## 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.

“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;

c. Closable for any product intended for more than a single use or containing multiple servings, and

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

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

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

“Department” means the Colorado Department of Revenue.

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

"Division" means the Marijuana Enforcement Division.

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

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

“Executive Director” means the Executive Director of the Department of Revenue.

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

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

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

"Flowering" means the reproductive state of *Cannabis* in which the plant in in a light cycle intended to stimulate production of flowers, trichromes, and cannabinoids characteristic of marijuana.

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

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

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

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

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

"Good Moral Character" means an individual who has a personal history demonstrating honesty, fairness, and respect for the rights of others and for the law.

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

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

"Immature plant" means a nonflowering Retail Marijuana or Medical Marijuana plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping or seedling.

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

"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.

"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.

“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 307

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

M 307 – Waste Disposal

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

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

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

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

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

    1. Grinding and incorporating the marijuana waste with non-consumable, solid wastes listed below such that the resulting mixture is at least 50 percent non-marijuana waste:

        a. Paper waste;

        b. Plastic waste;

        c. Cardboard waste;

        d. Food waste;

        e. Grease or other compostable oil waste;

        f. Bokashi, or other compost activators;

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

        h. Soil.

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

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

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

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

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

H. Inventory Tracking Requirements

1. In addition to all other tracking requirements set forth in these rules, a Licensee shall utilize MITS to ensure its post-harvest waste materials are identified, weighed and tracked while on the Licensed Premises until disposed of.

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

3. A Licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of Marijuana. *See* Rule M 901 – Business Records Required.

4. A Licensee is required to maintain accurate and comprehensive records regarding any waste material produced through the trimming or pruning of a Medical Marijuana plant prior to harvest, which must include weighing and documenting all waste. Unless required by a MITS procedure, records of waste produced prior to harvest must be maintained on the Licensed Premises. All waste, whether produced prior or subsequent to harvest, must be disposed of in accordance with this rule and be made unusable and unrecognizable.

## Basis and Purpose – M 407

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 minimum health and safety regulation for Medical Marijuana Centers. It sets forth general standards and basic sanitary requirements for Medical Marijuana Centers. It covers the physical premises where the products are made as well as the individuals handling the products. This rule also authorizes the State Licensing Authority to require an independent consultant conduct a health and sanitary audit of a Medical Marijuana Center. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana Business's refusal to cooperate or pay for the audit. The State Licensing Authority modeled this rule after those adopted by the Colorado Department of Public Health and Environment. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Centers.

## M 407 - Health and Safety Regulations: Medical Marijuana Center

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

B. Sanitary Conditions. 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 Medical Marijuana and Medical Marijuana-Infused Product shall be excluded from any operations which may be expected to result in contamination until the condition is corrected;

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

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

    a. Maintaining adequate personal cleanliness;

    b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated; and

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

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

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

6. That there is adequate lighting in all areas where Medical Marijuana and Medical Marijuana-Infused Product are stored or sold, and where equipment or utensils are cleaned;

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

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

9. That toxic cleaning compounds, sanitizing agents, and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana or Medical Marijuana-Infused Product and in a manner that is in accordance with any applicable local, state or federal law, rule, regulation or ordinance;

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

11. That each Medical Marijuana Center provides its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and

12. That Medical Marijuana and Medical Marijuana-Infused Product that can support the rapid growth of undesirable microorganisms are held in a manner that prevents the growth of these microorganisms.

A. Independent Health and Sanitary Audit

1. State Licensing Authority May Require A Health and Sanitary Audit

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

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

c. The Medical Marijuana Center 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. The Division has reasonable grounds to believe that the Medical Marijuana Center is in violation of one or more of the requirements set forth in this rule or other applicable public health or sanitary laws, rules or regulations; or

    b. The Division has reasonable grounds to believe that the Medical Marijuana Center was the cause or source of contamination of Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana-Infused Product.

