

Basis and Purpose – R 103

The statutory authority for this rule is found at subsection 12-43.4-202(2)(b), 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.

R 103 – Definitions

Definitions. The following definitions of terms, in addition to those set forth in section 12-43.4-103, C.R.S., shall apply to all rules promulgated pursuant to the Retail 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 Retail Marijuana Establishment, or to purchase particular Retail Marijuana or a Retail Marijuana Product. "Advertising" includes marketing, but does not include packaging and labeling. "Advertising" proposes a commercial transaction or otherwise constitutes commercial speech.

"Additive" means any substance added to Retail Marijuana Product that is not a common baking or cooking item.

"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.

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

"Cannabinoid" means any of the chemical compounds that are the active principles of 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 WELLBEING;
 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 available to the public.
- b. Opaque so that the ~~product cannot be seen from outside the~~ packaging DOES NOT ALLOW THE PRODUCT TO BE SEEN WITHOUT OPENING THE PACKAGING MATERIAL;
- c. ~~Closable~~ RESEALABLE for any product intended for more than a single use or containing multiple servings, and
- d. Labeled properly as required by the R 1000 Series.

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

"Denied Applicant" means any Person whose application for licensure pursuant to the Retail 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 Retail Marijuana Product" means any Retail Marijuana Product which 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 Retail Marijuana or Retail Marijuana Product already within a Container are placed.

"Final Agency Order" means an Order of the State Licensing Authority issued in accordance with the Retail 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 is in a light cycle intended to stimulate production of flowers, trichomes, and cannabinoids characteristic of marijuana.

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

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

- a. The Licensee or Applicant has violated, does not meet, or has failed to comply with any of the terms, conditions, or provisions of the Retail Code, any rules promulgated pursuant to 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 jurisdiction; or
- c. The Licensee's Licensed Premises have been operated in a manner that adversely affects the public health or welfare or the safety of the immediate neighborhood in which the establishment is located.

"Good Moral Character" means 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 Retail 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.

"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. Either party may file exceptions to the Initial Decision. The State Licensing Authority will review the Initial Decision and any exceptions filed thereto, and will issue a Final Agency Order.

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

"Licensee" means any Person licensed pursuant to the Retail Code or, in the case of an Occupational License Licensee, any individual licensed pursuant to the Retail Code or Medical Code.

"Limited Access Area" means a building, room, or other contiguous area upon the Licensed Premises where Retail 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.

"LIQUID EDIBLE RETAIL MARIJUANA PRODUCT" MEANS AN EDIBLE RETAIL MARIJUANA PRODUCT THAT IS A LIQUID BEVERAGE OR FOOD-BASED PRODUCT AND INTENDED TO BE CONSUMED ORALLY, SUCH AS A SOFT DRINK OR COOKING SAUCE.

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

"MITS" means Marijuana Inventory Tracking Solution.

"MITS Trained Administrator" means an Owner or an occupationally licensed employee of a Retail Marijuana Establishment who has attended and successfully completed MITS training and who has completed any additional training required by the Division.

"MITS User" means an Owner or occupationally licensed Retail Marijuana Establishment employee who is granted MITS User account access for the purposes of conducting inventory tracking functions in the MITS system and who has been successfully trained by a MITS Trained Administrator in the proper and lawful use of MITS.

"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 Medical Marijuana Center, a Medical Marijuana-Infused Product Manufacturer, or an Optional Premises Cultivation Operation.

"Medical Marijuana Center" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-402, C.R.S., and sells medical marijuana to registered patients or primary caregivers as defined in Article XVIII, Section 14 of the Colorado Constitution, but is not a primary caregiver.

"Medical Marijuana 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 product, 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 Retail Marijuana Establishment Licensed Premises, for the purpose of summoning a law enforcement officer to the premises during alarm conditions.

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

"MULTIPLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT" MEANS AN EDIBLE RETAIL MARIJUANA PRODUCT UNIT FOR SALE TO CONSUMERS CONTAINING MORE THAN 10MG OF ACTIVE THC AND NO MORE THAN 100MG OF ACTIVE THC. IF THE OVERALL EDIBLE RETAIL MARIJUANA PRODUCT UNIT FOR SALE TO THE CONSUMER CONSISTS OF MULTIPLE PIECES WHERE EACH INDIVIDUAL PIECE MAY CONTAIN LESS THAN 10MG ACTIVE THC, YET IN TOTAL ALL PIECES COMBINED WITHIN THE UNIT FOR SALE CONTAIN MORE THAN 10MG OF ACTIVE THC, THEN THE EDIBLE RETAIL MARIJUANA PRODUCT SHALL BE CONSIDERED A MULTIPLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT.

"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 or 12-43.4-401, C.R.S.

"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, have an opportunity to gain profit from the operation or

sale of the establishment, and have a controlling interest in a Retail Marijuana Establishment license, and includes any other Person that qualifies as an Owner pursuant to Rule R 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 Retail 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 Retail Marijuana; or (b) any amount of Retail Marijuana Product of the same exact type, produced using the same ingredients, standard operating procedures and the same Production Batch(es) of Retail 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 Retail 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 Retail Marijuana Store where Retail Marijuana and Retail Marijuana Product are sold, possessed for sale, and displayed for sale, and where no one under the age of 21 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 to 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 only to other Retail Marijuana Products Manufacturing Facilities and Retail Marijuana Stores.

"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 Retail Marijuana Establishment or Medical Marijuana Business that is provided to a Retail Marijuana Testing Facility for testing. The following is a non-exhaustive list of types of Samples: Retail Marijuana, Retail Marijuana Product, Retail Marijuana Concentrate, 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 Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product in bulk to other Retail Marijuana Establishments.

"SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT" MEANS AN EDIBLE RETAIL MARIJUANA PRODUCT UNIT FOR SALE TO CONSUMERS CONTAINING NO MORE THAN 10MG OF ACTIVE THC.

"Solvent-Based Retail Marijuana Concentrate" means a Retail Marijuana Concentrate that was produced by extracting ~~cannabinoids~~ CANNABINOIDS from Retail Marijuana through the use of a solvent approved by the Division pursuant to Rule R 605.

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

"STANDARDIZED SERVING OF MARIJUANA" MEANS A STANDARDIZED SINGLE SERVING OF ACTIVE THC. THE SIZE OF A STANDARDIZED SERVING OF MARIJUANA SHALL BE NO MORE THAN 10MG OF ACTIVE THC.

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

"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. A Test Batch may not be a combination of any two or three of the following: Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product.

"Universal Symbol" means the image established by the Division and made available to Licensees through the Division's website indicating Retail Marijuana or a Retail Marijuana Product is within a Container.

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

Basis and Purpose – R 231

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(III), 12-43.4-305, and 12-43.4-306 and section 24-76.5-101 *et. seq.*, C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(III). The purpose of this rule is to 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 staff of licensed entities.

R 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 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 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. 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. Owners . An Owner Applicant 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 part, 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 Retail Marijuana Establishment;
6. The Applicant can prove that he or she 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 can prove that he or she 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 27, 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 if the Person were convicted of the offense on the date he or she applied for a license;
8. The Applicant can establish that he or she does not employ another person who does not have a valid Occupational License issued pursuant to either the Retail Code or the Medical Code.
9. The Applicant can establish 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;
10. The Applicant can establish that its premises proposed to be licensed is not currently licensed as a retail food establishment or wholesale food registrant;
11. The Applicant has been a resident of Colorado for at least two years prior to the date of the Application. See Rule R 232 – Factors Considered When Determining Residency: Individuals.

D. Occupational Licenses . An Occupational License Applicant 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 at least 21 years of age;
4. The Applicant can establish that he or she is currently a resident of Colorado.
5. The Applicant can prove that he or she has not discharged a sentence for a conviction of a felony in the five years immediately preceding his or her application date;
6. The Applicant can prove that he or she 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 27, 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 if the person were convicted of the offense on the date he or she applied for a license;

7. The Applicant can establish 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;

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 and these rules SHALL ONLY WORK AT LICENSED PREMISES THAT ARE EXCLUSIVELY A RETAIL MARIJUANA ESTABLISHMENT AND 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 - R 407

THE STATUTORY AUTHORITY FOR THIS RULE IS FOUND AT SECTION 12-43.3-1101, AND SUBSECTIONS, 12-43.4-202(2)(B), 12-43.4-202(3)(A)(XII), 12-43.4-202(3)(B)(VII), AND 12-43.4-202(3)(B)(IX), C.R.S. THE PURPOSE OF THIS RULE IS TO ESTABLISH MINIMUM STANDARDS FOR RESPONSIBLE VENDOR PROGRAMS THAT PROVIDE TRAINING TO PERSONNEL AT RETAIL MARIJUANA STORES. 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 RETAIL MARIJUANA STORES.

R 407 - RETAIL MARIJUANA STORE: RESPONSIBLE VENDOR PROGRAM

A. GENERAL STANDARDS.

1. TO BE CONSIDERED A RESPONSIBLE VENDOR OF RETAIL MARIJUANA, RETAIL MARIJUANA PRODUCT AND RETAIL MARIJUANA CONCENTRATE AT ANY LICENSED RETAIL MARIJUANA STORE, A LICENSEE SHALL COMPLY WITH THIS RULE.
2. ALL OWNERS, MANAGERS AND EMPLOYEES SELLING RETAIL MARIJUANA, RETAIL MARIJUANA PRODUCT AND RETAIL 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 RETAIL MARIJUANA, RETAIL MARIJUANA PRODUCT AND RETAIL 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 RETAIL MARIJUANA STORE SHALL SUCCESSFULLY COMPLETE THE PROGRAM ONCE EVERY YEAR THEREAFTER TO MAINTAIN DESIGNATION AS A RESPONSIBLE VENDOR.

B. CERTIFICATION TRAINING PROGRAM STANDARDS.

1. THE PROGRAM SHALL INCLUDE AT LEAST (2) HOURS OF INSTRUCTION TIME.
2. THE PROGRAM SHALL BE TAUGHT IN A CLASSROOM SETTING.
3. 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 DURING NORMAL BUSINESS HOURS.
4. 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.
5. 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;
 - 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;
 - d. PROVISIONS FOR CONFISCATING FRAUDULENT IDENTIFICATIONS; AND
 - e. 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 STATE MARIJUANA INVENTORY TRACKING SYSTEM REGULATIONS;
 - c. ADMINISTRATIVE AND CRIMINAL LIABILITY;
 - d. LICENSE SANCTIONS AND COURT SANCTIONS;
 - e. PATRONS PROHIBITED FROM BRINGING MARIJUANA ONTO LICENSED PREMISES;
 - f. PERMITTED HOURS OF SALE;
 - g. CONDUCT OF ESTABLISHMENT;
 - h. PERMITTING INSPECTIONS BY STATE AND LOCAL LICENSING AND ENFORCEMENT AUTHORITIES;
 - i. LICENSEE RESPONSIBLE FOR ACTIVITIES OCCURRING WITHIN LICENSED PREMISES;
 - j. MAINTENANCE OF RECORDS;
 - k. PRIVACY ISSUES; AND
 - l. PROHIBITED PURCHASES.

