Cultivation Operation that is either converting to or adding a Retail Marijuana Cultivation Facility license must create a Retail Marijuana Inventory Tracking System account for each license it is converting or adding.

iii. An Optional Premises Cultivation Operation must transfer all relevant Medical Marijuana and Medical Marijuana Concentrate into the Retail Marijuana Cultivation Facility's Inventory Tracking System account and affirmatively declare those items as Retail Marijuana or Retail Marijuana Concentrate as appropriate.

iv. The marijuana subject to the one-time transfer is subject to the excise tax upon the first transfer from the Retail Marijuana Cultivation Facility to another Retail Marijuana Establishment.

v. All other transfers are prohibited, including but not limited to transfers from a Medical Marijuana Center or Medical Marijuana-Infused Products Manufacturer to any Retail Marijuana Establishment.

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

E. RFID Tags Required

1. Authorized Tags Required and Costs. Licensees are required to use RFID tags issued by a Division-approved vendor that is authorized to provision RFID tags for the Inventory Tracking System. Each licensee is responsible for the cost of all RFID tags and any associated vendor fees.

2. Use of RFID Tags Required. A Licensee is responsible to ensure its inventories are properly tagged where the Inventory Tracking System requires RFID tag use. A Medical Marijuana Business must ensure it has an adequate supply of RFID tags to properly tag Medical Marijuana and Medical Marijuana-Infused Product as required by the Inventory Tracking System.

F. General Inventory Tracking System Use

1. Reconciliation with Inventory. All inventory tracking activities at a Medical Marijuana Business must be tracked through use of the Inventory Tracking System. A Licensee must reconcile all on-premises and in-transit Medical Marijuana and Medical Marijuana-Infused Product inventories each day in the Inventory Tracking System at the close of business.

2. Common Weights and Measures.

a. A Medical Marijuana Business must utilize a standard of measurement that is supported by the Inventory Tracking System to track all Medical Marijuana and Medical Marijuana-Infused Product.

b. A scale used to weigh such product prior to entry into the Inventory Tracking System shall be ~~certified~~ tested and approved in accordance with ~~measurement standards established in Article 14 of Title 35,~~35-14-127, C.R.S.

3. Inventory Tracking System Administrator and User Accounts – Security and Record

a. A Medical Marijuana Business shall maintain an accurate and complete list of all Inventory Tracking System Administrators and Inventory Tracking System Users for each Licensed Premises. A Medical Marijuana Business shall update this list when a new Inventory Tracking System User is trained. A Medical Marijuana Business must train and authorize any new Inventory Tracking System Users before those Owners or employees may access Inventory Tracking System or input, modify, or delete any information in the Inventory Tracking System.

b. A Medical Marijuana Business must cancel any Inventory Tracking System Administrators and Inventory Tracking System Users from their

associated Inventory Tracking System accounts once any such individuals are no longer employed by the Licensee or at the Licensed Premises.

c. A Medical Marijuana Business is accountable for all actions employees take while logged into the Inventory Tracking System or otherwise conducting Medical Marijuana or Medical Marijuana-Infused Product inventory tracking activities.

d. Each individual user is also accountable for all of his or her actions while logged into the Inventory Tracking System or otherwise conducting Medical Marijuana or Medical Marijuana-Infused Product inventory tracking activities, and must maintain compliant with all relevant laws.

4. Secondary Software Systems Allowed

a. Nothing in this rule prohibits a Medical Marijuana Business from using separate software applications to collect information to be used by the business including secondary inventory tracking or point of sale systems.

b. A Licensee must ensure that all relevant Inventory Tracking System data is accurately transferred to and from the Inventory Tracking System for the purposes of reconciliations with any secondary systems.

c. A Medical Marijuana Business must preserve original Inventory Tracking System data when transferred to and from a secondary application(s). Secondary software applications must use Inventory Tracking System data as the primary source of data and must be compatible with updating to the Inventory Tracking System.

G. Conduct While Using Inventory Tracking System

1. Misstatements or Omissions Prohibited. A Medical Marijuana Business and its designated Inventory Tracking System Administrator(s) and Inventory Tracking System User(s) shall enter data into the Inventory Tracking System that fully and transparently accounts for all inventory tracking activities. Both the ~~A~~ Medical Marijuana Business and the individuals using the Inventory Tracking System ~~is~~are responsible for the accuracy of all information entered into the Inventory Tracking System. Any misstatements or omissions may be considered a license violation affecting public safety.

2. Use of Another User's Login Prohibited. Individuals entering data into the Inventory Tracking System ~~system~~ shall only use that individual's Inventory Tracking System account. In addition, individuals utilizing or entering data in the Inventory Tracking System shall not utilize data for any other Medical Marijuana Business or Retail Marijuana Establishment.

3. Loss of System Access. If at any point a Medical Marijuana Business loses access to the Inventory Tracking System for any reason, the Medical Marijuana Business must keep and maintain comprehensive records detailing all Medical Marijuana and Medical Marijuana-Infused Product tracking inventory activities that were conducted during the loss of access. *See* Rule M 901 – Business Records Required. Once access is restored, all Medical Marijuana and Medical Marijuana- Infused Product inventory tracking activities that occurred during the loss of access must be entered into the Inventory Tracking System. A Medical

Marijuana Business must document when access to the system was lost and when it was restored. A Medical Marijuana Business shall not transport any Medical Marijuana or Medical Marijuana-Infused Product to another Medical Marijuana Business until such time as access is restored and all information is recorded into the Inventory Tracking System.

H. System Notifications

1. Compliance Notifications. A Medical Marijuana Business must monitor all compliance notifications from the Inventory Tracking System. The Licensee must resolve the issues detailed in the compliance notification in a timely fashion. Compliance notifications shall not be dismissed in the Inventory Tracking System until the Medical Marijuana Business resolves the compliance issues detailed in the notification.

2. Informational Notifications. A Medical Marijuana Business must take appropriate action in response to informational notifications received through the Inventory Tracking System, including but not limited to notifications related to RFID billing, enforcement alerts, and other pertinent information.

I. Lawful Activity Required. Proper use of the Inventory Tracking System does not relieve a Licensee of its responsibility to maintain compliance with all laws, rules, and other requirements at all times.

J. Inventory Tracking System Procedures Must Be Followed. A Medical Marijuana Business must utilize the Inventory Tracking System in conformance with these rules and Inventory Tracking System procedures

~~K. Transition Period. Notwithstanding any other rule, a Medical Marijuana Business shall not be required to utilize the Inventory Tracking System until that Medical Marijuana Business has an Inventory Tracking System Trained Administrator and has accounted for all of its on-hand Medical Marijuana and Medical Marijuana-Infused Product in the Inventory Tracking System. Until that time, a Medical Marijuana Business must ensure that its books and records are maintained in such a manner that its entire inventory is fully accounted for, which includes tracking all Medical Marijuana from seed, cutting or receipt to sale or transfer and all Medical Marijuana-Infused Products from manufacture or receipt to sale or transfer. Additionally, a Medical Marijuana Business must obtain a valid transport manifest from the Division, which must carried by a Licensee transporting any Medical Marijuana or Medical Marijuana-Infused Products at all times. This rule, M 309.K, will be considered ineffective on January 1, 2014, at which time all Medical Marijuana Businesses will be required to comply with all MTIS rules and procedures.~~

M 400 Series – Medical Marijuana Centers

Basis and Purpose – M 401

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F),12-43.3-310(7), ~~and~~ 12-43.3-310(4), and 12-43.3-402, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana Center Licensee to exercise any privileges other than those granted by the State Licensing Authority, and to clarify the license privileges.

M 401 – Medical Marijuana Center: License Privileges

A. Privileges Granted. A Medical Marijuana Center shall only exercise those privileges granted to it by the State Licensing Authority.

B. Licensed Premises. To the extent authorized by Rule M 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation, a Medical Marijuana Center may share a location with a commonly-owned Retail Marijuana Store. However, a separate license is required for each specific business or business entity, regardless of geographical location.

C. Authorized Sources of Medical Marijuana. A Medical Marijuana Center may only sell Medical Marijuana that it has purchased from an Optional Premises Cultivation Operation or that the center has cultivated itself, after first obtaining an Optional Premises Cultivation Operation License. *See* Rule M 501 – Optional Premises Cultivation Operation: License Privileges.

D. Authorized Sources of Medical Marijuana-Infused Product Inventory. A Medical Marijuana Center may sell Medical Marijuana-Infused Product that it has purchased from a Medical Marijuana-Infused Products Manufacturer, so long as each product are pre-packaged and labeled upon purchase from the manufacturer.

E. Samples Provided for Testing.

1. This rule M 401(E)(1) is repealed effective July 1, 2016. A Medical Marijuana Center may provide Samples of its products for testing and research purposes to a Retail Marijuana Testing Facility that has obtained a vendor registration and an Occupational License to test and research Medical Marijuana for testing and research purposes. The Medical Marijuana Center shall maintain the testing results as part of its business books and records. *See* Rule ~~R~~ M 901 – Business Records Required.

1.5. This rule M 401(E)(1.5) is effective beginning July 1, 2016. A Medical Marijuana Center may provide Samples of its products to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Center shall maintain the testing results as part of its business books and records. See Rule M 901 – Business Records Required.

F. Authorized On-Premises Storage. A Medical Marijuana Center is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area or Restricted Access Area, and tracked consistently with the inventory tracking rules.

Basis and Purpose – M 403

The statutory authority for this rule is found at subsections 12-43.3-103(2)(b), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), and 12-43.3-310(4), and section 12-43.3-201, 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 Center. This rule also restricts the amount of its inventory a Medical Marijuana Center may sell to other Medical Marijuana Businesses to 30 percent.

The quantity limitations on sales provision is intended to inform stakeholders in order to aid in compliance with a patient's lawful medical marijuana limit. Clarifying the quantity limitations on sales provides Medical Marijuana Centers 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).

M 403 – Medical Marijuana Sales: General Limitations or Prohibited Acts

~~A. Transactions Must Occur During Statutory Business Hours. During the hours established in section 12-43.3-901(4)(l), C.R.S., Medical Marijuana may be sold to other licensed Medical Marijuana Centers or licensed Medical Marijuana-Infused Products Manufacturers, under the following conditions:~~

~~B~~A. 30 Percent Rule. Pursuant to section 12-43.3-402(4), C.R.S., a Medical Marijuana Center may purchase not more than thirty percent of its total on-hand medical marijuana inventory from another licensed Medical Marijuana Center in Colorado. A Medical Marijuana Center may sell no more than thirty percent of its total on-hand Medical Marijuana inventory to another Medical Marijuana Center.

Total on-hand inventory as used in section 12-43.3-402(4), C.R.S., shall only include Medical Marijuana grown on the Medical Marijuana Center's dedicated Optional Premises Cultivation Operation that has been processed and the total amount or quantity has been accounted for in the licensed Medical Marijuana Center's inventory during the previous calendar year, or in the case of a newly licensed business, its first 12 months of business. For purposes of this rule, a calendar year means January 1st to December 31st.

~~C~~B. Medical Marijuana-Infused Products Manufacturers. A Medical Marijuana Center may also contract for the manufacture of Medical Marijuana-Infused Product with Medical Marijuana-Infused Product Licensees utilizing a contract as provided for in Rule M 602 – Medical Marijuana-Infused Products Manufacturer: General or Prohibited Acts (Infused Product Contracts). Medical Marijuana distributed to a Medical Marijuana-Infused Products Manufacturer by a Medical Marijuana Center pursuant to such a contract for use solely in Medical Marijuana-Infused Product(s) that are returned to the contracting Medical Marijuana Center shall not be included for purposes of determining compliance with subsection A.

~~D~~C. Consumption Prohibited. Licensees shall not permit the consumption of marijuana or a marijuana product on the Licensed Premises.

~~E~~D. Quantity Limitations On Sales. A Medical Marijuana Center and its employees are prohibited from selling more than two ounces of Medical Marijuana or its equivalent in Medical Marijuana-Infused Product during a ~~single~~ sales transaction to a patient unless that patient has designated the Medical Marijuana Center as its primary center and supplied it with documentation from the patient's physician that allows the patient more than two ounces of Medical Marijuana or its equivalent in Marijuana-Infused Product. A Medical Marijuana Center is prohibited from selling more than two ounces of Medical

Marijuana or its equivalent in Marijuana-Infused Product to any patient who has not registered that Medical Marijuana Center as its primary center.

~~F~~E. Licensees May Refuse Sales. Nothing in these rules prohibits a Licensee from refusing to sell Medical Marijuana or Medical Marijuana-Infused Product to a patient.

~~G~~F. Storage and Display Limitations. A Medical Marijuana Center shall not display Medical Marijuana and Medical Marijuana-Infused Product outside of a designated Restricted Access Area or in a manner in which Medical Marijuana or Medical Marijuana-Infused Product can be seen from outside the Licensed Premises. Storage of Medical Marijuana and Medical Marijuana-Infused Product shall otherwise be maintained in Limited Access Areas or Restricted Access Area.

~~H~~G. Sale of Expired Product Prohibited. A Medical Marijuana Center shall not sell any expired Medical Marijuana-Infused Product.

~~I~~H. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

500 Series – Medical Marijuana Optional Premises Cultivation Operation: License Privileges

Basis and Purpose – M 501

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(e), 12-43.3-202(2)(a)(XVI), 12-43.3-202(2)(a)(XX), 12-43.3-310(7), and 12-43.3-310(4), C.R.S. The purpose of this rule is to establish that it is unlawful for an Optional Premises Cultivation Operation to exercise any privileges other than those granted by the State Licensing Authority, and to clarify the license privileges.

M 501 – Medical Marijuana Optional Premises Cultivation Operation: License Privileges

A. Privileges Granted. A Medical Marijuana Optional Premises Cultivation Operation shall only exercise those privileges granted to it by the State Licensing Authority.

B. Licensed Premises. To the extent authorized by Rule M 304 – Medical Marijuana Business and Retail Marijuana Establishment – Shared Licensed Premises and Operational Separation, a Medical Marijuana Optional Premises Cultivation Facility may share a location with a commonly-owned Retail Marijuana Cultivation Facility. However, a separate license is required for each specific business entity regardless of geographical location.

C. Cultivation of Medical Marijuana Authorized. A Medical Marijuana Optional Premises Cultivation Operation may Propagate,, cultivate, harvest, prepare, cure, package, store, and label Medical Marijuana, whether in concentrated form or otherwise.

D. Authorized Sales. A Medical Marijuana Optional Premises Cultivation Operation may only transfer Medical Marijuana to the Medical Marijuana Center or Medical Marijuana Infused Products Manufacturer it is designated to pursuant to section 12-43.3-403, C.R.S.

E. Packaging Processed Medical Marijuana. Processed Medical Marijuana plants shall be packaged in units of ~~one~~ ten pounds or less and labeled pursuant to Rule M 1002 - Labeling Requirements: General Requirements and securely sealed in a tamper-evident manner. The packages must be transported to the Medical Marijuana Business within 48 hours and recorded as inventory at the receiving Medical Marijuana Business.

Basis and Purpose – M 505

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F),12-43.3-402(6), and 12-43.3-404(10), C.R.S. The purpose of this rule is to permit laboratory testing of Medical Marijuana and establish minimum health and safety regulation for Optional Premises Cultivation Operation. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses.

M 505 – Optional Premises Cultivation Operation: Testing

A. Samples on Demand. Medical Marijuana Optional Premises Cultivation Operation shall, upon request of the Division, submit a sufficient quantity of Medical Marijuana to a Retail or Medical Marijuana Testing Facility to enable laboratory or chemical analysis thereof. The Division will notify the Licensee of the results of the analysis. *See* Rule M. 309 – Medical Marijuana Business: Inventory Tracking System and Rule M 901 – Business Records Required.

B. Samples Provided for Testing.

1. This rule M 505(B)(1) is repealed effective July 1, 2016. A Medical Marijuana Optional Premises Cultivation Operation may provide Samples of its Medical Marijuana to a Retail Marijuana Testing Facility with a vendor certification and Occupational License for Medical Marijuana testing and research. *See* Rule M 701- Vendor Registration and Occupational License for Medical Marijuana Testing and Research. The Optional Premises Cultivation Operation shall maintain the testing results as part of its business books and records. *See* Rule M 901 – Business Records Required.

1.5. This rule M 505(B)(1.5) is effective beginning July 1, 2016. A Medical Marijuana Optional Premises Cultivation Operation may provide Samples of its Medical Marijuana to a Medical Marijuana Testing Facility for testing and research purposes. The Optional Premises Cultivation Operation shall maintain the testing results as part of its business books and records. *See* Rule M 901 – Business Records Required.

M 600 Series – Medical Marijuana-Infused Products Manufacturers

Basis and Purpose – M 601

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I) and 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I)(A-F), and section 12-43.3-404, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana-Infused Products Manufacturer to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

M 601 – Medical Marijuana-Infused Products Manufacturer: License Privileges

A. Privileges Granted. A Medical Marijuana-Infused Products Manufacturer shall only exercise those privileges granted to it by the State Licensing Authority.

B. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. A Retail Marijuana Products Manufacturing Facility may share a location with a commonly owned Medical Marijuana-Infused Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location.

C. Sales Restricted. A Medical Marijuana-Infused Products Manufacturer may only sell its own Medical Marijuana-Infused Product to Medical Marijuana Centers.

D. Manufacture of Medical Marijuana-Infused Product Authorized. A Medical Marijuana-Infused Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana-Infused Product, whether in concentrated form or that are comprised of Medical Marijuana and other ingredients intended for use or consumption, such as edible products, ointments, or tinctures.

E. Location Prohibited. A ~~Retail~~ Medical Marijuana-Infused Products Manufacturer may not manufacture, prepare, package, store, or label Medical Marijuana-Infused Product in a location that is operating as a retail food establishment or a wholesale food registrant.

F. Samples Provided for Testing.

1. This rule M 601(F)(1) is repealed effective July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Retail Marijuana Testing Facility that has obtained an Occupational License to test and research Medical Marijuana for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. *See* Rule M 901 – Business Records Required.

1.5. This rule M 601(F)(1.5) is effective beginning July 1, 2016. A Medical Marijuana-Infused Products Manufacturer may provide samples of its Medical Marijuana-Infused Product to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana-Infused Products Manufacturer shall maintain the testing results as part of its business books and records. *See* Rule M 901 – Business Records Required.