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

4. Suspension of Operations.

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

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

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

        ii. If an agreement to suspend operations is reached, then the Medical Marijuana Center may continue to care for its inventory and conduct any necessary internal business operations but it may not sell any Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product to a patient or other Medical Marijuana Business during the period of time specified in the agreement.

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

Basis and Purpose – M 504

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 minimum health and safety regulation for Optional Premises Cultivation Operations. The rule prohibits an Optional Premises Cultivation Operation from treating or otherwise adulterating Medical Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell. This rule also authorizes the State Licensing Authority to require an independent consultant conduct an independent health and sanitary audit of an Optional Premises Cultivation Operation. This rule explains when an independent health and sanitary audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana Business's refusal to cooperate or pay for the audit. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses.

M 504 – Optional Premises Cultivation Operation: Health and Safety Regulations

A. Local Safety Inspections. An Optional Premises Cultivation Operation may be subject to inspection of its Licensed Premises 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 licensing authority restrictions related to Medical Marijuana or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

B. General Sanitary Requirements. An Optional Premises Cultivation Operation 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 Medical Marijuana shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;

    2. That all persons working in direct contact with Medical Marijuana shall conform to hygienic practices while on duty, including but not limited to:

        a. Maintaining adequate personal cleanliness;

        b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated;

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

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

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

4. 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;

5. That there is adequate lighting in all areas where Medical Marijuana is stored and where equipment or utensils are cleaned;

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

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

8. That toxic cleaning compounds, sanitizing agents, and solvents shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana or Medical Marijuana Concentrate, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance. All Pesticide must be stored and disposed of in accordance with the information provided on the product's label;

9. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana or Medical Marijuana Concentrate 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 an Optional Premises Cultivation Operation and used in accordance with labeled instructions;

10. 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;

11. 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;

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

13. That each Optional Premises Cultivation Operation shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and

14. That Medical Marijuana that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms.

C. Pesticide Application. An Optional Premises Cultivation Operation may only use Pesticide in accordance with the "Pesticide Act" C.R.S. 35-9-101 et. seq., "Pesticides Applicators' Act," C.R.S. 35-10-101 et. seq., and all other applicable federal, state, and local laws, statutes, rules and regulations. This includes, but shall not be limited to, the prohibition on detaching, altering, defacing or destroying, in whole or in part, any label on any Pesticide.

D. Application of Other Agricultural Chemicals. An Optional Premises Cultivation Operation may only use agricultural chemicals, other than Pesticide, in accordance with all applicable federal, state, and local laws, statutes, rules and regulations.

E. Required Documentation.

1. Standard Operating Procedures. An Optional Premises Cultivation Operation must establish written standard operating procedures for the cultivation of Medical Marijuana. The standard operating procedures must at least include when, and the manner in which, all Pesticide and other agricultural chemicals are to be applied during its cultivation process. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Optional Premises Cultivation Operation.

2. Material Change. If an Optional Premises Cultivation Operation makes a Material Change to its cultivation procedures, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

3. Material Safety Data Sheet. An Optional Premises Cultivation Operation must obtain a material safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. An Optional Premises Cultivation Operation must maintain a current copy of the material safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.

4. Labels of Pesticide and Other Agricultural Chemicals. An Optional Premises Cultivation Operation must have the original label or a copy thereof at its Licensed Premises for all Pesticide and other agricultural chemicals used during its cultivation process.

5. Pesticide Application Documentation. An Optional Premises Cultivation Operation that applies any Pesticide or other agricultural chemical to any portion of a Medical Marijuana plant, water or feed used during cultivation or generally within the Licensed Premises must document, and maintain a record on its Licensed Premises of, the following information:

    a. The name, signature and Occupational License number of the individual who applied the Pesticide or other agricultural chemical;

    b. Applicator certification number if the applicator is licensed through the Department of Agriculture in accordance with C.R.S. Title 35, Article 10 of the Pesticide Applicators' Act;

    c. The date and time of the application;

    d. The EPA registration number of the Pesticide or CAS number of any other agricultural chemical(s) applied;

