COLORADO
Department of Revenue
Marijuana Enforcement Division

DRAFT RULE REVISIONS

Colorado Marijuana Rules
1 CCR 212-3

NOTES:

These draft rule revisions were presented to the August 31, 2023 and September 18, 2023 stakeholder work groups. The following draft rule revisions have been updated and are intended to solicit stakeholder feedback informing whether the draft rule revision should be incorporated into final proposed rules presented to the State Licensing Authority for final adoption.

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

Yellow highlighting designates revisions made following the September 13, 2023 Permanent Rulemaking Notice rule revisions.

Part 1 – General Applicability

Basis and Purpose – 1-115

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(j), and 44-10-103, C.R.S., and all of the Marijuana Code. The purpose of this rule is to provide necessary definitions of terms used throughout the rules. Defined terms are capitalized where they appear in the rules, to let the reader know to refer back to these definitions. When a term is used in a conventional sense, and is not intended to be a defined term, it is not capitalized. This Rule 1-115 was previously Rules M and R 103, 1 CCR 212-1 and 1 CCR 212-2.

Please Note: *The following revised and new definitions stem from the adoption of SB 23-271 and HB 23-1021. Not all definitions added in the SB 23-271 are reflected in these proposed rules. Revised and new definitions reflected below represent those terms that are utilized in the rules throughout Parts 2 - 8. Additionally, terms like "industrial hemp" and "industrial hemp product" have been revised throughout the rules to remove "industrial" in accordance with SB 23-271. Revisions may also address other typographical errors identified by MED.*

1-115 – Definitions

Definitions. The following definitions of terms, in addition to those set forth in section 44-10-103, C.R.S., apply to all rules promulgated pursuant to the Marijuana Code, unless the context requires otherwise:

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

"Genetic Material" means:

a. Small amounts or fragments of the marijuana plant that are unusable and unrecognizable as marijuana or a consumable marijuana product that are:

i. Intended for use for the purposes of propagation of plants in an artificial environment, also known as tissue culture; or

ii. Intended for the purposes of genetic testing, such as a hop latent viroid testing or plant sex testing.

b. Genetic Material does not mean:

i. Immature Plants;

ii. Marijuana seeds;

iii. Marijuana plant material that is used for the extraction of cannabinoids or terpenes, or the production of any consumable product or ingredient;

iv. Genetic Material not extracted directly from marijuana;

v. Genetic Material derived from artificially genetically modified organisms;

vi. Any substance derived from or intended for use in biosynthetic substances or processes.

"Hemp" means the plant Cannabis sativa L. and any part of the plant, including the seeds of the plant and all derivatives, extracts, cannabinoids isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent on a dry weight basis.

"Hemp Product" means a finished product that contains Hemp and that:

a. Is a cosmetic, a dietary supplement, a food, a food additive, or an herb;

b. Is intended for human use or consumption;

c. Contains any part of the Hemp plant, including naturally occurring cannabinoids, compounds, concentrates, extracts isolates, or resins;

d. Is produced from Hemp;

e. Contains no more than 1.75 milligrams of tetrahydrocannabinol (THC) per serving; and

f. Contains a ratio of cannabidiol (CBD) to THC of greater than or equal to 15 to one (15:1).

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

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

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

~~b. Is for human use or consumption;~~

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

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

"Intoxicating Cannabinoid" means a cannabinoid that is classified as an intoxicating cannabinoid in section 44-10-209 or by the State Licensing Authority by rule, in coordination with the Department of Public Health and Environment.

"Microbial Control Step" means a post-harvest process that is intended to reduce the presence of microbial contaminant(s) in a Harvest Batch or Production Batch that is performed prior to testing consistently on all Harvest Batches or Production Batches of a particular type, strain, or intended use, as documented in the Regulated Marijuana Business's standard operating procedures.

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

"Notice of Destruction" means a written statement from the State Licensing Authority, articulating the objective and reasonable grounds that the health, safety, or welfare of the public requires the destruction of embargoed Regulated Marijuana.

"Notice of Embargo" means a written statement from a Division investigator who has objective and reasonable grounds to believe identified Regulated Marijuana poses a threat to the health, safety, or welfare of the public and that cannot be Transferred, transported, or destroyed unless otherwise allowed under these Rules.

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

"Retail Marijuana" means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including but not limited to Retail Marijuana Concentrate, that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Business. "Retail Marijuana" does not include ~~industrial~~ hemp, nor does it include fiber produced from stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other Ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other product. If the context requires, Retail Marijuana includes Retail Marijuana Concentrate and Retail Marijuana Product.

"Safe Harbor Hemp Product" means a hemp-derived compound or cannabinoid, whether a finished product or in the process of being produced, that is permitted to be manufactured for distribution, produced for distribution, packaged for distribution, processed for distribution, prepared for distribution, treated for distribution, transported for distribution, or held for distribution in Colorado for export from Colorado but that is not permitted to be sold or distributed in Colorado.

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

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

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

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

"Semi-synthetic Cannabinoid" means a substance that is created by a chemical reaction that converts one cannabinoid extracted from a cannabis plant directly into a different cannabinoid.

a. Semi-synthetic cannabinoid includes cannabinoids, such as cannabinol (CBN) that was produced by the conversion of cannabidiol (CBD).

b. Semi-synthetic cannabinoid does not include cannabinoids produced via decarboxylation of naturally occurring acidic forms of cannabinoids, such as tetrahydrocannabinolic acid, into the corresponding neutral cannabinoid, such as THC, through the use of heat or light, without the use of chemical reagents or catalysts, and that results in no other chemical change.

"Synthetic Cannabinoid" means a cannabinoid-like compound that was produced by using chemical synthesis, chemical modification, or chemical conversion, including by using in-vitro biosynthesis or other bioconversion of such a method.

a. Synthetic cannabinoid does not include:

i. A compound produced through the decarboxylation of naturally occurring cannabinoids from their acidic forms; or

ii. A semi-synthetic cannabinoid.

Part 3 – Regulated Marijuana Business Operations

3-100 Series – General Privileges and Limitations

Basis and Purpose – 3-110

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-401(2), 44-10-701(1)(a), 44-10-701(3)(d), and 44-10-701(3)(f), C.R.S. The purpose of this rule is to clarify that, except for in a Licensed Hospitality Business, it is unlawful for a Regulated Marijuana Business to allow consumption on the Licensed Premises.

3-110 – Regulated Marijuana Businesses: General Restrictions

A. Marijuana Consumption Prohibited.

1. Applicability. This subparagraph (A) applies to all Regulated Marijuana Businesses, except Licensed Hospitality Businesses.

2. Licensees shall not permit the consumption of marijuana or marijuana product on the Licensed Premises or in transport vehicles, including any Sampling Units Transferred to a Sampling Manager.

B. Alcohol Beverage License Prohibited. A Person may not operate a license issued pursuant to the Marijuana Code and these rules at the same Licensed Premises as a license or permit issued pursuant to article 3, 4 or 5 of Title 44.

C. Natural Medicine Prohibited.

1. Licensees shall not transfer natural medicine or natural medicine products on the Licensed Premises or in transport vehicles.

2. A Person may not operate a license issued pursuant to the Marijuana Code and these rules at the same Licensed Premises as a license or permit issued pursuant to article 50 of Title 44.

D. Safe Harbor Hemp Products. A Regulated Marijuana Business may not possess or Transfer Safe Harbor Hemp Products.

3-300 Series – Health and Safety Regulations

Basis and Purpose – 3-320

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(dd)(X), and 44-10-203(3)(c), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). This rule prohibits a Regulated Marijuana Business from Transferring any contaminated Regulated Marijuana or Regulated Marijuana Product to any Person or another Regulated Marijuana Business. Additionally, this rule provides permitted approved Decontamination or Microbial Control Step methods that a Licensee may utilize in the course of their business. These provisions outline the minimum requirements a Licensee must comply with to utilize approved Decontamination or Microbial Control Step methods and do not reflect an endorsement of these methods.

Please Note: *The following proposed rule revisions are the results of ongoing discussions with and proposals stakeholders through the MED-CDPHE Quarterly Science and Policy Forum. While MED has been actively engaged through stakeholder discussions and surveys to understand the decontamination methods being used in the industry today, we are continuing to evaluate, seeks feedback on, and will determine prior to the permanent rulemaking hearing whether to propose these revisions for final adoption. Specifically, MED is requesting feedback and input from stakeholders regarding the following questions related to all methods of decontamination (as relevant) that may be incorporated into rules:*

1. *Do any of the methods proposed introduce occupational or product safety concerns that should be flagged for discussion or otherwise addressed through proposed rule revisions?*
2. *Are there additional safety requirements that should be required for any of the methods proposed?*
3. *Do the proposed rule revisions adequately address concerns regarding the uniform treatment of Harvest Batches? Are there recommendations for additional language to ensure uniform treatment of Harvest Batches?*
4. *Should products that have been subject to decontamination following a failed test have any additional testing requirements such as potency because of potential impacts from the decontamination method?*
5. *Should products that have been subject to decontamination be required to include additional labeling?*

Additionally, *the Division has incorporated further proposed revisions raised by work group members and in public comment to distinguish between post-failed test result Decontamination and post-harvest Microbial Control Steps, which Licensees may choose to build into their standard operating procedures.*

The Division is continuing to evaluate potential impacts to other rules and any additional necessary revisions to incorporate this distinction throughout the rules.

3-320 – Contaminated Product: Approved Decontamination and Microbial Control Step Methods

A. A Regulated Marijuana Business shall not accept or Transfer to any Person any Regulated Marijuana that has failed required testing pursuant to Rule 4-120 or Rule 4-125, unless otherwise permitted in these rules. *See* Rule 4-135. If, despite the prohibitions in these rules, another Regulated Marijuana Business Transfers any Regulated Marijuana that has failed or subsequently fails required testing pursuant to Rule 4-120 or Rule 4-125, the receiving Regulated Marijuana Business shall ensure that all Regulated Marijuana that failed required testing are safely disposed of in accordance with Rule 3-230.

B. Approved Decontamination and Microbial Control Step Methods. Licensees are permitted to use only the following Decontamination or Microbial Control Step techniques to treat an entire Harvest Batch or Production Batch and are not approved for use on plants that have not been harvested. Licensees must not use a technique to treat a Test Batch alone. Inclusion of a technique in this Rule does not imply that a substance or device is compliant with other requirements or regulations. Regulated Marijuana Businesses must comply with any applicable state and federal requirements regarding the use of any substance or device used for Decontamination or Microbial Control Steps. Any substance or device used for Decontamination or Microbial Control Step must be registered in accordance with state and federal requirements. Any substance that would be considered a pesticide must meet all criteria at 8 CCR 1203-2 Part 17.

1. Ozone treatment.

a. Equipment requirements: Non-enclosed ozone generating equipment. A Licensee who seeks to use non-enclosed ozone generating equipment for Decontamination, or Microbial Control Step must comply with the following safety requirements, which must be documented in a standard operating procedure:

i. Sufficient air filtration and/or handling systems to protect worker safety, meet manufacturer safety recommendations, and comply with any federal, state, or local regulations pertaining to ozone generating equipment, exposure limits, and exhaust; and

ii. Review by an Industrial Hygienist that includes, at a minimum:

A. Consideration of volume and storage of chemicals;

B. Fire safety considerations;

C. Ambient levels of chemicals (e.g. ozone, etcetera);

D. Environmental monitoring;

E. Appropriate personal protective equipment (PPE); and

F. Any Material Change in the Licensee's standard operating procedures or processes requires subsequent Industrial Hygienist review and approval.

b. Equipment requirements: Sealed enclosure ozone generating equipment. A Licensee who seeks to use sealed enclosure ozone generating equipment for Decontamination or Microbial Control Steps must comply with the following

safety requirements, which must be documented in a standard operating procedure:

i. Sufficient air filtration and/or handling systems to protect worker safety, meet manufacturer safety recommendations, and comply with any federal, state, or local regulations pertaining to ozone generating equipment, exposure limits, and exhaust; and

ii. To be considered a sealed enclosure, the equipment must have a device that degrades ozone into molecular oxygen (O_2) or other components that are safe for human exposure

2. X-ray irradiation in a sealed enclosure instrument. A Licensee who uses x-ray irradiation in a sealed enclosure instrument for Decontamination or Microbial Control Steps must comply with the following safety requirements, which must be documented in a standard operating procedure:

a. Radiation survey and dosimeter badges for operators in compliance with manufacturer safety recommendations; and

b. Inspection by a Colorado registered qualified inspector and certification by the Colorado Department of Public Health and Environment X-ray Certification Unit.

3. Ultraviolet light (UV) irradiation. A Licensee who seeks to use UV light irradiation for Decontamination, or Microbial Control Steps must have radiation survey and dosimeter badges for operators in compliance with manufacturer safety recommendations, which must be documented in a standard operating procedure:

4. Microwave. A Licensee who seeks to use microwave for Decontamination or Microbial Control Steps must comply with the following safety requirements, which must be documented in a standard operating procedure:

a. Radiation survey and dosimeter badges for operators in compliance with manufacturer safety recommendations; and

b. Microwave equipment used for Decontamination or Microbial Control Step shall be constructed, inside and outside, in a manner that it may be adequately cleaned.