Basis and Purpose – R 604

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(VIII), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(a)(XII), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(V), and 12-43.4-404(3), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish minimum health and safety regulation for Retail Marijuana Products Manufacturing Facilities. It requires all Owners and Occupational Licensees to demonstrate an understanding of basic food handling safety practices or attend a food handler training course prior to manufacturing any Edible Retail Marijuana Product. It sets forth general standards and basic sanitary requirements for Retail Marijuana Products Manufacturing Facilities. It covers the physical premises where the products are made as well as the individuals handling the products. The State Licensing Authority intends for this rule to reduce any product contamination, which will benefit both the Licensees and consumers. The State Licensing Authority modeled this rule after those adopted by the Colorado Department of Public Health and Environment. This rule also authorizes the State Licensing Authority to require an independent consultant to conduct a health and sanitary audit of a Retail Marijuana Products Manufacturing Facility. This rule explains when a health and sanitary audit may be deemed necessary and sets forth possible consequences of a Retail Marijuana Establishment's refusal to cooperate or pay for the audit. THIS RULE ALSO ESTABLISHES REQUIREMENTS FOR EACH EDIBLE RETAIL MARIJUANA PRODUCT MANUFACTURED BY A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY. Overall, the State Licensing Authority intends this rule to help maintain the integrity of Colorado's Retail Marijuana businesses and the safety of the public.

R 604 – ~~Health and Safety Regulations~~: Retail Marijuana Products Manufacturing Facility: HEALTH AND SAFETY REGULATIONS

A. Training

1. Prior to engaging in the manufacture of any Edible Retail Marijuana 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 Retail Marijuana Products Manufacturing Facility must obtain documentation evidencing that each Owner and each 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 Retail Marijuana Product.

B. General Standards

1. A Retail Marijuana Products Manufacturing Facility 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 Retail 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 Retail Marijuana Products Manufacturing Facility that manufactures edible Retail Marijuana Product shall comply with all kitchen-related health and safety standards of the relevant local jurisdiction and, to the extent applicable, with all Colorado Department of Public Health and Environment health and safety regulations applicable to retail food establishments, as set forth in 6 CCR 1010-2.

C. PRODUCT SAFETY

1. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY THAT MANUFACTURES EDIBLE RETAIL MARIJUANA PRODUCT SHALL COMPLY FULLY WITH PARAGRAPH C OF THIS RULE NO LATER THAN NOVEMBER 1, 2014.
2. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY THAT MANUFACTURES EDIBLE RETAIL MARIJUANA PRODUCT SHALL CREATE AND MAINTAIN STANDARD PRODUCTION PROCEDURES AND DETAILED MANUFACTURING PROCESSES FOR EACH EDIBLE RETAIL MARIJUANA PRODUCT IT MANUFACTURES. THESE PROCEDURES AND PROCESSES MUST BE DOCUMENTED AND MADE AVAILABLE ON THE LICENSED PREMISES FOR INSPECTION BY THE MARIJUANA ENFORCEMENT DIVISION, THE COLORADO DEPARTMENT OF PUBLIC HEALTH & ENVIRONMENT, AND LOCAL LICENSING AUTHORITIES.
3. THE SIZE OF A STANDARDIZED SERVING OF MARIJUANA SHALL BE NO MORE THAN 10MG OF ACTIVE THC. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY THAT MANUFACTURES EDIBLE RETAIL MARIJUANA PRODUCT SHALL DETERMINE THE TOTAL NUMBER OF STANDARDIZED SERVINGS OF MARIJUANA FOR EACH PRODUCT THAT IT MANUFACTURES. NO INDIVIDUAL EDIBLE RETAIL MARIJUANA PRODUCT UNIT FOR SALE SHALL CONTAIN MORE THAN 100 MILLIGRAMS OF ACTIVE THC.
4. THE FOLLOWING INFORMATION MUST BE DOCUMENTED IN THE STANDARD PRODUCTION PROCEDURES FOR EACH EDIBLE RETAIL MARIJUANA PRODUCT: THE AMOUNT IN MILLIGRAMS OF STANDARDIZED SERVING OF MARIJUANA, THE TOTAL NUMBER OF STANDARDIZED SERVINGS OF MARIJUANA, AND THE TOTAL AMOUNT OF ACTIVE THC CONTAINED WITHIN THE PRODUCT.
5. MULTIPLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT EACH SINGLE STANDARDIZED SERVING OF MARIJUANA OF A MULTIPLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT IS PHYSICALLY DEMARKED IN A WAY THAT ENABLES A

REASONABLE PERSON TO INTUITIVELY DETERMINE HOW MUCH OF THE PRODUCT CONSTITUTES A SINGLE SERVING OF ACTIVE THC. EACH DEMARKED STANDARDIZED SERVING OF MARIJUANA MUST BE EASILY SEPARABLE IN ORDER TO ALLOW AN AVERAGE PERSON 21 YEARS OF AGE AND OVER TO PHYSICALLY SEPARATE, WITH MINIMAL EFFORT, INDIVIDUAL SERVINGS OF THE PRODUCT.

6. IF AN EDIBLE RETAIL MARIJUANA PRODUCT IS OF THE TYPE THAT IS IMPRACTICABLE TO CLEARLY DEMARK EACH STANDARDIZED SERVING OF MARIJUANA OR TO MAKE EACH STANDARDIZED SERVING OF MARIJUANA EASILY SEPARABLE, THEN THE PRODUCT MUST CONTAIN NO MORE THAN 10 MG OF ACTIVE THC PER UNIT OF SALE, AND THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT THE PRODUCT COMPLIES WITH SUBPARAGRAPH (B)(2)(A) OF RULE R 1004.5.

D. 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 Retail Marijuana or Retail Marijuana 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 Retail Marijuana 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 Retail Marijuana or Retail Marijuana 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 Retail Marijuana Concentrate or manufacture of a Retail Marijuana 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 Retail Marijuana or Retail Marijuana 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 Retail Marijuana or Retail Marijuana 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 Retail Marijuana or Retail Marijuana 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 Retail Marijuana or Retail Marijuana 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 Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in a Retail Marijuana Products Manufacturing Facility and used in accordance with labeled instructions;
11. That toxic cleaning compounds, sanitizing agents, solvents used in the production of Retail Marijuana concentrate and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana 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 Retail Marijuana Products Manufacturing Facility 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 Retail Marijuana or Retail Marijuana Product shall be conducted in accordance with adequate sanitation principles;
16. That Retail Marijuana or Retail Marijuana 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 Retail Marijuana Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.

E. Standard Operating Procedures

1. A Retail Marijuana Products Manufacturing Facility must have written standard operating procedures for each category of Retail Marijuana Concentrate and type of Retail Marijuana Product that it produces.
 - a. All standard operating procedures for the production of a Retail Marijuana Concentrate must follow the requirements in Rule R 605.
 - b. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Retail Marijuana Products Manufacturing Facility.
2. If a Retail Marijuana Products Manufacturing Facility makes a Material Change to its standard Retail Marijuana Concentrate or Retail Marijuana Product production process, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

F. Additives. A Retail Marijuana Products Manufacturing Facility shall not include any Additive that is toxic within a Retail Marijuana Product; nor include any Additive for the purposes of making the product more addictive, appealing to children or misleading consumers.

G. 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 Retail Marijuana Products Manufacturing Facility to undergo such an audit. The scope of the audit may include, but need not be limited to, whether the Retail Marijuana Products Manufacturing Facility is in compliance with the requirements set forth in this rule or other applicable food handling laws, rules or regulations or compliance with the concentrate production rules in Rule R 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 Retail Marijuana Products Manufacturing Facility. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.
- c. The Retail Marijuana Products Manufacturing Facility will be responsible for all 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 Retail Marijuana Products Manufacturing Facility does not provide requested records related to the food handling training required for Owners or Occupational Licensees engaged in the production of Edible Retail Marijuana Product to the Division;
 - b. A Retail Marijuana Products Manufacturing Facility does not provide requested records related to the production of Retail Marijuana Concentrate, including but not limited to, certification of its Licensed Premises, equipment or standard operating procedures, training of Owners or Occupational Licensees, or Production Batch specific records;
 - c. The Division has reasonable grounds to believe that the Retail Marijuana Products Manufacturing Facility is in violation of one or more of the requirements set forth in this rule or Rule R 605;
 - d. The Division has reasonable grounds to believe that the Retail Marijuana Products Manufacturing Facility was the cause or source of contamination of Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product; or
 - e. Multiple Production Batches of Retail Marijuana Concentrate or Retail Marijuana Product produced by the Retail Marijuana Products Manufacturing Facility failed contaminant testing.
3. Compliance Required. A Retail Marijuana Products Manufacturing Facility 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 Retail Marijuana Products Manufacturing Facility's license. See Rule R 1302 – Disciplinary Process: Summary Suspensions.
 - b. Prior to or following the issuance of such an order, the Retail Marijuana Products Manufacturing Facility 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 R 1302 – Disciplinary Process: Summary Suspensions.
 - ii. If an agreement to suspend operations is reached, then the Retail Marijuana Products Manufacturing Facility may continue to care for its inventory and conduct any necessary internal business operations but it may not sell, transfer or wholesale Retail

Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product to another Retail Marijuana Establishment during the period of time specified in the agreement. Depending on the condition of the Retail Marijuana Products Manufacturing Facility and required remedial measures, the Division may permit a Retail Marijuana Products Manufacturing Facility to produce Retail Marijuana Concentrate or manufacture Retail Marijuana Product while operations have been suspended.

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

Basis and Purpose – R 605

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(VIII), 12-43.4-202(3)(a)(XI), and 12-43.4-2-2(3)(b)(IX), C.R.S. The purpose of this rule is to establish the categories of Retail Marijuana Concentrate that may be produced at a Retail Marijuana Products Manufacturing Facility and establish standards for the production of Retail Marijuana Concentrate.

R 605 –Retail Marijuana Products Manufacturing Facility: Retail 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 Retail Marijuana Concentrate Production

1. A Retail Marijuana Products Manufacturing Facility may produce Water-Based Retail Marijuana Concentrate and Food-Based Retail Marijuana Concentrate.
2. A Retail Marijuana Products Manufacturing Facility may also produce Solvent-Based Retail Marijuana Concentrate using only the following solvents: butane, propane, CO₂, 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 Retail Marijuana Products Manufacturing Facility may submit a request to the Division to consider the approval of solvents not permitted for use under this rule during the next formal rulemaking.

B. General Applicability. A Retail Marijuana Products Manufacturing Facility that engages in the production of Retail Marijuana Concentrate, regardless of the method of extraction or category of concentrate being produced, must:

1. Ensure that the space in which any Retail Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule R 901- Business Records Required.
2. Ensure that all applicable sanitary rules are followed. See R 604.