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

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

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

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

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

F. Prohibited Chemicals. The following chemicals shall not be used in Medical Marijuana cultivation. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this rule. Prohibited chemicals are:

Chemical Name

CAS Registry Number (or EDF Substance ID)

ALDRIN

309-00-2

ARSENIC OXIDE (3)

1327-53-3

ASBESTOS (FRIABLE)

1332-21-4

AZODRIN

6923-22-4

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

118-75-2

BINAPACRYL

485-31-4

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

126-15-8

BROMOXYNIL BUTYRATE

EDF-186

CADMIUM COMPOUNDS

CAE750

CALCIUM ARSENATE [2ASH3O4.2CA]

7778-44-1

CAMPHECHLOR

8001-35-2

CAPTAFOL

2425-06-1

CARBOFURAN

1563-66-2

CARBON TETRACHLORIDE

56-23-5

CHLORDANE

57-74-9

CHLORDECONE (KEPONE)

143-50-0

CHLORDIMEFORM

6164-98-3

CHLOROBENZILATE

510-15-6

CHLOROMETHOXYPROPYLMERCURIC ACETATE [CPMA] EDF-183

COPPER ARSENATE

10103-61-4

2,4-D, ISOOCTYL ESTER

25168-26-7

DAMINOZIDE

1596-84-5

DDD

72-54-8

DDT

50-29-3

DI(PHENYLMERCURY)DODECENYLSUCCINATE [PMDS] EDF-

187

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

96-12-8

1,2-DIBROMOETHANE

106-93-4

1,2-DICHLOROETHANE

107-06-2

DIELDRIN

60-57-1

4,6-DINITRO-O-CRESOL

534-52-1

DINITROBUTYL PHENOL

88-85-7

ENDRIN

72-20-8

EPN

2104-64-5

ETHYLENE OXIDE

75-21-8

FLUOROACETAMIDE

640-19-7

GAMMA-LINDANE

58-89-9

HEPTACHLOR

76-44-8

HEXACHLOROBENZENE

118-74-1

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

608-73-1

1,3-HEXANEDIOL, 2-ETHYL-

94-96-2

LEAD ARSENATE

7784-40-9

LEPTOPHOS

21609-90-5

MERCURY

7439-97-6

METHAMIDOPHOS

10265-92-6

METHYL PARATHION

298-00-0

MEVINPHOS

7786-34-7

MIREX

2385-85-5

NITROFEN

1836-75-5

OCTAMETHYLDIPHOSPHORAMIDE

152-16-9

PARATHION

56-38-2

PENTACHLOROPHENOL

87-86-5

PHENYLMERCURIC OLEATE [PMO]

EDF-185

PHOSPHAMIDON

13171-21-6

PYRIMINIL

53558-25-1

SAFROLE

94-59-7

SODIUM ARSENATE

13464-38-5

SODIUM ARSENITE

7784-46-5

2,4,5-T

93-76-5

TERPENE POLYCHLORINATES (STROBANE6)

8001-50-1

THALLIUM(I) SULFATE

7446-18-6

2,4,5-TP ACID (SILVEX)

93-72-1

TRIBUTYLTIN COMPOUNDS

EDF-184

2,4,5-TRICHLOROPHENOL

95-95-4

VINYL CHLORIDE

75-01-4

G. The use of Dimethylsulfoxide (DMSO) in the production of Medical Marijuana shall be prohibited and possession of DMSO upon the Licensed Premises is prohibited.

H. Adulterants. An Optional Premises Cultivation Operation may not treat or otherwise adulterate Medical Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight or smell.