5. Vaporized hydrogen peroxide in a sealed enclosure instrument. A Licensee who seeks to use vaporized hydrogen peroxide in a sealed enclosure instrument for Decontamination or Microbial Control Steps must have sufficient air filtration and/or handling systems to protect worker safety, meet manufacturer safety recommendations, and comply with and federal, state or local regulations pertaining to reactive oxygen species generating equipment, exposure limits, and exhaust, which must be documented in a standard operating procedure.

C. Required Safety Measures. A Licensee who seeks to use any of the above approved Decontamination or Microbial Control Step methods must have standard operating procedures that also include:

1. Proper training of personnel operating the equipment or working in the vicinity of the equipment;

2. Proper use of appropriate personal protective equipment (PPE) and requiring that PPE be worn by anyone working in the vicinity of the decontamination or Microbial Control Step equipment;

3. Compliance with all manufacturer safety recommendations; and

4. Any additional safety mitigation measures recommended by the manufacturer.

D. The Decontamination method must be accurately documented in the Inventory Tracking System for packages that have been decontaminated.

1. Uniform treatment of Harvest Batches prior to Sample Increment Collection is required. Storage of Test Batches after collection and prior to Transfer to a Licensed Marijuana Testing Facility shall be consistent with storage conditions of the Harvest Batch that they were pulled from, including but not limited to temperature, airflow, and humidity. Equipment used for Decontamination or Microbial Control Steps shall be located in a Limited Access Area of the Licensed Premises.

2. Equipment used for Decontamination, Microbial Control Steps shall be used exclusively for the purpose of Decontamination or Microbial Control Steps.

3. No other activity is permitted to be used including, but not limited to preparing food.

E. Decontamination and Microbial Control Step Methods Approval Process. A Licensee may submit a request to the Division to consider approval of a Decontamination or Microbial Control Step method not permitted under this Rule. The request must include scientific data and evidence on the principles and efficacy of the method and detail all aspects of the Decontamination or Microbial Control Step method including associated safety risks and appropriate safety mitigation steps including training requirements, use of personal protective equipment (PPE), and the appropriate occupational, environmental, and product/consumer safety precautions, including any safety-related manufacturer recommendations.

Basis and Purpose – 3-325

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(dd)(X), and 44-10-203(3)(c), 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 clarify that a Regulated Marijuana Business engaged in the cultivation of Regulated Marijuana is prohibited from using certain chemicals or pesticides that may cause harm to employees or consumers.

3-325 – Prohibited Chemicals

A. Applicability. This Rule 3-325 applies to Medical Marijuana Cultivation Facilities, Medical Marijuana Products Manufacturer, Retail Marijuana Cultivation Facilities, Retail Marijuana Products Manufacturer, Accelerator Cultivator, Accelerator Manufacturer, and Marijuana Research and Development Licensees.

B. The following chemicals are prohibited and shall not be used in the production of Regulated Marijuana ~~cultivation~~. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this Rule. Additionally, possession of Regulated Marijuana, ~~or~~ Regulated Marijuana Concentrate, Regulated Marijuana Product, or Industrial Hemp Product on which any of the following chemicals is detected shall constitute a violation of this Rule.

1. Any Pesticide the use of which would constitute a violation of the Pesticide Act, section 35-9-101 *et seq*., C.R.S., the Pesticide Applicators' Act, section 35-10-101 et seq., C.R.S., or the rules and regulations pursuant thereto.

2. Other chemicals (listed by chemical name and 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

C. DMSO. Except for R&D Licensees, the use of Dimethylsulfoxide (DMSO) in the production of Regulated Marijuana and the possession of DMSO upon the Licensed Premises is prohibited.

Basis and Purpose – 3-330

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-203(3)(c), 44-10-203(3)(e), and 44-10-1001, C.R.S. The purpose of this rule is to clarify the minimum health and safety requirements imposed on a Medical or Retail Marijuana Cultivation Facility. The State Licensing Authority has determined the cultivation of Medical or Retail Marijuana requires the application of processes and procedures, and the use of materials, chemicals, and pesticides which, if improperly used, may be potentially harmful to employees and consumers. Therefore, the cultivation of Medical or Retail Marijuana must be performed in a manner that reduces the likelihood of exposure to such materials, chemicals and pesticides, or other microbials or molds. The State Licensing Authority intends for this rule to reduce any product contamination, which will benefit both the Licensees and consumers. The State Licensing

Authority modeled this rule after those adopted by the Colorado Department Revenue for Medical Marijuana and those adopted by the Colorado Department of Public Health and Environment. Overall, the State Licensing Authority intends this rule to help maintain the integrity of Colorado's Retail Marijuana businesses and the safety of the public.

3-330 – Cultivation of Regulated Marijuana: Specific Health and Safety Requirements

A. Additional Sanitary Requirements. In addition to the general sanitary requirements in Rule 3-310, a Regulated Marijuana Cultivation Facility shall take all reasonable measure and precautions to ensure the following:

1. That all contact surfaces, including utensils and equipment used for the preparation of Regulated Marijuana, Physical Separation-Based Medical Marijuana Concentrate, or Physical Separation-Based Retail Marijuana Concentrate, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable and shall be properly maintained. Only sanitizers and disinfectants registered with the Environmental Protection Agency shall be used in a Regulated Marijuana Cultivation Facility;

2. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Licensed Premises' needs. Reclaimed water may also be used only for the cultivation of Regulated Marijuana to the extent authorized under the Reclaimed Water Control Regulations (5 CCR 1002-84), and subject to approval of the Water Quality Control Division of the Colorado Department of Public Health and Environment and the local water provider;

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

4. That any room used for the cultivation of Regulated Marijuana has measures to prevent the accumulation of dangerous levels of CO_2.

B. Pesticide Application. A Regulated Marijuana Cultivation Facility may only use Pesticide in accordance with the "Pesticide Act" sections 35-9-101 et seq., C.R.S., the "Pesticides Applicators' Act," sections 35-10-101 et seq., C.R.S., and all other applicable federal, state, and local laws, statutes, rules and regulations. This includes, but shall not be limited to, the prohibition on detaching, altering, defacing or destroying, in whole or in part, any label on any Pesticide. The Colorado Department of Agriculture's determination that the Licensee used any quantity of a Pesticide that would constitute a violation of the Pesticide Act or the Pesticide Applicators' Act shall constitute prima facie evidence of a violation of this Rule.

C. Application of Other Agricultural Chemicals. A Regulated Marijuana Cultivation Facility may only use agricultural chemicals, other than a Pesticide, in accordance with all applicable federal, state, and local laws, statutes, rules, and regulations.

Please Note: *The following are stakeholder proposals from the Quarterly Science and Policy Forum that the MED is continuing to evaluate and provide feedback on. The Division continues to have questions, as expressed in previous Science & Policy Forums, related to the operability of these provisions and required resources the Division would need in order to implement, monitor, and manage compliance*

related to these revisions. For example, the Division urges stakeholders to consider more specific standards that are publicly available and measurable against that can assist both Licensees and the Division in evaluating overall compliance with Reduced Testing Allowance. Additionally, if this proposal moves forward for the State Licensing Authority's consideration, there may be additional terms requiring definitions (e.g. Biological Hazard, Critical Control Point, etc.)

D. Required Documentation.

1. Standard Operating Procedures. A Regulated Marijuana Cultivation Facility must establish written standard operating procedures for the cultivation, harvesting, drying, curing, trimming, packaging, storing, and sampling for testing of Regulated Marijuana, and the processing, packaging, storing, and sampling for testing of Regulated Marijuana Concentrate, and the processing, rolling, filling or similar process, packaging, storing and sampling for testing of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana made from Physical Separation-Based Concentrate. A copy of all standard operating procedures must be maintained on the Licensed Premises of the Regulated Marijuana Cultivation Facility.

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

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

      i. The standard operating procedures must also include detailed descriptions of any methods and processes related to Decontamination or Microbial Control Steps of Harvest Batches including steps to meet safety mitigation requirements associated with the Decontamination or Microbial Control Step method in use. This documentation must demonstrate that appropriate occupational, environmental, and product / consumer safety procedures are in place, including any safety-related manufacturer recommendations. Standard operating procedures must also document steps to ensure uniformity of treatment of the entire Harvest Batch or Production Batch during the Decontamination or Microbial Control Steps process.

      ii. Use of Decontamination and Remediation techniques must be accurately documented in the Inventory Tracking System.

   c. If a Regulated Marijuana Cultivation Facility produces Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana made from Physical Separation-Based Concentrate, the standard operating procedures must include all methods and processes related to the creation of each type of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana product, including but not limited to, the strains used, where strains are sourced, which parts of Harvest Batches are used (e.g. flower, shake, trim), the size of the product (e.g. 1 gram pre-rolls), and how much and what type of Regulated Marijuana Concentrate is added (if applicable) for each type of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana it produces.

   d. Provide adequate training to every Owner Licensee and Employee Licensee who performs a task or set of tasks that are referenced in the standard operating procedures. Adequate training must include, but need not be limited to, providing a copy of the standard operating procedures for that Licensed Premises detailing

at least all of the topics required to be included in the standard operating procedures.

e. Effective July 1, 2024, a Regulated Marijuana Cultivation Facility may achieve a Reduced Testing Allowance for microbial contaminant testing pursuant to Rule 4-120 if the Licensee has a Hazard Analysis and Critical Control Point (HACCP) System containing elements defined in ASTM D8250-19: "Standard Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products" that addresses each product type to receive Reduced Testing Allowance for microbial contaminant testing. The pre-requisite programs requirement by the standard will be considered to have been met if the Regulated Marijuana Cultivation Facility includes documentation on how the sanitary and health requirements from Rules 3-310 and 3-330 are implemented to ensure the hygienic and safe processing of consumable marijuana. This HACCP System must address biological hazards at minimum, and may also address additional hazards such as chemical hazards and physical hazards.

i. If a Critical Control Point (CCP) is found to be outside of the Critical Limits (CLs) established in the HACCP plan during the production of a Harvest Batch(es) then this Harvest Batch(es) shall be submitted for microbial contaminant testing.

A. If the Harvest Batch passes microbial contaminant testing, then there is no effect on the Reduced Testing Allowance and the Harvest Batch may be Transferred.

B. If the Harvest Batch fails microbial contaminant testing, then the Licensee shall follow Rule 4-120(F)(2) to reauthorize the Reduced Testing Allowance for microbial contaminants.

ii. The HACCP System shall be documented as per ASTM D8250-19.6.1.12. The following records must be kept during the time that a Regulated Marijuana Cultivation Facility qualifies for and maintains a Reduced Testing Allowance for microbial contaminants and for one year after the Reduced Testing Allowance expires for any reason:

A. List of the HACCP team, including relevant experience;

B. Product description and intended use for each product type receiving a Reduced Testing Allowance for microbial contaminants;

C. Verified Process Flow Diagram, including Critical Control Points (CCPs);

D. Hazard Analysis;

E. List of CCPs and reasoning as to how they were identified;

F. List of Critical Limits (CLs) and reasoning as to how they were selected;

G. List of Monitoring Procedures for CCPs;

H. List of pre-planned Corrective Actions in case of deviations;

I. List of verification procedures;

J. HACCP system summary page that includes:

1. CCPs;

2. Critical Limits (CLs);

3. Monitoring Procedures;

4. Corrective Actions related to specific CCPs;

5. Verification procedures; and

6. Record Titles associated with the CCP activities (i.e. The Water Activity Monitoring Logbook, etc.);

K. Support documentation of the CCP validation (i.e. microbial contaminants testing results for Reduced Testing Allowance qualification and maintenance periods); and

L. Documents generated during operational activities related to the HACCP system, including at minimum: Verified Monitoring Logs for CCPs, Corrective and Preventive Actions documentation related to CCPs, and Material Changes related to HACCP system.

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

3. Safety Data Sheet. A Regulated Marijuana Cultivation Facility must obtain a safety data sheet for any Pesticide or other agricultural chemical used or stored on its Licensed Premises. A Regulated Marijuana Cultivation Facility must maintain a current copy of the safety data sheet for any Pesticide or other agricultural chemical on the Licensed Premises where the product is used or stored.

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

5. Pesticide Application Documentation. A Regulated Marijuana Cultivation Facility that applies any Pesticide to any portion of a Regulated Marijuana plant during cultivation or generally within the Licensed Premises must document, and maintain a record on its Licensed Premises of, the following information:

a. The name, signature, and Employee License number of the individual who applied the Pesticide;

b. Applicator certification number if the applicator is licensed through the Department of Agriculture in accordance with the “Pesticides Applicators’ Act,” sections 35-10-101 et seq., C.R.S.;

c. The date and time of the application;

d. The EPA registration number of the Pesticide applied;

e. Any of the active ingredients of the Pesticide applied;

f. Brand name and product name of the Pesticide applied;

g. The restricted entry interval from the product label of any Pesticide applied;

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

i. The total amount of each Pesticide applied.