3. Ensure that the standard operating procedure for each method used to produce a Retail 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 Retail Marijuana for processing;
 - c. Extract cannabinoids and other essential components of Retail Marijuana;
 - d. Purge any solvent or other unwanted components from a Retail Marijuana Concentrate,
 - e. Clean all equipment, counters and surfaces thoroughly; and
 - f. Dispose of any waste produced during the processing of Retail Marijuana in accordance with all applicable local, state and federal laws, rules and regulations. See Rule R 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 Retail 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 Retail Marijuana Products Manufacturing Facility'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 Retail Marijuana Concentrate.

- a. Adequate training must include, but need not be limited to, providing a copy of the training manual for that Licensed Premises and live, in-person instruction detailing at least all of the topics required to be included in the training manual.
 - b. The individual training an Owner 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 Retail Marijuana Concentrate. See Rule R 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 R 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 Retail Marijuana Concentrate and the step that individual performed. See Rule R 901- Business Records Required.

C. Water-Based Retail Marijuana Concentrate and Food-Based Retail Marijuana Concentrate. A Retail Marijuana Products Manufacturing Facility that engages in the production of a Water-Based Retail Marijuana Concentrate or a Food-Based Retail Marijuana Concentrate must:

- 1. Ensure that all equipment, counters and surfaces used in the production of a Water-Based Retail Marijuana Concentrate or a Food-Based Retail Marijuana Concentrate is food-grade including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials, molds and fungi and can be easily cleaned.
- 2. Ensure that all equipment, counters, and surfaces used in the production of a Water-Based Retail Marijuana Concentrate or a Food-Based Retail Marijuana Concentrate are thoroughly cleaned after the completion of each Production Batch.
- 3. Ensure that any room in which dry ice is stored or used in processing Retail Marijuana into a Retail Marijuana Concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO₂.
- 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 Retail Marijuana Concentrate or Food-Based Retail 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 Retail Marijuana Concentrate.

6. Ensure that if propylene glycol or glycerin is used in the production of a Food-Based Retail Marijuana Concentrate, then the propylene glycol or glycerin to be used is food-grade.
 7. Follow all of the rules related to the production of a Solvent-Based Retail Marijuana Concentrate if a pressurized system is used in the production of a Water-Based Retail Marijuana Concentrate or a Food-Based Retail Marijuana Concentrate.
- D. Solvent-Based Retail Marijuana Concentrate. A Retail Marijuana Products Manufacturing Facility that engages in the production of Solvent-Based Retail 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, each of which is available to the public;
 - a. Flammable Solvent Determinations. If a Flammable Solvent is to be used in the processing of Retail Marijuana into a Retail Marijuana Concentrate, then the ~~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 and junction boxes, must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored in accordance with applicable laws, rules and regulations;
 - iii. Determine whether a gas monitoring system must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations; and
 - iv. Determine whether fire suppression system must be installed within the room in which Retail Marijuana Concentrate is to be produced or Flammable Solvents are to be stored, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
 - b. CO₂ Solvent Determination. If CO₂ is used as solvent at the Licensed Premises, then the ~~Certified~~ Industrial Hygienist or Professional Engineer must determine whether a CO₂ gas monitoring system must be installed

within the room in which Retail Marijuana Concentrate is to be produced or CO₂ 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 Retail Marijuana Concentrate is to be produced, and if required the system's specifications, in accordance with applicable laws, rules and regulations.
- d. Material Change. If a Retail Marijuana Products Manufacturing Facility 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 Retail Marijuana Products Manufacturing Facility by the designer or manufacturer of any equipment used in the processing of Retail Marijuana into a Retail Marijuana Concentrate.
- f. Records Retention. A Retail Marijuana Products Manufacturing Facility 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 Retail Marijuana Concentrate on the Licensed Premises.

- 2. Ensure that all equipment, counters and surfaces used in the production of a Solvent-Based Retail Marijuana Concentrate are food-grade and do not react adversely with any of the solvents to be used in the Licensed Premises. Additionally, all counters and surface areas must be constructed in a manner that reduces the potential development of microbials, molds and fungi and can be easily cleaned;
- 3. Ensure that the room in which Solvent-Based Retail Marijuana Concentrate shall be produced must contain an emergency eye-wash station;
- 4. Ensure that only a professional grade, closed-loop extraction system capable of recovering the solvent is used to produce Solvent-Based Retail Marijuana Concentrate;

a. UL or ETL Listing.

- i. If the system is UL or ETL listed, then a Retail Marijuana Products Manufacturing Facility may use the system in accordance with the manufacturer's instructions.
- ii. If the system is UL or ETL listed but the Retail Marijuana Products Manufacturing Facility intends to use a solvent in the system that is not listed in the manufacturer's instructions for use in the system, then, prior to using the unlisted solvent within the

system, the Retail Marijuana Products Manufacturing Facility must obtain written approval for use of the non-listed solvent in the system from either the system's manufacturer or a Professional Engineer after the Professional Engineer has conducted a peer review of the system. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.

iii. If the system is not UL or ETL listed, then there must a designer of record. If the designer of record is not a Professional Engineer, then the system must be peer reviewed by a Professional Engineer. In reviewing the system, the Professional Engineer shall review and consider any information provided by the system's designer or manufacturer.

b. Ethanol or Isopropanol. A Retail Marijuana Products Manufacturing Facility need not use a professional grade, closed-loop system extraction system capable of recovering the solvent for the production of a Solvent-Based Retail Marijuana Concentrate if ethanol or isopropanol are the only solvents being used in the production process.

5. Ensure that all solvents used in the extraction process are food-grade or at least 99% pure;

a. A Retail Marijuana Products Manufacturing Facility must obtain a material safety data sheet for each solvent used or stored on the Licensed Premises. A Retail Marijuana Products Manufacturing Facility 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 R 901- Business Records Required.

b. A Retail Marijuana Products Manufacturing Facility is prohibited from using denatured alcohol to produce a Retail 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 Retail Marijuana Products Manufacturing Facility 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 Retail Marijuana Concentrate; and

8. Ensure that a trained Owner or Occupational Licensee is present at all times during the production of a Solvent-Based Retail Marijuana Concentrate whenever an extraction process requires the use of pressurized equipment.

E. Ethanol and Isopropanol. If a Retail Marijuana Products Manufacturing Facility only produces Solvent-Based Retail Marijuana Concentrate using ethanol or isopropanol at its Licensed Premises and no other solvent, then it shall be considered exempt from paragraph D of this rule and instead must follow the requirements in paragraph C of this rule. Regardless

of which rule is followed, the ethanol or isopropanol must be food grade or at least 99% pure and denatured alcohol cannot be used.

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

Basis and Purpose – R 712

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(V), 12-43.4-202(3)(c)(VI), 12-43.4-202(3)(c)(VII), and 12-43.4-405, 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 Retail Marijuana Testing Facilities.

R 712 – Retail Marijuana Testing Facility: Mandatory Sampling and Testing Program

- A. Division Authority. The Division may elect to require that a Test Batch be submitted to a specific Retail Marijuana Testing Facility for testing to verify compliance, perform investigations, compile data or address a public health and safety concern.
- B. Test Batches
1. Retail Marijuana and Retail Marijuana Concentrate. A Retail Marijuana Testing Facility must establish a standard minimum weight of Retail Marijuana and Retail Marijuana Concentrate that must be included in a Test Batch for every type of test that it conducts.
 2. Retail Marijuana Product. A Retail Marijuana Testing Facility must establish a standard number of finished product(s) it requires to be included in each Test Batch of Retail Marijuana Product for every type of test that it conducts.
- C. Rejection of Test Batches and Samples
1. A Retail Marijuana Testing Facility may not accept a Test Batch that is smaller than its standard minimum amount.
 2. Beginning on July 1, 2014, a Retail Marijuana Testing Facility may not accept a Test Batch or Sample that it knows was not taken in accordance these rules or any additional Division sampling procedures or was not collected by Division personnel or a Division Approved Sampler.
- D. Notification of Retail Marijuana Establishment. If Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product failed a contaminant test, then the Retail Marijuana Testing Facility must immediately notify the Retail Marijuana Establishment that submitted the sample for testing and report the failure in accordance with all MITS procedures.
- E. Permissible Levels of Contaminants. If Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana 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 (Bacteria, Molds, Mildew, Fungus, Filth)

Escherichia coli – Bacteria	Negative – None Detected
Salmonella species – Bacteria	Negative – None Detected
Bile tolerant gram negative bacteria- (Enterobacteriaceae, Pseudomonas, Aeromonas)	Max Limit: 10000 CFU
Aspergillus sp. – Molds, Fungus	Negative – None Detected
Mucor sp. – Molds, Fungus	Negative – None Detected
Penicillium sp. – Molds, Fungus	Negative – None Detected
Thermophilic Actinomyces sp. – Molds, Fungus	Negative – None Detected
Aflatoxin	Max Limit – 20 ppb
Filth Analysis	Insect Filth – Average of 5% or more insect infested pieces by weight
	Mammalian excreta – Average of 1 mg or more mammalian excreta per pound
	Rodent filth – Average of 2 or more rodent hairs per 10 grams

<u>SUBSTANCE</u>	<u>ACCEPTABLE LIMITS PER GRAM</u>	<u>PRODUCT TO BE TESTED</u>
–SHIGA-TOXIN PRODUCING ESCHERICHIA COLI (STEC)* - BACTERIA	< 1 COLONY FORMING UNIT (CFU)	FLOWER; RETAIL MARIJUANA PRODUCTS; WATER- AND FOOD-BASED CONCENTRATES
SALMONELLA SPECIES* – BACTERIA	< 1 COLONY FORMING UNIT (CFU)	
ASPERGILLUS FUMIGATUS, ASPERGILLUS FLAVUS, ASPERGILLUS NIGER - FUNGUS	< 1 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 and Metals

N-Butane	<50.0 Parts Per Million (PPM)
Iso-Butane	<50.0 Parts Per Million (PPM)
Propane	<50.0 Parts Per Million (PPM)
Heptane	<10.0 Parts Per Million (PPM)
2-propanol (isopropyl alcohol)	<10.0 Parts Per Million (PPM)
Ethanol	<10.0 Parts Per Million (PPM)
Any solvent not permitted for use pursuant to Rule R 605.	None Detected
Metals (Arsenic, Cadmium, Lead and Mercury)	Lead – Max Limit: 0.1 ppm
	Arsenic – Max Limit: 30 ppb
	Cadmium – Max Limit: 0.5 ppm
	Mercury – Max Limit: 0.5 ppm

<u>SUBSTANCE</u>	<u>ACCEPTABLE LIMITS PER GRAM</u>	<u>PRODUCT TO BE TESTED</u>
BUTANES	< 800 PARTS PER MILLION (PPM)	SOLVENT-BASED CONCENTRATES
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 R 605, LIMITS HAVE BEEN LISTED HERE ACCORDINGLY.

