**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.

"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.

"~~Certified~~ Industrial Hygienist" means an individual who ~~holds a valid and current certification from the American Board of Industrial Hygiene.~~ 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.

"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) ~~and ASTM classification standard D3475-13, http://www.astm.org/Standards/D3475.htm~~. Note that this rule does not include any later amendments or editions to the Code of Federal Regulations ~~or the ASTM classification standards~~. The Division has maintained a copy of the applicable federal regulation ~~and ASTM classification standard~~, which ~~are~~ 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.~~, and~~

~~d. Labeled properly as required by the M 1000 series.~~

"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.

"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.

"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.

"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.

"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 to 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 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.

"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 402**

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 a Medical Marijuana Center can only grow Medical Marijuana in its Optional Premises Cultivation Operation for a patient that has designated that Medical Marijuana Center as being his or her primary center. The rule also helps to ensure that Medical Marijuana plants designated to a particular patient are only being grown at one Medical Marijuana Center.

**M 402 – Registration of a Primary Medical Marijuana Center**

A. Patient Designation Required . A Medical Marijuana Center may only grow Medical Marijuana plants for patients who have designated the Medical Marijuana Center as being his or her primary center..

B. Change Only Allowed Every 30 Days . A Medical Marijuana Center shall not register a patient as being the patient's primary center if the patient has designated another Medical Marijuana Center as his or her primary center in the preceding 30 days. The Medical

Marijuana Center and its employees must require a patient to sign in writing that he or she has not designated another Medical Marijuana Center as his or her primary center before growing medical marijuana plants on behalf of the patient.

C. Required Questions . A Medical Marijuana Center must maintain a written record of the following questions and their answers at the time a patient indicates a desire to designate said center as his or her primary center:

1. Questions to the patient:

a. Which Medical Marijuana Center is currently the patient's primary center; and

b. How many plants is the patient's current primary center is cultivating for that patient.

2. Questions to the current primary center:

a. How many plants is the Medical Marijuana Center cultivating for the patient; and

b. How many of the patient's plants has the Medical Marijuana Center harvested.

D. Other Requirements . The new primary center shall also maintain written authorization from the patient and any relative plant count waivers to support the number of plants designated for that patient.

E. Violation of Public Safety. Notwithstanding the provisions in M 402 (B), it may be considered a violation of public safety for a Medical Marijuana Center and its employees to ~~knowingly~~ become a patient's primary center when ~~the Medical Marijuana Center or its employees knew that~~ the patient already had designated one or more other Medical Marijuana Centers as his or her primary center.

**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. 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.

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

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

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

**Basis and Purpose - M 408**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(X),12-43.3-202(2)(a)(XIII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), 12-43.3-1101, and 12-43.3-1102, C.R.S. The purpose of this rule is to establish minimum standards for responsible vendor programs that provide training to personnel at Medical Marijuana Centers seeking designation as a "responsible vendor." It sets forth general standards and basic requirements for responsible vendor programs. This rule also establishes the timeframe for new staff to complete a responsible vendor program and the requirements for recertification. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Centers.

**M 408 - Medical Marijuana Center: Responsible Vendor Program**

A. General Standards.

1. To be designated a "responsible vendor" of Medical Marijuana, Medical Marijuana-Infused Product and Medical Marijuana Concentrate at any licensed Medical Marijuana Center, a Medical Marijuana Center licensee shall comply with this rule.
2. To be designated a "responsible vendor" all Owners, managers and employees involved in the handling and sale of Medical Marijuana, Medical Marijuana Infused-Product or Medical Marijuana Concentrate shall attend and successfully complete a responsible vendor program.
3. Once a licensee is designated a "responsible vendor," all new employees involved in the handling and sale of Medical Marijuana, Medical Marijuana Infused-Product or Medical Marijuana Concentrate shall successfully complete the training described in this rule within 90 days of hire.
4. After initial successful completion of a responsible vendor program, each Owner, manager and employee of a Medical Marijuana Center shall successfully complete the program once every two years thereafter to maintain designation as a "responsible vendor."