I. Independent Health and Sanitary Audit.

1. State Licensing Authority May Require A 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 an Optional Premises Cultivation Operation to undergo such an audit. The scope of the audit may include, but need not be limited, to whether the Optional Premises Cultivation Operation is in compliance with the requirements set forth in this rule and other applicable public health or sanitary laws and regulations.

b. In such instances, the Division may attempt to mutually agree upon the selection of the independent consultant with an Optional Premises Cultivation Operation. However, the Division always retains the authority to select the independent consultant regardless of whether mutual agreement can be reached.

c. The Optional Premises Cultivation Operation 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. An Optional Premises Cultivation Operation does not provide requested records related to the use of Pesticide or other agricultural chemicals during in the cultivation process;

b. The Division has reasonable grounds to believe that the Optional Premises Cultivation Operation is in violation of one or more of the requirements set forth in this rule or other applicable public health or sanitary laws, rules or regulations;

c. The Division has reasonable grounds to believe that the Optional Premises Cultivation Operation was the cause or source of contamination of Medical Marijuana or Medical Marijuana Concentrate; or

d. Multiple Harvest Batches or Production Batches produced by the Optional Premises Cultivation Operation failed contaminant testing.

3. Compliance Required. An Optional Premises Cultivation Operation 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 Optional Premises Cultivation Operation's license. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

b. Prior to or following the issuance of such an order, Optional Premises Cultivation Operation may attempt to come to a mutual agreement with the Division to suspend its operations until the completion of the independent audit and the implementation of any required remedial measures.

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

ii. If an agreement to suspend operations is reached, then the Optional Premises Cultivation Operation may continue to care for its inventory and conduct any necessary internal business operations but it may not sell, transfer or wholesale Medical Marijuana or Medical Marijuana Concentrate to other Medical Marijuana Business during the period of time specified in the agreement.

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

Basis and Purpose – M 506

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 an Optional Premises Cultivation Operation and standards for the production of those concentrate.

M 506 – Optional Premises Cultivation Operation: Medical Marijuana Concentrate Production

A. Permitted Production of Certain Categories of Retail Marijuana Concentrate. An Optional Premises Cultivation Operation may only produce Water-Based Medical Marijuana Concentrate on its Licensed Premises and only in an area clearly designated for concentrate production on the current diagram of the Licensed Premises. *See* Rule M 901- Business Records Required. No other method of production or extraction for Medical Marijuana Concentrate may be conducted within the Licensed Premise of an Optional Premises Cultivation Operation unless the Owner(s) of the Optional Premises Cultivation Operation also has a valid Medical Marijuana-Infused Products Manufacturer license and the room in which Medical Marijuana Concentrate is to be produced is physically separated from all cultivation areas and has clear signage identifying the room.

B. Safety and Sanitary Requirements for Concentrate Production. If an Optional Premises Cultivation Operation produces Water-Based Medical Marijuana Concentrate, then all areas in which those concentrate are produced and all Owners and Occupational Licensees engaged in the production of those concentrate shall be subject to all of requirements imposed upon a Medical Marijuana-Infused Products Manufacturer that produces Medical Marijuana Concentrate, including general requirements. See Rule M 604 – Medical Marijuana-Infused Products Manufacturer: Health and Safety Regulations and Rule M 605 Medical Marijuana-Infused Products Manufacturer: Medical Marijuana Concentrate Production.

C. Possession of Other Categories of Medical Marijuana Concentrate. It shall be considered a violation of this rule if an Optional Premises Cultivation Operation possess a Medical Marijuana Concentrate other than a Water-Based Medical Marijuana Concentrate on its Licensed Premises unless the Owner(s) of the Optional Premises Cultivation Operation also has a valid Medical Marijuana-Infused Products Manufacturer license.