3. METALS

<u>SUBSTANCE</u>	<u>ACCEPTABLE LIMITS PER GRAM</u>	<u>PRODUCT TO BE TESTED</u>
METALS (ARSENIC, CADMIUM, LEAD AND MERCURY)	LEAD – MAX LIMIT: < 10 PPM ARSENIC – MAX LIMIT: < 10 PPM CADMIUM – MAX LIMIT: <4.1 PPM MERCURY – MAX LIMIT: <2.0 PPM	FLOWER; WATER-, FOOD-, AND SOLVENT-BASED CONCENTRATES; AND RETAIL MARIJUANA PRODUCTS

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.

4. Division Notification. A Retail 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 Retail Marijuana Testing Facility may test and report results for any cannabinoid provided the test is conducted in accordance with the Division's Retail Marijuana Testing Facility Certification Policy Statement.
2. Reporting of Results
 - a. For potency tests on Retail Marijuana and Retail 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 Retail Marijuana Product, WHETHER CONDUCTED ON EACH INDIVIDUAL PRODUCTION BATCH OR VIA PROCESS VALIDATION PER RULE R 1503, results must be reported by listing the total number of milligrams contained within a single ~~individually packaged product~~ RETAIL MARIJUANA PRODUCT UNIT FOR SALE for each cannabinoid and AFFIRMING ~~whether~~ the THC content is homogenous.
3. Dried Flower. All potency tests conducted on Retail Marijuana must occur on dried and cured Retail Marijuana that is ready for sale.
4. Failed Potency Tests for Retail Marijuana Products
 - a. If an individually packaged Edible Retail Marijuana Product contained within a Test Batch is determined to have more than 100 mgs of THC within it, then the Test Batch shall be considered to have failed potency testing.
 - b. If the THC content of a Marijuana Product is determined through testing to not be homogenous, then it shall be considered to have failed potency testing. A Retail Marijuana Product shall be considered to not be homogenous if 10% of the infused portion of the Retail Marijuana Product contains more than 20% of the total THC contained within entire Retail Marijuana Product.

Basis and Purpose – R 1004

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), and 12-43.4-202(3)(a)(VII), 12-43.4-404(6), and 25-4-1614(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure that every Retail Marijuana Products Manufacturing Facility labels each Shipping Container and Container holding a Retail Marijuana Product with all of the necessary and relevant information for the receiving Retail Marijuana Establishment. In addition, this rule clarifies basic packaging requirements. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques to each Retail Marijuana Product as this is a public health and safety concern.

R 1004 – Packaging and Labeling Requirements of a Retail Marijuana Product by a Retail Marijuana Products Manufacturing Facility

- A. THIS RULE IS REPEALED EFFECTIVE NOVEMBER 1, 2014. RETAIL MARIJUANA PRODUCT MANUFACTURING FACILITIES SHALL REFER TO RULE R 1004.5 FOR RETAIL MARIJUANA PRODUCT PACKAGING AND LABELING REQUIREMENTS BEGINNING NOVEMBER 1, 2014.
- B. Packaging of Retail Marijuana Product by a Retail Marijuana Products Manufacturing Facility
1. Every Retail Marijuana Products Manufacturing Facility must ensure that each Retail Marijuana Product is individually packaged within a Container prior to transport or transfer to another Retail Marijuana Establishment.
 2. Every Retail Marijuana Products Manufacturing Facility must ensure that each Container holding a Retail Marijuana Product is placed in a Shipping Container prior to transport or transfer to another Retail Marijuana Establishment.
- C. Labeling of Retail Marijuana Product Containers by a Retail Marijuana Products Manufacturing Facility . A Retail Marijuana Products Manufacturing Facility must ensure that a label(s) is affixed to every Container holding a Retail Marijuana Product that includes all of the information required by this rule prior to transport or transfer to another Retail Marijuana Establishment.
1. Required Information (General) . Every Retail Marijuana Products Manufacturing Facility must ensure the following information is affixed to every Container holding a Retail Marijuana Product:
 - a. The license number of the Retail Marijuana Cultivation Facility(-ies) where the Retail Marijuana used to produce the Retail Marijuana Product was grown;
 - b. The Production Batch Number(s) of Retail Marijuana concentrate(s) used in the production of the Retail Marijuana Product.
 - c. The license number of the Retail Marijuana Products Manufacturing Facility that produced the Retail Marijuana Product.
 - d. The Production Batch Number(s) assigned to the Retail Marijuana Product.
 - e. A statement about whether the Container is Child-Resistant.
 - f. A clear set of usage instructions for non-Edible Retail Marijuana Product.

- g. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Retail Marijuana used to produce the Retail Marijuana Product.
 - h. A complete list of solvents and chemicals used in the creation of any Retail Marijuana concentrate that was used to produce the Retail Marijuana Product.
2. Required Information (Edible Retail Marijuana Product) . Every Retail Marijuana Products Manufacturing Facility must ensure that the following information or statement is affixed to every Container holding an Edible Retail Marijuana Product:
- a. Ingredient List . A list of all ingredients used to manufacture the Edible Retail Marijuana Product; which may include a list of any potential allergens contained within.
 - b. Statement Regarding Refrigeration . If the Retail Marijuana Product is perishable, a statement that the Retail Marijuana Product must be refrigerated.
 - c. Serving Size Statement . **"The standardized serving size for this product includes no more than ten milligrams of active THC."**
 - d. Statement of Expiration Date . A product expiration date, for perishable Retail Marijuana 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 a Retail Marijuana 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 Retail Marijuana Product) . Every Retail Marijuana Products Manufacturing Facility may affix a label(s) with the following information to every Container holding an Edible Retail Marijuana Product:
- a. The Retail Marijuana Product's compatibility with dietary restrictions; and
 - b. A nutritional fact panel that, if included, must be based on the number of THC servings within the Container.
4. Required Statement When Contaminant Tests are Performed . Every Retail Marijuana Products Manufacturing Facility must ensure that a label is affixed to each Container holding a Retail Marijuana Product with a statement asserting that the Retail Marijuana Product was tested for contaminants and the results of those tests, if:
- a. A Retail Marijuana Testing Facility(ies) tested every Harvest Batch used to produce the Retail Marijuana Product for (1) molds, mildew and filth; (2) microbials; (3) herbicides, pesticides and fungicides, (4) and harmful chemicals;
 - b. A Retail Marijuana Testing Facility tested every Production Batch of Retail Marijuana concentrate used to produce the Retail Marijuana Product for residual solvents, poisons or toxins; and

- c. A Retail Marijuana Testing Facility(ies) tested the Production Batch of the Retail Marijuana Product for microbials and molds, mildew and filth.
- 5. Required Statement if Cannabinoid Potency is Tested . If a Retail Marijuana Testing Facility tested the Production Batch of the Retail Marijuana Product within the Container for potency, then every Retail Marijuana Products Manufacturing Facility must ensure that a label is affixed to the Container with a potency profile expressed in milligrams and the number of THC servings within the Container.
- 6. Required Statement When No Containment Testing is Completed . Every Retail Marijuana Products Manufacturing Facility must ensure that a label is affixed to each Container that holds a Retail Marijuana Product with the statement: **"The marijuana product contained within this package has not been tested for contaminants."** unless:
 - a. A Retail Marijuana Testing Facility(ies) tested every Harvest Batch used to produce the Retail Marijuana Product for (1) molds, mildew and filth; (2) microbials; (3) herbicides, pesticides and fungicides, (4) and harmful chemicals;
 - b. A Retail Marijuana Testing Facility tested every Production Batch of Retail Marijuana concentrate used to produce the Retail Marijuana Product for residual solvents, poisons or toxins; and
 - c. A Retail Marijuana Testing Facility(ies) tested the Production Batch of the Retail Marijuana Product for microbials and molds, mildew and filth.
- 7. Required Statement When No Potency Testing Completed . If a Retail Marijuana Testing Facility did not test the Production Batch of the Retail Marijuana Product within a Container for potency, then every Retail Marijuana Products Manufacturing Facility must ensure that a label is affixed to the Container with the a statement: **"The marijuana product contained within this package has not been tested for potency, consume with caution."**
- D. Labeling of Retail Marijuana Product Shipping Containers by Retail Marijuana Products Manufacturing Facility . Prior to transporting or transferring any Retail Marijuana Product to another Retail Marijuana Establishment, a Retail Marijuana Manufacturing Products Facility must ensure that a label is affixed to a Shipping Container holding Retail Marijuana Product that includes all of the information required by this rule. A Retail Marijuana Products Manufacturing Facility must include the following information on every Shipping Container:
 - 1. The number of Containers holding a Retail Marijuana Product within the Shipping Container; and
 - 2. The license number of the Retail Marijuana Products Manufacturing Facility(-ies) that produced the Retail Marijuana Product within the Shipping Container.

BASIS AND PURPOSE – R 1004.5

THE STATUTORY AUTHORITY FOR THIS RULE IS FOUND AT SUBSECTIONS 12-43.4-202(2)(B), 12-43.4-202(3)(A)(IV), AND 12-43.4-202(3)(A)(VII), 12-43.4-404(6), AND 25-4-1614(3)(A), C.R.S. AUTHORITY ALSO EXISTS IN THE COLORADO CONSTITUTION AT ARTICLE XVIII, SUBSECTION 16(5)(A)(VI). THE PURPOSE OF THIS RULE IS TO ENSURE THAT EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY LABELS EACH SHIPPING CONTAINER AND CONTAINER HOLDING A

RETAIL MARIJUANA PRODUCT WITH ALL OF THE NECESSARY AND RELEVANT INFORMATION FOR THE RECEIVING RETAIL MARIJUANA ESTABLISHMENT. 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 RETAIL MARIJUANA PRODUCT AS THIS IS A PUBLIC HEALTH AND SAFETY CONCERN.

R 1004.5 – PACKAGING AND LABELING REQUIREMENTS OF A RETAIL MARIJUANA PRODUCT BY A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY

- A. APPLICABILITY. THIS RULE SHALL APPLY TO ALL RETAIL MARIJUANA PRODUCTS MANUFACTURED ON OR AFTER NOVEMBER 1, 2014.

- B. PACKAGING OF RETAIL MARIJUANA PRODUCT BY A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY
 1. GENERAL STANDARD.
 - a. EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT EACH CONTAINER HOLDING A RETAIL MARIJUANA PRODUCT IS PLACED IN A SHIPPING CONTAINER PRIOR TO TRANSPORT OR TRANSFER TO ANOTHER RETAIL MARIJUANA ESTABLISHMENT.

 2. SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT.
 - a. EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT EACH SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT IS INDIVIDUALLY PACKAGED WITHIN A CHILD-RESISTANT CONTAINER PRIOR TO TRANSPORT OR TRANSFER TO ANOTHER RETAIL MARIJUANA ESTABLISHMENT.

 - b. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MAY BUNDLE SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCTS THAT ARE INDIVIDUALLY PACKAGED IN CHILD-RESISTANT PACKAGING INTO A LARGER PACKAGE SO LONG AS THE TOTAL AMOUNT OF ACTIVE THC CONTAINED WITHIN THE BUNDLED PACKAGE DOES NOT EXCEED 100 MILLIGRAMS AND THE EXTERNAL PACKAGING COMPLIES WITH THE SERVING SIZE AND TOTAL ACTIVE THC STATEMENT REQUIREMENT OF SUBPARAGRAPH (C)(2)(C) OF THIS RULE.