Definition to be added rule M 103:

"Universal Symbol" means the image established by the Division and made available to Licensees through the Division's website indicating the Medical Marijuana or Medical Marijuana Infused-Product contains marijuana.

Basis and Purpose – M 604

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), ~~and~~ 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), ~~C.R.S.,~~ and section 12-43.3-404, C.R.S. The purpose of this rule is to establish minimum health and safety regulations for Medical Marijuana-Infused Products Manufacturers. It requires all Owners and Occupational Licensees to attend a food handler training course prior to manufacturing any Edible Medical Marijuana Product. This rule also authorizes the State Licensing Authority to require that an independent consultant conduct an independent food safety audit of a Medical Marijuana Infused-Products Manufacturing Facility. This rule explains when an independent food safety audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana-Infused Products Manufacture's refusal to cooperate or pay for the audit. It sets forth general standards and basic sanitary requirements for Medical Marijuana-Infused Products Manufacturers. It covers the physical premises where the products are made as well as the individuals handling the products. The State Licensing Authority modeled this rule after those adopted by the Colorado Department of Public Health and Environment. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses and the safety of the public. Product safety requirements are being adopted to aid in making Medical Marijuana-Infused Products more readily identifiable to the general public outside of packaging as containing Medical Marijuana. While product safety requirements are stated in this rule, nothing in the requirements interferes with a manufacturer's ability to determine standard doses for its products or to provide a mechanism with the product for accurately measuring a standard dose.

M 604 – Medical Marijuana-Infused Products Manufacturer: Health and Safety Regulations

A. Training

1. Prior to engaging in the manufacture of any Edible Medical Marijuana-Infused Product each Owner or Occupational 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-Infused Products Manufacturer must obtain documentation evidencing that each Owner or Occupational 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 or Occupational Licensee is engaged in the manufacturing of an Edible Medical Marijuana-Infused Product.

B. General Standards

1. A Medical Marijuana-Infused Products Manufacturer may be subject to inspection by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local jurisdiction restrictions related to Medical Marijuana. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

2. A Medical Marijuana-Infused Products Manufacturer that manufacturers Edible Medical Marijuana-Infused Product shall comply with all kitchen-related health and safety standards of the relevant local licensing authority 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. General Sanitary Requirements. The Licensee shall take all reasonable measures and precautions to ensure the following:

1. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for Medical Marijuana or Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;

2. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and/or in Medical Marijuana-Infused Product preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

3. That all persons working in direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product shall conform to hygienic practices while on duty, including but not limited to:

   a. Maintaining adequate personal cleanliness;

   b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the production of a Medical Marijuana Concentrate or manufacture of a Medical Marijuana-Infused Product and at any other time when the hands may have become soiled or contaminated; and

   c. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

4. That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of Medical Marijuana or Medical Marijuana-Infused Product;

5. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Medical Marijuana or Medical Marijuana-Infused Product are exposed;

6. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;

7. That there is adequate safety-type lighting in all areas where Medical Marijuana or Medical Marijuana-Infused Product are processed or stored and where equipment or utensils are cleaned;

8. That the Licensed Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

9. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;

10. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused 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 in a Medical Marijuana-Infused Products Manufacturer and used in accordance with labeled instructions;

11. That toxic cleaning compounds, sanitizing agents, solvents used in the production of Medical Marijuana Concentrate and other chemicals shall be identified, held, stored and disposed of in a manner that protects against

contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance;

12. 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;

13. 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;

14. That each Medical Marijuana-Infused Products Manufacturer shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair;

15. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Medical Marijuana or Medical Marijuana-Infused Product shall be conducted in accordance with adequate sanitation principles;

16. That Medical Marijuana or Medical Marijuana-Infused Product that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms; and

17. That storage and transport of finished Medical Marijuana-Infused Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.

C.5. Product Safety.

Paragraph (C.5) is effective beginning October 1, 2016.

1. A Medical Marijuana-Infused Products Manufacturer that manufactures Edible Medical Marijuana-Infused Product shall create and maintain standard production procedures and detailed manufacturing processes for each Edible Medical Marijuana-Infused 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. A Medical Marijuana-Infused Products Manufacturer may determine a standard dose of THC for each Edible Medical Marijuana-Infused Product it manufactures. If a Medical Marijuana-Infused Products Manufacturer determines a standard dose for an Edible Medical Marijuana-Infused Product, that information must be documented in the product's standard production procedure.

3. For each Edible Medical Marijuana-Infused Product, the total amount of active THC contained within the product must be documented in the standard production procedures.

4. Universal Symbol Marking Requirements.

a. The following categories of Edible Medical Marijuana-Infused Products shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the Medical Marijuana-Infused Product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable.

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 located in the center of the Edible Medical Marijuana-Infused Product;

ii. Be of a size that covers at least 25% of one side of the Edible Medical Marijuana-Infused Product's surface, but not less than ¼ inch by ¼ inch; and

iii. Include the word "Medical" below the Universal Symbol.

c. If a Medical Marijuana-Infused Products Manufacturer demarks each individual dose of marijuana in an Edible Medical Marijuana-Infused Product, then the Universal Symbol and the word "Medical" shall be applied to each dose and in accordance with the requirements of subsubparagraph (C.5)(4)(b) of this rule M 604.

d. Edible Medical Marijuana-Infused Products that are liquids, loose bulk goods (e.g. granola, cereals, popcorn), or powders, are exempt from the Universal Symbol marking requirements provided that they comply with the labeling and Child-Resistant Container packaging requirements of rule M 1004.5.

5. Remanufactured Products Prohibited. A Medical Marijuana-Infused Products Manufacturer shall not utilize a commercially manufactured food product as their Edible Medical Marijuana-Infused Product. The following exceptions to this prohibition apply:

a. A food product that was commercially manufactured specifically for use by the Medical Marijuana-Infused Products Manufacturer Licensee to infuse with 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 Medical Marijuana-Infused Products Manufacturer.

b. Commercially manufactured food products may be used as ingredients in a Medical Marijuana-Infused Products Manufacturer's Edible Medical Marijuana-Infused 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-Infused Product, and (2) the Medical Marijuana-Infused Products Manufacturer does not state or advertise to the consumer that the final Edible Medical Marijuana-Infused Product contains the commercially manufactured food product.

6. Trademarked Food Products. Nothing in this rule alters or eliminates a Medical Marijuana-Infused Products Manufacturer's responsibility to comply with the trademarked food product provisions required by the Medical Code per 12-43.3-404(11)(a-c), C.R.S.

D. Standard Operating Procedures

1. A Medical Marijuana-Infused Products Manufacturer must have written standard operating procedures for each category of Medical Marijuana Concentrate and type of Medical Marijuana-Infused Product that it produces.

a. All standard operating procedures for the production of a Medical Marijuana Concentrate must follow the requirements in Rule M 605.

b. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Medical Marijuana-Infused Products Manufacturer.

2. If a Medical Marijuana-Infused Products Manufacturer makes a Material Change to its standard Medical Marijuana Concentrate or Medical Marijuana-Infused 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.

E. Independent Health and Sanitary Audit

1. State Licensing Authority May Require An Independent Health and Sanitary Audit

a. When the State Licensing Authority determines a health and sanitary audit by an independent consultant is necessary, it may require a Medical Marijuana-Infused Products Manufacturer to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Medical Marijuana-Infused Products Manufacturer is in compliance with the requirements set forth in this rule or other applicable food handling laws, rules or regulations and in compliance with the concentrate production rules in Rule M 605 or other applicable laws, rules and regulations.

b. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with a Medical Marijuana-Infused Products Manufacturer. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.

c. The Medical Marijuana-Infused Products Manufacturer will be responsible for all direct costs associated with the independent health and sanitary audit.

2. When Independent Health and Sanitary Audit Is Necessary. The State Licensing Authority has discretion to determine when an audit by an independent consultant is necessary. The following is a non-exhaustive list of examples that may justify an independent audit:

a. A Medical Marijuana-Infused Products Manufacturer does not provide requested records related to the food handling training required for Owners and Occupational Licensees engaged in the production of Edible Medical Marijuana-Infused Products to the Division;

b. A Medical Marijuana-Infused Products Manufacturer does not provide requested records related to the production of Medical Marijuana Concentrate, including but not limited to, certification of its Licensed Premises, equipment or standard operating procedures, training of Owners or employees, or Production Batch specific records;

c. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer is in violation of one or more of the requirements set forth in this rule or Rule M 605; or

d. The Division has reasonable grounds to believe that the Medical Marijuana-Infused Products Manufacturer was the cause or source of contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product; or

e. Multiple Production Batches of Medical Marijuana Concentrate or Medical Marijuana-Infused Product produced by the Medical Marijuana-Infused Products Manufacturer failed contaminant testing.

3. Compliance Required. A Medical Marijuana-Infused Products Manufacturer must pay for and timely cooperate with the State Licensing Authority's requirement that it undergo an independent health and sanitary audit in accordance with this rule.

4. Suspension of Operations

a. If the State Licensing Authority has objective and reasonable grounds to believe and finds upon reasonable ascertainment of the underlying facts that the public health, safety or welfare imperatively requires emergency action and incorporates such findings into its order, it may order summary suspension of the Medical Marijuana-Infused Products Manufacturer's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

b. Prior to or following the issuance of such an order, the Medical Marijuana-Infused Products Manufacturer may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.

i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly institute license suspension or revocation procedures. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

ii. If an agreement to suspend operations is reached, then the Medical Marijuana-Infused Products Manufacturer may continue to care for its inventory and conduct any necessary internal business operations but it may not sell, transfer or wholesale Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product to another Medical Marijuana Business during the period of time specified in the agreement. Depending on the condition of the Licensed Premises and required remedial measures, the Division may permit a Medical Marijuana-Infused Products Manufacturer to produce Medical Marijuana Concentrate or manufacture Medical Marijuana-Infused Product while operations have been suspended.

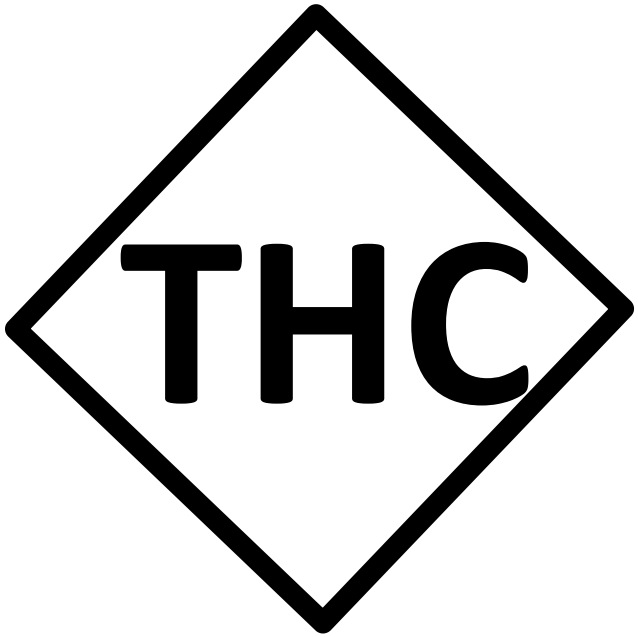
F. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

Medical

On Label

Contains Marijuana. For Medical Use Only.
Keep out of the reach of children.

On Product



MEDICAL

Basis and Purpose – M 605

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), 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-Infused 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.

M 605 – Medical Marijuana-Infused Products Manufacturer: Medical Marijuana Concentrate Production.

~~**Paragraph B of this rule is not effective until March 1, 2014.**~~

~~**Paragraph C of this rule is not effective until April 1, 2014.**~~

~~**Paragraph D of this rule is not effective until July 1, 2014.**~~

A. Permitted Categories of Medical Marijuana Concentrate Production

1. A Medical Marijuana-Infused Products Manufacturer may produce Water-Based Medical Marijuana Concentrate and Food-Based Medical Marijuana Concentrate.

2. A Medical Marijuana-Infused Products Manufacturer may also produce Solvent-Based Medical Marijuana Concentrate using only the following solvents: butane, propane, CO_2, ethanol, isopropanol, acetone, and heptane. The use of any other solvent is expressly prohibited unless and until it is approved by the Division.

3. Beginning on July 1, 2014, a Medical Marijuana-Infused 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-Infused 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 M 901- Business Records Required.

2. Ensure that all applicable sanitary rules are followed. *See* M 604.

3. Ensure that the standard operating procedure for each method used to produce a Medical Marijuana Concentrate on its Licensed Premises 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 M 307 – Waste Disposal.

4. Establish written and documentable quality control procedures designed to maximize safety for Owners and Occupational Licensees and minimize potential product contamination.

5. Establish written emergency procedures to be followed by Owners or Occupational 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 on its Licensed Premises. 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 at that Licensed Premises;

b. The Medical Marijuana-Infused Products Manufacturer's quality control procedures;

c. The emergency procedures for that Licensed Premises;

d. The appropriate use of any necessary safety or sanitary equipment;

e. The hazards presented by all solvents used within the Licensed Premises as described in the material 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 or Occupational 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 or Occupational 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 or Occupational Licensee can safely produce a Medical Marijuana Concentrate. *See* Rule M 901- Business Records Required.

c. The Owner or Occupational 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 period cleaning required to maintain compliance with all applicable sanitary rules. *See* Rule M 901- Business Records Required.

8. Maintain clear and comprehensive records of the name, signature and Owner or Occupational 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 M 901- Business Records Required.

C. Water-Based Medical Marijuana Concentrate and Food-Based Medical Marijuana Concentrate. Medical Marijuana-Infused Products Manufacturer that engages in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate must:

1. Ensure that all equipment, counters and surfaces used in the production of a Water-Based Medical Marijuana Concentrate or a Food-Based 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 Water-Based Medical Marijuana Concentrate or a Food-Based 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 or Occupational Licensee engaged in the production of a Water-Based Medical Marijuana Concentrate or Food-Based Medical Marijuana Concentrate.

5. Ensure that only finished drinking water and ice made from finished drinking water is used in the production of a Water-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 Water-Based Medical Marijuana Concentrate or a Food-Based Medical Marijuana Concentrate.

D. Solvent-Based Medical Marijuana Concentrate. A Medical Marijuana-Infused 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-Infused Products Manufacturer makes a Material Change to its Licensed Premises, 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 Licensed Premises and equipment as well.

e. Manufacturer's Instructions. The Industrial Hygienist or Professional Engineer may review and consider any information provided to the Medical Marijuana-Infused 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-Infused 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 on the Licensed Premises.

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-Infused 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-Infused 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-Infused 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-Infused 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-Infused Products Manufacturer must obtain a material safety data sheet for each solvent used or stored on the Licensed Premises. A Medical Marijuana-Infused Products Manufacturer must maintain a current copy of the material safety data sheet and a receipt of purchase for all solvents used or to be used in an extraction process. See Rule M 901- Business Records Required.

b. A Medical Marijuana-Infused Products Manufacturer is prohibited from using denatured alcohol to produce a Medical Marijuana Concentrate.

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-Infused 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 or Occupational Licensee engaged in the production of a Solvent-Based Medical Marijuana Concentrate; and

8. Ensure that a trained Owner or Occupational 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.

E. Ethanol and Isopropanol. If a Medical Marijuana-Infused 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.

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

M 700 Series – ~~Retail Marijuana Testing Facilities with Medical Marijuana Vendor Registration and Key Occupational Licensure to Test and Research Medical Marijuana~~Medical Marijuana Testing Facilities

Basis and Purpose – M 701

The statutory basis for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XX), 12-43.3-402(6), and 12-43.3-404(10), C.R.S. The purpose of this rule is to clarify the means by which the Division may utilize to ensure Medical Marijuana and Medical Marijuana-Infused Product are safe for patient consumption and that any Medical Marijuana or Medical Marijuana-Infused Product sold for human consumption do not contain contaminants that are injurious to health, and to help ensure sufficient and correct labeling.

M 701 – Vendor Registration and Occupational License for Medical Marijuana Testing and Research

A. Rule M 701 is repealed effective July 1, 2016.

B. Occupational License For Testing and Research

1. If a Retail Marijuana Testing Facility wishes to test and research Medical Marijuana, it shall first:

   a. Complete a current Division application, pay all applicable fees and obtain a registration as a vendor;

   b. Complete a current Division application, pay all applicable fees and obtain an Occupational License for at least one Owner to engage in testing and research.

2. The vendor registration and Occupational License referenced in this rule may only be granted to or held by a Retail Marijuana Testing Facility whose license and certification are current, valid and in good standing.

~~B~~C. Requirements and Violations

1. A Person holding a vendor registration and Occupational License to test and research Medical Marijuana must comply with all requirements in the Retail Marijuana Rules, 700 Series.

2. Any violation of such requirements in connection with testing and research of Medical Marijuana shall constitute a violation of these rules and a violation in connection with the Person's Retail Marijuana Testing Facility license.

Basis and Purpose – M 701.5

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2.5)(a)(I)(A), 12-43.3-310(8)(a), 12-43.3-402(6), 12-43.3-404(10), and section 12-43.3-405, C.R.S. The purpose of this rule is to establish that it is unlawful for a Medical Marijuana Testing Facility Licensee to exercise any privileges other than those granted by the State Licensing Authority and to clarify the license privileges.

M 701.5 - Medical Marijuana Testing Facilities: License Privileges

This rule shall be effective on July 1, 2016.

A. Privileges Granted. A Medical Marijuana Testing Facility shall only exercise those privileges granted to it by the State Licensing Authority.

B. Licensed Premises. A separate License is required for each specific Medical Marijuana Testing Facility and only those privileges granted by the Medical Code and any rules promulgated pursuant to it may be exercised on the Licensed Premises.

C. Testing of Medical Marijuana and Medical Marijuana Infused-Product Authorized. A Medical Marijuana Testing Facility may accept Samples of Medical Marijuana or Medical Marijuana Infused-Product from Medical Marijuana Businesses for testing and research purposes only. The Division may require a Medical Marijuana Business to submit a sample of Medical Marijuana or Medical Marijuana Infused-Product to a Medical Marijuana Testing Facility upon demand.

D. Product Development Authorized. A Medical Marijuana Testing Facility may develop Medical Marijuana Infused-Product, but is not authorized to engage in the manufacturing privileges described in section 12-43.3-404, C.R.S. and Rule M 601 – Medical Marijuana Infused-Products Manufacturer: License Privileges.