E. Adulterants. A Regulated Marijuana Cultivation Facility may not treat or otherwise adulterate Regulated Marijuana with any chemical or other compound whatsoever to alter its color, appearance, weight, or smell.

Basis and Purpose – 3-335

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-202(2)(y), 44-10-203(3)(b), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-203(3)(g), and 44-10-1001, C.R.S. The State Licensing Authority has determined the manufacturing of Medical or Retail Marijuana Infused Products involves the application of processes and procedures, materials, chemicals, and additives, which, if improperly applied, may cause harm to employees and consumers. Therefore, the purpose of this Rule is to clarify the minimum and specific health and safety requirements imposed on a Medical or Retail Marijuana Products Manufacturing Facility. This Rule clarifies which Edible Medical or Retail Marijuana Products, due to their specific composition, are *per se* practicable to mark with the Universal Symbol but exempts certain Liquid Products from the Universal Symbol requirements. Additionally, the Rule imposes manufacturing and production requirements (e.g. prohibiting products from being shaped like fruit or humans), identifies the standard THC portion, prohibits licensees from using commercial food products to remanufacture Medical or Retail Marijuana Products, and prohibits the use of toxic additives.

Please Note: *The Division is considering rule revisions related to semi-synthetic and synthetic cannabinoid production, as permitted or prohibited under the authority granted in SB 23-271. In considering whether or not to allow semi-synthetic or synthetic cannabinoid production, the Division has the following questions (also included in the Work Group #1 Agenda):*

1. *What are the range of semi-synthetic or synthetic cannabinoids that regulated marijuana products manufacturers are interested in producing?*
2. *Is there data on demand for these products derived from marijuana?*
3. *What are the scope of risks that we can anticipate if manufacturers are allowed to produce semi-synthetic cannabinoids? Synthetic cannabinoids?*
4. *What public health and safety considerations (consumer, occupational, environmental, hazardous waste, etcetera) should any rules that allow or prohibit production of semi-synthetic or synthetic cannabinoids cover?*
5. *What additional testing requirements should be included in rule if the State Licensing Authority adopts rules that allow manufacturers to produce semi-synthetic cannabinoids? Synthetic cannabinoids?*

Additionally, *the proposed provisions below are based on stakeholder comments and SB 23-271's mandate to the Department of Revenue to conduct a feasibility study to evaluate how the state can operably establish a standing scientific committee to evaluate cannabinoids for both safety and intoxication profiles. In addition to the questions outlined above, the Division is interested in feedback*

regarding this initial allowance to help promote research into appropriate processes for semi-synthetic and synthetic cannabinoid production.

3-335 – Production of Regulated Marijuana Concentrate and Regulated Marijuana Products: Specific Health and Safety Requirements

A. Training.

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

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

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

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

ii. Personal hygiene and food handling practices;

iii. Approved sources of food;

iv. Potentially hazardous foods and food temperatures;

v. Sanitization and chemical use; and

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

2. A Medical Marijuana Products Manufacturer, an Accelerator Manufacturer, or Retail Marijuana Products Manufacturer must obtain documentation evidencing that each Owner Licensee or Employee Licensee has successfully completed the examination or course required by this Rule and is in good standing. A copy of the documentation must be kept on file at any Licensed Premises where that Owner Licensee or Employee Licensee is engaged in the manufacturing of an Edible Medical Marijuana Product or Edible Retail Marijuana Product.

B. Other State and Local Health and Safety Standards Apply. A Medical Marijuana Products Manufacturer, an Accelerator Manufacturer, or Retail Marijuana Products Manufacturer that manufactures Edible Medical Marijuana Products or Edible Retail Marijuana Products shall comply with all kitchen-related health and safety standards of the relevant Local Licensing Authority or Local Jurisdiction and, to the extent applicable, with all Colorado Department of Public Health and Environment health and safety regulations applicable to retail food establishments, as set forth in 6 CCR 1010-2.

C. Additional Sanitary Requirements. A Medical Marijuana Products Manufacturer, an Accelerator Manufacturer, or Retail Marijuana Products Manufacturer shall take all reasonable measures and precautions to ensure the following:

1. That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of Regulated Marijuana or Regulated Marijuana Products;

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

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

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

5. That storage and transport of finished Regulated Marijuana Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any Container.

D. Product Safety.

1. A Regulated Marijuana Products Manufacturer that manufactures Edible Regulated Marijuana Product shall create and maintain standard production procedures and detailed manufacturing processes for each Edible Medical Marijuana Product or Edible Retail Marijuana Product it manufactures. These procedures and processes must be documented and made available on the Licensed Premises for inspection by the Division, the Colorado Department of Public Health & Environment, and local licensing authorities.

2. Universal Symbol Marking Requirements.

a. The following categories of Edible Medical Marijuana Products and Edible Retail Marijuana Products are considered to be per se practicable to mark, and shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the Regulated Marijuana Product:

i. Chocolate;

ii. Soft confections;

iii. Hard confections or lozenges;

iv. Consolidated baked goods (e.g. cookie, brownie, cupcake, granola bar);

v. Pressed pills and capsules.

b. The Universal Symbol marking shall:

i. Be marked, stamped, or otherwise imprinted in its entirety on at least one side of the Edible Medical Marijuana Product or Edible Retail Marijuana Product. The shape of the product shall not be included or take place of any part of the Universal Symbol;

ii. Be centered either horizontally or vertically on the Edible Medical Marijuana Product or Edible Retail Marijuana Product;

iii. If centered horizontally on the Edible Medical Marijuana Product or Edible Retail Marijuana Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's height, but not less than ¼ inch by ¼ inch.

iv. If centered vertically on the Edible Medical Marijuana Product or Edible Retail Marijuana Product, the height and width of the Universal Symbol shall be of a size that is at least 25% of the product's height, but not less than ¼ inch by ¼ inch.

c. The following categories of Edible Medical Marijuana Product and Edible Retail Marijuana Product are considered to be per se impracticable to mark with the Universal Symbol marking requirements, provided that they comply with labeling and Container requirements of 3-1000 Series Rules.

i. Loose bulk goods (e.g. granola, cereals, popcorn);

ii. Powders;

iii. Liquid Edible Medical Marijuana Products;

iv. Liquid Edible Retail Marijuana Products.

3. Medical Marijuana Products Manufacturer Specific Requirements.

a. Standard Portion of THC. A Medical Marijuana Products Manufacturer may determine a standard portion of THC for each Edible Medical Marijuana Product it manufactures. If a Medical Marijuana Products Manufacturer determines a standard portion for an Edible Medical Marijuana Product, that information must be documented in the product's standard production procedure.

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

c. If a Medical Marijuana Products Manufacturer elects to determine standard portions for an Edible Medical Marijuana Product, then the Universal Symbol shall be applied to each portion in accordance with the requirements of subparagraph (D)(2)(b) of this Rule 3-335. Except that the size of the Universal Symbol marking shall be determined by the size of the portion instead of the overall product size and shall not be less than ¼ inch by ¼ inch.

d. Medical Marijuana Concentrate Recommended Serving Size and Visual Representation.

i. The recommended serving size for Medical Marijuana Concentrate in Vaporized Delivery Devices should not exceed one (1) inhalation lasting two (2) seconds per serving.

ii. The recommended serving size for Medical Marijuana Concentrate intended to be inhaled in any manner other than a Vaporizer Delivery Device is a sphere identified in the tangible educational resource required to be provided to a patient pursuant to Rule 5-125(D) and Rule 5-115(C.5).

4. Retail Marijuana Products Manufacturer Specific Requirements.

a. Standardized Serving of Marijuana. The size of a Standardized Serving of Marijuana shall be no more than 10mg of active THC. A Retail Marijuana Products Manufacturer or an Accelerator Manufacturer that manufactures Edible Retail Marijuana Product shall determine the total number of Standardized Servings of Marijuana for each product that it manufactures. No individual Edible Retail Marijuana Product unit packaged for Transfer to a consumer shall contain more than 100 milligrams of active THC.

b. Documentation. The following information must be documented in the standard production procedures for each Edible Retail Marijuana Product: the amount in milligrams of Standardized Serving of Marijuana, the total number of Standardized Servings of Marijuana, and the total amount of active THC contained within the product.

c. Notwithstanding the requirement of subparagraph (D)(2)(b), an Edible Retail Marijuana Product shall contain no more than 10 mg of active THC per Container and the Retail Marijuana Products Manufacturer or an Accelerator Manufacturer must ensure that the product is packaged in accordance with the Rules 3-1005(C)(1) and 1010(D)(1), when:

i. The Edible Retail Marijuana Product is of the type that is impracticable to mark, stamp, or otherwise imprint with the Universal Symbol directly on the product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable; or

ii. The Edible Retail Marijuana Product is of the type that is impracticable to clearly demark each Standardized Serving of Marijuana or to make each Standardized Serving of Marijuana separable.

d. Liquid Edible Retail Marijuana Product.

i. Pursuant to 44-10-603(4)(b), C.R.S., Liquid Edible Retail Marijuana Products are impracticable to mark with the Universal Symbol and are exempt from the provision in subparagraph (D)(4)(c) of this Rule 3-335 that requires Edible Retail Marijuana Products that are impracticable to mark with the Universal Symbol to contain 10mg or less active THC per Container.

ii. This exemption permits the manufacture and Transfer of Multi-Serving Liquid Edible Retail Marijuana Products so long as the product is packaged in accordance with Rules 3-1005(C)(1) and 3-1010(D)(1)(c)(ii).

e. Multiple-Serving Edible Retail Marijuana Product.

i. A Retail Marijuana Products Manufacturer or an Accelerator Manufacturer must ensure that each single Standardized Serving of Marijuana of a Multiple-Serving Edible Retail Marijuana Product is physically demarked in a way that enables a reasonable person to intuitively determine how much of the product constitutes a single serving of active THC.

ii. Each demarked Standardized Serving of Marijuana must be easily separable in order to allow an average person 21 years of age and over to physically separate, with minimal effort, individual servings of the product.

iii. Each single Standardized Serving of Marijuana contained in a Multiple-Serving Edible Retail Marijuana Product shall be marked, stamped, or otherwise imprinted with the Universal Symbol directly on the product in a manner to cause the Universal Symbol to be distinguishable and easily recognizable. The Universal Symbol marking shall comply with the requirements of subparagraph (D)(2)(b) of this Rule 3-335.

iv. A Multiple-Serving Edible Retail Marijuana Product that is a Liquid Edible Retail Marijuana Product shall comply with the requirements in subparagraph (D)(4)(d)(ii) of this Rule 3-335 and is exempt from subparagraphs (i)-(iii) of this subparagraph (D)(4)(e)(iv).

f. Retail Marijuana Concentrate Recommended Serving Size and Visual Representation.

i. The recommended serving size for Retail Marijuana Concentrate in Vaporized Delivery Devices should not exceed one (1) inhalation lasting two (2) seconds per serving.

ii. The recommended serving size for Retail Marijuana Concentrate intended to be inhaled in any manner other than a Vaporizer Delivery Device is a sphere identified in the tangible educational resource required to be provided to a ~~patient~~ consumer pursuant to Rule 6-110(C.5) and Rule 6-1110(C.5).

E. Remanufactured Products Prohibited. A Regulated Marijuana Products Manufacturer shall not utilize a commercially manufactured food product as its Edible Medical Marijuana Product or Edible Retail Marijuana Product. The following exceptions to this prohibition apply:

1. A food product that was commercially manufactured specifically for use by a Regulated Marijuana Products Manufacturer to infuse with Regulated Marijuana shall be allowed. The Licensee shall have a written agreement with the commercial food product manufacturer that declares the food product's exclusive use by the Regulated Marijuana Products Manufacturer.

2. Commercially manufactured food products may be used as Ingredients in an Edible Medical Marijuana Product or Edible Retail Marijuana Product so long as: (1) they are used in a way that renders them unrecognizable as the commercial food product in the final Edible Medical Marijuana Product or Edible Retail Marijuana Product, and (2) the Regulated Marijuana Products Manufacturer does not state or advertise to the consumer that the final Edible Medical Marijuana Product or Edible Retail Marijuana Product contains the commercially manufactured food product.

F. Trademarked Food Products. Nothing in this Rule alters or eliminates a Regulated Marijuana Products Manufacturer's responsibility to comply with the trademarked food product provisions required by the Marijuana Code per section 44-10-503(9)(a-c), C.R.S.

G. Edibles Prohibited that are Shaped like a Human, Animal, or Fruit.

1. The production, Transfer, and donation of Edible Medical Marijuana Products or Edible Retail Marijuana Products in the following shapes is prohibited:

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

ii. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.

2. The prohibition on human, animal, and fruit shapes does not apply to the logo of a licensed Regulated Marijuana Business. Nothing in this subparagraph (G)(2) alters or eliminates a Licensee's obligation to comply with the requirements of the 3-1000 Series Rules – Labeling, Packaging, and Product Safety.