 3. MULTIPLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT.
 - a. EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT EACH MULTIPLE-SERVING EDIBLE MARIJUANA PRODUCT IS INDIVIDUALLY PACKAGED WITHIN A CHILD-RESISTANT CONTAINER THAT MAINTAINS ITS CHILD-RESISTANT EFFECTIVENESS FOR MULTIPLE OPENINGS PRIOR TO TRANSPORT OR TRANSFER TO ANOTHER RETAIL MARIJUANA ESTABLISHMENT.

 4. LIQUID EDIBLE RETAIL MARIJUANA PRODUCT.
 - a. LIQUID EDIBLE RETAIL MARIJUANA PRODUCT THAT CONTAINS NO MORE THAN ONE STANDARDIZED SERVING OF MARIJUANA. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT EACH PRODUCT COMPLIES WITH SUBPARAGRAPH (B)(2)(A) OF THIS RULE.

- b. LIQUID EDIBLE RETAIL MARIJUANA PRODUCT THAT CONTAINS MORE THAN ONE STANDARDIZED SERVING OF MARIJUANA. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT EACH PRODUCT IS PACKAGED IN A CHILD-RESISTANT CONTAINER THAT MAINTAINS ITS CHILD-RESISTANT EFFECTIVENESS FOR MULTIPLE OPENINGS. THE CONTAINER SHALL CLEARLY DEMARK EACH STANDARDIZED SERVING OF MARIJUANA IN A WAY THAT ENABLES A REASONABLE PERSON TO INTUITIVELY DETERMINE HOW MUCH OF THE PRODUCT CONSTITUTES A SINGLE SERVING OF ACTIVE THC. THE PORTION OF THE CONTAINER THAT CLEARLY DEMARKS EACH STANDARDIZED SERVING OF MARIJUANA NEED NOT BE OPAQUE.
- C. LABELING OF RETAIL MARIJUANA PRODUCT CONTAINERS BY A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT A LABEL(S) IS AFFIXED TO EVERY CONTAINER HOLDING A RETAIL MARIJUANA PRODUCT THAT INCLUDES ALL OF THE INFORMATION REQUIRED BY THIS RULE PRIOR TO TRANSPORT OR TRANSFER TO ANOTHER RETAIL MARIJUANA ESTABLISHMENT.
- 1. REQUIRED INFORMATION (GENERAL). EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THE FOLLOWING INFORMATION IS AFFIXED TO EVERY CONTAINER HOLDING A RETAIL MARIJUANA PRODUCT:
 - a. THE LICENSE NUMBER OF THE RETAIL MARIJUANA CULTIVATION FACILITY(-IES) WHERE THE RETAIL MARIJUANA USED TO PRODUCE THE RETAIL MARIJUANA PRODUCT WAS GROWN;
 - b. THE PRODUCTION BATCH NUMBER(S) OF RETAIL MARIJUANA CONCENTRATE(S) USED IN THE PRODUCTION OF THE RETAIL MARIJUANA PRODUCT.
 - c. THE LICENSE NUMBER OF THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY THAT PRODUCED THE RETAIL MARIJUANA PRODUCT.
 - d. THE PRODUCTION BATCH NUMBER(S) ASSIGNED TO THE RETAIL MARIJUANA PRODUCT.
 - e. A STATEMENT ABOUT WHETHER THE CONTAINER IS CHILD-RESISTANT.
 - f. A CLEAR SET OF USAGE INSTRUCTIONS FOR NON-EDIBLE RETAIL MARIJUANA PRODUCT.
 - g. THE IDENTITY STATEMENT AND STANDARDIZED GRAPHIC SYMBOL OF THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY THAT MANUFACTURED THE RETAIL MARIJUANA 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;
 - h. THE UNIVERSAL SYMBOL, INDICATING THAT THE CONTAINER HOLDS MARIJUANA, WHICH MUST BE NO SMALLER THAN ¼ OF AN INCH BY ¼ OF AN INCH;
 - i. THE FOLLOWING WARNING STATEMENTS:
 - i. "THERE MAY BE HEALTH RISKS ASSOCIATED WITH THE CONSUMPTION OF THIS PRODUCT."

- ii. "THIS PRODUCT IS INFUSED WITH MARIJUANA."
 - iii. "THIS PRODUCT WAS PRODUCED WITHOUT REGULATORY OVERSIGHT FOR HEALTH, SAFETY, OR EFFICACY."
 - iv. "THE INTOXICATING EFFECTS OF THIS PRODUCT MAY BE DELAYED BY TWO OR MORE HOURS."
 - 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."
- j. A COMPLETE LIST OF ALL NONORGANIC PESTICIDES, FUNGICIDES, AND HERBICIDES USED DURING THE CULTIVATION OF THE RETAIL MARIJUANA USED TO PRODUCE THE RETAIL MARIJUANA PRODUCT.
 - k. A COMPLETE LIST OF SOLVENTS AND CHEMICALS USED IN THE CREATION OF ANY RETAIL MARIJUANA CONCENTRATE THAT WAS USED TO PRODUCE THE RETAIL MARIJUANA PRODUCT.
2. REQUIRED INFORMATION (EDIBLE RETAIL MARIJUANA PRODUCT). EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT THE FOLLOWING INFORMATION OR STATEMENT IS AFFIXED TO EVERY CONTAINER HOLDING AN EDIBLE RETAIL MARIJUANA PRODUCT:
- a. INGREDIENT LIST. A LIST OF ALL INGREDIENTS USED TO MANUFACTURE THE EDIBLE RETAIL MARIJUANA PRODUCT; WHICH MAY INCLUDE A LIST OF ANY POTENTIAL ALLERGENS CONTAINED WITHIN.
 - b. STATEMENT REGARDING REFRIGERATION. IF THE RETAIL MARIJUANA PRODUCT IS PERISHABLE, A STATEMENT THAT THE RETAIL MARIJUANA PRODUCT MUST BE REFRIGERATED.
 - c. SERVING SIZE AND TOTAL ACTIVE THC STATEMENT. INFORMATION REGARDING: THE SIZE OF STANDARDIZED SERVING OF MARIJUANA FOR THE PRODUCT BY MILLIGRAMS, THE TOTAL NUMBER OF STANDARDIZED SERVINGS OF MARIJUANA IN THE PRODUCT, AND THE TOTAL AMOUNT OF ACTIVE THC IN THE PRODUCT BY MILLIGRAMS. FOR EXAMPLE: "THE SERVING SIZE OF ACTIVE THC IN THIS PRODUCT IS X MG, THIS PRODUCT CONTAINS X SERVINGS OF MARIJUANA, AND THE TOTAL AMOUNT OF ACTIVE THC IN THIS PRODUCT IS X MG."
 - d. STATEMENT OF EXPIRATION DATE. A PRODUCT EXPIRATION DATE, FOR PERISHABLE RETAIL MARIJUANA 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 A RETAIL MARIJUANA 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 RETAIL MARIJUANA PRODUCT). EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MAY AFFIX A LABEL(S) WITH THE FOLLOWING INFORMATION TO EVERY CONTAINER HOLDING AN EDIBLE RETAIL MARIJUANA PRODUCT:
- a. THE RETAIL MARIJUANA PRODUCT'S COMPATIBILITY WITH DIETARY RESTRICTIONS; AND

- b. A NUTRITIONAL FACT PANEL THAT, IF INCLUDED, MUST BE BASED ON THE NUMBER OF THC SERVINGS WITHIN THE CONTAINER.
 - 4. REQUIRED STATEMENT WHEN CONTAMINANT TESTS ARE PERFORMED. EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT A LABEL IS AFFIXED TO EACH CONTAINER HOLDING A RETAIL MARIJUANA PRODUCT WITH A STATEMENT ASSERTING THAT THE RETAIL MARIJUANA PRODUCT WAS TESTED FOR CONTAMINANTS AND THE RESULTS OF THOSE TESTS, IF:
 - a. A RETAIL MARIJUANA TESTING FACILITY(IES) TESTED EVERY HARVEST BATCH USED TO PRODUCE THE RETAIL MARIJUANA PRODUCT FOR CONTAMINANTS REQUIRED TO BE TESTED PER RULE R 1501;
 - b. A RETAIL MARIJUANA TESTING FACILITY TESTED EVERY PRODUCTION BATCH OF RETAIL MARIJUANA CONCENTRATE USED TO PRODUCE THE RETAIL MARIJUANA PRODUCT FOR CONTAMINANTS REQUIRED TO BE TESTED PER RULE R 1501; AND
 - c. A RETAIL MARIJUANA TESTING FACILITY(IES) TESTED THE PRODUCTION BATCH OF THE RETAIL MARIJUANA PRODUCT FOR CONTAMINANTS REQUIRED TO BE TESTED PER RULE R 1501.
 - 5. REQUIRED STATEMENT WHEN CANNABINOID POTENCY IS TESTED. EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT A LABEL IS AFFIXED TO THE CONTAINER WITH A POTENCY PROFILE EXPRESSED IN MILLIGRAMS PURSUANT TO RULE R 1503 AND THE NUMBER OF THC SERVINGS WITHIN THE CONTAINER.
 - 6. REQUIRED STATEMENT WHEN NO CONTAMINANT TESTING IS COMPLETED. EVERY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST ENSURE THAT A LABEL IS AFFIXED TO EACH CONTAINER THAT HOLDS A RETAIL MARIJUANA PRODUCT WITH THE STATEMENT: **"THE MARIJUANA PRODUCT CONTAINED WITHIN THIS PACKAGE HAS NOT BEEN TESTED FOR CONTAMINANTS."** UNLESS:
 - a. A RETAIL MARIJUANA TESTING FACILITY(IES) TESTED EVERY HARVEST BATCH USED TO PRODUCE THE RETAIL MARIJUANA PRODUCT FOR CONTAMINANTS REQUIRED TO BE TESTED PER RULE R 1501;
 - b. A RETAIL MARIJUANA TESTING FACILITY TESTED EVERY PRODUCTION BATCH OF RETAIL MARIJUANA CONCENTRATE USED TO PRODUCE THE RETAIL MARIJUANA PRODUCT FOR CONTAMINANTS REQUIRED TO BE TESTED PER RULE R 1501; AND
 - c. A RETAIL MARIJUANA TESTING FACILITY(IES) TESTED THE PRODUCTION BATCH OF THE RETAIL MARIJUANA PRODUCT FOR CONTAMINANTS REQUIRED TO BE TESTED PER RULE R 1501.
- D. LABELING OF RETAIL MARIJUANA PRODUCT SHIPPING CONTAINERS BY RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY. PRIOR TO TRANSPORTING OR TRANSFERRING ANY RETAIL MARIJUANA PRODUCT TO ANOTHER RETAIL MARIJUANA ESTABLISHMENT, A RETAIL MARIJUANA MANUFACTURING PRODUCTS FACILITY MUST ENSURE THAT A LABEL IS AFFIXED TO A SHIPPING CONTAINER HOLDING RETAIL MARIJUANA PRODUCT THAT INCLUDES ALL OF THE INFORMATION REQUIRED BY THIS RULE. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST INCLUDE THE FOLLOWING INFORMATION ON EVERY SHIPPING CONTAINER:
- 1. THE NUMBER OF CONTAINERS HOLDING A RETAIL MARIJUANA PRODUCT WITHIN THE SHIPPING CONTAINER; AND

2. THE LICENSE NUMBER OF THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY(-IES) THAT PRODUCED THE RETAIL MARIJUANA PRODUCT WITHIN THE SHIPPING CONTAINER.