E. Sending Samples to Another Licensed and Certified Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility may send Samples to another Medical Marijuana Testing Facility for testing. All laboratory reports provided to a Medical Marijuana Business must identify the Medical Marijuana Testing Facility that actually conducted the test.

Basis and Purpose – M 702

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-405(3), 12-43.3-901, 12-43.4-405, 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.

M 702 – Medical Marijuana Testing Facilities: General Limitations or Prohibited Acts

This rule shall be effective on July 1, 2016.

A. Prohibited Financial Interest. A Person who is an Owner of an Optional Premises Cultivation, Medical Marijuana Infused-Products Manufacturing Facility, Medical Marijuana Center, Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturing Facility, or a Retail Marijuana Store shall not be an Owner of a Medical Marijuana Testing Facility.

B. Sale of Marijuana Prohibited. A Medical Marijuana Testing Facility is prohibited from selling, distributing, or transferring Retail Marijuana, Retail Marijuana Product, Medical Marijuana, or Medical Marijuana-Infused Product to a Retail Marijuana Establishment, a Medical Marijuana Business, or a consumer, except that a Medical Marijuana Testing Facility may transfer a Sample to another Medical Marijuana Testing Facility.

C. Destruction of Received Medical Marijuana. 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 M 307 – Waste Disposal.

D. Consumption Prohibited. A Medical Marijuana Testing Facility shall not permit the consumption of marijuana or marijuana products on its Licensed Premises.

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 its Samples are identified and tracked from the point they are transferred from a Medical Marijuana Business through the point of destruction or disposal. *See also* Rule M 309 – Medical Marijuana Business: Inventory Tracking System. 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 also* Rule M 901 – Business Records Required.

H. Industrial Hemp Testing Prohibited. A Medical Marijuana Testing Facility shall not perform testing on Industrial Hemp.

Basis and Purpose – M 703

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish a frame work for certification for Medical Marijuana Testing Facilities.

M 703 – Medical Marijuana Testing Facilities: Certification Requirements

This rule shall be effective on July 1, 2016.

A. Certification Types. A Medical Marijuana Testing Facility may only perform tests on Samples that the Medical Marijuana Testing Facility is certified by the Division to perform.

1. Microbials;

2. Residual solvents;

3. Chemical Contaminants;

4. Biological Contaminants; and

5. THC and other Cannabinoid potency.

B. Certification Procedures. The Medical Marijuana Testing Facility certification program is contingent upon successful on-site inspection, successful participation in proficiency testing, and ongoing compliance with the applicable requirements in this rule.

1. Certification Inspection. A Medical Marijuana Testing Facility must be inspected prior to initial certification and annually thereafter by an inspector approved by the Division.

2. Standards for Certification. A Medical Marijuana Testing Facility must meet standards of performance, as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: personnel qualifications, standard operating procedure manual, analytical processes, proficiency testing, quality control, quality assurance, security, chain of custody, specimen retention, space, records, and results reporting.

3. Personnel Qualifications

   a. Laboratory Director. A Medical Marijuana Testing Facility must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. *See* Rule M 704 – Retail Marijuana Testing Facilities: Personnel.

   b. Employee Competency. A Medical Marijuana Testing Facility must have a written and documented system to evaluate and document the competency in performing authorized tests for employees. Prior to independently analyzing samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls).

4. Standard Operating Procedure Manual. A Medical Marijuana Testing Facility must have a written procedure manual meeting the minimum standards set forth in these rules detailing the performance of all methods employed by the facility used to test the analytes it reports and made available for testing analysts to follow at all times.

   a. The current laboratory director must approve, sign and date each procedure. If any modifications are made to those procedures, the laboratory director must approve, sign and date the revised version prior to use.

   b. A Medical Marijuana Testing Facility must maintain a copy of all Standard Operating Procedures to include any revised copies for a minimum of three years. *See* Rule M 901 – Business Records Required.

5. Analytical Processes. A Medical Marijuana Testing Facility must maintain a listing of all analytical methods used and all analytes tested and reported. The Medical Marijuana Testing Facility must provide this listing to the Division upon request.

6. Proficiency Testing. A Medical Marijuana Testing Facility must successfully participate in a Division approved proficiency testing program in order to obtain and maintain certification.

7. Quality Assurance and Quality Control. A Medical Marijuana Testing Facility must establish and follow a quality assurance and quality control program to ensure sufficient monitoring of laboratory processes and quality of results reported.

8. Security. A Medical Marijuana Testing Facility must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.

9. Chain of Custody. A Medical Marijuana Testing Facility must establish a system to document the complete chain of custody for samples from receipt through disposal.

10. Space. A Medical Marijuana Testing Facility must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state and local requirements.

11. Records. A Medical Marijuana Testing Facility must establish a system to retain and maintain records for a period not less than three years.

12. Results Reporting. A Medical Marijuana Testing Facility must establish processes to ensure results are reported in a timely and accurate manner.

Basis and Purpose – M 704

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish personnel standards for the operation of a Medical Marijuana Testing Facility.

M 704 – Medical Marijuana Testing Facilities: Personnel

This rule shall be effective on July 1, 2016.

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; 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; or

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.

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 M 901 – 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 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 specimens, perform test procedures and report test results promptly and proficiently, 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 specimen processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results.

D. 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.

E. 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 Medical Marijuana Testing Facility, an individual must at least meet the educational requirements for a testing analyst.

M 705 – Basis and Purpose

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish Standard Operating Procedure Manual standards for the operation of a Medical Marijuana Testing Facility.

M 705 – Medical Marijuana Testing Facilities: Standard Operating Procedure Manual

This rule shall be effective on July 1, 2016.

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

1. Specimen receiving;

2. Specimen accessioning;

3. Specimen storage;

4. Identifying and rejecting unacceptable specimens;

5. Recording and reporting discrepancies;

6. Security of specimens, aliquots and extracts and records;

7. Validating a new or revised method prior to testing specimens to include: accuracy, precision, analytical sensitivity, analytical specificity (interferences), LOD, LOQ, and verification of the reportable range;

8. Aliquoting specimens to avoid contamination and carry-over;

9. Sample retention to assure stability for 90 days;

10. Disposal of specimens;

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 reviewing the results of testing calibrators, controls, standards, and subject tests 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 specimens are requested for referral and testing by another certified laboratory.

M 706 – Basis and Purpose

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish analytical processes standards for the operation of a Medical Marijuana Testing Facility.

M 706 – Medical Marijuana Testing Facilities: Analytical Processes

This rule shall be effective on July 1, 2016.

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 compare ion ratios and retention times between calibrators, controls and specimens 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 match an analyte, the relative retention time and mass spectra from a known standard or control must be run on the same system before reporting the results; 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 specimens 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 specimens 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. Other Analytical Methodology. A Medical Marijuana Testing Facility using other methodology or new methodology 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.

M 707 – Basis and Purpose

The statutory authority for this rule is found at subsection 12-43.3-202(2)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish a proficiency testing program for Medical Marijuana Testing Facilities.

M 707 – Medical Marijuana Testing Facilities: Proficiency Testing

This rule shall be effective on July 1, 2016.

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.

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.

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 for product testing.

E. Proficiency Testing Challenge Attestation. The laboratory director and all testing analysts that participated in a proficiency test must sign corresponding attestation statements.

F. Laboratory Director Must Review Results. The laboratory director must review and evaluate all proficiency test results.

G. When Remedial Action Required. A Medical Marijuana Testing Facility must take and document remedial action when a score of less than 100% is achieved during a proficiency test. Remedial action documentation must include a review of Samples tested and results reported since the last successful proficiency testing challenge.

H. What Constitutes Successful or Unsatisfactory Participation in Proficiency Testing Event. Successful participation is the positive identification of 80% of the target analytes that the Medical Marijuana Testing Facility reports to include quantitative results when applicable. Any false positive results reported will be considered an unsatisfactory score for the proficiency testing event.

I. Consequence of Unsuccessful Participation in Proficiency Testing Event. Unsuccessful participation in a proficiency test may result in limitation, suspension or revocation of certification.

M 708 – Basis and Purpose

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish quality assurance and quality assurance standards for a Medical Marijuana Testing Facility.

M 708 – Medical Marijuana Testing Facilities: Quality Assurance and Quality Control

This rule shall be effective on July 1, 2016.

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.

M 709 – Basis and Purpose

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, 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.

M 709 – Medical Marijuana Testing Facilities: Chain of Custody

This rule shall be effective on July 1, 2016.

General Requirements. A Medical Marijuana Testing Facility must establish an adequate chain of custody and Sample requirement instructions that must include, but not be limited to;

1. Issue instructions for the minimum 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 Sample;

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

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

5. Document all transfers of 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 Samples;

10. Ensure Samples are stored appropriately; and

11. Document the disposal of Samples, aliquots, and extracts.

Basis and Purpose – M 710

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish records retention standards for a Medical Marijuana Testing Facility.

M 710 – Medical Marijuana Testing Facilities: Records Retention

This rule shall be effective on July 1, 2016.

A. General Requirement. A Medical Marijuana Testing Facility must maintain all required business records. *See* Rule M901 - Business Records Required.

B. Specific Business Records Required: Three Year Retention. A Medical Marijuana Testing Facility must establish processes to preserve records for a minimum of three years that includes, but is not limited to;

1. Test Results;

2. Quality Control and Quality Assurance Records;

3. Standard Operating Procedures;

4. Personnel Records;

5. Chain of Custody Records;

6. Proficiency Testing Records; and

7. Analytical Data to include printouts generated by the instrumentation.

C. Specific Business Records Required: Five Year Retention. A Medical Marijuana Testing Facility must establish processes to preserve records for a minimum of five years of testing to include, accession numbers, specimen type, raw data of calibration standards and curves, controls and subject results, final and amended reports, acceptable reference range parameters, and identification of analyst and date of analysis.

Basis and Purpose – M 711

The statutory authority for this rule is found at subsection 12-43.3-202(2.5)(a)(I) and section 12-43.3-405, C.R.S. The purpose of this rule is to establish reporting standards for a Medical Marijuana Testing Facility.

M 711 – Reporting

This rule shall be effective on July 1, 2016.

Required Procedures. A Medical Marijuana Testing Facility must establish procedures to ensure that results are accurate, precise and scientifically valid prior to reporting that include the following processes;

1. Report quantitative results that are only above the lowest concentration of calibrator or standard used in the analytical run;

2. Verify results that are below the lowest concentration of calibrator or standard and above the LOQ by using a blank and a standard that falls below the expected value of the analyte in the sample in duplicate prior to reporting a quantitative result;

3. Qualitatively report results below the lowest concentration of calibrator or standard and above the LOD as either trace or using a non-specific numerical designation;

4. Adequately document the available external chain of custody information;

5. Ensure all final reports contain the name and location of the Medical Marijuana Testing Facility Licensee, name and unique identifier of sample, submitting client, sample received date, date of report, type of specimen tested, test result, units of measure, and any other information or qualifiers needed for interpretation when applicable to the test method and results being reported, to include any identified and documented discrepancies;

6. Provide the final report to the submitting client in a timely manner; and

7. Provide copies of final reports to the Division when results of tested samples exceed maximum levels of allowable contamination within 72 hours of obtaining the final result.

Basis and Purpose – M 712

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.4-203(2.5)(a), 12-43.3-202(2)(a)(XIV), 12-43.4-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XX), and 12-43.3-405, 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 random sampling program that is applicable to Medical Marijuana Testing Facilities.

M 712 – Medical Marijuana Testing Facility: Sampling and Testing Program

This rule shall be effective on July 1, 2016.

A. Division Authority. The Division may elect to require that a Test Batch be submitted to a specific Medical Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.

B. Test Batches

1. Medical Marijuana and Medical Marijuana Concentrate. A Medical Marijuana Testing Facility must establish a standard minimum weight of Medical Marijuana and Medical Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.

2. Medical Marijuana Infused-Product. A Medical Marijuana Testing Facility must establish a standard number of finished product(s) it requires to be included in each Test Batch of Medical Marijuana Infused-Product for every type of test that it conducts.

C. Rejection of Test Batches and Samples

1. A Medical Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.

2. A Medical Marijuana Testing Facility may not accept a Test Batch or Sample that it knows was not taken in accordance with these rules or any additional Division sampling procedures or was not collected by Division personnel.

D. Notification of Medical Marijuana Business. If Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product failed a contaminant test, then the Medical Marijuana Testing Facility must immediately notify the Medical Marijuana Business that submitted the sample for testing and report the failure in accordance with all Inventory Tracking System procedures.

E. Permissible Levels of Contaminants. If Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana Infused-Product 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

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
–Shiga-toxin producing Escherichia coli (STEC)*- Bacteria	< 1 Colony Forming Unit (CFU)	Flower; Medical Marijuana Infused-Product; Water- and Food-Based Medical Marijuana Concentrates
Salmonella species* – Bacteria	< 1 Colony Forming Unit (CFU)	
Total Yeast and Mold	< 10^5 Colony Forming Unit (CFU)	

*Testing facilities should contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits.

2. Residual Solvents

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
Butanes	< 800 Parts Per Million (PPM)	Solvent-Based Medical Marijuana Concentrate
Heptanes	< 500 Parts Per Million (PPM)	
Benzene**	< 1 Parts Per Million (PPM)	
Toluene**	< 1 Parts Per Million (PPM)	
Hexane**	< 10 Parts Per Million (PPM)	
Total Xylenes (m,p, o-xylenes)**	< 1 Parts Per Million (PPM)	
Any solvent not permitted for use pursuant to Rule R 605.	None Detected	

** Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use per Rule M 605, limits have been listed here accordingly.

3. Metals

Substance	**Acceptable Limits Per Gram**	**Product to be Tested**
Metals (Arsenic, Cadmium, Lead and Mercury)	Lead – Max Limit: < 10 ppm Arsenic – Max Limit: < 10 ppm	Flower; Water-, Food-, and Solvent-Based Medical Marijuana

	Cadmium – Max Limit: <4.1 ppm Mercury – Max Limit: <2.0 ppm	Concentrates; and Medical Marijuana-Infused Product

4. Other Contaminants

Pesticide	If testing identifies the use of a banned Pesticide or the improper application of a permitted Pesticide, then that Test Batch shall be considered to have failed contaminant testing.
Chemicals	If Test Batch is found to contain levels of any chemical that could be toxic if consumed, then the Division may determine that the Test Batch has failed contaminant testing.
Microbials	If Test Batch is found to contain levels of any microbial that could be toxic if consumed, then the Division may determine that the Test Batch has failed contaminant testing.
Molds, Mildew, and Filth	If a Test Batch is found to contain levels of any mold, mildew, or filth that could be toxic if consumed, then that Test Batch shall be considered to have failed contaminant testing.

5. Division Notification. A Medical Marijuana Testing Facility must notify the Division 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.

F. Potency Testing

1. Cannabinoids Potency Profiles. A Medical Marijuana Testing Facility may test and report results for any cannabinoid provided the test is conducted in accordance with the Division's Medical Marijuana Testing Facility Certification Policy Statement.

2. Reporting of Results

a. For potency tests on Medical Marijuana and Medical Marijuana Concentrate, results must be reported by listing a single percentage concentration for each cannabinoid that represents an average of all samples within the Test Batch.

b. For potency tests conducted on Medical Marijuana Infused-Product, results must be reported by listing the total number of milligrams contained within a single Medical Marijuana-Infused Product unit for sale for each cannabinoid and affirming the THC content is homogenous.

3. Dried Flower. All potency tests conducted on Medical Marijuana must occur on dried and cured Medical Marijuana that is ready for sale.

4. Failed Potency Tests for Medical Marijuana Infused-Product

a. If the THC content of a Medical Marijuana Infused-Product is determined through testing not to be homogenous, then it shall be considered to have failed potency testing. A Medical Marijuana Infused-Product shall be considered not to be homogenous if 10% of the infused portion of the Medical Marijuana Infused-Product contains more than 20% of the total THC contained within entire Medical Marijuana Infused-Product.

5. Potency Variance. A potency variance of no more than plus or minus 15% is allowed.

M 800 Series – Transport and Storage

Basis and Purpose – M 801

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XI), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of the rule is to provide clarity as to the requirements associated with the delivery of Medical Marijuana and Medical Marijuana-Infused Product between Licensed Premises. It also prescribes the manner in which licensed entities will track inventory in the transport process to prevent diversionary practices.

M 801 – Transport of Medical Marijuana, Medical Marijuana Vegetative plants, and Medical Marijuana-Infused Product

A. Persons Authorized to Transport. The only Persons authorized to transport Medical Marijuana, Medical Marijuana Vegetative plants, or Medical Marijuana-Infused Product are those individuals licensed by the State Licensing Authority pursuant to section 12-43.3-401, C.R.S.; including Owners or others holding Occupational Licenses. An individual who does not possess a current and valid Occupational License from the State Licensing Authority may not transport Medical Marijuana, Medical Marijuana Vegetative plants, or Retail Marijuana Product between Licensed Premises.

B. Transport Between Licensed Premises.

1. Medical Marijuana and Medical Marijuana-Infused Product. Medical Marijuana and Medical Marijuana-Infused Product shall only be transported between Licensed Premises and between Licensed Premises and a permitted off-premises storage facility. Licensees transporting Medical Marijuana and Medical Marijuana-Infused Product are responsible for ensuring that all Medical Marijuana and Medical Marijuana-Infused Product are secured at all times during transport.

2. Medical Marijuana Vegetative plants. Medical Marijuana Vegetative plants shall only be transported between Licensed Premises due to an approved change of location pursuant to rule M 206 – Changing Location of Licensed Premises: Medical Marijuana Businesses, or due to a one-time transfer pursuant to rule M 211 – Conversion - Medical Marijuana Business to Retail Marijuana Establishment. Transportation of Vegetative plants to a permitted off-premises storage facility shall not be allowed.

C. Inventory Tracking System-Generated Transport Manifest Required. A Licensee may only transport Medical Marijuana, Medical Marijuana Vegetative plants and Medical Marijuana-Infused Product if he or she has a hard copy of an Inventory Tracking System-generated transport manifest that contains all the information required by this rule and shall be in the format prepared by the State Licensing Authority.

1. Medical Marijuana and Medical Marijuana-Infused Product. A Licensee may transport Medical Marijuana or Medical Marijuana-Infused Product from an originating location to multiple destination locations so long as the transport manifest correctly reflects the specific inventory destined for specific licensed locations.