3. Edible Medical Marijuana Products and Edible Retail Marijuana Products that are geometric shapes and simply fruit flavored are not considered fruit and are permissible; and

4. Edible Medical Marijuana Products and Edible Retail Marijuana Products that are manufactured in the shape of a marijuana leaf are permissible.

G.5. Production of Semi-Synthetic Cannabinoids and Synthetic Cannabinoids.

1. Semi-Synthetic Cannabinoids. Only a Marijuana Research and Development Licensee may manufacture semi-synthetic cannabinoids.

2. Synthetic Cannabinoids Prohibited. Licensees are prohibited from manufacturing, producing, or Transferring any Synthetic Cannabinoid.

H. Inactive Ingredients.

1. Only non-cannabis derived inactive Ingredients listed in the Federal Food and Drug Administration Inactive Ingredient Database https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm, or approved by another equivalent international government agency, may be used in the manufacture of Audited Product and Regulated Marijuana Concentrate intended for use through a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.

2. All non-cannabis derived inactive Ingredients contained in any Audited Product or in any Regulated Marijuana Concentrate intended for use through a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler must be less than or equal to the concentration listed in the Federal Food and Drug Administration Inactive Ingredient Database, or approved by another equivalent international government agency for:

a. The inhalation route of administration for any Audited Product to be used in a metered dose nasal spray, or any Regulated Marijuana Concentrate to be used in a Vaporizer Delivery Device or pressurized metered dose inhaler;

b. The vaginal route of administration for any Audited Product to be used for vaginal administration; or

c. The rectal route of administration for any Audited Product to be used for rectal administration.

I. Other Permitted Ingredients. Nothing in paragraph H above prohibits a Regulated Marijuana Products Manufacturer from using marijuana-derived ingredients or Botanically Derived Compounds and/or terpenoids.

J. Processing Aids and Additives. A Regulated Marijuana Products Manufacturer shall not include any Processing Aid or Additive that is toxic, prohibited, or present at levels over the acceptable limits pursuant to Rule 4-115(D) within a Regulated Marijuana Product; nor include any Additive for the purposes of making the product more addictive, appealing to children, or misleading to patients or consumers.

K. Prohibited Ingredients.

1. A Regulated Marijuana Products Manufacturer shall not use the following Ingredients in the production or Transfer of Regulated Marijuana Concentrate and Regulated Marijuana Product for which the inhaled product is the intended use in accordance with Rule 3-1015:

a. Polyethylene glycol (PEG);

b. Vitamin E Acetate;

c. Medium Chain Triglycerides (MCT Oil);

2. A Licensee authorized to manufacture Regulated Marijuana Concentrate or Regulated Marijuana Product shall not use ingredients, other than Regulated Marijuana, with over 0.3% combined D8-THC, D9-THC, D10-THC, Exo-THC or other THC isomers, salts, or salt isomers of tetrahydrocannabinol in the manufacture, production, or Transfer of Regulated Marijuana Concentrate or Regulated Marijuana Product.

L. Standard Operating Procedures.

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

a. All standard operating procedures for the production of a Medical Marijuana Concentrate or Retail Marijuana Concentrate must follow the requirements in Rules 5-315 and 6-315.

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

c. If a Regulated Marijuana Products Manufacturer produces Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana, the standard operating procedures must include all methods and processes related to the creation of each type of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana product, including but not limited to, the strains used, where strains are sourced, which parts of Harvest Batches are used (e.g. flower, shake, trim), the size of the product (e.g. 1 gram pre-rolls), and how much and what type of Regulated Marijuana Concentrate is added (if

applicable) for each type of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana it produces.

d. Provide adequate training to every Owner Licensee and Employee Licensee who performs a task or set of tasks that are referenced in the standard operating procedures. Adequate training must include, but need not be limited to, providing a copy of the standard operating procedures for that Licensed Premises detailing at least all of the topics required to be included in the standard operating procedures.

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

M. Expiration Date for Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers. Effective July 1, 2022, a Regulated Marijuana Products Manufacturer that produces a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler shall establish an expiration date upon which the Vaporized Delivery Device or Pressurized Metered Dose Inhaler will no longer be fit for consumption. The Licensee shall determine the expiration date by conducting potency and contaminant testing pursuant to Rules 4-120 and 4-125 on the final Vaporizer Delivery Device or Pressurized Metered Dose Inhaler prior to Transfer to ensure the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler can pass potency and contaminant testing prior to the established expiration date.

1. When determining the expiration date for a Vaporizer Delivery Device or Pressurized Metered Dose Inhaler pursuant to this rule, the Licensee shall also consider the following:

i. Any expiration dates of additives used to produce the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler;

ii. The interaction with hardware;

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

iv. The ideal storage conditions for the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.

2. The License may, but is not required to, use accelerated stability tests to demonstrate compliance with this rule.

3. Expiration date determinations, along with any data used to establish the expiration date, shall be documented and maintained in the Licensee's business records pursuant to these rules.

N. DMSO. Except for R&D Licensees, the use of Dimethylsulfoxide (DMSO) in the production of Regulated Marijuana Product and possession of DMSO upon the Licensed Premises is prohibited.

3-800 Series – Inventory Tracking Requirements

Basis and Purpose – 3-810

The statutory authority for this rule includes but is not limited to sections, 44-10-201, 44-10-202(1)(a), 44-10-202(1)(c), 44-10-203(2)(n), 44-10-501(1)(b), 44-10-502(2), 44-10-503(1)(b), 44-10-505(3), 44-10-601(1)(d), 44-10-601(4), 44-10-602(1), 44-10-602(6)(f), 44-10-603(1)(b), and 44-10-605(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 maintain a system that will allow the State Licensing Authority and the industry to jointly track Regulated Marijuana from either seed or immature plant stage until the Regulated Marijuana is sold to the patient or consumer or destroyed.

3-810 – Minimum Tracking Requirements

A. Requirement to Track Regulated Marijuana From Seed-to-Sale.

1. Licensees must use the Inventory Tracking System to ensure Regulated Marijuana is identified and tracked from the point the Regulated Marijuana is Propagated from seed or cutting to the point when it is Transferred to another Regulated Marijuana Business, the Medical Marijuana Transporter or Retail Marijuana Transporter takes control of the Regulated Marijuana by removing it from the originating Licensee's Licensed Premises and placing the Regulated Marijuana in the transport vehicle, or it is Transferred to a Sampling Manager as a designated Sampling Unit, and through the delivery, point-of-sale, or the Regulated Marijuana is otherwise disposed of. *See* Rule 3-805 – Inventory Tracking System.

2. Licensees must immediately input any Genetic Material that is received in accordance with Rules 5-305 and 6-305 into the Inventory Tracking System as an Immature Plant batch.

B. Ability to Reconcile Required. Licensees must have the ability to reconcile transported and on-hand Regulated Marijuana inventory with the Inventory Tracking System and the associated transaction history and transportation order receipts. *See* Rule 3-905 – Business Records Required.

C. Decontamination. Licensees must input any Decontamination method utilized into the Inventory Tracking System.

Basis and Purpose – 3-825

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-203(2)(d)(I), 44-10-504, and 44-10-604 The Purpose of this rule is to establish reporting standards for Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities.

3-825 – Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities Specific Tracking Requirements

A. Required Procedures. A Regulated Marijuana Testing Facility must establish procedures to ensure that results are accurate, precise, and scientifically valid prior to reporting such results.

B. Reports. Every final report, whether submitted to the Division, to a Regulated Marijuana Business, or to any other Person authorized to receive the report, must include the following:

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

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

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

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

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

6. Provide the final report to the Division, as well as the Regulated Marijuana Business, and/or any other Person authorized to receive the report in a timely manner.

C. Inventory Tracking System. Each Regulated Marijuana Testing Facility shall:

1. Report all test results to the Division as part of daily reconciliation by the close of business and in accordance with all Inventory Tracking System Procedures under Rule 3-805 – All Regulated Marijuana Businesses: Inventory Tracking System. The requirement to report all test results includes:

a. Both positive and negative test results;

b. Results from both mandatory and voluntary testing; and

c. For quantitative tests, a quantitative value.

2. As part of Inventory Tracking System reporting, when results of tested Samples exceed maximum levels of allowable potency or contamination, or otherwise result in failed potency, homogeneity, or contaminant testing, the Regulated Marijuana Testing Facility shall, in the Inventory Tracking System, indicate failed test results for the Inventory Tracking System package associated with the failed Sample. This requirement only applies to testing of Samples that are comprised of Regulated Marijuana.

3. Report all Transfers of Genetic Material to a Regulated Marijuana Cultivation Facility in the Inventory Tracking System.

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

3-900 Series – Business Records

Basis and Purpose – 3-905

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-301, and 44-10-1001(1), C.R.S. This rule explains what business records a Licensee must maintain and clarifies that such records must be made available to the Division on demand. This Rule 3-905 was previously Rules M and R 901, 1 CCR 212-1 and 1 CCR 212-2.

3-905 – Business Records Required

A. General Requirements.

1. A Regulated Marijuana Business must maintain the information required in this Rule in a format that is readily understood by a reasonably prudent business person and may be stored electronically.

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

   a. On premises records: The Regulated Marijuana Business's books and records for the preceding six months (or complete copies of such records) must be maintained on the Licensed Premises at all times. Electronic records that are accessible from, but not physically located at, a Licensee's Licensed Premises may also satisfy the requirements of this Rule 3-905.

   b. On- or off-premises records: Books and records associated with older periods may be archived on or off of the Licensed Premises.

3. Books and records necessary to fully account for the business transactions conducted under its License shall be made available to the State Licensing Authority or Division upon request.

B. The books and records must fully account for the transactions of the business and must include, but shall not be limited to:

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

2. Security Alarm Systems documents required by Rule 3-220(A)(3).

3. Advertising Records – All records related to Advertising and marketing, including, but not limited to, audience composition data.

4. Child Resistance Certificates – A copy of the certificate that each Container into which a Licensee places Regulated Marijuana is Child Resistant.

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

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

7. All records normally retained for tax purposes.

8. Waste Log and Fibrous Waste Records – Comprehensive records regarding all waste and Fibrous Waste material that accounts for, reconciles, and evidences all waste and Fibrous Waste activity related to the disposal of marijuana.

9. Consumer Waste Records – All contracts, standard operating procedures, and receipts relating to collection and Transfer of Marijuana Consumer Waste as required by Rule 3-240.

10. Surveillance Logs – Surveillance logs identify all authorized employees and service personnel who have access to the surveillance system and maintenance and activity log as required by Rule 3-225.

11. Every Licensee shall maintain a record of its identity statement and Standardized Graphic Symbol. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule.

12. Testing Records Required to be Maintained by Regulated Marijuana Testing Facilities:

    a. All testing records required by Rule 5-450 and Rule 6-450.

    b. Digital photographs of each Test Batch.

    c. Any delegation of responsibilities from the laboratory director to a qualified supervisory analyst as permitted by Rule 5-240(B)9 or 6-240(B).

13. Testing Records Required to be Maintained by Regulated Marijuana Businesses and Accelerator Licensees:

    a. Documentation of Designated Test Batch Collector Training required by Rule 4-110(C)(3).

    b. Records regarding wet whole plant that was not tested for microbials pursuant to Rule 4-121(F)(3).

    c. Evidence of any achieved Reduced Testing Allowance -- If a Licensee utilizes any Reduced Testing Allowances, then they must maintain documentation demonstrating how it was obtained and maintained throughout the allowance with all applicable rules.

14. Sampling Unit Records – All records related to designated Sampling Managers, identified Sampling Units, and Transfers of Sampling Units. *See* Rules 3-810, 5-230, 5-320, 6-225, 6-320. This includes, but is not limited to, standard operating procedures that explain the requirements of sections 44-10-502(5), 44-10-503(10), 44-10-602(6) and 44-10-603(10), C.R.S., the personal possession limits pursuant to section 18-18-406, C.R.S., and the requirements imposed by Rules 5-230, 5-320, 6-225, 6-320. 6-725, and 6-280.

15. License Application Records – All records provided by the Licensee to both the state and local licensing authorities in connection with an application for licensure pursuant to the Marijuana Code and these Rules.

16. Standard Operating Procedures – All standard operating procedures as required by these Rules, including up-to-date records of employee training, as follows:

    a. Identification of required training of employees;

    b. Documentation of training topic, training method, date of initial training, date of any necessary re-training, name and signature of trainer, and name and signature of employee;

    c. Competency and effectiveness of employee training shall be adequately assessed in an appropriate manner determined by the Licensee that is described in the standard operating procedures.

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

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

19. Certificates of analysis or other records demonstrating the full composition of each Ingredient used in the manufacture of Vaporizer Delivery Devices or Pressurized Metered Dose Inhalers as required by Rule 5-310(F).

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

21. Recall records required by Rule 3-336 including the recall plan, recall notice, and results of any action taken pursuant to the recall plan.