Basis and Purpose – R 1006

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-402(4), and 25-4-1614(3)(a), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure that the labeling on each Container holding a Retail Marijuana 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. Further, the State Licensing Authority believes based on written and oral comments it has received through the rulemaking process that prohibiting labels that are intended to target individuals under the age of 21 and requiring child-resistant packaging is of a state wide concern and would assist in limiting exposure and diversion to minors. The State Licensing Authority wants to ensure the regulated community employs proper labeling techniques to each Retail Marijuana Product as this is a public health and safety concern.

R 1006 – Packaging and Labeling of Retail Marijuana Product by a Retail Marijuana Store

- A. THIS RULE IS REPEALED EFFECTIVE NOVEMBER 1, 2014. RETAIL MARIJUANA STORES SHALL REFER TO RULE R 1006.5 FOR RETAIL MARIJUANA PRODUCT PACKAGING AND LABELING REQUIREMENTS BEGINNING NOVEMBER 1, 2014.
- B. Packaging of Retail Marijuana Product by a Retail Marijuana Store . A Retail Marijuana Store must ensure that each Retail Marijuana Product is placed within a Container prior to sale to a consumer. If the Container is not Child-Resistant, the Retail Marijuana Store must place the Container within an Exit Package that is Child-Resistant.
- C. Labeling of Retail Marijuana Product by a Retail Marijuana Store . Every Retail Marijuana Store must ensure that a label(s) is affixed to every Container holding a Retail Marijuana Product that includes all of the information required by this rule prior to sale to a consumer:
 1. Required Information (General) . Every Retail Marijuana Store must ensure the following information is affixed to every Container holding a Retail Marijuana Product:
 - a. The license number of the Retail Marijuana Cultivation Facility(-ies) where the Retail Marijuana used to produce the Retail Marijuana Product was grown;
 - b. The Production Batch Number(s) assigned to the Retail Marijuana concentrate used to produce the Retail Marijuana Product;
 - c. The license number of the Retail Marijuana Products Manufacturing Facility that produced the Retail Marijuana Product;
 - d. The Production Batch Number(s) assigned to the Retail Marijuana Product;

- e. The license number of the Retail Marijuana Store that sold the Retail Marijuana Product to the consumer;
- f. A statement about whether the Container is Child-Resistant;
- g. The Identity Statement and Standardized Graphic Symbol of the Retail Marijuana Store that sold the Retail Marijuana 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;
- h. The date of sale to the consumer;
- i. The following warning statements:
 - i. **"There may be health risks associated with the consumption of this product."**
 - ii. **"This product is intended for use by adults 21 years and older. Keep out of the reach of children."**
 - iii. **"This product is unlawful outside the State of Colorado."**
 - iv. **"This product is infused with marijuana."**
 - v. **"This product was produced without regulatory oversight for health, safety, or efficacy."**
 - vi. **"The intoxicating effects of this product may be delayed by two or more hours."**
 - vii. **"There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant."**
 - viii. **"Do not drive a motor vehicle or operate heavy machinery while using marijuana."**
- j. The Universal Symbol, indicating that the Container holds marijuana, which must be no smaller than ¼ of an inch by ¼ of an inch;
- k. A clear set of instructions for proper usage for non-Edible Retail Marijuana Product;
- l. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Retail Marijuana used to produce the Retail Marijuana Product; and
- m. A complete list of solvents and chemicals used in the creation of any Retail Marijuana concentrate used in the produce of the Retail Marijuana Product.

2. Required Information (Edible Retail Marijuana Product) . Every Retail Marijuana Store must ensure that the following information or statement is affixed to every Container holding an Edible Retail Marijuana Product:
 - a. Ingredient List . A list of all ingredients used to manufacture the Edible Retail Marijuana Product; which may include a list of any potential allergens contained within.
 - b. Statement Regarding Refrigeration . If the Retail Marijuana Product is perishable, a statement that the Retail Marijuana Product must be refrigerated.
 - c. Serving Size Statement . **"The standardized serving size for this product includes no more than ten milligrams of active THC."**
 - d. Statement of Expiration Date . A product expiration date, for perishable Retail Marijuana 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 a Retail Marijuana 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 Retail Marijuana Product) . Every Retail Marijuana Store may affix a label(s) with the following information to every Container holding an Edible Retail Marijuana Product:
 - a. The Retail Marijuana Product's compatibility with dietary restrictions; and
 - b. A nutritional fact panel that, if included, must be based on the number of THC servings within the Container.
4. Required Statement When Contaminant Tests are Performed . Every Retail Marijuana Store must ensure that a label is affixed to each Container holding a Retail Marijuana Product with a statement asserting that the Retail Marijuana Product was tested for contaminants and the results of those tests, if:
 - a. A Retail Marijuana Testing Facility(ies) tested every Harvest Batch used to produce the Retail Marijuana Product for (1) molds, mildew and filth; (2) microbials; (3) herbicides, pesticides and fungicides, (4) and harmful chemicals;
 - b. A Retail Marijuana Testing Facility tested every Production Batch of Retail Marijuana concentrate used to produce the Retail Marijuana Product for residual solvents, poisons or toxins; and
 - c. A Retail Marijuana Testing Facility(ies) tested the Production Batch of the Retail Marijuana Product for microbials and molds, mildew and filth.
5. Required Statement if Cannabinoid Potency is Tested . If a Retail Marijuana Testing Facility tested the Production Batch of the Retail Marijuana Product within the Container for potency, then every Retail Marijuana Store must ensure that a label is affixed to the Container with a potency profile expressed milligrams and the number of THC servings within the Container.

6. Required Statement When No Containment Testing is Completed . Every Retail Marijuana Store must ensure that a label is affixed to each Container that holds a Retail Marijuana Product with the statement: **"The marijuana product contained within this package has not been tested for contaminants."** unless:
 - a. A Retail Marijuana Testing Facility(ies) tested every Harvest Batch used to produce the Retail Marijuana Product for (1) molds, mildew and filth; (2) microbials; (3) herbicides, pesticides and fungicides, (4) and harmful chemicals;
 - b. A Retail Marijuana Testing Facility tested every Production Batch of Retail Marijuana concentrate used to produce the Retail Marijuana Product for residual solvents, poisons or toxins; and
 - c. A Retail Marijuana Testing Facility(ies) tested the Production Batch of the Retail Marijuana Product for microbials and molds, mildew and filth.

7. Required Statement When No Potency Testing Completed . If a Retail Marijuana Testing Facility did not test the Production Batch of the Retail Marijuana Product within a Container for potency, then every Retail Marijuana Store must ensure that a label is affixed to the Container with the a statement: **"The marijuana product contained within this package has not been tested for potency, consume with caution."**

BASIS AND PURPOSE – R 1006.5

THE STATUTORY AUTHORITY FOR THIS RULE IS FOUND AT SUBSECTIONS 12-43.4-202(2)(B), 12-43.4-202(3)(A)(IV), 12-43.4-202(3)(A)(VII), 12-43.4-402(4), AND 25-4-1614(3)(A), C.R.S. AUTHORITY ALSO EXISTS IN THE COLORADO CONSTITUTION AT ARTICLE XVIII, SUBSECTION 16(5)(A)(VI). THE PURPOSE OF THIS RULE IS TO ENSURE THAT THE LABELING ON EACH CONTAINER HOLDING A RETAIL MARIJUANA 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. FURTHER, THE STATE LICENSING AUTHORITY BELIEVES BASED ON WRITTEN AND ORAL COMMENTS IT HAS RECEIVED THROUGH THE RULEMAKING PROCESS THAT PROHIBITING LABELS THAT ARE INTENDED TO TARGET INDIVIDUALS UNDER THE AGE OF 21 AND REQUIRING CHILD-RESISTANT PACKAGING IS OF A STATE WIDE CONCERN AND WOULD ASSIST IN LIMITING EXPOSURE AND DIVERSION TO MINORS. THE STATE LICENSING AUTHORITY WANTS TO ENSURE THE REGULATED COMMUNITY EMPLOYS PROPER PACKAGING AND LABELING TECHNIQUES FOR EACH RETAIL MARIJUANA PRODUCT AS THIS IS A PUBLIC HEALTH AND SAFETY CONCERN.

R 1006.5 – PACKAGING AND LABELING OF RETAIL MARIJUANA PRODUCT BY A RETAIL MARIJUANA STORE

- A. APPLICABILITY. THIS RULE SHALL APPLY TO ALL RETAIL MARIJUANA STORES BEGINNING NOVEMBER 1, 2014.

- B. PACKAGING REQUIREMENTS FOR A RETAIL MARIJUANA STORE.
 1. BEGINNING DECEMBER 1, 2014, A RETAIL MARIJUANA STORE SHALL NOT PURCHASE OR TAKE POSSESSION OF EDIBLE RETAIL MARIJUANA PRODUCT THAT DOES NOT COMPLY WITH RULE R 1004.5.

BEGINNING FEBRUARY 1, 2015, A RETAIL MARIJUANA STORE SHALL NOT SELL EDIBLE RETAIL MARIJUANA PRODUCT THAT DOES NOT COMPLY WITH RULE R 1004.5.