2. Medical Marijuana Vegetative plants. A Licensee shall transport Medical Marijuana Vegetative plants only from the originating Licensed Premises to the destination Licensed Premises due to a change of location that has been

approved by the Division, or from a Medical Marijuana Business to a Retail Marijuana Establishment due to a one-time transfer pursuant to rule M 211.

D. Motor Vehicle Required. Transport of Medical Marijuana and Medical Marijuana-Infused Product shall be conducted by a motor vehicle that is properly registered in the state of Colorado pursuant to motor vehicle laws, but need not be registered in the name of the Licensee. Except that when a rental truck is required for transporting Medical Marijuana Vegetative plants, Colorado motor vehicle registration is not required.

E. Documents Required During Transport. Transport of Medical Marijuana, Medical Marijuana Vegetative plants, or Medical Marijuana-Infused Product shall be accompanied by a copy of the originating Medical Marijuana Business's business license, the driver's valid Owner or Occupational License, the driver's valid motor vehicle operator's license, and all required vehicle registration information.

F. Use of Colorado Roadways. State law does not prohibit the transport of Medical Marijuana, Medical Marijuana Vegetative plants, and Medical Marijuana-Infused Product on any public road within the state of Colorado as authorized in this rule. However, nothing herein authorizes a Licensee to violate specific local ordinances or resolutions enacted by any city, town, city and county, or county related to the transport of Medical Marijuana, Medical Marijuana Vegetative plants, or Medical Marijuana-Infused Product.

G. Preparation of Medical Marijuana and Medical Marijuana-Infused Product for Transport

1. Final Weighing and Packaging. A Medical Marijuana Business shall comply with the specific rules associated with the final weighing and packaging of Medical Marijuana or Medical Marijuana-Infused Product before such items are prepared for transport pursuant to this rule. The scale used to weigh product to be transported shall be ~~certified~~ tested and approved in accordance with measurement standards established in 35-14-127,~~Article 14 of Title 35~~, C.R.S.

2. Preparation in Limited Access Area. Medical Marijuana and Medical Marijuana-Infused Product shall be prepared for transport in a Limited Access Area, including the packing and labeling of Shipping Containers.

3. Shipping Containers. All Shipping Containers must be affixed with an RFID tag prior to transport. Sealed packages or Containers may be placed in larger Shipping Containers, so long as such Shipping Containers are labeled with type and amount of Medical Marijuana or Medical Marijuana-Infused Product contained therein. The contents of Shipping Containers shall be easily accessible and may be inspected by the State Licensing Authority, local licensing authorities, and state and local law enforcement agency for a purpose authorized by the Medical Code or for any other state or local law enforcement purpose.

G.5 Required RFID Tags for Medical Marijuana Vegetative Plants. Each Medical Marijuana Vegetative plant that is transported pursuant to this rule must have a RFID tag affixed to it prior to transport.

H. Creation of Records and Inventory Tracking

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

a. Medical Marijuana or Medical Marijuana-Infused Product. Licensees who transport Medical Marijuana or Medical Marijuana-Infused Product shall create an Inventory Tracking System-generated transport manifest to

reflect inventory that leaves the Licensed Premises for destinations to other licensed locations. The transport manifest may either reflect all deliveries for multiple locations within a single trip or separate transport manifests may reflect each single delivery. In either case, no inventory shall be transported without an Inventory Tracking System-generated transport manifest.

b. Medical Marijuana Vegetative Plants. Licensees who transport Medical Marijuana Vegetative plants shall create an Inventory Tracking System-generated transport manifest to reflect inventory that leaves the originating Licensed Premises to be transported to the destination Licensed Premises due to a change of location approved by the Division pursuant to rule M 206, or a one-time transfer pursuant to rule M 211.

2. Copy of Transport Manifest to Receiver. A Licensee shall provide a copy of the transport manifest to each Medical Marijuana Business receiving the inventory described in the transport manifest. In order to maintain transaction confidentiality, the originating Licensee may prepare a separate Inventory Tracking System-generated transport manifest for each receiving Medical Marijuana Business.

3. The Inventory Tracking System-generated transport manifest shall include the following:

a. Departure date and approximate time of departure;

b. Name, location address, and license number of the originating Medical Marijuana Business;

c. Name, location address, and license number of the destination Medical Marijuana Business(es), or the destination Retail Marijuana Establishment in the event of a one-time transfer;

d. Product name and quantities (by weight or unit) of each product to be delivered to each specific destination location(s);

e. Arrival date and estimated time of arrival;

f. Delivery vehicle make and model and license plate number; and

g. Name, Occupational License number, and signature of the Licensee accompanying the transport.

I. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a Medical Marijuana Business shall be responsible for all the procedures associated with the tracking of inventory that is transported between Licensed Premises. *See* Rule M 901 – Business Records Required.

1. Responsibilities of Originating Licensee.

a. Medical Marijuana or Medical Marijuana-Infused Product. Prior to departure, the originating Medical Marijuana Business shall adjust its records to reflect the removal of Medical Marijuana or Medical Marijuana-Infused Product. The scale used to weigh product to be transported shall be ~~certified~~ tested and approved in accordance with measurement

standards established in 35-14-127,~~Article 14 of Title 35~~, C.R.S. Entries to the records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.

b. Medical Marijuana Vegetative Plants. Prior to departure, the originating Optional Premises Cultivation Operation shall adjust its records to reflect the removal of Medical Marijuana Vegetative plants. Entries to the records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.

2. Responsibilities of Receiving Licensee.

a. Medical Marijuana or Medical Marijuana-Infused Product. Upon receipt, the receiving Licensee shall ensure that the Medical Marijuana or Medical Marijuana-Infused Product received are as described in the transport manifest and shall immediately adjust its records to reflect the receipt of inventory. The scale used to weigh product being received shall be ~~certified~~ tested and approved in accordance with measurement standards established in 35-14-127,~~Article 14 of Title 35~~, C.R.S. Entries to the inventory records shall note the Inventory Tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.

b. Medical Marijuana Vegetative Plants. Upon receipt, the receiving Licensee shall ensure that the Medical Marijuana Vegetative plants received are as described in the transport manifest, accounting for all RFID tags and each associated plant, and shall immediately adjust its records to reflect the receipt of inventory.

3. Discrepancies. A receiving Licensee shall separately document any differences between the quantity specified in the transport manifest and the quantities received. Such documentation shall be made in the Inventory Tracking System and in any relevant business records.

J. Adequate Care of Perishable Medical Marijuana-Infused Product. A Medical Marijuana Business must provide adequate refrigeration for perishable Medical Marijuana-Infused Product during transport.

Basis and Purpose – M 802

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(h), 12-43.3-202(2)(a)(XI), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish that Medical Marijuana and Medical Marijuana-Infused Product may not be stored outside of Licensed Premises unless the Licensee obtains an off-premises storage permit. Rule 802.G was amended to require Medical Marijuana Businesses to submit proof of local approval or acknowledgement with an application for an off-premises storage facility. This change was made due to comments received from local government.

M 802 – Off-Premises Storage of Medical Marijuana and Medical Marijuana-Infused Product

A. Off-premises Storage Permit Authorized. A Licensee may only store Medical Marijuana or Medical Marijuana-Infused Product in its Licensed Premises or in its one permitted off-premises storage facility.

B. Permitting. To obtain a permit for an off-premises storage facility, a Medical Marijuana Business must apply on current Division forms and pay any applicable fees.

C. Extension of Licensed Premises. A permitted off-premises storage facility shall constitute an extension of the Medical Marijuana Business' Licensed Premises and be subject to all to the conditions and restrictions established in Rule M 301 – Limited Access Areas.

D. Limitation on Inventory to be Stored. The Licensee may only have upon the permitted off-premises storage facility Medical Marijuana or Medical Marijuana-Infused Product that are part of its finished goods inventory. The Licensee may not share the premises with, nor store inventory belonging to, a Retail Marijuana Establishment or Medical Marijuana Business that is not commonly-owned.

E. Restrictions. The permitted off-premises storage facility may be utilized for storage only. A Licensee may not sell, cultivate, manufacture, process, test, or consume any Medical Marijuana or Medical Marijuana-Infused Product within the premises of the permitted off-premises storage facility.

F. Display of Off-premises Storage Permit and License. The off-premises storage facility permit and a copy of the Medical Marijuana Business' license must be displayed in a prominent place within the permitted off-premises storage facility.

G. Local Licensing Authority Approval

1. Prior to submitting an application for an off-premises storage facility permit, the Licensee must obtain approval from the relevant local licensing authority.

2. A copy of the relevant local licensing authority's approval must be submitted by the Licensee in conjunction with its application for an off-premises storage facility.

3. No Medical Marijuana or Medical Marijuana-Infused Product may be stored within a permitted storage facility until the relevant local licensing authority has been provided a copy of the off-premises storage facility permit.

4. Any off-premises storage permit issued by the Division shall be conditioned upon the Medical Marijuana Business' receipt of all required local approvals.

H. Security in Storage Facility. A permitted off-premises storage facility must meet all video and security requirements applicable to a Licensed Premises.

I. Transport to or from a Permitted Off-premises Storage Facility. A Medical Marijuana Business must comply with Rule M 801 - Transport of Medical Marijuana and Medical Marijuana-Infused Product when transporting any Medical Marijuana or Medical Marijuana-Infused Product to a permitted off-premises storage facility.

J. Inventory Tracking. In addition to all the other tracking requirements set forth in these rules, a Medical Marijuana Business shall utilize the Inventory Tracking System to track its inventories from the point of transfer to or from a permitted off-premises storage facility. *See* Rules M 901 – Business Records Required and M 309- Medical Marijuana Business: Inventory Tracking System.

K. Inventory Tracking System Access and Scale. Every permitted off-premises storage facility must have an Inventory Tracking System terminal and a scale ~~certified~~ tested and

approved in accordance with measurement standards established in 35-14-127,~~Article 14 of Title 35~~, C.R.S.

L. Adequate Care of Perishable Medical Marijuana-Infused Product. A Medical Marijuana Business must provide adequate refrigeration for perishable Medical Marijuana-Infused Product and shall utilize adequate storage facilities and transport methods.

M. Consumption Prohibited. A Medical Marijuana Business shall not permit the consumption of marijuana or marijuana products on the premises of its permitted off-premises storage facility.

M 900 Series – Business Records

Basis and Purpose – M 901

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XVII), and 12-43.3-202(2)(a)(XX), C.R.S. This rule explains what business records a Licensee must maintain. It also clarifies that such records must be made available to the Division on demand. Rule R 901.B was added due to written commentary received from an industry representative.

M 901 – Business Records Required

A. General Requirements

1. A Medical 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 Medical 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 Medical Marijuana Business' books and records for the preceding six months (or complete copies of such records) must be maintained on its 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. The books and records must fully account for the transactions of the business and must include, but shall not be limited to:

   a. Current Employee List – This list must provide the full name and Occupational License number of each employee and all non-employee Owners, who work at a Medical Marijuana Business.

      i. Once the functionality is developed, each Licensed Premises shall enter the full name and Occupational license number of every employee that works on the premises into the Inventory Tracking System. The Licensed Premises shall update its list of employees in the Inventory Tracking System within 10 days of an employee commencing or ceasing employment on the premises.

   b. Secure Facility Information – For its Licensed Premises and any associated permitted off-premises storage facility, a Medical Marijuana Business must maintain the business contact information for vendors that maintain video surveillance systems and Security Alarm Systems.

   c. Licensed Premises – Diagram of all approved Limited Access Areas and any permitted off-premises storage facilities.

   d. Visitor Log – List of all visitors entering Limited Access Areas or Restricted Access Areas.

   e. All records normally retained for tax purposes.

B. 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. Violation Affecting Public Safety. Violation of this rule may constitute a license violation affecting public safety.

D. Records Related to Inventory Tracking. A Medical Marijuana Business must maintain accurate and comprehensive inventory tracking records that account for, reconcile, and evidence all inventory activity for Medical Marijuana from either seed or Immature Plant stage until the Medical Marijuana or Medical Marijuana-Infused Product is destroyed or sold to another Medical Marijuana Business or a patient.

E. Records Related to Transport. A Medical Marijuana Business must maintain adequate records for the transport of all activities related to Medical Marijuana and Medical Marijuana-Infused Product. *See* Rule M 801 – Transport of Medical Marijuana or Medical Marijuana-Infused Product.

F. Provision of Requested Records 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 – M 904

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XVII), 12-43.3-202(2)(a)(XX), and 12-43.3-310(12), C.R.S. The State Licensing Authority must know the individuals serving as managers of Medical Marijuana Businesses. Accordingly, this rule reiterates the statutory mandate that a Medical Marijuana Business must report any management change to the Division ~~within seven days of any~~prior to the change. The rule also clarifies that a Medical Marijuana Business must save a copy of any management change report to the Division and that failure to follow this rule can result in discipline.

M 904 – ~~Manager Change Must Be Reported~~Medical Marijuana Business Reporting Requirements

A. Manager Change Must Be Reported.

1. When Required. A Medical Marijuana Business shall provide the Division a written report ~~within seven days after~~prior to any change in manager occurs.

~~B~~ 2. Licensee Must Maintain Record of Reported Change. A Medical Marijuana Business must also maintain a copy of this written report with its business records.

~~C~~ 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 Othewise Related to a Medical Marijuana Business. A Medical Marijuana Business and all Licensees employed by the Medical 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 Medical 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 Medical

Marijuana Business or Licensee may have to report criminal activity to a local law enforcement agency.

M 1000 Series – Labeling, Packaging, and Product Safety

Basis and Purpose – M 1001

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), and 12-43.3-202(2)(a)(XX), C.R.S. Extensive labeling and secure packaging of Medical Marijuana and Medical Marijuana-Infused Product is of statewide concern. The purpose of this rule, and other rules in this series, is to ensure that all Medical Marijuana and Medical Marijuana-Infused Product are sold and delivered to lawful patients in packaging that is not easily opened by children. This rule also clarifies packaging and labeling terms that will be used throughout this rule and rules in the same series to ensure that Coloradoans are adequately informed.

M 1001 – Packaging Requirements: General Requirements

Rule M 1001 is repealed effective October 1, 2016

Packaging of Medical Marijuana and Medical Marijuana-Infused Product by a Medical Marijuana Center. A Medical Marijuana Center must ensure that all Medical Marijuana and Medical Marijuana-Infused Product is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Opaque and Resealable Exit Package that is Child-Resistant.

Basis and Purpose – M 1001.5

The statutory authority for this rule is found at subsections 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-404(5), and 12-43.3-901(3), C.R.S. The State Licensing Authority finds it essential to regulate and establish labeling and secure packaging requirements for Medical Marijuana, Medical Marijuana Concentrates, and Medical Marijuana Infused-Product. The purpose of this rule, and the rules in this series, is to ensure that all Medical Marijuana and Medical Marijuana Infused-Product are sold and delivered to lawful consumers in packaging that is not easily opened by children.

M 1001.5 – Labeling and Packaging Requirements: General Applicability

Rule M 1001.5 is effective beginning October 1, 2016

A. Ship Product Ready for Sale. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer may package smaller quantities of Medical Marijuana, Medical Marijuana Concentrates, and Medical Marijuana Infused-Product in a Container prior to transport, provided the Containers are placed within a Shipping Container. See Rule M 309 – Inventory Tracking System and Rule M 801 – Transport of Medical Marijuana and Medical Marijuana Infused-Product.

B. Inventory Tracking Compliance.

1. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer must package all Medical Marijuana, Medical Marijuana Concentrates, and Medical Marijuana Infused-Product in accordance with all Inventory Tracking System rules and procedures.

2. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer must place an RFID tag on every Shipping Container holding Medical Marijuana, Medical Marijuana Concentrates, or Medical Marijuana Infused-Product prior to transport or transfer of possession to another

Medical Marijuana Business. *See* Rule R 309 – Inventory Tracking System and Rule M 801 – Transport of Medical Marijuana and Medical Marijuana Infused-Product.

C. Packaging May Not Be Designed to Appeal to Children. A Medical Marijuana Business shall not place any content on a Container holding Medical Marijuana, Medical Marijuana Concentrates, or a Medical Marijuana Infused-Product in a manner that specifically targets individuals under the age of 21, including but not limited to, cartoon characters or similar images.

D. Health and Benefit Claims. Labeling text on a Container may not make any false or misleading statements regarding health or physical benefits to the consumer.

E. Font Size. Labeling text on a Container must be no smaller than 1/16 of an inch.

F. Use of English Language. Labeling text on a Container must be clearly written or printed and in the English language.

G. Unobstructed and Conspicuous. Labeling text on a Container must be unobstructed and conspicuous. A Licensee may affix multiple labels to a Container, provided that none of the information required by these rules is completely obstructed.

H. Use of the Word "Candy" Prohibited. Licensees shall not use the word "candy" on the product, packaging or labeling for Medical Marijuana or Medical Marijuana-Infused Product.

Basis and Purpose – M 1002

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure that the labeling on each Container of Medical Marijuana and Medical Marijuana-Infused Product includes necessary and relevant information for consumers, is easily accessible to consumers, and is clear and noticeable. This rule also ensures that Medical Marijuana and Medical Marijuana-Infused Products labeling does not include health and physical benefit claims.

M 1002 – Labeling Requirements: General Requirements

Rule M 1002 is repealed effective October 1, 2016

A. Labeling Required. All Medical Marijuana and Medical Marijuana-Infused Product sold, transferred, or otherwise provided to a consumer must be in a Container that is labeled with all required information, *see* Rules M 1001 – Packaging Requirements: General Requirements, M 1003 – Labeling Requirements: Specific Requirements, Medical Marijuana and Medical Marijuana-Infused Product and M 1004 – Labeling Requirements: Specific Requirements, Edible Medical Marijuana-Infused Product, and that specifically excludes certain text.

B. Health and Benefit Claims. Labeling text on a Container may not make any false or misleading statements regarding health or physical benefits to the consumer.

C. Font Size. Labeling text on a Container must be no smaller than 1/16 of an inch.

D. Use of English Language. Labeling text on a Container must be clearly written or printed and in the English language.

E. Unobstructed and Conspicuous. Labeling text on a Container must be unobstructed and conspicuous. A Licensee may affix multiple labels to a Container, provided that none of the information required by these rules is completely obstructed.

Basis and Purpose – M 1002.5

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2.5)(a)(I), 12-43.3-402(7), 12-43.3-404(10), and 12-43.3-901(3), C.R.S. The purpose of this rule is to ensure that every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer label each Shipping Container and Container of Medical Marijuana with all of the necessary and relevant information for the receiving Medical Marijuana Business. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques for all Medical Marijuana as this is a public health and safety concern.