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

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

24. Internal Security Controls – Licensees must establish and maintain a security plan for each Licensed Premises, including at a minimum:

    a. Protocols for the end-of-day handling of Regulated Marijuana and cash;

    b. Protocols for reporting theft or burglaries when they are discovered to Local Law Enforcement, the Division, and Local Licensing Authority or Local Jurisdiction;

    c. Protocols for reconciling inventory after a theft or burglary has been discovered;

    d. Identification of exterior lighting of the Licensed Premises and any exterior camera angles, and protocols for maintenance of the lighting and cameras; and

    e. Identification of ingress and egress routes for the property and identification of any access control measures taken outside of the Licensed Premises.

25. Patient Documents – Documents required for a patient to register a primary Medical Marijuana Store as required by Rule 5-1105~~05~~(D).

26. Regulated Marijuana Concentrate Production Records – All records required by Rules 5-315, 6-315, and 6-815 regarding production of Regulated Marijuana Concentrate.

27. Marijuana Research and Development Facility Records – Documents and correspondence sent to or received from an independent reviewer or the Scientific Advisory Council and any testing records if required by Rule 5-725.

28. Documents Related to Pesticide Manufacturers – Affidavit from a Pesticide Manufacturer that it meets the requirements of the Rule and the written agreement between the Licensee and the Pesticide Manufacturer as required by Rule 7-115.

29. Expiration date and use-by date documents required by Rule~~s 3-330(F) and~~ 3-335(M), 3-1005, and 3-1015.

30. Written report of change of management personnel as required by Rule 3-920(A)(2).

31. Current Owner and Employee List – This list must provide the full name and License number of all Owner Licensees and every employee who works for a Regulated Marijuana Business. The list shall include all employees who work for the Regulated

Marijuana Business, whether or not they report to the Licensed Premises as part of their employment. A Regulated Marijuana Business can fulfill the requirements of this Rule by listing all employees in the Inventory Tracking System for each Licensed Premises. If a Regulated Marijuana Business does not use the Inventory Tracking System to list all employees, it must maintain a separate record for employees who do not report to the Licensed Premises.

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

33. Source Genetic Material Records - Licensees receiving Genetic Material in accordance with Rules 5-305 and 6-305 must, at a minimum, maintain the following records:

    a. The name, address, and license/registration/permit identification of the source of the Genetic Material;

    b. All certificates of analysis associated with the Genetic Material; and

    c. Any other records that clearly document the chain of custody of the Genetic Material.

34. All other records required by these Rules.

C. Records Required to be Maintained in the Inventory Tracking System. The following records must be maintained by Licensees in the Inventory Tracking System:

1. Records Related to Inventory Tracking. A Regulated Marijuana Business must maintain accurate and comprehensive inventory tracking records that account for, reconcile, and evidence all inventory activity for Regulated Marijuana from either seed or Immature Plant stage until the Regulated Marijuana is destroyed or Transferred to another Regulated Marijuana Business, a consumer, a patient, or a Pesticide Manufacturer.

2. Records Related to Transport. A Regulated Marijuana Business must maintain adequate records for the transport of all Regulated Marijuana. See Rule 3-605 – Transport: All Regulated Marijuana Businesses.

3. Employees Required to be Listed in the Inventory Tracking System. A Regulated Marijuana Business must use the Inventory Tracking System to list all employees who report to the Licensed Premises. The employee list in the Inventory Tracking System must include the full name and Employee License number of every employee who works on the premises. The Regulated Marijuana Business is responsible for updating its list of employees who work at the Licensed Premises in the Inventory Tracking System within 10 days of an employee commencing or ceasing employment.

4. Testing results.

D. Loss of Records and Data. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this Rule. Licensees are required to exercise due diligence in preserving and maintaining all required records.

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

F. Provision of Any Requested Record to the Division. A Licensee must provide on-demand access to on-premises records following a request from the Division during normal business hours or

hours of apparent operation, and must provide access to off-premises records within three business days following a request from the Division.

3-1000 Series – Labeling, Packaging, and Product Safety

Basis and Purpose – 3-1005

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(f), 44-10-203(1)(k), 44-10-203(3)(a)-(b), 44-10-601(2)(a), 44-10-601(5), 44-10-603(1)(d), 44-10-603(4)(a), and 44-10-603(8), C.R.S. The purpose of this rule is to define minimum packaging and labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product Transferred between Regulated Marijuana Businesses. The State Licensing Authority finds it essential to regulate and establish labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product and that this is in the interest of the health and safety of the people of Colorado. This rule identifies information that is required on all labels to provide information necessary for the Division to regulate the cultivation, production, and sale of Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. This rule also seeks to minimize, to the extent practicable, the burden of labeling compliance to Licensees. The labeling requirements in this rule apply to all Containers immediately containing Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. This Rule 3-1005 was previously Rules M and R 1001-1, 1 CCR 212-1 and 1 CCR 212-2.

3-1005 - Packaging and Labeling: Minimum Requirements Prior to Transfer to a Regulated Marijuana Business, except to a Regulated Marijuana Testing Facility

A. Applicability. This Rule establishes minimum requirements for packaging and labeling Regulated Marijuana prior to Transfer to a Regulated Marijuana Business, except to a Regulated Marijuana Testing Facility. See Rule 3-1025 for minimum requirements for packaging and labeling Regulated Marijuana prior to Transfer to a Regulated Marijuana Testing Facility. The labeling requirements in this Rule apply to all Containers immediately containing Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, and Retail Marijuana Product.

B. Packaging and Labeling of Regulated Marijuana Flower, Trim, Wet Whole Plant, and Regulated Marijuana Concentrate, Prior to Transfer to a Regulated Marijuana Business. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Medical Marijuana flower, trim, wet whole plant, or Medical Marijuana Concentrate to another Medical Marijuana Business, or Retail Marijuana flower, trim, wet whole plant, or Retail Marijuana Concentrate to another Retail Marijuana Business:

1. Packaging of Regulated Marijuana Flower and Trim, and Regulated Marijuana Concentrate.

    a. Prior to Transfer to a Regulated Marijuana Business, Regulated Marijuana flower, trim, wet whole plant, or Regulated Marijuana Concentrate shall be placed into a Container. The Container may but is not required to be Child-Resistant.

    b. Each Container of Regulated Marijuana flower or trim that is Transferred to a Regulated Marijuana Business shall not exceed 50 pounds of Regulated Marijuana flower or trim, but may include pre-weighed units that are within the sales limit in Rules 5-115(C),6-110(C), and 6-925(G).

    c. A Container of wet whole plant that is Transferred to a Regulated Marijuana Business may exceed 50 pounds, but shall not exceed 100 pounds.

d. Each Container of Medical Marijuana Concentrate that is Transferred to a Medical Marijuana Business, or Retail Marijuana Concentrate that is Transferred to a Retail Marijuana Business, shall not exceed 50 pounds of Medical Marijuana Concentrate or Retail Marijuana Concentrate, but may include pre-weighed units that are within the applicable sales limit in Rules 5-115(C),6-110(C), and 6-925(G).

2. Labeling of Regulated Marijuana Flower, Trim, Wet Whole Plant, and Regulated Marijuana Concentrate. Prior to Transfer to a Regulated Marijuana Business, every Container of Regulated Marijuana flower, trim, wet whole plant, or Regulated Marijuana Concentrate shall be affixed with a label that includes at least the following information:

a. The license number of the Medical Marijuana Cultivation Facility where the Medical Marijuana was grown, the Retail Marijuana Cultivation Facility where the Retail Marijuana was grown, or the Accelerator Cultivator where the Retail Marijuana was grown;

b. The Harvest Batch Number(s) assigned to the Regulated Marijuana or the Production Batch Number(s) assigned to the Regulated Marijuana Concentrate;

c. If applicable, the license number of the Medical Marijuana Cultivation Facility(ies) that produced the Physical Separation-Based Medical Marijuana Concentrate, the Retail Marijuana Cultivation Facility(ies) that produced the Physical Separation-Based Retail Marijuana Concentrate, or the license number of the Accelerator Cultivator;

d. If applicable, the license number of the Medical Marijuana Products Manufacturer(s) where the Medical Marijuana Concentrate was produced, the Retail Marijuana Products Manufacturer(s) where the Retail Marijuana Concentrate was produced, or the Accelerator Manufacturer(s) where the Retail Marijuana Concentrate was produced;

e. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Regulated Marijuana or Regulated Marijuana Concentrate prior to its placement in the Container; and

f. Potency test results as required to permit the receiving Regulated Marijuana Business to label the Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, or Retail Marijuana Concentrate as required by these rules.

g. Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers. A list of all Ingredients, including Additives, used to manufacture the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler.

h. Expiration/Use-By Date. Beginning January 1, 2024, the expiration or use-by date as required in Rule 3-1015.

i. Storage Conditions. Beginning January 1, 2024, if a Licensee establishes a use-by date that is longer than nine months based on shelf stability testing in accordance with Rule 3-1015(B)(2)(a.5), then the label for the Regulated Marijuana shall include storage conditions as determined by the Regulated Marijuana Business that cultivated or manufactured the Regulated Marijuana.

C. Packaging and Labeling of Regulated Marijuana Product Prior to Transfer to a Regulated Marijuana Business. A Regulated Marijuana Business shall comply with the following minimum

packaging and labeling requirements prior to Transferring Medical Marijuana Product to another Medical Marijuana Business, or Transferring Retail Marijuana Product to another Retail Marijuana Business:

1. Packaging of Regulated Marijuana Product.

   a. Transfer to a Regulated Marijuana Business Other Than a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Regulated Marijuana Business other than a Medical Marijuana Store or Retail Marijuana Store, Regulated Marijuana Product shall be placed into a Container. The Container may but is not required to be Child-Resistant.

   b. Transfer to a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Medical Marijuana Store or Retail Marijuana Store, all Regulated Marijuana Product shall be packaged in a Child-Resistant Container that is ready for sale to the patient or consumer as required by the Rule 3-1010(D).

2. Labeling of Regulated Marijuana Product.

   a. Transfer to a Regulated Marijuana Business other than a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Regulated Marijuana Business other than a Medical Marijuana Store or Retail Marijuana Store, every Container of Regulated Marijuana Product shall be affixed with a label that includes at least the following information:

      i. The license number of the Regulated Marijuana Cultivation Facility(ies) where the Medical Marijuana or Retail Marijuana was grown;

      ii. The license number of the Regulated Marijuana Products Manufacturer that produced the Medical Marijuana Product or Retail Marijuana Product;

      iii. The Production Batch Number(s) assigned to the Regulated Marijuana Product;

      iv. The net contents, using a standard of measure compatible with the Inventory Tracking System, of the Regulated Marijuana Product prior to its placement in the Container; and

      v. Potency test results as required to permit the receiving Regulated Marijuana Business to label the Regulated Marijuana Product as required by these rules.

   b. Transfer to a Medical Marijuana Store or Retail Marijuana Store. Prior to Transfer to a Regulated Marijuana Store, every Container of Regulated Marijuana Product shall be affixed with a label ready for sale to the patient or consumer including all information required by Rules 3-1010(D)(2) and 3-1015(B).

D. Packaging and Labeling of Regulated Marijuana Seeds, ~~and~~ Immature Plants, and Genetic Material Prior to Transfer to a Regulated Marijuana Business. A Regulated Marijuana Business shall comply with the following minimum packaging and labeling requirements prior to Transferring Regulated Marijuana seeds, ~~or~~ Immature P~~p~~lants, or Genetic Material to another Regulated Marijuana Business:

1. Packaging of Regulated Marijuana Seeds.

a. Prior to Transfer to a Regulated Marijuana Business, Regulated Marijuana seeds shall be placed into a Container. The Container may but is not required to be Child-Resistant.

b. Each Container of Regulated Marijuana seeds that is Transferred to a Regulated Marijuana Business shall not exceed 10 pounds of Regulated Marijuana seeds.

2. Packaging of Immature Plants and Genetic Material. Prior to Transfer to a Regulated Marijuana Business, Immature ~~p~~Plants and Genetic Material shall be placed into a receptacle. The receptacle may but is not required to be Child-Resistant.

3. Labeling of Regulated Marijuana Seeds and Immature Plants. Prior to Transfer to a Regulated Marijuana Business, every Container of Regulated Marijuana seeds and all receptacles holding an Immature ~~p~~Plant shall be affixed with a label that includes at least the license number of the Regulated Marijuana Cultivation Facility where the Regulated Marijuana that produced the seeds or the Immature ~~p~~Plant was grown.

4. Labeling of Genetic Material. Prior to Transfer to another Regulated Marijuana Business, every receptacle of Genetic Material shall be affixed with a label that includes at least the license number of the Regulated Marijuana Cultivation Facility Transferring the Genetic Material and must be accompanied with records required in Rule 3-905.

E. Packaging and Labeling of Sampling Units. Regulated Marijuana Cultivation Facilities and Regulated Marijuana Products Manufacturers shall comply with the following minimum packaging and labeling requirements prior to Transferring any Sampling Unit to a Sampling Manager.