2. A RETAIL MARIJUANA STORE MUST ENSURE THAT EACH RETAIL MARIJUANA PRODUCT THAT IS NOT AN EDIBLE RETAIL MARIJUANA PRODUCT IS PLACED WITHIN A CONTAINER PRIOR TO SALE TO A CONSUMER. IF THE CONTAINER IS NOT CHILD-RESISTANT, THE RETAIL MARIJUANA STORE MUST PLACE THE CONTAINER WITHIN AN EXIT PACKAGE THAT IS CHILD-RESISTANT.
 3. A RETAIL MARIJUANA STORE MUST INSPECT EACH EDIBLE RETAIL MARIJUANA PRODUCT PRIOR TO CONCLUDING THE SALE OF THE PRODUCT TO THE CONSUMER IN ORDER TO ENSURE THAT IT MEETS ALL CHILD-RESISTANT PACKAGING REQUIREMENTS OF RULE R 1004.5.
 4. A RETAIL MARIJUANA STORE MUST ENSURE THAT EACH EDIBLE RETAIL MARIJUANA PRODUCT PLACED WITHIN A CONTAINER FOR SALE TO A CONSUMER PURSUANT TO THIS RULE MUST ALSO BE PLACED IN AN OPAQUE EXIT PACKAGE AT THE POINT OF SALE TO THE CONSUMER.
- C. LABELING OF RETAIL MARIJUANA PRODUCT BY A RETAIL MARIJUANA STORE. EVERY RETAIL MARIJUANA STORE 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:
1. REQUIRED INFORMATION (GENERAL). EVERY RETAIL MARIJUANA STORE MUST ENSURE THE FOLLOWING INFORMATION IS AFFIXED TO EVERY CONTAINER HOLDING A RETAIL MARIJUANA PRODUCT:
 - a. THE LICENSE NUMBER OF THE RETAIL MARIJUANA STORE THAT SOLD THE RETAIL MARIJUANA PRODUCT TO THE CONSUMER;
 - b. A STATEMENT ABOUT WHETHER THE CONTAINER IS CHILD-RESISTANT;
 - c. THE IDENTITY STATEMENT AND STANDARDIZED GRAPHIC SYMBOL OF THE RETAIL MARIJUANA STORE THAT SOLD THE RETAIL MARIJUANA 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;
 - d. THE DATE OF SALE TO THE CONSUMER;
 - e. THE FOLLOWING WARNING STATEMENTS:
 - i. "THERE MAY BE HEALTH RISKS ASSOCIATED WITH THE CONSUMPTION OF THIS PRODUCT."
 - ii. "THIS PRODUCT IS INTENDED FOR USE BY ADULTS 21 YEARS AND OLDER. KEEP OUT OF THE REACH OF CHILDREN."
 - iii. "THIS PRODUCT IS UNLAWFUL OUTSIDE THE STATE OF COLORADO."
 - iv. "THIS PRODUCT IS INFUSED WITH MARIJUANA."

- v. "THIS PRODUCT WAS PRODUCED WITHOUT REGULATORY OVERSIGHT FOR HEALTH, SAFETY, OR EFFICACY."
 - vi. "THE INTOXICATING EFFECTS OF THIS PRODUCT MAY BE DELAYED BY TWO OR MORE HOURS."
 - vii. "THERE MAY BE ADDITIONAL HEALTH RISKS ASSOCIATED WITH THE CONSUMPTION OF THIS PRODUCT FOR WOMEN WHO ARE PREGNANT, BREASTFEEDING, OR PLANNING ON BECOMING PREGNANT."
 - viii. "DO NOT DRIVE A MOTOR VEHICLE OR OPERATE HEAVY MACHINERY WHILE USING MARIJUANA."
- f. THE UNIVERSAL SYMBOL, INDICATING THAT THE EXIT PACKAGE HOLDS MARIJUANA, WHICH MUST BE NO SMALLER THAN ¼ OF AN INCH BY ¼ OF AN INCH.

BASIS AND PURPOSE - R 1204

THE STATUTORY AUTHORITY FOR THIS RULE IS FOUND AT SUBSECTIONS 12-43.4-202(2)(B), 12-43.4-202(3)(B)(I), AND 12-43.4-202(3)(B)(III), 12-43.4-202(3)(B)(VIII), AND 12-43.4-202(3)(B)(IX), 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.

R 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 RETAIL 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 THE RETAIL CODE, OR THE RULES AND REGULATION THEREUNDER.
- D. THE STATE LICENSING AUTHORITY MAY APPROVE OR REVIEW AN ASSURANCE OF VOLUNTARY COMPLIANCE.

Basis and Purpose – R 1501

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(a)(XII), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(VII), 12-43.4-402(4), 12-43.4-403(5), and 12-43.4-404(6), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the process validation portion of the Division's Retail Marijuana Sampling and Testing Program.

R 1501 – Retail Marijuana Testing Program – ~~Process Validation~~ CONTAMINANT TESTING

This rule shall be effective on October 1, 2014.

A. Contaminant Testing Required. Until a Retail Marijuana Cultivation Facility's or a Retail Marijuana Product Manufacturing Facility's cultivation or production process has been validated UNDER THIS RULE, it shall not wholesale, transfer, or process into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product unless Samples from the Harvest Batch or Production Batch from which that Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product was derived was tested by a Retail Marijuana Testing Facility for contaminants and passed all contaminant tests required by paragraph C of this rule.

B. Validation of Process - CONTAMINANT TESTING

1. Retail Marijuana. A Retail Marijuana Cultivation Facility's cultivation process shall be deemed valid REGARDING CONTAMINANTS if every Harvest Batch that it produced during a 12 week period passed all contaminant tests required by paragraph C of this rule. This must include at least 12 Test Batches that were submitted at least six days apart and contain Samples from entirely different Harvest Batches.
2. Retail Marijuana Concentrate or Retail Marijuana Product. A Retail Marijuana Cultivation Facility's or a Retail Marijuana Products Manufacturing Facility's production process shall be deemed valid REGARDING CONTAMINANTS if every Production Batch that it produced during a four week period passed all contaminant tests required by paragraph C of this rule. This must include at least four Test Batches that were submitted at least six days apart which contain Samples from entirely different Production Batches.

C. Required Contaminant Tests

1. Microbial Contaminant Testing. Each Harvest Batch of Retail Marijuana and Production Batch of WATER- OR FOOD-BASED Retail Marijuana Concentrate and Retail Marijuana Product must be tested for microbial contamination by a Retail 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 ASPERGILLUS. ~~other bile tolerant bacteria.~~
2. Mold Contaminant Testing. ~~Each Harvest Batch of Retail Marijuana and Production Batch of Retail Marijuana Concentrate and Retail Marijuana Product must be tested for mold contamination by a Retail Marijuana Testing Facility. The mold contamination test must include, but need not be limited to, testing to determine presence and the level of Aspergillus sp., Mucor sp., Penicillium sp., and Thermophilic Actinomycetes sp.~~

~~3. Filth Contaminant Testing. Each Harvest Batch of Retail Marijuana produced by a Retail Marijuana Cultivation Facility must be tested for filth and other visible contamination by a Retail Marijuana Testing Facility. The filth contamination test must include, but need not be limited to, the detection, separation, quantification, identification and interpretation of extraneous materials (including insects, rodent droppings, visible adulterants and other contaminants) in Retail Marijuana flowers and trim.~~

2. Residual Solvent Contaminant Testing. Each Production Batch of Solvent-Based Retail Marijuana Concentrate produced by a Retail Marijuana Products Manufacturing Facility must be tested for residual solvent contamination by a Retail 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, propane, ethanol, isopropanol, acetone, and 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 R 605.

D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to a Retail Marijuana Cultivation Facility or a Retail Marijuana Product Manufacturing Facility wholesaling, transferring, or processing into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product from that Harvest Batch or Production Batch. Additional tests may include, but need not be limited to, screening for Pesticide, harmful chemicals, adulterants or other types of microbials, molds, METALS, filth or residual solvents.

E. Exemptions

1. Retail Marijuana Concentrate. A Production Batch of Retail Marijuana Concentrate shall be considered exempt from this rule if the Retail Marijuana Products Manufacturing Facility that produced it does not wholesale or transfer any of portion of the Production Batch and uses the entire Production Batch to manufacture Retail Marijuana Product, except that a Solvent-Based Retail Marijuana Concentrate produced using butane, propane, ethanol, isopropanol, acetone or heptane must still be submitted for a residual solvent contaminant test.

2. CO₂ Only. A Retail Marijuana Products Manufacturing Facility shall not be required to have residual solvent testing conducted on the Product Batch of a Solvent-Based Retail Marijuana Concentrate if only CO₂ was used during the production of the Retail Marijuana Concentrate.

F. Required Re-Validation - CONTAMINANTS.

1. Material Change Re-validation. If a Retail Marijuana Cultivation Facility or a Retail Marijuana Product Manufacturing Facility 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 Retail Marijuana Establishment's process must be re-validated.

- a. Pesticide. It shall be considered a Material Change if a Retail Marijuana Cultivation Facility 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 Retail Marijuana Products Manufacturing Facility begins using a new or different solvent or combination of solvents.
- c. Notification. A Retail Marijuana Cultivation Facility or a Retail Marijuana Product Manufacturing Facility that makes a Material Change must notify the Retail 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 Retail Marijuana Cultivation Facility or a Retail Marijuana Product Manufacturing Facility that produced it may not wholesale, transfer or process into a Retail Marijuana Concentrate or Retail Marijuana Product any of the Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product from that Harvest Batch or Production Batch.

- 2. Failed Contaminant Testing Re-Validation. If six of the 10 most recently tested Test Batches produced by a Retail Marijuana Cultivation Facility or a Retail Marijuana Product Manufacturing Facility fail contaminant testing, then the Retail Marijuana Establishment shall be required to re-validate its process.

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

Basis and Purpose – R 1502

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XI), 12-43.4-202(3)(a)(XII), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(VII), 12-43.4-402(4), 12-43.4-403(5), and 12-43.4-404(6), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the mandatory testing portion of the Division's Retail Marijuana Sampling and Testing Program.

R 1502 – Retail Marijuana Testing Program – Mandatory Testing

This rule shall be effective on July 1, 2014.

A. Required Sample Submission. A Retail Marijuana Establishment may be required by the Division to submit a Sample(s) of Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product it possesses to a Retail 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, harmful chemicals and adulterants.

2. When a Sample(s) is required to be submitted for testing, the Retail Marijuana Establishment may not sell, wholesale, transfer or process into a Retail Marijuana Concentrate or Retail Marijuana Product any Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product from the package, Harvest Batch or Production Batch from which the Sample was taken.

B. Methods for Determining Required Testing

1. Ongoing Testing. Once a Retail Marijuana Cultivation Facility's or a Retail Marijuana Product Manufacturing Facility's cultivation or production process has been validated REGARDING CONTAMINANT TESTING, the Division shall 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.
2. Inspection or Enforcement Tests. The Division may require a Retail Marijuana Establishment to submit a Sample for testing if the Division has reasonable grounds to believe that:
 - a. Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product is contaminated or mislabeled;
 - b. A Retail Marijuana Establishment 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. Prior to October 1, 2014, the Division may require a Retail Marijuana Establishment to submit Samples from certain randomly selected Harvest Batches or Production Batches for potency or contaminant testing.

C. Minimum Required Testing. Each Retail Marijuana Cultivation Facility and Retail Marijuana Product Manufacturing Facility shall be required to have Samples taken from at least 10% of the Harvest Batches or Production Batches it produces on an annual basis and have those Samples submitted to a Retail Marijuana Testing Facility to be tested for potency or contaminants.