M 1002.5 – Packaging and Labeling of Medical Marijuana by a Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer

Rule M 1002.5 is effective beginning October 1, 2016

A. Packaging of Medical Marijuana by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that all Medical Marijuana is placed within a sealed, tamper-evident Shipping Container that has no more than ten pounds of Medical Marijuana within it prior to transport or transfer of any Medical Marijuana to another Medical Marijuana Business.

B. Labeling of Medical Marijuana Shipping Containers by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that a label(s) is affixed to every Shipping Container holding Medical Marijuana that includes all of the information required by this rule prior to transport or transfer to another Medical Marijuana Business.

1. Required Information. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure the following information is affixed to every Shipping Container holding Medical Marijuana:

a. The license number of the Optional Premises Cultivation Operation where the Medical Marijuana was grown;

b. The Harvest Batch Number(s) assigned to the Medical Marijuana;

c. The net weight, using a standard of measure compatible with the Inventory Tracking System, of the Medical Marijuana prior to its placement in the Shipping Container; and

d. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana.

2. Required Potency Statement. For each Harvest Batch of Medical Marijuana packaged within a Shipping Container, the potency of at least the Medical

Marijuana'sTHC and CBD shall be included on a label that is affixed to the Shipping Container. The potency shall be expressed as a range of percentages that extends from the lowest percentage to the highest percentage of concentration for each cannabinoid listed, from every test conducted on that strain of Medical Marijuana cultivated by the same Optional Premises Cultivation Operation within the last three months.

3. Required Contaminant Testing Statement.

a. When All Required Contaminant Tests Are Not Performed. If a Medical Marijuana Testing Facility did not test a Harvest Batch for microbials, mold, mildew, and filth, then the Shipping Container shall be labeled with the following statement: **"The marijuana contained within this package has not been tested for contaminants."** Except that when an Optional Premises Cultivation Operation has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Shipping Container instead shall be labeled with the following statement: "**The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501.**"

b. When All Required Contaminant Tests Are Performed and Passed. If a Medical Marijuana Testing Facility tested a Harvest Batch for microbials, mold, mildew, and filth, and the required test(s) passed, then the Shipping Container shall be labeled with the following statement: "**The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501**."

c. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

C. Labeling of Medical Marijuana Containers by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. If an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer packages Medical Marijuana within a Container that is then placed within a Shipping Container, each Container must be affixed with a label(s) containing all of the information required by Rule M 1002.5(B), except that the net weight statement required by Rule M 1002.5(B)(1)(c) shall be based upon the weight in the Container and not the Shipping Container.

Basis and Purpose – M 1003

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure that each Container of Medical Marijuana and Medical Marijuana-Infused Product includes necessary and relevant labeling information for consumers.

M 1003 – Labeling Requirements: Specific Requirements, Medical Marijuana and Medical Marijuana-Infused Product

Rule M 1003 is repealed effective October 1, 2016

A. Labels Required. No Licensee shall sell, transfer, or give away any Medical Marijuana that does not contain a Label with a list of all ingredients, including all chemical additives, including but not limited to nonorganic pesticides, herbicides, and fertilizers that were used in its cultivation and production. The label must also list:

1. The Batch Number or numbers assigned by the Optional Premises Cultivation Operation to the marijuana plant or plants from which the Medical Marijuana contained within the Container was harvested; and

2. A complete list of solvents and chemicals used in the creation of any Medical Marijuana concentrate.

B. Medical Marijuana Container Labeling Must Include the Following Information:

1. The license number of the Optional Premises Cultivation Facility, if different than the Medical Marijuana Center's license number, identifying where the Medical Marijuana within the Container was grown;

2. The license number of the Medical Marijuana Center that sold the Medical Marijuana to the patient;

3. The date of sale; and

4. The patient registry number of the purchaser.

C. Medical Marijuana-Infused Product Container Labeling Must Include the Following Information:

1. The license number of the Medical Marijuana Business(es) where the Medical Marijuana used to manufacture the Medical Marijuana-Infused Product within the Container was grown;

2. The license number of the Medical Marijuana Center that sold the Medical Marijuana-Infused Product to the patient;

3. The following statement: "This product contains medical marijuana and was produced without regulatory oversight for health, safety or efficacy and there may be health risks associated with the consumption of the product."

4. For Medical Marijuana-Infused Product, the product identity and net weight statements must appear on the portion of the label displayed to the patient.

5. When a Medical Marijuana-Infused Product is made specifically for a designated patient, the label of that product shall state the patient's Medical Marijuana Registry number.

6. The list of ingredients and company name statements must be conspicuously listed on the Medical Marijuana-Infused Product package.

7. A nutrition facts panel may be required if nutritional claims are made on the label of any Medical Marijuana-Infused Product.

D. Minimum print size. The minimum print size for each of the required statements for non-infused products and for each of the required statements for Medical Marijuana-Infused

Product is 1/16 inch. The size of the characters in the net weight statement is determined by the area of the principal display panel and may be greater than 1/16 inch.

Basis and Purpose – M 1003.5

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2.5)(a)(I), 12-43.3-402(7), 12-43.3-404(5), 12-43.3-404(10), 12-43.3-404(11)(b-c), and 12-43.3-901(3), C.R.S. The purpose of this rule is to ensure that every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer labels each Shipping Container and Container of Medical Marijuana Concentrate with all of the necessary and relevant information for the receiving Medical Marijuana Business. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques for all Medical Marijuana Concentrate because it is a public health and safety concern.

M 1003.5 – Packaging and Labeling of Medical Marijuana Concentrate by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer.

Rule M 1003.5 is effective beginning October 1, 2016

A. Packaging of Medical Marijuana Concentrate by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that all Medical Marijuana Concentrate is placed within a sealed, tamper-evident Shipping Container that has no more than one pound of Medical Marijuana Concentrate within it prior to transport or transfer to another Medical Marijuana Business.

B. Labeling Medical Marijuana Concentrate Shipping Containers by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure that a label(s) is affixed to every Shipping Container holding Medical Marijuana Concentrate that includes all of the information required by this rule prior to transport or transfer to another Medical Marijuana Business.

1. Required Information. Every Optional Premises Cultivation Operation and Medical Marijuana-Infused Products Manufacturer must ensure the following information is affixed to every Shipping Container holding Medical Marijuana Concentrate:

a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana used to produce the Medical Marijuana Concentrate was grown;

b. The license number of the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana Concentrate;

c. The Production Batch Number assigned to the Medical Marijuana Concentrate contained within the Shipping Container;

d. The net weight, using a standard of measure compatible with the Inventory Tracking System, of the Medical Marijuana Concentrate prior to its placement in the Shipping Container;

e. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana used to produce the Medical Marijuana Concentrate contained within; and

f. A complete list of solvents and chemicals used to create the Medical Marijuana Concentrate.

2. Required Potency Statement. For each Production Batch of Medical Marijuana Concentrate packaged within a Shipping Container, the potency of at least the Medical Marijuana Concentrate's THC and CBD shall be included on a label that is affixed to the Shipping Container. The potency shall be expressed in milligrams for each cannabinoid.

3. Required Contaminant Testing Statement.

a. When All Required Contaminant Tests Are Not Performed.

i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Solvent-Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, then the Shipping Container shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package has not been tested for contaminants."** Except that when a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, the Shipping Container instead shall be labeled with the following statement: "**The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501.**"

ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Food- or Water-Based Medical Marijuana Concentrate for microbials, mold, and mildew, then the Shipping Container shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package has not been tested for contaminants."** Except that when an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Shipping Container instead shall be labeled with the following statement: "**The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501.**"

b. When All Required Contaminant Tests Are Performed and Passed.

i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch of Solvent-

Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, and the required test(s) passed, then the Shipping Container shall be labeled with the following statement: "**The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501**."

ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch for microbials, mold, and mildew, and the required test(s) passed, then the Shipping Container shall be labeled with the following statement: "**The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501**."

c. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana Concentrate that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

C. Labeling of Medical Marijuana Concentrate Containers by an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer. If an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer packages a Medical Marijuana Concentrate within a Container that is then placed within a Shipping Container, each Container must be affixed with a label(s) containing all of the information required by Rule M 1003.5(B), except that the net weight statement required by Rule M 1003.5(B)(1)(d) shall be based upon the weight in the Container and not the Shipping Container.

Basis and Purpose – M 1004

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to ensure that each Container of an Edible Medical Marijuana-Infused Product includes necessary and relevant information for patients.

M 1004 – Labeling Requirements: Specific Requirements, Medical Marijuana-Infused Product

Rule M 1004 is repealed effective October 1, 2016

A. Ingredient List. A list of all ingredients used to manufacture the Edible Medical Marijuana-Infused Product; which may include a list of any potential allergens contained within, or used in the manufacture of, the Medical Marijuana-Infused Product.

B. Statement Regarding Refrigeration. A statement that the Medical Marijuana-Infused Product, if perishable, must be refrigerated.

C. Statement of Expiration Date. A product expiration date, for perishable Medical Marijuana-Infused Product, upon which the product will no longer be fit for consumption, or a use-by-date, upon which the product will no longer be optimally fresh. Once a label with a use-by or expiration date has been affixed to a Container of a Medical Marijuana-

Infused Product, a Licensee shall not alter that date or affix a new label with a later use-by or expiration date.

Basis and Purpose – M 1004.5

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2.5)(a)(I), 12-43.3-402(2)(a)(I-III), 12-43.3-402(7), 12-43.4-404(5), 12-43.4-404(10), 12-43.4-404(11), and 12-43.3-901(3), C.R.S. The purpose of this rule is to ensure that every Medical Marijuana-Infused Products Manufacturer labels each Shipping Container and Container holding a Medical Marijuana Infused-Product with all of the necessary and relevant information for the receiving Medical Marijuana Business. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper packaging and labeling techniques for each Medical Marijuana Infused-Product because it is a public health and safety concern.

Product safety requirements are being adopted to aid in making Medical Marijuana-Infused Products more readily identifiable to the general public as containing Medical Marijuana. While product safety requirements are stated in this rule, nothing in the requirements interferes with a manufacturer's ability to determine standard doses for its products or to provide a mechanism with the product for accurately measuring a standard dose.

M 1004.5 – Packaging and Labeling Requirements of a Medical Marijuana Infused-Product by a Medical Marijuana-Infused Products Manufacturer

Rule M 1004.5 shall be effective beginning October 1, 2016

A. Packaging of Medical Marijuana Infused-Product by a Medical Marijuana-Infused Products Manufacturer

1. General Standard. Every Medical Marijuana-Infused Products Manufacturer must ensure that each Container holding a Medical Marijuana Infused-Product is placed in a Shipping Container prior to transport or transfer to another Medical Marijuana Business.

2. Edible Medical Marijuana Infused-Product.

a. Every Medical Marijuana-Infused Products Manufacturer must ensure that each Edible Medical Marijuana Infused-Product is packaged within a Child-Resistant Container prior to transport or transfer to another Medical Marijuana Business.

b. If the Edible Medical Marijuana-Infused Product contains multiple doses then it must be packaged in a Child-Resistant Container that maintains its Child-Resistant effectiveness for multiple openings

3. Medical Marijuana Infused-Product that is not Edible Medical Marijuana Infused-Product. Every Medical Marijuana-Infused Products Manufacturer must ensure that each Medical Marijuana Infused-Product that is not an Edible Medical Marijuana Infused-Product is individually packaged within a Container prior to transport or transfer to another Medical Marijuana Business.

B. Labeling of Medical Marijuana Infused-Product Containers by a Medical Marijuana-Infused Products Manufacturer. A Medical Marijuana-Infused Products Manufacturer must ensure that a label(s) is affixed to every Container holding a Medical Marijuana

Infused-Product that includes all of the information required by this rule prior to transport or transfer to another Medical Marijuana Business.

1. Required Information (General). Every Medical Marijuana-Infused Products Manufacturer must ensure the following information is affixed to every Container holding a Medical Marijuana Infused-Product:

   a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana used to produce the Medical Marijuana Infused-Product was grown;

   b. The Production Batch Number(s) of Medical Marijuana Concentrate(s) used in the production of the Medical Marijuana Infused-Product.

   c. The license number of the Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana Infused-Product.

   d. A net weight statement.

   e. The Production Batch Number(s) assigned to the Medical Marijuana Infused-Product.

   f. A statement about whether the Container is Child-Resistant.

   h. The Identity Statement and Standardized Graphic Symbol of the Medical Marijuana-Infused Products Manufacturer that manufactured the Medical Marijuana Infused-Product. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;

   i. The Universal Symbol, which must be located on the front of the Container and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. For Medical Use Only. Keep out of the reach of children."

   j. The following warning statements:

      i. **"There may be health risks associated with the consumption of this product."**

      ii. **"This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S."**

      iii. **"This product was produced without regulatory oversight for health, safety, or efficacy."**

      iv. **"There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."**

k. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana used to produce the Medical Marijuana Infused-Product.

l. A complete list of solvents and chemicals used in the creation of any Medical Marijuana Concentrate that was used to produce the Medical Marijuana Infused-Product.

2. Required Information (Edible Medical Marijuana Infused-Product). Every Medical Marijuana-Infused Products Manufacturer must ensure that the following information or statement is affixed to every Container holding an Edible Medical Marijuana Infused-Product:

a. Ingredient List. A list of all ingredients used to manufacture the Edible Medical Marijuana Infused-Product; which shall include a list of any potential allergens contained within.

b. Statement Regarding Refrigeration. If the Edible Medical Marijuana Infused-Product is perishable, a statement that the Edible Medical Marijuana Infused-Product must be refrigerated.

c. Statement of Production Date. The date on which the Edible Medical Marijuana Infused-Product was produced.

d. Statement of Expiration Date. A product expiration date, for perishable Edible Medical Marijuana Infused-Product, upon which the product will no longer be fit for consumption, or a use-by-date, upon which the product will no longer be optimally fresh. Once a label with a use-by or expiration date has been affixed to a Container holding an Edible Medical Marijuana Infused-Product, a Licensee shall not alter that date or affix a new label with a later use-by or expiration date.

3. Permissive Information (Edible Medical Marijuana Infused-Product). Every Medical Marijuana-Infused Products Manufacturer may affix a label(s) with the following information to every Container holding an Edible Medical Marijuana Infused-Product:

a. The Medical Marijuana Infused-Product's compatibility with dietary restrictions.

b. A nutritional fact panel.

4. Required Potency Statement.

a. Every Medical Marijuana-Infused Products Manufacturer must ensure that a label is affixed to the Container that includes at least the Medical Marijuana Infused-Product's THC and CBD content.

b. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana Infused-Product that has failed potency testing and has not subsequently passed the additional potency testing required by rule R 1507(C).

5. Required Contaminant Testing Statement.

a. When All Required Contaminant Tests Are Not Performed. If a Medical Marijuana Testing Facility did not test a Production Batch of Medical Marijuana Infused-Product for microbials, mold, and mildew, then the Container shall be labeled with the following statement: **"The Medical Marijuana Infused-Product contained within this package has not been tested for contaminants."** Except that when a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants for the particular Medical Marijuana Infused-Product pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: "**The Medical Marijuana Infused-Product contained within this package complies with the mandatory contaminant testing required by rule M 1501.**"

b. When All Contaminant Tests Are Performed and Passed. If a Medical Marijuana Testing Facility tested a Production Batch of Medical Marijuana Infused-Product for microbials, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: "**The Medical Marijuana Infused-Product contained within this package complies with the mandatory contaminant testing required by rule M 1501**."

c. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana Infused-Product that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

D. Labeling of Medical Marijuana Infused-Product Shipping Containers by Medical Marijuana-Infused Products Manufacturer. Prior to transporting or transferring any Medical Marijuana Infused-Product to another Medical Marijuana Business, a Medical Marijuana Manufacturing Products Facility must ensure that a label is affixed to a Shipping Container holding Medical Marijuana Infused-Product that includes all of the information required by this rule. A Medical Marijuana-Infused Products Manufacturer must include the following information on every Shipping Container:

1. The number of Containers holding a Medical Marijuana Infused-Product within the Shipping Container; and

2. The license number of the Medical Marijuana-Infused Products Manufacturer(s) that produced the Medical Marijuana Infused-Product within the Shipping Container.

Basis and Purpose – M 1005

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-202(2.5)(a)(I), 12-43.3-402(7), and 12-43.3-901(3), C.R.S. The purpose of this rule is to ensure that the labeling on each Container of Medical Marijuana includes necessary and relevant information for patients, does not include health and physical benefit claims, is easily accessible to patients, and is clear and noticeable. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques for all Medical Marijuana because it is a public health and safety concern.

M 1005 – Packaging and Labeling of Medical Marijuana by a Medical Marijuana Center

Rule M 1005 shall be effective beginning October 1, 2016

A. Packaging of Medical Marijuana by a Medical Marijuana Center.

1. A Medical Marijuana Center must ensure that all Medical Marijuana is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Exit Package that is Child-Resistant.

2. Except that when a patient provides written documentation signed by his or her physician attesting to the fact that it would be unreasonably difficult for the patient to open packaging that is Child-Resistant:

a. A Medical Marijuana Center shall not be required to package the Medical Marijuana in a Child-Resistant Container for sale to the patient; and

b. A Medical Marijuana Center shall not be required to utilize a Child-Resistant Exit Package for the patient.

B. Labeling of Medical Marijuana by a Medical Marijuana Center. A Medical Marijuana Center must affix all of the information required by this rule to every Container in which Medical Marijuana is placed no later than at the time of sale to a patient:

1. A Medical Marijuana Center must include the following information on every Container:

a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana was grown;

b. The license number of the Medical Marijuana Center that sold the Medical Marijuana to the patient;

c. The Identity Statement and Standardized Graphic Symbol of the Medical Marijuana Center that sold the Medical Marijuana to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;

d. The Harvest Batch Number(s) assigned to the Medical Marijuana within the Container;

e. The date of sale to the patient;

f. The patient registry number of the purchaser;

g. The net weight, in grams to at least the tenth of a gram, of the Medical Marijuana prior to its placement in the Container;

h. The following warning statements:

i. **"There may be health risks associated with the consumption of this product."**

ii. **"This marijuana's potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S."**

iii. **"There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."**

i. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana.

j. The Universal Symbol, which must be located on the front of the Container and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. For Medical Use Only. Keep out of the reach of children."