1. Packaging of Sampling Units. Prior to Transfer to a Sampling Manager, a Sampling Unit must be placed in a Container. If the Sampling Unit is Regulated Marijuana flower, trim, Medical Marijuana Concentrate, or Retail Marijuana Concentrate, the Container may, but is not required to, be Child-Resistant; however, the Container shall be placed into a Child-Resistant Exit Package at the point of Transfer to the Sampling Manager. If the Sampling Unit is composed of Regulated Marijuana Product, the Sampling Unit shall be packaged in a Child-Resistant Container.

2. Labeling of Sampling Units. Prior to Transfer to a Sampling Manager, every Container for a Sampling Unit shall be affixed with a label that includes at least the following information:

a. Required License Number. The license number for the Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer Transferring the Sampling Unit.

b. Batch Number(s). The relevant Harvest Batch number and/or Production Batch number from which the Sampling Unit was designated.

c. Universal Symbol. The Universal Symbol on the front of the Container and any Marketing Layer, no smaller than ½ of an inch by ½ of an inch, with the following statement directly below the Universal Symbol: "**Contains Marijuana. Keep away from children.**"

d. Required Potency Statement.

i. For a Sampling Unit composed of Regulated Marijuana, Medical Marijuana Concentrate, or Retail Marijuana Concentrate, the potency of the Sampling Unit's active THC and CBD expressed as a percentage.

ii. For a Sampling Unit composed of Regulated Marijuana Product, the potency of the Sampling Unit's active THC and CBD expressed in milligrams. If the potency of the Sampling Unit's active THC or CBD is less than 1 milligram, the potency may be expressed as "<1 mg."

iii. The required potency statement shall be displayed either: (1) In a font that is bold, and enclosed within an outlined shape such as a circle or square; or (2) highlighted with a bright color, such as yellow.

e. Date of Transfer. The label shall include the date of Transfer to the Sampling Unit.

f. Patient Number. If the Sampling Unit contains Medical Marijuana, Medical Marijuana Concentrate, or Medical Marijuana Product, the label must also include the patient registration number of the recipient Sampling Manager.

g. Required Warning Statements. Either the label affixed to the Container or the Marketing Layer shall include the following information:

i. "This product was received as a Sampling Unit and may have been produced with undisclosed allergens, solvents, or pesticides, and may pose unknown physical or mental health risks. This product is not for resale and should not be used by anyone else."

F. Prohibited Transfers – All Regulated Marijuana Businesses. A Regulated Marijuana Business shall not Transfer to a Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, or Retail Marijuana Hospitality and Sales Business—and a Medical Marijuana Store, Retail Marijuana Store, Accelerator Store, or Retail Marijuana Hospitality and Sales Business shall not accept nor offer for sale—any Regulated Marijuana that is not packaged and labeled in conformance with the requirements of these rules or that does not provide all information necessary to permit the Medical Marijuana Store, Retail Marijuana Store, Accelerator Store or Retail Marijuana Hospitality and Sales Business to package and label the Regulated Marijuana prior to Transfer to a patient or consumer. However, a Medical Marijuana Store or Retail Marijuana Store is not required to open any tamper evident Marketing Layer received from a Medical Marijuana Cultivation Facility, Retail Marijuana Cultivation Facility, Medical Marijuana Products Manufacturer, or a Retail Marijuana Products Manufacturer to verify the Container is Child-Resistant or labeled.

G. Shipping Containers. Licensees may Transfer multiple Containers of Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product to a Regulated Marijuana Business in a Shipping Container.

1. Inventory Tracking System ~~RFID~~ Tag Required. Licensees shall ensure that either the multiple Containers placed within a Shipping Container each have an Inventory Tracking System ~~RFID~~ tag, or the Shipping Container itself must have an Inventory Tracking System ~~RFID~~ tag. If the Licensee elects to place the Inventory Tracking System ~~RFID~~ tag on the Shipping Container, the Shipping Container shall contain only one Harvest Batch of Regulated Marijuana, one Production Batch of Regulated Marijuana Concentrate, or one Production Batch of Regulated Marijuana Product. If a Shipping Container consists of more than one Harvest Batch or Production Batch, then each group of multiple Containers shall be affixed with an Inventory Tracking System ~~RFID~~ tag. *See* Rule 3-805

– Inventory Tracking System; Rule 3-605 – Transport: All Regulated Marijuana Businesses.

2. Labeling of Shipping Containers. Any Shipping Container that will not be displayed to the consumer is not required to be labeled according to these rules.

H. Packaging and Labeling of Regulated Marijuana Flower and Trim Prior to Transfer to a Pesticide Manufacturer or a Marijuana Research and Development Facility. The packaging and labeling requirements in these 3-1000 Series Rules also apply to any Transfer of Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product to a Pesticide Manufacturer or a Marijuana Research and Development Facility.

I. Marijuana Research and Development Facility Transfers to Persons as Part of an Approved Research Project. Any Marijuana Research and Development Facility conducting research as part of an approved Research Project involving human subjects shall comply with all packaging and labeling requirements that are applicable to a Medical Marijuana Store prior to Transfer to a patient, unless the Marijuana Research and Development Facility requests and receives in advance a waiver of specific packaging or labeling requirements in connection with the approved Research Project.

J. Research Transfers Prohibited. A Medical Marijuana Store, Retail Marijuana Store, or Accelerator Store shall not Transfer any Medical Marijuana, Medical Marijuana Concentrate, Medical Marijuana Product, Retail Marijuana, Retail Marijuana Concentrate, or Retail Marijuana Product to a Pesticide Manufacturer or a Licensed Research Business.

K. Violation Affecting Public Safety. A violation of any rule in these 3-1000 Series Rules may be considered a license violation affecting public safety.

Basis and Purpose – 3-1015

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(c), 44-10-202(6), 44-10-203(2)(d)(IV)(A)-(C), 44-10-203(2)(f), 44-10-203(2)(w), 44-10-203(1)(a), 44-10-601(2)(a), 44-10-603(4)(a), and 44-10-603(8), C.R.S. The purpose of this rule is to define additional labeling requirements for Regulated Marijuana, Regulated Marijuana Concentrate, and/or Regulated Marijuana Product (except Regulated Marijuana seeds and Immature Plants) based on its intended use. These labeling requirements are in addition to, not in lieu of, the labeling requirements in Rule 3-1010. This Rule 3-1015 was previously Rules M and R 1003-1, 1 CCR 212-1 and 1 CCR 212-2. The Division and State Licensing Authority intend to monitor data regarding Regulated Marijuana use-by dates following implementation of these rules, and will make any necessary changes, including but not limited to, reducing the nine months use-by date if Licensees choose not to conduct stabilization studies.

3-1015 – Additional Labeling Requirements Prior to Transfer to a Patient or Consumer

A. Applicability. This Rule establishes additional labeling requirements for Regulated Marijuana (except seeds and Immature Plants), Regulated Marijuana Concentrate, and Regulated Marijuana Product prior to Transfer to a patient or consumer. The labeling requirements in this Rule apply to all Containers immediately containing Regulated Marijuana, Regulated Marijuana Concentrate, and Regulated Marijuana Product. These labeling requirements based on intended use are in addition to, not in lieu of, the requirements in Rule 3-1010.

1. Exemption for Transfers to Consumers by a Retail Marijuana Hospitality and Sales Business. Unless otherwise provided by these rules, a Retail Marijuana Hospitality and Sales Business Transferring Retail Marijuana to consumers in compliance with the packaging and labeling requirements of Rule 3-1020 is exempt from the requirements of this Rule.

B. Additional Information Required on Every Container (Except Seeds and Immature Plants) Prior to Transfer to a Patient or Consumer. Prior to Transfer to a patient or consumer, every Container of Regulated Marijuana (except seeds and Immature Plants), Regulated Marijuana Concentrate, or Regulated Marijuana Product and any Marketing Layer must have a label that includes at least the following additional information.

1. Statement of Intended Use. The Container and any Marketing Layer shall identify one or more intended use(s) for Medical Marijuana, Retail Marijuana, Medical Marijuana Concentrate, Retail Marijuana Concentrate, Medical Marijuana Product, and Retail Marijuana Product from the following exclusive list:

a. Inhaled Product:

i. Flower, shake, or trim;

ii. Pre-Rolled Marijuana and Infused-Pre-Rolled Marijuana;

iii. Solvent-Based Medical Marijuana Concentrate;

iv. Solvent-Based Retail Marijuana Concentrate;

v. Physical Separation-Based Medical Marijuana Concentrate;

vi. Physical Separation-Based Retail Marijuana Concentrate;

vii. Heat/Pressure-Based Medical Marijuana Concentrate;

viii. Heat/Pressure-Based Retail Marijuana Concentrate;

ix. Vaporizer Delivery Device;

x. Pressurized Metered Dose Inhaler.

b. For Oral Consumption:

i. Food or drink infused with Regulated Marijuana;

ii. Regulated Marijuana Concentrate intended to be consumed orally;

iii. Pills and capsules;

iv. Tinctures.

c. Skin and Body Products:

i. Topical;

ii. Transdermal.

d. Audited Product:

i. Metered Dose Nasal Spray;

ii. Vaginal Administration;

iii. Rectal Administration.

2. Inhaled Product. The "Inhaled Product" intended use may be used only for products intended for consumption by smoking or Vaporizer Delivery Device where the product is heated or burned prior to consumption, or through use of a Pressurized Metered Dose Inhaler. The label(s) on all inhaled product intended use shall also include:

a. The potency statement required by Rule 3-1010 for: (1) flower, shake, or trim, (2) Pre-Rolled Marijuana, (3) Infused-Pre-Rolled Marijuana, (4) Solvent-Based Medical Marijuana Concentrate, (5) Solvent-Based Retail Marijuana Concentrate, (6) Physical Separation-Based Medical Marijuana Concentrate, (7) Physical Separation-Based Retail Marijuana Concentrate, (8) Heat/Pressure-Based Medical Marijuana Concentrate, (9) Heat/Pressure-Based Retail Marijuana Concentrate shall be stated as the percentage of Total THC and CBD. If CBD is not detected, then total CBD potency is not required.

a.5. Use-By Date. Effective January 1, 2024, a product use-by date, upon which the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product will no longer be fit for consumption, or upon which the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product will no longer be optimally fresh. Once a label with a use-by date has been affixed to a Container containing Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product and any Marketing Layer, a Licensee shall not alter that use-by date or affix a new label with a later use-by date. The use-by date shall not be longer than nine months from the harvest or production date, unless shelf stability testing, including but not limited to potency, microbial, and water activity testing, supports a longer shelf life. All use-by dates must be entered into the Inventory Tracking System prior to Transfer. Prior to Transfer to a patient or consumer, a Regulated Marijuana Store or Accelerator Store must inform the patient or consumer if the Regulated Marijuana, Regulated Marijuana Concentrate, or Regulated Marijuana Product is past its use-by date.

b. The potency statement required by Rule 3-1010 for Vaporizer Delivery Devices and Pressurized Metered Dose Inhalers shall be stated as either the percentage of Total THC and CBD, or the number of milligrams of Total THC and CBD, per cartridge, pen, or inhaler. If the potency value for Total THC or CBD of the Vaporizer Delivery Devices or Pressurized Metered Dose Inhalers is less than one milligram, the potency may be expressed as "<1 mg." If CBD is not detected in the Vaporizer Delivery Device or Pressurized Metered Dose Inhaler, then total CBD potency is not required.

c. Additional Labeling Requirement for Regulated Marijuana Concentrate to Promote Consumer Health and Awareness: Effective January 1, 2023, if a Regulated Marijuana Concentrate that is an Inhaled Product cannot easily be measured or separable to the recommended serving size established under Rule 3-335(D)(3)(d) and (4)(f), the Regulated Marijuana Manufacturer that manufacturers the Regulated Marijuana Concentrate must:

i. Affix the Container of Regulated Marijuana Concentrate with a measuring device that permits the patient or consumer to measure each serving in a manner consistent with the recommended serving established under Rule 3-335(D); or

ii. Include a label on the Container of Regulated Marijuana Concentrate that provides instructions to allow the patient or consumer to measure each recommended serving pursuant to Rule 3-335(D).