Basis and Purpose – M 604

The statutory authority for this rule is found at subsections 12-43.3-202(1)(b)(I), 12-43.3-202(2)(a)(XII), 12-43.3-202(2)(a)(XV) and 12-43.3-202(2)(a)(XX), C.R.S., and section 12-43.3-404, C.R.S. The purpose of this rule is to establish minimum health and safety regulations for Medical Marijuana-Infused Products Manufacturers. It requires all owners and occupational licensees to attend a food handler training course prior to manufacturing any Edible Medical Marijuana Product. This rule also authorizes the State Licensing Authority to require that an independent consultant conduct an independent food safety audit of a Retail Marijuana Products Manufacturing Facility. This rule explains when an independent food safety audit may be deemed necessary and sets forth possible consequences of a Medical Marijuana-Infused Products Manufacture's refusal to cooperate or pay for the audit. It sets forth general standards and basic sanitary requirements for Medical Marijuana-Infused Products Manufacturers. It covers the physical premises where the products are made as well as the individuals handling the products. The State Licensing Authority modeled this rule after those adopted by the Colorado Department of Public Health and Environment. The State Licensing Authority intends this rule to help maintain the integrity of Colorado's Medical Marijuana Businesses and the safety of the public.

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

A. Training.

1. Prior to engaging in the manufacture of any Edible Medical Marijuana-Infused Product each Owner or Occupational Licensee must:

    a. Have a currently valid ServSafe Food Handler Certificate obtained through the successful completion of an online assessment or print exam; or

    b. Take a food safety course that includes basic food handling training and is comparable to, or is a course given by, the Colorado State University extension service or a state, county, or district public health agency, and must maintain a status of good standing in accordance with the course requirements, including attending any additional classes if necessary. Any course taken pursuant to this rule must last at least two hours and cover the following subjects:

        i. Causes of foodborne illness, highly susceptible populations and worker illness;

        ii. Personal hygiene and food handling practices;

        iii. Approved sources of food;

        iv. Potentially hazardous foods and food temperatures;

        v. Sanitization and chemical use; and

        vi. Emergency procedures (fire, flood, sewer backup).

2. A Medical Marijuana-Infused Products Manufacturer must obtain documentation evidencing that each Owner or Occupational Licensee has successfully completed the examination or course

required by this rule and is in good standing. A copy of the documentation must be kept on file at any Licensed Premises where that Owner or Occupational Licensee is engaged in the manufacturing of an Edible Medical Marijuana-Infused Product.

B. General Standards

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

2. A Medical Marijuana-Infused Products Manufacturer that manufacturers Edible Medical Marijuana-Infused Product shall comply with all kitchen-related health and safety standards of the relevant local licensing authority and, to the extent applicable, with all Colorado Department of Public Health and Environment health and safety regulations applicable to retail food establishments, as set forth in 6 CCR 1010-2.

C. General Sanitary Requirements. The Licensee shall take all reasonable measures and precautions to ensure the following:

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

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

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

    a. Maintaining adequate personal cleanliness;

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

    c. Refraining from having direct contact with preparation of Medical Marijuana or Medical Marijuana-Infused Product if the person has or may have an illness, open lesion, including

boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

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

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

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

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

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

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

10. That all contact surfaces, including utensils and equipment used for the preparation of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in a Medical Marijuana-Infused Products Manufacturer and used in accordance with labeled instructions;

11. That toxic cleaning compounds, sanitizing agents, solvents used in the production of Medical Marijuana Concentrate and other chemicals shall be identified, held, stored and disposed of in a manner that protects against contamination of Medical Marijuana, Medical Marijuana Concentrate or Medical Marijuana-Infused Product, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance;

12. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises needs;

13. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the Licensed Premises. There shall be no cross-connections between the potable and waste water lines;

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

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

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

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

D. Standard Operating Procedures.

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

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

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

2. If a Medical Marijuana-Infused Products Manufacturer makes a Material Change to its standard Medical Marijuana Concentrate or Medical Marijuana-Infused Product production process, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Licensed Premises.

E. Independent Health and Sanitary Audit.

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

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

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

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

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

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

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

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

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

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

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

4. Suspension of Operations.

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

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

      i. If an agreement cannot be reached or the State Licensing Authority, in its sole discretion, determines that such an agreement is not in the best interests of the public health, safety or welfare, then the State Licensing Authority will promptly

institute license suspension or revocation procedures. See Rule M 1302 – Disciplinary Process: Summary Suspensions.

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

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

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 Premise 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 that 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 the 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 a 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 C02 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 a 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 a 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.