2. Required Potency Statement. For each Harvest Batch of Medical Marijuana packaged within a Container, the Medical Marijuana Center shall ensure the potency of at least the Medical Marijuana's THC and CBD is included on a label that is affixed to the Container. The potency shall be expressed as a range of percentages that extends from the lowest percentage to the highest percentage of concentration for each cannabinoid listed, from every test conducted on that strain of Medical Marijuana cultivated by the same Optional Premises Cultivation Operation within the last three months.

3. Required Contaminant Testing Statement.

a. When All Required Contaminant Tests Are Not Performed. If a Medical Marijuana Testing Facility did not test a Harvest Batch for microbials, mold, mildew, and filth, then a Medical Marijuana Center must ensure that a label is affixed to a Container holding any Medical Marijuana from that Harvest Batch with the following statement: **"The marijuana contained within this package has not been tested for contaminants."** Except that when an Optional Premises Cultivation Operation has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: "**The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501**."

b. When All Required Contaminant Tests Are Performed and Passed. If a Medical Marijuana Testing Facility tested a Harvest Batch for microbials, mold, mildew, and filth, and all the required test(s) passed, then the Container shall be labeled with the following statement: "**The marijuana contained within this package complies with the mandatory contaminant testing required by rule M 1501**."

c. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

Basis and Purpose – M 1006

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5), 12-43.3-402(2)(a)(I-III), 12-43.4-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-404(5), 12-43.3-404(10), and 12-43.3-901(3), C.R.S. The purpose of this rule is to ensure that the labeling on each Container holding a Medical Marijuana Infused-Product includes necessary and relevant information for consumers, does not include health and physical benefit claims, is easily accessible to consumers, and is clear and noticeable. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper packaging and labeling techniques for each Medical Marijuana Infused-Product because this is a public health and safety concern.

M 1006 – Packaging and Labeling of Medical Marijuana Infused-Product by a Medical Marijuana Center

Rule M 1006 shall be effective beginning October 1, 2016

A. Packaging Requirements for a Medical Marijuana Center.

1. Beginning December 1, 2016, a Medical Marijuana Center shall not purchase, take possession of, or sell Medical Marijuana-Infused Product that does not comply with rules M 604 and M 1004.5.

2. A Medical Marijuana Center must ensure that each Medical Marijuana Infused-Product is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Exit Package that is Child-Resistant.

3. Except that when a patient provides written documentation signed by his or her physician attesting to the fact that it would be unreasonably difficult for the patient to open packaging that is Child-Resistant:

a. If the Medical Marijuana-Infused Product is packaged in a Child-Resistant Container, a Medical Marijuana Center may defeat the Medical Marijuana-Infused Product's Child-Resistant packaging on behalf of the patient, so long as the Medical Marijuana-Infused Product remains with the packaging after the Child-Resistant properties have been defeated; or

b. If the Medical Marijuana-Infused Product is not packaged in a Child-Resistant Container, a Medical Marijuana Center shall not be required to package the Medical Marijuana-Infused Product in a Child-Resistant Container for sale to the patient; and

c. A Medical Marijuana Center shall not be required to utilize a Child-Resistant Exit Package for the patient.

B. Labeling of Medical Marijuana Infused-Product by a Medical Marijuana Center. Every Medical Marijuana Center must ensure that a label(s) is affixed to every Exit Package at the time of sale to a consumer that includes all of the information required by this rule. If an Exit Package is not required pursuant to subparagraph (A)(2) of this rule M 1006, and the Medical Marijuana Center elects not to provide one, then the Medical Marijuana Center must ensure the labels required by this rule are affixed to each Container of Medical Marijuana Infused-Product no later than at the time of sale to a consumer.

1. Required Information.

a. The license number of the Medical Marijuana Center that sold the Medical Marijuana Infused-Product to the consumer;

b. The Identity Statement and Standardized Graphic Symbol of the Medical Marijuana Center that sold the Medical Marijuana Infused-Product to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;

c. The date of sale to the consumer;

d. The patient registry number of the purchaser;

e. The following warning statements;

i. **"There may be health risks associated with the consumption of this product."**

ii. **"This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S."**

iii. **"This product was produced without regulatory oversight for health, safety, or efficacy."**

iv. **"There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."**

f. The Universal Symbol, which must be located on the front of the Container or Exit Package as appropriate and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. For Medical Use Only. Keep out of the reach of children.".

Basis and Purpose – M 1007

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XIV.5),12-43.3-202(2.5)(a)(I), 12-43.4-402(2)(a)(I-III), 12-43.4-402(6), 12-43.4-404(5), and 12-43.3-901(3), C.R.S. The purpose of this rule is to ensure that the labeling on each Container holding a Medical Marijuana Concentrate includes necessary and relevant information for patients, does not include health and physical benefit claims, is easily accessible to patients, and is clear and noticeable. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques to each Medical Marijuana Concentrate as this is a public health and safety concern.

M 1007 – Packaging and Labeling of Medical Marijuana Concentrate by a Medical Marijuana Center

Rule M 1007 shall be effective beginning October 1, 2016

A. Packaging of Medical Marijuana Concentrates by an Optional Premises Cultivation Operation.

1. A Medical Marijuana Center must ensure that all Medical Marijuana Concentrate is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Medical Marijuana Center must place the Container within an Exit Package that is Child-Resistant.

2. Except that when a patient provides written documentation signed by his or her physician attesting to the fact that it would be unreasonably difficult for the patient to open packaging that is Child-Resistant:

a. A Medical Marijuana Center shall not be required to package the Medical Marijuana Concentrate in a Child-Resistant Container for sale to the patient; and

b. A Medical Marijuana Center shall not be required to utilize a Child-Resistant Exit Package for the patient.

B. Labeling of Medical Marijuana Concentrates by Medical Marijuana Centers. Every Medical Marijuana Center must ensure that a label(s) is affixed to every Container holding Medical Marijuana Concentrate that includes all of the information required by this rule no later than at the time of sale to a consumer:

1. Every Medical Marijuana Center must ensure the following information is affixed to every Container holding a Medical Marijuana Concentrate:

a. The license number(s) of the Optional Premises Cultivation Operation(s) where the Medical Marijuana used to produce the Medical Marijuana Concentrate within the Container was grown;

b. The license number of the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced the Medical Marijuana Concentrate;

c. The Production Batch Number assigned to the Medical Marijuana Concentrate;

d. The license number of the Medical Marijuana Center that sold the Medical Marijuana Infused-Product to the consumer;

e. The net weight, in grams to at least the tenth of a gram, of the Medical Marijuana Concentrate prior to its placement in the Container;

f. The date of sale to the consumer;

g. The patient registry number of the purchaser;

h. The following warning statements:

i. **"There may be health risks associated with the consumption of this product."**

ii. **"This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance pursuant to 12-43.3-202(2.5)(a)(I)(E), C.R.S."**

iv. **"This product was produced without regulatory oversight for health, safety, or efficacy."**

v. **"There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."**

i. The Universal Symbol, which must be located on the front of the Container and no smaller than ½ of an inch by ½ of an inch, and the following statement which must be labeled directly below the Universal Symbol: "Contains Marijuana. For Medical Use Only. Keep out of the reach of children."

j. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana used to produce the Medical Marijuana Concentrate; and

k. A complete list of solvents and chemicals used to produce the Medical Marijuana Concentrate.

2. Required Potency Statement. For each Production Batch of Medical Marijuana Concentrate packaged within a Container, the Medical Marijuana Center shall ensure the potency of at least the Medical Marijuana Concentrate's THC and CBD is included on a label that is affixed to the Container. The potency shall be expressed in milligrams for each cannabinoid.

3. Required Contaminant Testing Statement.

a. When All Required Contaminant Tests Are Not Performed.

i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Solvent-Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, then the Container shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package has not been tested for contaminants."** Except that when a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, then the Container instead shall be labeled with the following statement: "**The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501.**"

ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility did not test a Production Batch of Food- or Water-Based Medical Marijuana Concentrate for microbials, mold, and mildew, then the Container shall be labeled with the following statement: **"The Medical Marijuana Concentrate contained within this package has not been tested for contaminants."** Except that when an Optional Premises Cultivation Operation or a Medical Marijuana-Infused Products Manufacturer has successfully validated its process regarding contaminants pursuant to rule M 1501, then the

Container instead shall be labeled with the following statement: "**The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501.**"

b. When All Required Contaminant Tests Are Performed and Passed.

i. Solvent-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch of Solvent-Based Medical Marijuana Concentrate for residual solvents, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: "**The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501**."

ii. Food- and Water-Based Medical Marijuana Concentrate. If a Medical Marijuana Testing Facility tested a Production Batch for microbials, mold, and mildew, and the required test(s) passed, then the Container shall be labeled with the following statement: "**The Medical Marijuana Concentrate contained within this package complies with the mandatory contaminant testing required by rule M 1501**."

c. Nothing in this rule permits a Medical Marijuana Business to transfer, wholesale, or sell Medical Marijuana Concentrate that has failed contaminant testing and has not subsequently passed the additional contaminant testing required by rule M 1507(B).

M 1200 Series – Enforcement

Basis and Purpose – M 1201

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.3-201(5), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(d), 12-43.3-202(2)(a)(II), and 12-43.3-202(2)(a)(XX), and sections 16-2.5-101, 16-2.5-121, and 16-2.5-124.5, C.R.S. The purpose of this rule is to allow for officers and employees of the Division to investigate all aspects of the Licensees to ensure the fair, impartial, stringent, and comprehensive administration of the Medical Code and rules promulgated pursuant to it.

M 1201 – Duties of Employees of the State Licensing Authority

A. Duties of Director

1. The State Licensing Authority may delegate an act required to be performed by the State Licensing Authority related to the day-to-day operation of the Division to the Director.

2. The Director may authorize ~~investigators and~~Division employees ~~of the Division~~ to perform tasks delegated from the State Licensing Authority.

B. Duties of Division Investigators. The State Licensing Authority, the Department's Senior Director of Enforcement, the Director, and Division investigators shall have all the powers of any peace officer to:

1. Investigate violations or suspected violations of the Medical Code and any rules promulgated pursuant to it. Make arrests, with or without warrant, for any violation of the Medical Code, any rules promulgated pursuant to it, Article 18 of Title 18, C.R.S., any other laws or regulations pertaining to Medical Marijuana in this state, or any criminal law of this state, if, during an officer's exercise of powers or performance of duties pursuant to the Medical Code, probable cause exists that a crime related to such laws has been or is being committed;

2. Serve all warrants, summonses, subpoenas, administrative citations, notices or other processes relating to the enforcement of laws regulating Medical Marijuana and Medical Marijuana-Infused Product;

3. Assist or aid any law enforcement officer in the performance of his or her duties upon such law enforcement officer's request or the request of other local officials having jurisdiction;

4. Inspect, examine, or investigate any ~~Licensed P~~premises where the Licensee's Medical Marijuana or Medical Marijuana-Infused Product are grown, stored, cultivated, manufactured, tested, distributed, or sold, and any books and records in any way connected with any licensed activity;

5. Require any Licensee, upon demand, to permit an inspection of Licensed Premises during business hours or at any time of apparent operation, marijuana equipment, and marijuana accessories, or books and records; and, to permit the testing of or examination of Medical Marijuana or Medical Marijuana-Infused Product;

6. Require Applicants to submit complete and current applications and fees and other information the Division deems necessary to make licensing decisions and approve material changes made by the Applicant or Licensee;

7. Conduct investigations into the character, criminal history, and all other relevant factors related to suitability of all Licensees and Applicants for Medical Marijuana licenses and such other Persons with a direct or indirect interest in an Applicant or Licensee, as the State Licensing Authority may require; and

8. Exercise any other power or duty authorized by law.

C. Duties of All Division Employees.

1. Division employees shall maintain the confidentiality of Division records and information.

2. Pursuant to subsection 12-43.3-201(4), C.R.S., State Licensing Authority employees with regulatory oversight responsibilities for marijuana businesses licensed by the State Licensing Authority shall not work for, represent, or provide consulting services to or otherwise derive pecuniary gain from a marijuana business licensed by the State Licensing Authority or other business entity established for the primary purpose of providing services to the marijuana industry for a period of six months following his or her last day of employment with the State Licensing Authority.

3. Pursuant to subsection 12-43.3-201(5), C.R.S., disclosure of confidential records or information in violation of the provisions of the Medical Code constitutes a class 1 misdemeanor.

Basis and Purpose – M 1202

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), and 12-43.3-202(2)(a)(XX), C.R.S. This rule explains that Licensees must cooperate with Division employees when they are acting within the normal scope of their duties and that failure to do so may result in sanctions. It also explains the administrative hold process, ~~the preservation of evidence,~~ the handling of inventory subject to administrative hold and under investigation and the process for voluntary surrender of Medical Marijuana and Medical Marijuana-Infused Product.

M 1202 – Requirement for Inspections and Investigations, Searches, Administrative Holds, Voluntary Surrenders and Such Additional Activities as May Become Necessary from Time to Time

A. Applicants and Licensees Shall Cooperate with Division Employees

1. Applicants and Licensees must cooperate with employees ~~and investigators~~ of the Division who are conducting inspections or investigations relevant to the enforcement of laws and regulations related to the Medical Code.

2. No Applicant or Licensee shall by any means interfere with, obstruct or impede the State Licensing Authority or any employee ~~or investigator~~ of the Division from exercising their duties under the provisions of the Medical Code and all rules promulgated pursuant to it. This would include, but is not limited to:

a. Threatening force or violence against an employee or investigator of the Division, or otherwise endeavoring to intimidate, obstruct, or impede employees or investigators of the Division, their supervisors, or any peace officers from exercising their duties. The term "threatening force" includes the threat of bodily harm to such individual or to a member of his or her family;

b. Denying ~~employees or~~ investigators of the Division access to premises where the Licensee's Medical Marijuana or Medical Marijuana-Infused Product are grown, stored, cultivated, manufactured, tested, distributed, or sold ~~a Licensed Premises~~ during business hours or times of apparent activity;

c. Providing false or misleading statements;

d. Providing false or misleading documents and records;

e. Failing to timely produce requested books and records required to be maintained by the Licensee; or

f. Failing to timely respond to any other request for information made by a Division employee or investigator in connection with an investigation of the qualifications, conduct or compliance of an Applicant or Licensee.

B. Administrative Hold

1. To prevent destruction of evidence, diversion or other threats to public safety, while permitting a Licensee to retain its inventory pending further investigation,

a Division investigator may order an administrative hold of Medical Marijuana or Medical Marijuana-Infused Product pursuant to the following procedure:

a. If during an investigation or inspection of a Licensee, a Division investigator develops reasonable grounds to believe certain Medical Marijuana or Medical Marijuana-Infused Product constitute evidence of acts in violation of the Medical Code or rules promulgated pursuant to it, or otherwise constitute a threat to the public safety, the Division investigator may issue a notice of administrative hold of any such Medical Marijuana or Medical Marijuana-Infused Product. The notice of administrative hold shall provide a documented description of the Medical Marijuana or Medical Marijuana-Infused Product to be subject to the administrative hold and a concise statement that is promptly issued and approved by the Director or his or her designee regarding the reasons for issuing the administrative hold.

b. Following the issuance of a notice of administrative hold, the Division will identify the Medical Marijuana or Medical Marijuana-Infused Product subject to the administrative hold in the Inventory Tracking System. The Licensee shall continue to comply with all tracking requirements. *See* Rule M 309 – Medical Marijuana Business: Inventory Tracking System.

c. The Licensee shall completely and physically segregate the Medical Marijuana or Medical Marijuana-Infused Product subject to the administrative hold in a Limited Access Area of the Licensed Premises under investigation, where it shall be safeguarded by the Licensee.

d. ~~Pending the outcome of the investigation and any related disciplinary proceeding~~While the administrative hold is in effect, the Licensee is prohibited from selling, giving away, transferring, transporting, or destroying the Medical Marijuana or Medical Marijuana-Infused Product subject to the administrative hold except as otherwise authorized by these Rules.

e. While the administrative hold is in effect, the Licensee must safeguard the Medical Marijuana and Medical Marijuana-Infused Product subject to the administrative hold and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Medical Code and the rules of the State Licensing Authority. *See* Rule M 1309 Administrative Warrants.

f. Nothing herein shall prevent a Licensee from voluntarily surrendering Medical Marijuana or Medical Marijuana-Infused Product that is subject

to an administrative hold, except that the Licensee must follow the procedures set forth below for voluntary surrender of Medical Marijuana or Medical Marijuana-Infused Product.

~~d~~g. Nothing herein shall prevent a Licensee from the continued possession, cultivation, or harvesting of the Medical Marijuana subject to the administrative hold. All Medical Marijuana or Medical Marijuana-Infused Product subject to an administrative hold must be put into separate Harvest Batches.

~~e~~h. ~~Following an investigation~~At any time after the initiation of the administrative hold, the Division may lift the administrative hold pending the administrative process, ~~order the continuation of the administrative hold,~~ or seek other appropriate relief ~~a Final Agency Order for the destruction of the marijuana~~.

C. Voluntary surrender of Medical Marijuana or Medical Marijuana-Infused Product

1. A Licensee, prior to a Final Agency Order and upon mutual agreement with the Division, may elect to ~~waive a right to a hearing and any associated rights, and~~ voluntarily surrender any Medical Marijuana or Medical Marijuana-Infused Product to the Division.

a. Such voluntary surrender may require destruction of any Medical Marijuana or Medical Marijuana-Infused Product in the presence of a Division investigator and at the Licensee's expense, and

b. The individual signing the Division's~~affidavit of~~ voluntary surrender form on behalf of the Licensee must certify that the individual has authority to represent and bind the Licensee.

2. The voluntary surrender form may be utilized in connection with a stipulated agency order through which the Licensee waives the right to hearing and any associated rights.

3. The voluntary surrender form may be utilized even if the Licensee does not waive the right to hearing and any associated rights, with the understanding that the outcome of the hearing does not impact the validity of the voluntary surrender.

4. A Licensee, after a Final Agency Order and upon mutual agreement with the Division, may elect to voluntarily surrender any marijuana or marijuana product to the Division.

a. The Licensee must complete and return the Division's voluntary surrender form within 15 calendar days of the date of the Final Agency Order.

b. Such voluntary surrender may require destruction of any marijuana or marijuana product in the presence of a Division investigator and at the Licensee's expense.

c. The individual signing the Division's voluntary surrender form on behalf of the Licensee must certify that the individual has authority to represent and bind the Licensee.