3. For Oral Consumption. The label(s) on all Edible Medical Marijuana Products and Edible Retail Marijuana Products, including but not limited to confections, liquids, pills, capsules and tinctures, shall also include:

    a. Potency Statement. The potency statement required by Rule 3-1010 shall be stated as: (1) milligrams of active THC and CBD per serving and (2) milligrams of active THC and CBD per Container where the Container contains more than one serving. The Target Potency may be used to fulfill the requirement of this Rule. If CBD is not detected, then active CBD potency is not required.

        i. If the Edible Medical Marijuana Product's or Edible Retail Marijuana Product's Target Potency or potency value of active THC or CBD is less than one milligram per serving, the potency may be expressed as "<1 mg." If "<1 mg" was used to display the active THC or CBD per serving, then a corresponding statement regarding the total THC or CBD content for the entire Container shall be included on the Container. For example, if there are five servings in the Container, "<5 mg" should be displayed for the active THC or CBD statement that was represented as "<1 mg" per serving.

    b. Additional Warning Statement Required. The following additional warning statement shall be included on the label on the Container or Marketing Layer for all Edible Medical Marijuana Product and Edible Retail Marijuana Product: **"The intoxicating effects of this product may be delayed by up to 4 hours.**"

    c. Expiration/Use-By Date. A product expiration date, upon which the Edible Medical Marijuana Product or Edible Retail Marijuana Product will no longer be fit for consumption, or a use-by-date, upon which the Edible Medical Marijuana Product or Edible Retail Marijuana Product will no longer be optimally fresh. Once a label with an expiration or use-by date has been affixed to a Container containing an Edible Medical Marijuana Product or Edible Retail Marijuana Product and any Marketing Layer, a Licensee shall not alter that expiration or use-by date or affix a new label with a later expiration or use-by date. All expiration or use-by dates must be entered into the Inventory Tracking System prior to Transfer. Prior to Transfer to a patient or consumer, a Regulated Marijuana Store or Accelerator Store must inform the patient or consumer if the Edible Medical Marijuana Product or Edible Retail Marijuana Product is past its expiration or use-by date.

    d. Production Date. The date on which the Edible Medical Marijuana Product or Edible Retail Marijuana Product was produced which may be included in the Batch Number required by Rule 3-1010.

    e. Statement Regarding Refrigeration. If an Edible Medical Marijuana Product or Edible Retail Marijuana Product is perishable, a statement that the product must be refrigerated.

4. Skin and Body Products (Topical and Transdermal). The "Skin and Body Products" intended use may be used only for products intended for consumption by topical or transdermal application, and must be intended for external use only. The label(s) on all skin and body products shall also include:

    a. Topical Product Potency Statement. For topical product the potency statement required by Rule 3-1010 shall be stated as the number of milligrams of active THC and CBD per Container. The Target Potency may be used to fulfill the requirement of this Rule. If CBD is not detected, then active CBD potency is not

required. If the THC or CBD comprises less than one percent of the total cannabinoids, the potency may be expressed as less than one percent of the total cannabinoids.

b. Transdermal Product Potency Statement. For transdermal product, the potency statement required by Rule 3-1010 shall be stated as the number of milligrams of active THC and CBD per transdermal product, and the total number of milligrams of active THC and CBD per Container. The Target Potency may be used to fulfill the requirement of this Rule. If CBD is not detected, then active CBD potency is not required.

i. If the transdermal product's Target Potency or potency value of active THC or CBD is less than one milligram per transdermal product, the potency may be expressed as "<1 mg." If "<1 mg" was used to display the active THC or CBD per transdermal product, then a corresponding statement regarding the total THC or CBD content for the entire Container shall be included on the Container. For example, if there are five servings in the Container, "<5 mg" should be displayed for the active THC or CBD statement that was represented as "<1 mg" per serving.

c. Expiration/Use-By Date. A product expiration or use-by date, after which the skin and body product will no longer be fit for use. Once a label with an expiration or use-by date has been affixed to any Container holding a skin and body product and any Marketing Layer, a Licensee shall not alter that expiration or use-by date or affix a new label with a later expiration or use-by date. All expiration or use-by dates must be entered into the Inventory Tracking System prior to Transfer. Prior to Transfer to a patient or consumer, a Regulated Marijuana Store or Accelerator Store must inform the patient or consumer if the skin and body product is past its expiration or use-by date.

d. Production Date. The date on which the skin and body product was produced which may be included in the Batch Number required by Rule 3-1010.

5. Audited Product. Packaging and labeling for all Audited Products: (i) metered dose nasal spray, (ii) vaginal administration, or (iii) rectal administration shall include:

a. All packaging and labeling requirements required by this 3-1000 Series for Regulated Marijuana Products; except Rules 5-325 and 6-325 control where the context otherwise clearly requires.

b. Audited Product shall be packaged and labeled for Transfer to a patient or consumer prior to Transfer from a Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer.

c. Expiration/Use-By Date. A product expiration date that is appropriate for the Audited Product when stored at room temperature as verified by testing required by Rules 5-325 and 6-325. Once a label with an expiration date has been affixed to a Container containing an Audited Product, a Licensee shall not alter that expiration date, or affix a new label with a later expiration date. All expiration or use-by dates must be entered into the Inventory Tracking System prior to Transfer. Prior to Transfer to a patient or consumer, a Regulated Marijuana Store or Accelerator Store must inform the patient or consumer if the Audited Product is past its expiration or use-by date.

d. Production Date. The date on which the Audited Product was produced, which may be included in the Batch Number required by Rule 3-1010.

C. No Other Intended Use Permitted. No intended use other than those identified in this Rule shall be identified on any label, except as permitted by an Alternative Use Designation approved by the State Licensing Authority pursuant to Rules 5-325 and 6-325. Licensees shall accurately identify all intended use(s) from the exclusive list of intended uses in this Rule, or as required by the Alternative Use Designation, on the label.

1. Alternative Use Product. No Regulated Marijuana Business shall Transfer or accept an Alternative Use Product unless the Alternative Use Product received an Alternative Use Designation in accordance with Rules 5-325 and 6-325 and complied with all the requirements of Rules 5-325, 6-325, and 3-1005 through 3-1015, and with any additional packaging and labeling requirements identified in the Alternative Use Designation. At a minimum the label(s) on all Alternative Use Products shall include:

a. All packaging and labeling requirements applicable to the Medical Marijuana Products Manufacturer or Retail Marijuana Products Manufacturer by these 3-1000 Series Rules unless inconsistent with the Alternative Use Designation in which case the Alternative Use Designation shall control.

b. Expiration/Use-By Date. A product expiration date that is appropriate for the Alternative Use Product when stored at room temperature as verified by a Regulated Marijuana Testing Facility. Once a label with an expiration date has been affixed to a Container containing Alternative Use Product, a Licensee shall not alter that expiration date, or affix a new label with a later expiration date.

c. Production Date. The date on which the Alternative Use Product was produced, which may be included in the Batch Number required by Rule 3-1010.

d. All other requirements identified by the Alternative Use Designation.

D. Multiple Intended Uses. Any Regulated Marijuana having more than one intended use shall identify every intended use on the label and shall comply with all labeling requirements for each intended use. If there is any conflict between the labeling requirements for multiple intended uses, the most restrictive labeling requirements shall be followed. Licensees shall not counsel or advise any patient or consumer to use Regulated Marijuana other than in accordance with the intended use(s) identified on the label.

Please Note*: *The following draft rule revisions are based on stakeholder feedback in the August 31 work group meeting and additional written comments.

E. Decontaminated Product. If a Licensee chooses to Decontaminate Regulated Marijuana following a failed test result, every Container of the Decontaminated Regulated Marijuana (except seeds and Immature Plants) must have a label indicating that the product was Decontaminated prior to Transfer to a patient or consumer.

Part 4 – Regulated Marijuana Testing Program

Basis and Purpose – 4-110

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the

Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing sampling procedures and rules for the Division's Regulated Marijuana sampling and testing program. This Rule 4-110 was previously Rules M and R 1504, 1 CCR 212-1 and 1 CCR 212-2.

4-110 – Regulated Marijuana Testing Program: Sampling Procedures

A. Collection of Samples.

1. Sample Increment Collection. All Samples submitted for testing pursuant to this Rule must be collected by Division representatives or in accordance with the Division's sampling policy reflected in the marijuana laboratory testing reference library available at the Colorado Department of Public Health and Environment's website. This reference library may be continuously updated as new materials become available in accordance with section 25-1.5-106(3.5)(d), C.R.S.

2. Sample Increment Selection. The Division may elect, at its sole direction, to assign Division representatives to collect Sample Increments, or may otherwise direct Sample Increment selection, including, but not limited to, through Division designation of a Harvest Batch or Production Batch in the Inventory Tracking System from which a Regulated Marijuana Business shall select Samples for testing. A Regulated Marijuana Business, its Controlling Beneficial Owners, Passive Beneficial Owners, and employees shall not attempt to influence the Sample Increments selected by Division representatives. If the Division does not select the Harvest Batch or Production Batch to be tested, a Regulated Marijuana Business must collect and submit Sample Increments that are representative of the Harvest Batch or Production Batch being tested.

3. Adulteration or Alteration Prohibited. Pursuant to section 44-10-701(3)(b) and (9), C.R.S., it is unlawful for a Licensee or its agent to knowingly adulterate or alter, or attempt to adulterate or alter, any Sample Increments or Test Batches of Regulated Marijuana. The Sample Increments collected and submitted for testing must be representative of the Harvest Batch or Production Batch being tested. A violation of this sub-paragraph (A)(3) shall be considered a license violation affecting public safety and the person who commits adulteration or alteration of Sample Increments or Test Batches commits a class 2 misdemeanor and may be punished as provided in section 18-1.3-501, C.R.S.

4. Timing of Sample Increments for Harvest Batches and Production Batches. A Licensee shall not collect Sample Increments or submit Test Batches for testing until the Test Batch has completed all required steps and is in its final form as outlined in the standard operating procedures of the Licensee submitting the Test Batch, with the exception of packaging and labeling requirements which shall comply with Rule 3-1025.

a. The following examples illustrate various methods, which are not limited to those listed herein, that a Licensee's standard operating procedures may include to verify a Test Batch completed all required steps and is in its final form pursuant to this Rule:

i. The Licensee's standard operating procedures may include procedures that ensure the addition of all Ingredients or Additives has occurred and that the Harvest Batch or Production Batch associated with the Test Batch is completely ready to be packaged pending results of testing required by these Rules. This also includes creating Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana;

ii. For a Production Batch of Concentrate, the Licensee's standard operating procedure may include procedures that ensure the entire Production Batch associated with the Test Batch has completed all sifting, extracting, purging, winterizing, and steps to remove plant pigments and ensuring the addition of all Ingredients and Additives has occurred.

iii. For a Production Batch of Regulated Marijuana Product, the Licensee's standard operating procedure may include procedures that ensure the addition of all Ingredients and Additives has occurred and the Production Batch associated with the Test Batch is completely ready to be packaged pending results of testing required by these Rules.

b. A Test Batch from a Harvest Batch or Production Batch shall be packaged and labeled according to Series 3-1025 prior to Transfer to a Regulated Marijuana Testing Facility.

c. This Rule 4-110(A)(4) does not apply for the submission of Test Batches submitted for R&D testing.

5. Vaporizer Delivery Device. This subsection (A)(5) is effective January 1, 2022. Retail Marijuana Concentrate that has been placed into a Vaporizer Delivery Device must be sampled and tested using a methodology that allows the laboratory to analyze the emission of the contents of the Vaporizer Delivery Device.

B. Designated Test Batch Collector Training, Documentation, and Designation.

1. Required Sample Increment Collection Training. To become a Designated Test Batch Collector an Owner Licensee or Employee Licensee involved in the Sample Increment Collection of Regulated Marijuana must be designated by a manager or Owner Licensee as such and must also complete either in-house training provided by the Regulated Marijuana Business or training from a third-party vendor. Nothing in this rule requires a Designated Test Batch Collector to be employed by the Regulated Marijuana Business making the designation.

2. Designated Test Batch Collection Training Required Topics. The training required to become a Designated Test Batch Collector must include at least the following topics:

a. Part 4–100 Series Rules - Regulated Marijuana Testing Program;

b. The Marijuana Business's standard operating procedures on creating a Sampling Plan and Test Batches, and the CDPHE's Sampling Procedures.

c. "Guidance on Marijuana Sampling Procedures" Training Video or an equivalent training covering the following subjects:

i. Introduction to Sample Increment Collection:

A. Cross contamination as it relates to Sample Increment Collection;

B. Sample Increment Collection and how it works;

C. Sample Increment Collection documentation and record keeping requirements;

D. Penalties for Sample Increment or Test Batch adulteration or alteration;

E. Use of and disinfection of the Designated Test Batch Collection Area; and

F. Use of the Sample Plan.

3. Documentation of Designated Test Batch Collector Training. Any individual receiving the Designated Test Batch Collector training must sign and date a document which shall be maintained by the Regulated Marijuana Business as a business record pursuant to Rule 3-905. The document must acknowledge the following:

a. The identity of the Person that created the training, such as the Regulated Marijuana Business or a third-party vendor; and

b. That all required topics of the training identified in this Rule have been reviewed and understood by the Owner Licensee or Employee Licensee.

C. Test Batch Collection Requirements.

1. Required Minimum of Two Test Batch Collectors. At a minimum, two Designated Test Batch Collectors shall be involved in the collection of Sample Increments such that at least one Designated Test Batch Collector is responsible for collecting the Sample Increments and another Designated Test Batch Collector is responsible for reviewing documentation associated with the collection of Sample Increments in a timely manner and prior to any Transfer of the Production Batch or Harvest Batch from which Sample Increments were collected. This review can be completed in person or may be completed remotely by reviewing image(s) of the Test Batch and associated documentation. All Designated Test Batch Collectors must be identified as such in the Inventory Tracking System account associated with the Regulated Marijuana Business.