B. Certification Training Program Standards.

1. No owner or employee of a responsible vendor program shall have an interest in a licensed Medical Marijuana Business or Retail Marijuana Establishment.
2. Program providers shall submit their programs to the Division for approval as a responsible vendor program.
3. Program providers shall submit their programs for approval every two years in order to maintain designation as a responsible vendor program.
4. The program shall include at least two hours of instruction time.
5. The program shall be taught in a real-time, interactive classroom setting where the instructor is able to verify the identification of each individual attending the program and certify completion of the program by the individual identified.
6. The program provider shall maintain its training records at its principal place of business during the applicable year and for the following three years. The provider shall make the records available for inspection by the licensing authority upon request during normal business hours.
7. The program shall provide written documentation of attendance and successful passage of a test on the knowledge of the required curriculum for each attendee.
    a. Attendees who can speak and write English must successfully pass a written test with a score of 70% or better.
    b. Attendees who cannot speak or write English may be offered a verbal test, provided that the same questions are given as are on the written test and the results of the verbal test are documented with a passing score of 70% or better.

8. Program providers shall solicit effectiveness evaluations from individuals who have completed their program.

C. Certification Training Class Core Curriculum.

1. Discussion concerning marijuana's effect on the human body. Training shall include:
   a. Marijuana's physical effects based on type of marijuana product;
   b. The amount of time to feel impairment;
   c. Visible signs of impairment; and
   d. Recognizing the signs of impairment.
2. Sales to minors. Training shall cover all pertinent Colorado law provisions.
3. Acceptable forms of Identification. Training shall include:
   a. How to check identification;
   b. Spotting false identification;
   c. Patient Registry Cards issued by the department of public health and environment and equivalent patient verification documents;
   d. Provisions for confiscating fraudulent identifications; and
   e. Common mistakes made in verification.
4. Other key state laws and rules affecting owners, managers, and employees. Training shall include:
   a. Local and state licensing and enforcement;
   b. Compliance with all Inventory Tracking System regulations;
   c. Administrative and criminal liability;
   d. License sanctions and court sanctions;
   e. Waste disposal;
   f. Health and safety standards;
   g. Patrons prohibited from bringing marijuana onto licensed premises;
   h. Permitted hours of sale;
   i. Conduct of establishment;
   j. Permitting inspections by state and local licensing and enforcement authorities;
   k. Licensee responsible for activities occurring within licensed premises;
   l. Maintenance of records;
   m. Privacy issues; and
   n. Prohibited purchases.

**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.

**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 ~~Certified~~ 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 ~~Certified~~ 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 ~~Certified~~ 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 ~~Certified~~ 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 ~~Certified~~ 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 ~~Certified~~ 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 ~~Certified~~ 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 ~~Certified~~ 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 ~~Certified~~ 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.

**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**

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 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**

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 ~~is~~ 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 1204**

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(I), 12-43.3-202(2)(a)(II), 12-43.3-202(2)(a)(IV), and 12-43.3-202(2)(a)(XX), C.R.S. This rule explains that the Director of the Division may exercise discretion to accept an assurance of voluntary compliance. It also explains the evidentiary value of an assurance of voluntary compliance should a licensee not comply with the agreement.

**M 1204 – Assurance of Voluntary Compliance**

A. The Director of the Division may accept an assurance of voluntary compliance regarding any act or practice alleged to violate the Medical Code, or the rules and regulations thereunder, from a person who has engaged in, is engaging in, or is about to engage in such acts or practices.

B. The assurance must be in writing and may include a stipulation for the voluntary payment of the cost commensurate with the acts or practices and an amount necessary to restore money or property which may have been acquired by the alleged violator because of the acts or practices.

C. An assurance of voluntary compliance may not be considered an admission of a violation for any purpose; however, proof of failure to comply with the assurance of voluntary compliance is prima facie evidence of a violation of the Medical Code, or the rules and regulation thereunder.

D. The State Licensing Authority may approve or review an assurance of voluntary compliance.