Basis and Purpose - M 1203

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(IV), and 12-43.3-202(1)(b)(XX), and section 12-43.3-602, C.R.S. The purpose of this rule is to provide guidance following either an agency decision or under any circumstances where the licensee is ordered to surrender and/or destroy Medical Marijuana and Medical Marijuana-Infused Product. This rule also provides guidance as to the need to preserve evidence during agency investigations or subject to agency order.

M 1203 – Disposition of Unauthorized Medical Marijuana

A. After a Final Agency Order Mandates the Destruction of ~~Medical~~ Marijuana or ~~Medical~~ Marijuana-Infused Product. If the State Licensing Authority issues a Final Agency Order pursuant to section 12-43.3-602, C.R.S., that mandates the destruction of some or all of the Licensee's unauthorized ~~Medical Marijuana~~ marijuana or unauthorized ~~Medical Marijuana~~marijuana-~~Infused~~ infused ~~Product~~product, the Licensee may:

1. Voluntarily Surrender. The Licensee may voluntarily surrender to the Division all of its unauthorized ~~Medical Marijuana~~ marijuana or unauthorized ~~Medical Marijuana~~marijuana-~~Infused~~ infused ~~Product~~ product that are described in the Final Agency Order in accordance with the provisions of Rule M 1202. ~~If the Licensee chooses to voluntarily surrender its plants and Product:~~

~~a. The Licensee must complete and return the Division's voluntary surrender form within 15 calendar days of the date of the Final Agency Order; and~~

~~b. The individual signing the affidavit of voluntary surrender on behalf of the Licensee must certify that the individual has authority to represent and bind the Licensee.~~

2. Seek a Stay. ~~File~~ The licensee may file a petition for a stay of the Final Agency Order with the Denver District Court within 15 days of the Final Agency Order.

3. Take No Action. If the Licensee does not either (1) voluntarily surrender its unauthorized ~~Medical Marijuana~~ marijuana or unauthorized ~~Medical Marijuana~~marijuana~~-Infused~~ infused ~~Product~~ product as set forth in Subsection (A)(1)(a). of this Rule; or (2) properly seek a stay of the Final Agency Order as set forth in section A.1.b. of this rule, the Division will enter the Licensed Premises and seize and destroy the unauthorized marijuana or marijuana product~~Medical Marijuana or unauthorized Medical Marijuana-Infused Product~~ that are the subject of the Final Agency Order. ~~The Division will only take such action if the district attorney for the judicial district in which the unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product are located has not notified the Division within 15 days of receiving notice from the Division that the subject unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product constitute evidence in a criminal proceeding such that it should not be destroyed.~~

B. General Requirements Applicable To All Licensees Following Final Agency Order To Destroy Unauthorized Medical Marijuana or Unauthorized Medical Marijuana-Infused Product. The following requirements apply regardless of whether the Licensee voluntarily surrenders its unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, seeks a stay of agency action, or takes no action:

1. The 15 day period set forth in section 12-43.3-602, C.R.S., and this rule shall include holidays and weekends.

2. During the period of time between the issuance of the Final Agency Order and the destruction of unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product, the Licensee shall not sell, destroy, or otherwise let any unauthorized Medical Marijuana or unauthorized Medical Marijuana-Infused Product that are subject to the Final Agency Order leave the Licensed Premises unless specifically authorized by the State Licensing Authority or a court of competent jurisdiction.

3. During the period of time between the issuance of the Final Agency Order and the destruction of unauthorized marijuana or unauthorized marijuana product, the Licensee must safeguard any marijuana or marijuana product in its possession or control and must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Medical Code and the rules of the State Licensing Authority.

~~3~~4. Unless the State Licensing Authority otherwise orders, the Licensee may cultivate, water, or otherwise care for any unauthorized Medical Marijuana or

unauthorized Medical Marijuana-Infused Product that are subject to the Final Agency Order during the period of time between the issuance of the Final Agency Order and the destruction of the unauthorized ~~Medical Marijuana or unauthorized Medical Marijuana-Infused Product~~marijuana or marijuana product.

~~4~~5. ~~If the local district attorney tells the Division that some of the marijuana is needed for evidence, the action the Division will take with regard to the subject marijuana will depend on the individual circumstances.~~ If a district attorney notifies the Division that some or all of the unauthorized marijuana or marijuana-infused product is involved in an investigation, the Division shall not destroy the unauthorized marijuana or marijuana-infused product until approved by the district attorney.

M 1300 Series – Discipline

Basis and Purpose – M 1301

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(c),12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), and 12-43.3-202(2)(a)(XX), and sections 12-43.3-601 and 24-4-105, C.R.S. The purpose of this rule is to clarify how the disciplinary process for non-summary license suspensions and license revocations is initiated.

M 1301 – 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 Medical 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 Case (administrative citation) as to why the Licensee's license should not be suspended, ~~or~~ 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 suspended, revoked, restricted, fined, or subject to other disciplinary sanction, ~~or revoked~~ should the charges contained in the notice be sustained upon final hearing.

B. Disciplinary Hearings. Disciplinary hearings will be conducted in accordance with Rule M 1304 – 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 – M 1302

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), ~~and~~ 12-43.3-202(2)(a)(XX), and ~~sections~~ 24-4-104(4)(a), and sections 12-43.3-601 and 24-4-105, C.R.S. The purpose of this rule is to set forth the process for summary suspensions when the State Licensing Authority has cause to immediately ~~revoke~~ suspend a license prior to and pending a hearing and final agency action. Summary suspension will be imposed~~. Such an occasion will occur~~ when the State Licensing Authority has reason to believe and finds that a Licensee has been guilty of a deliberate and willful violation of any applicable law or regulation, or ~~has committed an infraction of~~

~~such~~ that the public health, safety, or welfare imperatively requires emergency action.~~magnitude that it is imperative its license be revoked to protect the public safety and welfare.~~ The rule ensures proper due process for Licensees when their licenses are temporarily or summarily suspended by requiring prompt initiation of disciplinary proceedings after such suspensions.

M 1302 – Disciplinary Process: Summary Suspensions

A. How a Summary Suspension Action is Initiated

1. When the State Licensing Authority has reasonable grounds to believe and finds that a Licensee has been guilty of a deliberate and willful violation of any applicable law or regulation, or that the public health, safety, or welfare imperatively requires emergency action it shall serve upon the Licensee a Summary Suspension Order that temporarily or summarily suspends the license.

2. The Summary Suspension Order shall identify the nature of the State Licensing Authority's basis for the summary suspension. The Summary Suspension Order shall also provide an advisement that the License may be subject to further discipline or revocation should the charges contained in the notice be sustained following a hearing.

3. Proceedings for suspension or revocation shall be promptly instituted and determined after the Summary Suspension Order is issued.

4. After the Summary Suspension Order is issued, the State Licensing Authority shall issue and serve upon the Licensee an Order to Show Cause (administrative citation) as to why the Licensee's license should not be suspended, revoked, restricted, fined or subject to other disciplinary sanction.

5. 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 to Show Cause shall also provide an advisement that the license could be suspended, revoked, restricted, fined or subject to ther disciplinary sanction should the charges contained in the notice be sustained upon final hearing.

6. Unless lifted by the State Licensing Authority, the Summary Suspension Order shall remain in effect until issuance of a Final Agency Order.

B. Summary Suspension Hearings. Summary suspension hearings will be expedited to the extent practicable and will be conducted in accordance with Rule M 1304 – Administrative Hearings.

Basis and Purpose – M 1303

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), ~~and~~ 12-43.3-202(2)(a)(XX), and s~~ections~~ 24-4-104(4)(a), and sections 12-43.3-601 and 24-4-105, C.R.S. 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 Medical Marijuana and Medical Marijuana-Infused Product are adequately secured. In addition, the rule clarifies what activity is always prohibited during such suspension.

M 1303 – Suspension Process: Regular and Summary Suspensions

A. Signs Required During Active 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 at least 17 inches in length and ~~14~~ 11 inches in width containing lettering not less 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

MEDICAL MARIJUANA LICENSES ISSUED

FOR THESE PREMISES HAVE BEEN

SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY

FOR VIOLATION OF THE COLORADO MEDICAL 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

MEDICAL MARIJUANA LICENSES ISSUED

FOR THESE PREMISES HAVE BEEN

SUSPENDED BY ORDER OF THE STATE LICENSING AUTHORITY

FOR ALLEGED VIOLATION OF THE COLORADO MEDICAL 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 Suspension

1. ~~Medical Marijuana Center Licensee.~~ Unless otherwise ordered by the State Licensing Authority, during any period of ~~active license~~ suspension the Licensee shall not permit the acquisition, purchase, selling, serving, giving away, distribution, manufacture, sampling, testing, transfer, or transport of Medical Marijuana or Medical Marijuana-Infused Product on the Licensed Premises, nor allow patients to enter the Licensed Premises. ~~However, Medical Marijuana and Medical Marijuana-Infused Product shall not be removed from the Licensed Premises or destroyed unless and until the provisions described in section 12-43.3-602, 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 M 1203 – Disposition of Unauthorized Medical Marijuana.~~

2. ~~Optional Premises Cultivation Operation Licensee.~~ Unless otherwise ordered by the State Licensing Authority, during any period of suspension the Licensee may continue to possess, maintain, cultivate or harvest Medical Marijuana or Medical Marijuana-Infused Product on the Licensed Premises. The Licensee must fully account for all such Medical Marijuana and Medical Marijuana-Infused Product in the Inventory Tracking System. The Licensee must safeguard any Medical Marijuana or Medical Marijuana-Infused Product in its possession or control. The Licensee must fully comply with all security requirements including but not limited to surveillance, lock and alarm requirements set forth in the Medical Code and the rules of the State Licensing Authority. ~~Unless otherwise ordered by the State Licensing Authority, during any period of active license suspension the Licensee may maintain its on hand inventory and otherwise care for its Medical Marijuana inventories. However, marijuana shall not be sold or otherwise removed from the Licensed Premises or destroyed unless and until the provisions described in section 12-43.3-602, 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 M 1203 – Disposition of Unauthorized Medical Marijuana.~~

~~3. Medical Marijuana-Infused Products Manufacturer Licensee. Unless otherwise ordered by the State Licensing Authority, during any period of active license suspension the Licensee shall not manufacture any Medical Marijuana-Infused Product or Medical Marijuana concentrates during a period of active license suspension, nor permit the selling, distribution, transfer, or transport of Medical Marijuana or Medical Marijuana-Infused Product on or from the Licensed Premises. Unless otherwise ordered by the State Licensing Authority, during any period of active license suspension the Licensee may maintain Medical Marijuana-Infused Product on the Licensed Premises. However, Medical Marijuana-Infused Product shall not be removed from the Licensed Premises or destroyed unless and until the provisions described in section 12-43.3-602, 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 M 1203 – Disposition of Unauthorized Medical Marijuana.~~

C. Removal and Destruction of Marijuana and Marijuana-Infused Product. Medical Marijuana and Medical Marijuana-Infused Product shall not be removed from the Licensed Premises or destroyed unless and until:

1. The provisions described in section 12-43.3-602, 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 M 1203 – Disposition of Unauthorized Medical Marijuana;

2. The Licensee has voluntarily surrendered the Medical Marijuana or Medical Marijuana-Infused Product in accordance with Rule M 1202(C) – voluntary surrender;

3. The State Licensing Authority has seized the Medical Marijuana or Medical Marijuana-Infused Product pursuant to an Administrative Warrant. *See* Rule M 1309 - Administrative Warrant.

D. Renewal. The issuance of a suspension or an Order of Summary Suspension does not relieve the Licensee of the obligation to timely comply with all license renewal requirements.

Basis and Purpose – M 1304

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(1)(c), 12-43.3-202(1)(d), 12-43.3-202(2)(a)(V), 12-43.3-202(a)(XIX), and 12-43.3-202(2)(a)(XX), and sections 12-43.3-601 and 24-4-105, C.R.S. The purpose of this rule is to establish what entity conducts the

administrative hearings, the procedures governing~~scope of the~~ administrative hearings~~ rules~~, and other general hearings issues.

M 1304 – Administrative Hearings

A. General Procedures

1. Hearing Location. Hearings will generally be conducted by the Department of Revenue, Hearings Division. Unless the hearing officer orders a change of location based on good cause, as described in this ~~Rule~~rule, hearings generally will be conducted at a location in the greater Denver metropolitan area to be determined by the hearing officer. Under unusual circumstances where justice, judicial economy and convenience of the parties would be served, hearings may be held in other locations in the state of Colorado.

2. Scope of Hearing Rules. ~~The Administrative Hearings 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.

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:

Marijuana Enforcement Division

Attn: Hearing Request

455 Sherman Street, Suite 390

Denver, CO 80203

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.

~~3. A Denied Applicant or Respondent may waive his or her right to a hearing by submitting a written statement to the State Licensing Authority to that effect before the hearing.~~

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 administrative notice or 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 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.

2. ~~In connection with any request for a hearing, a Denied Applicant shall provide a written response to the Notice of Denial.~~ 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 administrative notice or 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 first-class mail to the last mailing address of record.

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. Summary suspension hearings 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. For purposes of this rule, good cause 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 hearing officer's own motion. If a prehearing conference is held and a prehearing order is issued by the hearing 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) unless the hearing officer grants a continuance over the objection of any party in accordance with subsections (D)(2)(b) and (c) of this rule.~~both parties stipulate to a continuance and the hearing officer grants the continuance.~~

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 hearing 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.

3. The hearing officer shall administer oaths 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 12-43.3-202(1)(d), C.R.S., may be introduced as exhibits at hearing. Such exhibits shall not be sealed from public inspection unless confidential pursuant to a provision of law other than Subsection 12-43.3-202(1)(d), C.R.S.

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, if such evidence is confidential pursuant to specific provision of law other than Subsection 12-43.3-202(1)(d), C.R.S.

~~4~~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 hearing 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 hearing officer.

~~5~~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.

~~6~~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 M 1306 – 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 – M 1308

The statutory authority for this rule is found at subsections 12-43.3-201(4), 12-43.3-201(5), 12-43.3-202(1)(b)(I), 12-43.3-202(1)(d), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(V), 12-43.3-202(2)(a)(VI), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to assure Licensees do not use unauthorized confidential information at any time and do not engage the services of former State Licensing Authority or Division employees for the first 6 months following State Licensing Authority or Division employment.

M 1308 –Confidential Information and former Division Employees

A. Misdemeanor if Disclosed. Disclosure of confidential records or information in violation of the Medical Code constitutes a class 1 misdemeanor pursuant to subsection 12-43.3-201(5), C.R.S.

1. Licensees, and employees or agents of a Licensee, shall not obtain or utilize confidential information the Licensee, employee or agent is not lawfully entitled to acquire or possess through use or misuse of Division processes or Division-approved systems.

2. Any Licensee, and any employee or agent of a Licensee, who is authorized to access the Division's Inventory Tracking System and/or have access to confidential information derived from Division sources, shall utilize the confidential information only for a purpose authorized by the Division or these Rules.

3. All Licensees, and all employees and agents of a Licensees, shall not use the Inventory Tracking System for any purpose other than tracking the Licensee's Medical Marijuana and Medical Marijuana-Infused Product.

B. Six-month Prohibition from Working with Former Division Employees. State Licensing Authority or Division employees with regulatory oversight responsibilities for Medical Marijuana Businesses or Retail Marijuana Establishments are prohibited from working for, representing, or providing consulting services to or otherwise deriving pecuniary gain from a Licensee for a period of six months following his or her last day of employment with the State Licensing Authority or Division.

1. Any Licensee who utilizes, employs, consults, seeks advice from, or contracts with a former employee of the State Licensing Authority or the Division prior to the conclusion of the six-month period shall be in violation of the Medical Code.

2. Any Licensee who possesses, utilizes or re-discloses confidential information obtained from a former State Licensing Authority or Division employee at any time shall be in violation of the Medical Code.

Basis and Purpose – M 1309

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(IV), 12-43.3-202(a)(X), and 12-43.3-202(2)(a)(XX), C.R.S. The purpose of this rule is to establish the circumstances under which the Division may seek from a district court an administrative warrant to search and/or seize marijuana and marijuana products. The Division has encountered circumstances that would have justified such a warrant. Establishing the criteria under which the Division may seek an administrative warrant will give fair notice to the regulated community regarding the types of violations that would lead to a request for an administrative warrant.

M 1309 – Administrative Warrants

A. Criteria. The Division may seek from a district court an administrative search warrant authorizing search and seizure in circumstances in which the Division makes a proper showing that:

a. A Licensee has refused entry of Division investigators during business hours or times of apparent activity;

b. A Licensee subject to an administrative hold or summary suspension has failed to comply with applicable rules; or

c. A Licensee otherwise has acted in a manner demonstrating disregard for the Medical Code and the State Licensing Authority's rules or that threatens the public health, safety, and welfare.

B. Affidavit. When seeking an administrative search warrant, the Division will supply the district court with a sworn affidavit explaining the bases for seeking the warrant.

C. Seized property. If the Division seizes marijuana, neither the Division nor the State Licensing Authority shall cultivate or care for any seized marijuana or marijuana products. The Division may seek from the district court an order to destroy any such marijuana or marijuana products.

M 1500 Series – Medical Marijuana Testing Program

Basis and Purpose – M 1501

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing the contaminant testing and related process validation portion of the Division's Medical Marijuana sampling and testing program.

M 1501 – Medical Marijuana Testing Program – Contaminant Testing

Rule M 1501 shall be effective beginning July 1, 2016.

A. Contaminant Testing Required. Until an Optional Premises Cultivation Operation's and Medical Marijuana-Infused Products Manufacturer's cultivation or production process has been validated under this rule, it shall not wholesale, transfer, or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product unless Samples from the Harvest Batch or Production Batch from which that Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product was derived was tested by a Medical Marijuana Testing Facility for contaminants and passed all contaminant tests required by paragraph C of this rule.

B. Validation of Process – Contaminant Testing

1. Medical Marijuana. An Optional Premises Cultivation Operation's cultivation process shall be deemed valid regarding Contaminants if every Harvest Batch that it produced during at least a six week period but no longer than a 12 week period passed all contaminant tests required by paragraph C of this rule. This must include at least 6 Test Batches that contain Samples from entirely different Harvest Batches.