D. Additional Sample Types. The Division may also require a Retail Marijuana Establishment to submit Samples comprised of items other than Retail Marijuana, Retail Marijuana Concentrate or Retail Marijuana Product to be tested for contaminants which may include, but may not be limited to, Pesticide, microbials, molds, filth, residual solvents, harmful chemicals and adulterants. 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 Retail Marijuana Concentrate,
4. Any ingredient or substance used in the manufacturing of a Retail Marijuana 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 – R 1503

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), 12-43.4-202(3)(a)(IV), 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(a)(X), 12-43.4-202(3)(a)(XII), 12-43.4-202(3)(b)(III), 12-43.4-202(3)(b)(IX), 12-43.4-202(3)(c)(V), 12-43.4-202(3)(c)(VI), 12-43.4-202(3)(c)(VII), 12-43.4-402(4), 12-43.4-403(5), and 12-43.4-404(6), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the potency testing portion of the Division's Retail Marijuana Sampling and Testing Program.

R 1503 – Retail Marijuana Testing Program – Potency Testing

Paragraphs A, D and E of this rule shall be effective on May 1, 2014. Paragraphs B and C of this rule shall be effective on June 1, 2014.

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 Retail Marijuana or from the same Production Batch of Retail Marijuana Concentrate or Retail Marijuana 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 Retail Marijuana.

1. Initial Potency Testing. A Retail Marijuana Cultivation Facility must have potency tests conducted by a Retail Marijuana Testing Facility on four Harvest Batches, created a minimum of three weeks apart, for each strain of Retail Marijuana that it cultivates.
 - a. The first potency test must be conducted on each strain prior to the Retail Marijuana Cultivation Facility wholesaling, transferring or processing into a Retail Marijuana Concentrate any Retail Marijuana of that strain.
 - b. All four potency tests must be conducted on each strain no later than December 1, 2014 or six months after the Retail Marijuana Cultivation Facility begins cultivating that strain, whichever is later.
2. Ongoing Potency Testing. After the initial four potency tests, a Retail Marijuana Cultivation Facility shall have each strain of Retail Marijuana that it cultivates tested for potency at least once every six months.

C. Potency Testing for Retail Marijuana Concentrate. A Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturing Facility must have a potency test conducted by a Retail Marijuana Testing Facility on every Production Batch of Retail Marijuana Concentrate that it produces prior to wholesaling, transferring or processing into a Retail Marijuana Product any of the Retail Marijuana Concentrate from that Production Batch.

D. Potency Testing for Retail Marijuana Product

1. Potency Testing Required. A Retail Marijuana Products Manufacturing Facility shall have potency tests conducted by a Retail Marijuana Testing Facility on every

Production Batch of Retail Marijuana Product that it produces prior to transferring or wholesaling any of the Retail Marijuana Product from that Production Batch UNLESS:

- a. THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY HAS SUCCESSFULLY PROCESS VALIDATED A SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT FOR POTENCY AND HOMOGENEITY AND REMAINED IN COMPLIANCE WITH THE PROCESS VALIDATION REQUIREMENTS OF SUBPARAGRAPHS (E)&(F) OF THIS RULE. ONLY SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCTS ARE ELIGIBLE FOR PROCESS VALIDATION REGARDING POTENCY AND HOMOGENEITY.
2. Required Tests. Potency tests conducted on Retail Marijuana Product must determine the level of concentration of the required cannabinoids and whether or not THC is homogeneously distributed throughout the product.
3. Partially Infused Retail Marijuana Products. If only a portion of a Retail Marijuana Product is infused with Retail Marijuana, then the Retail Marijuana Products Manufacturing Facility must inform the Retail Marijuana Testing Facility of exactly which portions of the Retail Marijuana Product are infused and which portions are not.

E. VALIDATION OF PROCESS - POTENCY AND HOMOGENEITY - SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT.

1. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MAY PROCESS VALIDATE POTENCY AND HOMOGENEITY FOR EACH SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT IT MANUFACTURES. IF THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY ELECTS NOT TO PROCESS VALIDATE FOR POTENCY AND HOMOGENEITY, THEN IT MUST COMPLY WITH THE POTENCY TESTING REQUIREMENTS OF R 1503(D)(1)&(2). MULTIPLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCTS ARE NOT ELIGIBLE FOR PROCESS VALIDATION AND MUST COMPLY WITH THE POTENCY TESTING REQUIREMENTS OF R 1503(D)(1)&(2).
2. A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY'S PRODUCTION PROCESS SHALL BE DEEMED VALID REGARDING POTENCY AND HOMOGENEITY IF THE FIRST FOUR PRODUCTION BATCHES THAT IT PRODUCES IN NO LONGER THAN AN EIGHT-WEEK PERIOD PASS ALL POTENCY TESTS REQUIRED BY R 1503(D)(2). EACH TEST BATCH SUBMITTED FOR PROCESS VALIDATION MUST BE SUBMITTED AT LEAST SIX DAYS APART AND CONTAIN SAMPLES FROM ENTIRELY DIFFERENT PRODUCTION BATCHES.
3. FOR A SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT TO MAINTAIN ITS VALIDATED STATUS, THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST SUBMIT A SAMPLE FROM TWO SEPARATE PRODUCTION BATCHES OF THE VALIDATED PRODUCT ON A QUARTERLY BASIS AFTER THE INITIAL VALIDATION OF PROCESS. IF ANY OF THE SAMPLES FAIL POTENCY TESTING, THEN THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY'S PROCESS MUST BE RE-VALIDATED.

F. REQUIRED RE-VALIDATION - POTENCY AND HOMOGENEITY - SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT.

1. MATERIAL CHANGE RE-VALIDATION. IF A RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY ELECTS TO PROCESS VALIDATE ANY SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT FOR POTENCY AND HOMOGENEITY AND IT MAKES A MATERIAL CHANGE TO ITS PRODUCTION PROCESS, THEN THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY MUST RE-VALIDATE THE PRODUCTION PROCESS.

- A. NEW EQUIPMENT. IT SHALL BE CONSIDERED A MATERIAL CHANGE IF THE RETAIL MARIJUANA PRODUCTS MANUFACTURING FACILITY BEGINS USING NEW OR DIFFERENT EQUIPMENT FOR ANY MATERIAL PART OF THE PRODUCTION PROCESS.
 - B. NOTIFICATION. A RETAIL MARIJUANA PRODUCT MANUFACTURING FACILITY THAT MAKES A MATERIAL CHANGE TO THE PRODUCTION PROCESS OF A VALIDATED SINGLE-SERVING EDIBLE RETAIL MARIJUANA PRODUCT MUST NOTIFY THE RETAIL MARIJUANA TESTING FACILITY THAT CONDUCTS POTENCY AND HOMOGENEITY TESTING ON THE FIRST FOUR PRODUCTION BATCHES PRODUCED USING THE NEW STANDARD OPERATING PROCEDURES.
 - C. TESTING REQUIRED PRIOR TO WHOLESALE OR TRANSFER. WHEN A PRODUCTION BATCH IS REQUIRED TO BE SUBMITTED FOR TESTING PURSUANT TO THIS RULE, THE MARIJUANA PRODUCT MANUFACTURING FACILITY THAT PRODUCED IT MAY NOT WHOLESALE OR TRANSFER RETAIL MARIJUANA PRODUCT FROM THAT PRODUCTION BATCH UNLESS OR UNTIL IT OBTAINS A PASSING TEST.
- G. Violation Affecting Public Safety. Failure to comply with this rule may constitute a license violation affecting public safety.

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 WELLBEING;
 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 available to the public.
- b. Opaque so that ~~the product cannot be seen from outside~~ the packaging DOES NOT ALLOW THE PRODUCT TO BE SEEN WITHOUT OPENING THE PACKAGING MATERIAL;
- c. ~~Closable~~ 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 is in a light cycle intended to stimulate production of flowers, trichomes, 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 to 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.

"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.

"MITS" means Marijuana Inventory Tracking Solution.

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

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

"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 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)(I), 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. ~~otherwise authorized by a physician.~~ 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, 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. 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 CONSIDERED A RESPONSIBLE VENDOR OF MEDICAL MARIJUANA, MEDICAL MARIJUANA-INFUSED PRODUCT AND MEDICAL MARIJUANA CONCENTRATE AT ANY LICENSED MEDICAL MARIJUANA CENTER, A LICENSEE SHALL COMPLY WITH THIS RULE.
 - 2. ALL OWNERS, MANAGERS AND EMPLOYEES SELLING 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 YEAR THEREAFTER TO MAINTAIN DESIGNATION AS A RESPONSIBLE VENDOR.
- B. CERTIFICATION TRAINING PROGRAM STANDARDS.
1. THE PROGRAM SHALL INCLUDE AT LEAST (2) HOURS OF INSTRUCTION TIME.
 2. THE PROGRAM SHALL BE TAUGHT IN A CLASSROOM SETTING.
 3. 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 DURING NORMAL BUSINESS HOURS.
 4. 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.
 5. 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;
 - 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;
 - d. PROVISIONS FOR CONFISCATING FRAUDULENT IDENTIFICATIONS; AND
 - e. 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 STATE MARIJUANA INVENTORY TRACKING SYSTEM REGULATIONS;
 - c. ADMINISTRATIVE AND CRIMINAL LIABILITY;
 - d. LICENSE SANCTIONS AND COURT SANCTIONS;
 - e. PATRONS PROHIBITED FROM BRINGING MARIJUANA ONTO LICENSED PREMISES;
 - f. PERMITTED HOURS OF SALE;
 - g. CONDUCT OF ESTABLISHMENT;
 - h. PERMITTING INSPECTIONS BY STATE AND LOCAL LICENSING AND ENFORCEMENT AUTHORITIES;
 - i. LICENSEE RESPONSIBLE FOR ACTIVITIES OCCURRING WITHIN LICENSED PREMISES;

- j. MAINTENANCE OF RECORDS;
- k. PRIVACY ISSUES; AND
- l. 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, CO₂, 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 CO₂.
- 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. CO₂ Solvent Determination. If CO₂ is used as solvent at the Licensed Premises, then the ~~Certified~~ Industrial Hygienist or Professional Engineer must determine whether a CO₂ gas monitoring system must be installed within the room in which Medical Marijuana Concentrate are to be produced or CO₂ 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

~~Medical Marijuana – General Packaging Requirement for Child-Resistant Packaging . The sale of Medical Marijuana to a consumer is prohibited unless previously placed within a Container by a Medical Marijuana Center. The Container must be designed to ensure that the contents are secure and are Child-Resistant. See Rule M-1003 – Labeling Requirements: Specific Requirements, Medical Marijuana and Medical Marijuana-Infused Product.~~

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-Infused Product – Child-Resistant Packaging . The sale of a Medical Marijuana-Infused Product is prohibited unless:~~

- ~~1. The Medical Marijuana-Infused Product has previously been placed within a Container by Medical Marijuana-Infused Products Manufacturer. The Container must be 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 and that does not allow the product to be seen without opening the packaging material; or~~
- ~~2. The Medical Marijuana-Infused Product has previously been placed in packaging that is labeled "Medicinal product – keep out of reach of children."~~

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 THE MEDICAL CODE, OR THE RULES AND REGULATION THEREUNDER.
- D. THE STATE LICENSING AUTHORITY MAY APPROVE OR REVIEW AN ASSURANCE OF VOLUNTARY COMPLIANCE.