2. Medical Marijuana Concentrate or Medical Marijuana Infused-Product. An Optional Premises Cultivation Operation's or a Medical Marijuana-Infused Products Manufacturer's production process shall be deemed valid regarding contaminants if every Production Batch that it produced during at least a four week period but no longer than an eight week period passed all contaminant tests required by paragraph C of this rule. This must include at least four Test Batches that contain Samples from entirely different Production Batches.

3. Process Validation is Effective for One Year. Once an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer has successfully obtained process validation for contaminants, the process validation shall be effective for one year from the date of the last passing test required to satisfy the process validation requirements.

C. Required Contaminant Tests

1. Microbial Contaminant Testing. Each Harvest Batch of Medical Marijuana and Production Batch of Water- or Food-Based Medical Marijuana Concentrate and Medical Marijuana-Infused Product must be tested for microbial contamination by a Medical Marijuana Testing Facility. The microbial contamination test must

include, but need not be limited to, testing to determine the presence of and amounts present of Salmonella sp., Escherichia coli., and total yeast and mold.

2. Biological Contaminant Testing.

a. Mold and Mildew Contaminant Testing. Each Harvest Batch of Medical Marijuana and Production Batch of Medical Marijuana Concentrate and Medical Marijuana Infused-Product must be visually inspected, in addition to other required mold testing, by a Medical Marijuana Testing Facility for toxic amounts of mold and mildew contamination.

b. Filth Contaminant Testing. Each Harvest Batch of Medical Marijuana must be visually inspected by a Medical Marijuana Testing Facility for toxic amounts of filth.

3. Residual Solvent Contaminant Testing. Each Production Batch of Solvent-Based Medical Marijuana Concentrate produced by a Medical Marijuana-Infused Products Manufacturer must be tested for residual solvent contamination by a Medical Marijuana Testing Facility. The residual solvent contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, butane, heptanes, benzene*, toluene*, hexane*, and 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 M 605.

D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer wholesaling, transferring, or processing into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch. Additional tests may include, but need not be limited to, screening for Pesticide, chemical contaminants or other types of biological contaminants, microbials, molds, metals, filth or residual solvents.

E. Exemptions

1. Medical Marijuana Concentrate. A Production Batch of Medical Marijuana Concentrate shall be considered exempt from this rule if the Medical Marijuana-Infused Products Manufacturer that produced it does not wholesale or transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Medical Marijuana-Infused Product, except that a Solvent-Based Medical Marijuana Concentrate must still be submitted for residual solvent contaminant testing.

F. Required Re-Validation - Contaminants.

1. Material Change Re-validation. If an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer makes a Material Change to its cultivation or production process, then it must have the first five Harvest Batches or Production Batches produced using the new standard operating procedures tested for all of the contaminants required by paragraph C of this rule regardless of whether its process has been previously validated regarding contaminants. If any of those tests fail, then the Medical Marijuana Business's process must be re-validated.

a. Pesticide. It shall be considered a Material Change if an Optional Premises Cultivation begins using a new or different Pesticide during its cultivation process and the first five Harvest Batches produced using the new or different Pesticide must also be tested for Pesticide.

b. Solvents. It shall be considered a Material Change if a Medical Marijuana-Infused Products Manufacturer begins using a new or different solvent or combination of solvents.

c. Notification. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that makes a Material Change must notify the Medical Marijuana Testing Facility that conducts contaminant testing on the first five Harvest Batches or Production Batches produced using the new standard operating procedures.

d. Testing Required Prior to Wholesale, Transfer or Processing. When a Harvest Batch or Production Batch is required to be submitted for testing pursuant to this rule, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer that produced it may not wholesale, transfer or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any of the Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from that Harvest Batch or Production Batch.

2. Failed Contaminant Testing Re-Validation. If a Sample the Division requires to be tested fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall follow the procedures in paragraph B of rule M 1507 for any package, Harvest Batch, or Production Batch from which the failed Sample was taken. The Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall also submit three additional Test Batches of the Medical Marijuana or Medical Marijuana-Infused Product for contaminant testing by a Medical Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails contaminant testing, the Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall re-validate its process for contaminants.

3. Expiration of Process Validation. An Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer shall be required to re-validate its process once the one year of process validation expires, or the Medical Marijuana Business shall comply with the requirements of paragraph A of this rule M 1501.

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

Basis and Purpose – M 1502

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-

404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing the mandatory testing portion of the Division's Medical Marijuana sampling and testing program.

M 1502 – Medical Marijuana Testing Program – Mandatory Testing

Rule M 1502 shall be effective beginning July 1, 2016.

A. Required Sample Submission. A Medical Marijuana Business may be required by the Division to submit a Sample(s) of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product it possesses to a Medical Marijuana Testing Facility at any time regardless of whether its process has been validated and without notice.

1. Samples collected pursuant to this rule may be tested for potency or contaminants which may include, but may not be limited to, Pesticide, microbials, molds, metals, filth, residual solvents, biological contaminants, and chemical contaminants.

2. When a Sample(s) is required to be submitted for testing, the Medical Marijuana Business may not sell, wholesale, transfer or process into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from the package, Harvest Batch or Production Batch from which the Sample was taken.

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 Medical Marijuana Business's process has been validated.

2. Inspection or Enforcement Tests. The Division may require a Medical Marijuana Business to submit a Sample for testing if the Division has reasonable grounds to believe that:

a. Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product is contaminated or mislabeled;

b. A Medical Marijuana Business is in violation of any product safety, health or sanitary law, rule or regulation; or

c. The results of a test would further an investigation by the Division into a violation of any law, rule or regulation.

3. Beta Testing. The Division may require a Medical 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 the M 1500 series are the minimum required testing standards. Medical Marijuana Businesses are responsible for receiving enough testing on any Medical Marijuana, Medical Marijuana Concentrate, and/or Medical Marijuana Infused-Product they produce to ensure the marijuana consumables are safe for human consumption.

D. Additional Sample Types. The Division may also require a Medical Marijuana Business to submit Samples comprised of items other than Medical Marijuana, Medical Marijuana

Concentrate or Medical Marijuana-Infused Product to be tested for contaminants which may include, but may not be limited to, Pesticide, microbials, molds, metals, filth, 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 plant(s) or any portion of a 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 Medical Marijuana Concentrate,

4. Any ingredient or substance used in the manufacturing of a Medical Marijuana-Infused Product; or

5. Swab of any equipment or surface.

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

Basis and Purpose – M 1503

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing the potency testing and related process validation portion of the Division's Medical Marijuana sampling and testing program.

R 1503 – Medical Marijuana Testing Program – Potency Testing

Rule M 1503 shall be effective beginning July 1, 2016.

A. Potency Testing – General

1. Test Batches. A Test Batch submitted for potency testing may only be comprised of Samples that are of the same strain of Medical Marijuana or from the same Production Batch of Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

2. Cannabinoid Profile. A potency test conducted pursuant to this rule must at least determine the level of concentration of THC, THCA, CBD, CBDA and CBN.

B. Potency Testing for Medical Marijuana.

1. Initial Potency Testing. An Optional Premises Cultivation Operation must have potency tests conducted by a Medical Marijuana Testing Facility on four Harvest Batches, created a minimum of one week apart, for each strain of Medical Marijuana that it cultivates.

a. The first potency test must be conducted on each strain prior to the Optional Premises Cultivation Operation wholesaling, transferring or

processing into a Medical Marijuana Concentrate any Medical Marijuana of that strain.

b. All four potency tests must be conducted on each strain no later than December 1, 2016 or six months after the Optional Premises Cultivation Operation begins cultivating that strain, whichever is later.

2. Ongoing Potency Testing. After the initial four potency tests, an Optional Premises Cultivation Operation shall have each strain of Medical Marijuana that it cultivates tested for potency at least once every six months.

C. Potency Testing for Medical Marijuana Concentrate. An Optional Premises Cultivation Operation or Medical Marijuana-Infused 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 wholesaling, transferring or processing into a Medical Marijuana-Infused Product any of the Medical Marijuana Concentrate from that Production Batch.

D. Potency Testing for Medical Marijuana-Infused Product

1. Potency Testing Required for Medical Marijuana-Marijuana Infused Product. A Medical Marijuana-Infused Products Manufacturer shall have potency tests conducted by a Medical Marijuana Testing Facility on every Production Batch of Medical Marijuana Infused-Product that it produces prior to transferring or wholesaling any of the Medical Marijuana-Infused Product from that Production Batch.

2. Required Tests. Potency tests conducted on Medical Marijuana-Infused 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 Medical Marijuana-Infused Products. If only a portion of a Medical Marijuana-Infused Product is infused with Medical Marijuana, then the Medical Marijuana-Infused Products Manufacturer must inform the Medical Marijuana Testing Facility of exactly which portions of the Medical Marijuana-Infused Product are infused and which portions are not infused.

E. Validation of Process - Potency and Homogeneity – Edible Medical Marijuana-Infused Products Containing 100 Milligrams or Less of THC

1. A Medical Marijuana-Infused Products Manufacturer may process validate potency and homogeneity for each type of Edible Medical Marijuana-Infused Product that it manufactures so long as the Edible Medical Marijuana-Infused Product contains 100 milligrams or less of THC.

2. A Medical Marijuana-Infused Products Manufacturer's production process for a particular type of Edible Medical Marijuana-Infused Product shall be deemed valid regarding potency and homogeneity if every Production Batch that it produces for that particular type of Edible Medical Marijuana-Infused Product during at least a four week period but no longer than an eight week period passes all potency tests required by rule M 1503(D)(2). This must include at least four Test Batches that contain Samples from entirely different Production Batches.

3. Process Validation is Effective for One Year. Once a Medical Marijuana-Infused Products Manufacturer has successfully obtained process validation for potency and homogeneity for a particular type of Edible Medical Marijuana-Infused Product that it produces, the process validation shall be effective for one year from the date of the last passing test required to satisfy the process validation requirements.

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

Basis and Purpose – M 1504

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing sampling procedures and rules for the Division's Medical Marijuana sampling and testing program.

M 1504 – Medical Marijuana Testing Program – Sampling Procedures

Rule M 1504 shall be effective beginning July 1, 2016.

A. Collection of Samples

1. Sample Collection. All Samples submitted for testing pursuant to this rule must be collected by Division personnel or in accordance with the Division's sampling policy.

2. Sample Selection. The Division may elect, at its sole direction, to assign Division personnel to collect Samples. A Medical Marijuana Business, its Owners and employees shall not attempt to influence the Samples selected by Division personnel.

B. Samples for Test Batches of Medical Marijuana and Medical Marijuana Concentrate. Each Test Batch of Medical Marijuana or Medical Marijuana Concentrate must be comprised of a representative selection of Samples.

1. Minimum Number of Samples. At a minimum, each Test Batch of Medical Marijuana or Medical Marijuana Concentrate must be comprised of at least the following number of separately taken Samples:

a. For Test Batches comprised of Harvest Batches or Production Batches weighing up to 10 pounds, eight separate Samples must be taken.

b. For Test Batches comprised of Harvest Batches or Production Batches weighing more than 10 pounds but less than 20 pounds, 12 separate Samples must be taken.

c. For Test Batches comprised of Harvest Batches or Production Batches weighing 20 pounds or more but less than 30 pounds, 15 separate Samples must be taken.

d. For Test Batches comprised of Harvest Batches or Production Batches weighing 30 pound or more but less than 40 pounds, 18 separate Samples must be taken.

e. For Test Batches comprised of Harvest Batches or Production Batches weighing 40 pounds or more but less than 100 pounds, 23 separate Samples must be taken.

f. For Test Batches comprised of Harvest Batches or Production Batches weighing 100 pounds or more, 29 separate Samples must be taken.

2. Multiple Harvest Batches or Production Batches. If more than one Harvest Batch or Production Batch is combined into a single Test Batch, then that Test Batch must include at least one Sample from each Harvest Batch or Production Batch.

C. Samples for Test Batches of Medical Marijuana-Infused Product.

1. Finished Product. Test Batches of Medical Marijuana-Infused Product must be comprised of finished product that is packaged for sale.

2. Multiple Production Batches. If more than one Production Batch of Medical Marijuana-Infused Product is combined into a single Test Batch, then that Test Batch must include at least one finished product that is packaged for sale from each Production Batch combined into that Test Batch.

D. Medical Marijuana Testing Facility Selection. The Division will generally permit a Medical Marijuana Business to select which Medical Marijuana Testing Facility will test a Sample collected pursuant to this rule. However, the Division may elect, at is sole discretion, to assign a Medical Marijuana Testing Facility to test the Sample.

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

Basis and Purpose – M 1505

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing rules governing Test Batches for the Division's Medical Marijuana sampling and testing program.

M 1505 – Medical Marijuana Testing Program – Test Batches

Rule M 1505 shall be effective beginning July 1, 2016.

A. No Combination of Product Types. A Test Batch may not be a combination of any two or three of the following: Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

B. Combining Samples

1. Harvest Batches and Production Batches. The Division will generally permit an Optional Premises Cultivation Operation or Medical Marijuana-Infused Products Manufacturer to combine Samples from any number of Harvest Batches or Production Batches created within a 7 day period into a single Test Batch for any contaminant testing required by rule. However, the Division may elect, at is sole discretion, to require a Test Batch to be comprised of Samples from only one

Harvest Batch, Production Batch or a specifically identified quantity of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

2. Packages. The Division will generally permit a Medical Marijuana Business to combine Samples from any number of packages of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product into a single Test Batch for any contaminant testing required by rule. However, the Division may elect, at is sole discretion, to require a Test Batch to be comprised of Samples from only one package or a specifically identified quantity of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Production.

C. Same Processes

1. General Applicability. All Harvest Batches or Production Batches combined into a single Test Batch must be cultivated or produced using the same standard operating procedure.

2. Medical Marijuana. All Harvest Batches of Medical Marijuana combined into a single Test Batch must be cultivated using the same Pesticide and other agricultural chemicals. If an Optional Premises Cultivation Operation applies a Pesticide or other agriculture chemicals to only a specific set of plants, then Samples from those plants must be placed within a separate Test Batch.

3. Medical Marijuana Concentrate. All Production Batches of Medical Marijuana Concentrate combined into a single Test Batch must be of the same category and produced using the same extraction methods and combination of solvents.

4. Medical Marijuana-Infused Product. All Production Batches of Medical Marijuana-Infused Product combined into a single Test Batch must be of the exact same product type and made using the same ingredients.

D. Failed Contaminant Testing. If a Test Batch fails a contaminant test, then each Harvest Batch or Production Batch that was combined into that Test Batch shall be considered to have failed contaminant testing. See Rule R 1507.

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

Basis and Purpose – M 1506

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing rules requiring Medical Marijuana Business's to cover certain costs associated with the Division's Medical Marijuana sampling and testing program.

M 1506 – Medical Marijuana Testing Program – Costs

Rule M 1506 shall be effective beginning July 1, 2016.

Costs. The cost for all sampling and tests conducted pursuant to these rules shall be the financial responsibility of the Medical Marijuana Business that is required to submit the Sample for testing.

Basis and Purpose – M 1507

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(IV), 12-43.3-202(2)(a)(XI), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XIV), 12-43.3-202(2)(a)(XV), 12-43.3-202(2)(a)(XX), 12-43.3-202(2.5)(a)(I), 12-43.3-402(6), 12-43.3-402(7), 12-43.3-404(4), and 12-43.3-404(10), C.R.S. The purpose of this rule is to protect the public health and safety by establishing rules governing the quarantining of potentially contaminated product and the destruction of product that failed contaminant or potency testing for the Division's Medical Marijuana sampling and testing program.

M 1507 – Medical Marijuana Testing Program – Contaminated Product and Failed Test Results

Rule M 1507 shall be effective beginning July 1, 2016.

A. Quarantining of Product

1. If the Division has reasonable grounds to believe that a particular Harvest Batch, Production Batch, package or quantity of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product is contaminated or presents a risk to public safety, then the Division may require a Medical Marijuana Business to quarantine it until the completion of the Division's investigation, which may include the receipt of any test results.

2. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch failed a contaminant or potency test, then the Medical Marijuana Business shall quarantine any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from any package, Harvest Batch or Production Batch combined into that Test Batch and must follow the procedures established pursuant to paragraphs B and/or C of this rule.

3. Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product that has been quarantined pursuant to this rule must be physically separated from all other inventory and may not be sold, wholesaled, transferred or processed into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

B. Failed Contaminant Testing. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch failed contaminant testing, then for each package, Harvest Batch or Production Batch combined into that Test Batch the Medical Marijuana Business must either:

1. Destroy and document the destruction of the entire portion of the package, Harvest Batch or Production Batch that it possesses, See Rule M 307 – Waste Disposal; or

2. Decontaminate the portion of the package, Harvest Batch or Production Batch that it possesses, if possible, and create two new Test Batches, each containing the requisite number of Samples, and have those Test Batches tested for the identified contaminant by a different Medical Marijuana Testing Facility.

a. If both new Test Batches pass the required contaminant testing, then any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product from any package, Harvest Batch or Production Batch included in that Test Batch may be sold, wholesaled, transferred or processed into a Medical Marijuana Concentrate or Medical Marijuana-Infused Product.

b. If one or both of the Test Batches do not pass contaminant testing, then the Medical Marijuana Business must destroy and document the destruction of the entire portion of the package, Harvest Batch or Production Batch included in that Test Batch that it possesses. See Rule M 307 – Waste Disposal.

C. Failed Potency Testing. If a Medical Marijuana Business is notified by the Division or a Medical Marijuana Testing Facility that a Test Batch of Medical Marijuana-Infused Product failed potency testing, then for the package or Production Batch from which that Test Batch was produced the Medical Marijuana Business must either:

1. Destroy and document the destruction of the entire portion of the package or Production Batch that it possesses, See Rule M 307 – Waste Disposal; or

2. Attempt corrective measures, if possible, and create two new Test Batches and have those Test Batches tested for potency by a different Medical Marijuana Testing Facility.

a. If both new Test Batches pass potency testing, then any Medical Marijuana-Infused Product from the Production Batch included in the Test Batch may be sold, wholesaled or transferred.

b. If one or both of the Test Batches fail potency testing, then the Medical Marijuana-Infused Products Manufacturer must destroy and document the destruction of the entire portion of the package or Production Batch that it possesses. See Rule M 307 – Waste Disposal.

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