2. Sample Plan Required. A Designated Test Batch Collector must establish a Sample Plan consistent with the Regulated Marijuana Business's Standard Operating Procedure for Sample Increment Collection. At a minimum, a Sample Plan must include the following:

a. The date, amount or weight, and specific location for each Sample Increment collected;

b. Identification of and acknowledgements from all Designated Test Batch Collectors involved in the Sample Increment Collection; and

c. If applicable, the strain name(s) for each Harvest Batch from which Sample Increments are collected.

D. Minimum Number of Sample Increments Per Test Batch Submission. These sampling rules shall apply until such time as the State Licensing Authority revises these rules to implement a statistical sampling model. Unless a greater amount is required to comply with these rules or is required by a Regulated Marijuana Testing Facility to perform all requested testing, each Test Batch of Regulated Marijuana must contain at least the number of Sample Increments prescribed by this Section.

1. A Test Batch of Regulated Marijuana must be packaged and labeled according to Rule 3-1025.

2. The minimum number of Sample Increments required to be collected for each Test Batch from a Harvest Batch of Retail Marijuana or Medical Marijuana shall be determined by Table 4-110.D.2.T.

3. The minimum number of Sample Increments required to be collected for each Test Batch from a Production Batch of Regulated Marijuana Product, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Audited Product and Alternative Use Product shall be determined by Table 4-110.D.2.T.

    a. The Retail Marijuana Products Manufacturer or Medical Marijuana Products Manufacturer shall determine what constitutes a "Serving" and thus how many Servings are contained in a Production Batch of Regulated Marijuana Product, except that no serving of Edible Retail Marijuana Product can contain more than 10mg of active THC

    b. Because all Test Batches of Regulated Marijuana Product, Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana are required to be submitted for testing in their final form, in the event the required number of Sample Increments does not match up within a finished package, the manufacturer must increase the number of Sample Increments collected for the Test Batch such that only finished packages of Regulated Marijuana Products, Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana are submitted for testing. For example, if a Production Batch of 4000 chocolate bars is manufactured, with each bar containing 100 mg THC and 10 servings per bar, the Production Batch would contain 40,000 Sample Increments which would require collection of at least 33 Sample Increments per Test Batch. But in this case, the manufacturer would have to collect 40 Sample Increments for testing (4 complete chocolate bars in final form).

    c. No matter how small the Production Batch of Regulated Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana a minimum of two finished packages in final form must be submitted for a Test Batch.

4. The minimum number of Sample Increments required to be collected for each Test Batch from a Production Batch of Retail Marijuana Concentrate or Medical Marijuana Concentrate shall be determined by Table 4-110.D.2.T.

    a. Because all Test Batches of Retail Marijuana Concentrate and Medical Marijuana Concentrate are required to be submitted for testing in their final form, in the event the required number of Sample Increments does not match up with the number of Sample Increments in a finished package, the manufacturer must increase the number of Sample Increments collected for the Test Batch such that only finished packages of Marijuana Concentrate are submitted for testing. For example, if a Production Batch of 4,000 Vaporizer Delivery Devices is manufactured, with each Vaporizer Delivery Device containing 500 milligrams of Marijuana Concentrate, the Production Batch would contain 2,000 grams of Marijuana Concentrate, which would require collection of at least 15 Sample Increments per Test Batch. But in this case, the manufacturer would have to collect 16 Sample Increments for testing (8 vaporizer Delivery Devices in final form).

    b. No matter how small the Production Batch of Retail Marijuana Concentrate or Medical Marijuana Concentrate, a minimum of two finished packages must be submitted for a Test Batch.

Table 4-110.D.2.T

Minimum Number of Sample Increments Required to be Collected per Test Batch	**Regulated Marijuana (Sample Increment = 0.5 grams)**		
	Total Weight of Harvest Batch (lbs)	Total Weight of Harvest Batch (grams)	**Minimum Weight of Test Batch (grams)**
5	0.000 -0.999	0.0 -453.5	**2.50**
8	1.00 -9.999	453.6 -4535.9	**4.00**
15	10.000 -19.999	4536.0 - 9071.8	**7.50**
22	20.000 -39.999	9071.9 - 18143.6	**11.00**
33	40.000 -99.999	18143.7 - 45359.2	**16.50**
43	100.000 - 199.999	45359.3 - 90718.4	**21.50**
53	200.000 - 499.999	90718.5 -226796.1	**26.50**
80	500 or more	226796.2 or more	**40.00**

Minimum Number of Sample Increments Required to be Collected per Test Batch	**Regulated Marijuana Concentrate (Sample Increment = 0.25 g)**		
	Total Weight of Production Batch (lbs)	Total Weight of Production Batch (grams)	**Minimum Weight of Test Batch (grams)**
5	0.000 -0.999	0.0-453.5	**1.25**
8	1.00 - 1.999	453.6-907.1	**2.00**
15	2.00 - 4.999	907.2-2267.9	**3.75**
22	5.000 - 14.999	2268.0-6803.8	**5.50**
33	15.000 – 49.999	6803.9-22679.6	**8.25**
43	50.000 – 99.999	22679.7-45359.2	**10.75**
53	100.000 – 249.999	45359.3-113398.0	**13.25**
80	250 or more	113398.1 or more	**20.00**

Minimum Number of Sample Increments Required to be	**Regulated Marijuana Products (Sample Increment = 1 Serving)**				
	Number of	**Minimum**	**Minimum**	**Minimum**	**Minimum**

Collected per Test Batch	Servings within Production Batch	**Number of Units for a Test Batch for a 5-Serving Unit***	**Number of Units for a Test Batch for a 10-Serving Unit***	**Number of Units for a Test Batch for a 20-Serving Unit***	**Number of Units for a Test Batch for a 100-Serving Unit***
5	0 - 99	**2**	**2**	**2**	**2**
8	100 - 999	**2**	**2**	**2**	**2**
15	1000 - 4999	**3**	**2**	**2**	**2**
22	5000 - 9999	**5**	**3**	**2**	**2**
33	10000 - 49999	**7**	**4**	**2**	**2**
43	50000 - 99999	**9**	**5**	**3**	**3**
53	100000 - 249999	**11**	**6**	**3**	**3**
80	250000 or more	**16**	**8**	**4**	**4**

*Other serving amounts per unit are acceptable. These are provided as examples.

Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana								
Minimum Number of Sample Increments Required to be Collected per Test Batch	**Number of Pre-Rolls within the Production Batch**	**Minimum Number of Pre-Rolls for a Test Batch when each Pre-Roll is**						
		< or = 0.39 g	**0.40g to 0.50g**	**0.51g to 0.75g**	**0.76g - 1.00g**	**1.01g - 2.00g**	**2.01g - 3.00g**	**3.01g +**
5	0 - 99	5	4	3	2	2	2	2
8	100 - 999	8	5	4	3	2	2	2
15	1000 - 4999	15	10	8	5	4	2	2
22	5000 - 9999	22	14	11	8	6	3	2
33	10000 - 49999	33	21	17	11	9	5	3
43	50000 - 99999	43	27	22	15	11	6	4
53	100000 - 249999	53	34	26	18	14	7	5

80	250000 or more	80	50	40	27	20	10	7

E. Regulated Marijuana Testing Facility Selection. Unless otherwise restricted or prohibited by these rules or ordered by the State Licensing Authority, a Regulated Marijuana Business may select which Medical Marijuana Testing Facility or Retail Marijuana Testing Facility will test a Test Batch made up of Sample Increments collected pursuant to this Rule. However, the Division may elect, at its sole discretion, to assign a Regulated Marijuana Testing Facility to which a Regulated Marijuana Business must submit for testing any Test Batch made up of Sample Increments collected pursuant to this Rule.

F. ~~Industrial~~ Hemp Product Sampling Procedures. Absent sampling and testing standards established by the Colorado Department of Public Health and Environment for the sampling and testing of ~~Industrial~~ Hemp Product, a Person Transferring a~~n Industrial~~ Hemp Product to a Licensee pursuant to the Marijuana Code and these Rules shall comply with the sampling and testing standards set forth in these 4-100 Series Rules – Regulated Marijuana Testing Program and as required by these Rules.

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

Basis and Purpose – 4-120

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(g), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1)(b), 44-10-504(2), 44-10-601(4), 44-10-602(4), 44-10-603(6), 44-10-604(1)(b), and 44-10-604(2), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to protect the public health and safety by establishing the contaminant testing and related Reduced Testing Allowance portion of the Division's Regulated Marijuana sampling and testing program. This Rule 4-120 was previously Rules M and R 1501, 1 CCR 212-1 and 1 CCR 212-2.

4-120 – Regulated Marijuana Testing Program: Contaminant Testing

A. Contaminant Testing Required.

1. A Regulated Marijuana Business shall not Transfer or process Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Regulated Marijuana Concentrate or Regulated Marijuana Product unless Test Batches from each Harvest Batch or Production Batch from which that Regulated Marijuana was derived has been tested by a Regulated Marijuana Testing Facility for contaminants and passed all contaminant tests required by this Rule, except as permitted in Rule 5-205(C), 6-205(C), or the cultivation or production process has achieved a Reduced Testing Allowance under this Rule.

Please Note: *The following are stakeholder proposals from the Quarterly Science and Policy Forum that the MED is continuing to evaluate and seek feedback on.*

B. Reduced Testing Allowance and Ongoing Testing – Contaminant Testing.

1. Regulated Marijuana. A Regulated Marijuana Cultivation Facility's cultivation process may achieve a Reduced Testing Allowance for contaminant testing if every Harvest Batch that it produced during at least a six-week period (minimum 42 days) but no longer than a 12-week period (maximum 84 days) passed all contaminant tests required by Paragraph (C) of this Rule. This must include at least six Test Batches. The period begins from the date of the creation of the first Harvest Batch that passed reduced testing allowance

testing. A Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator can achieve a Reduced Testing Allowance for all contaminants listed in paragraph (C) of this Rule at the same time or separately for each contaminant.

a. Visual Microbial Growth. If a Regulated Marijuana Cultivation Facility is aware that a Harvest Batch contains visual microbial contamination, the Regulated Marijuana Cultivation Facility shall subject the Harvest Batch to microbial contaminant testing pursuant to Rule 4-120(C)(1). If the Test Batch fails testing, then the Harvest Batch shall be subject to the requirements in Rule 4-135(C). The Licensees must also follow Rule 4-120(F)(2).

b. Effective July 1, 2024, to achieve a Reduced Testing Allowance for microbial contaminants, a Regulated Marijuana Cultivation Facility must conduct an internal audit to assess that they are in substantial compliance with the requirements of Rules 3-310, 3-330, 3-336, 4-110, 4-120, 6-210(D), and 6-210(E). This internal audit will be performed and scored per the rubric listed in Rule 4-120(B)(1)(b)(i). A copy of this internal audit shall be retained as business records for one year. Internal Audit Scoring Rubric. The internal audit will be scored as follows:

i. Scoring System: 0% - 100%

ii. Passing Score: 80% - 100%

iii. Non-Conformance Finding Deductions:

A. Minor: -1%

B. Major: -5%

C. Critical: -100%

iv. Definition of Non-Conformances:

A. Minor: A deficiency in the compliance to Rule that reasonably could lead to a risk in product safety.

B. Major: A deficiency in compliance to Rule that carries a highly likely-to-definite risk to product safety.

C. Critical: A clear deficiency in compliance to Rule that could lead to serious injury or death; or if any falsification of records is found.

c. Effective July 1, 2024, Attestation of Substantial Compliance with Rules. To achieve a Reduced Testing Allowance for Microbial Contaminants, an authorized representative of the Regulated Marijuana Cultivation Facility must sign an attestation that they are, to the best of their knowledge, in substantial compliance with Rules 3-330 and 4-120. A copy of this Attestation shall be retained as business records for one year.

2. Regulated Marijuana Concentrate, Regulated Marijuana Product, Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana. A Regulated Marijuana Business's production process may achieve a Reduced Testing Allowance for contaminant testing if for a particular type of Regulated Marijuana Concentrate, Regulated Marijuana Product, or Pre-Rolled

Marijuana or Infused Pre-Rolled Marijuana every Production Batch that it produced during at least a four-week period (minimum 28 days) but no longer than an eight-week period (maximum 56 days) passed all contaminant tests required by Paragraph (C) of this Rule. This must include Test Batches from at least four Production Batches. This period begins from the date of the creation of the first Production Batch that passed reduced testing allowance testing. If a Regulated Marijuana Concentrate or Regulated Marijuana Product is manufactured using a different extraction process or infusion process or using any different Additives or Botanically Derived Compounds, it will be considered a different type of Regulated Marijuana Concentrate or Regulated Marijuana Product and therefore must separately achieve a Reduced Testing Allowance. If Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana is produced using different input materials, such as a different marijuana category (e.g. flower or trim), different wrapper materials, different processes, or different equipment, they must achieve separate Reduced Testing Allowances.

3. Reduced Testing Allowances are Effective for One Year. Once a Regulated Marijuana Business has successfully achieved a Reduced Testing Allowance for each of the contaminants listed in paragraph (C) of this Rule, the Reduced Testing Allowance is effective for one year (365 days inclusive, or 366 days inclusive during a leap year) from the date of the first passing harvest date or production date required to satisfy the Reduced Testing Allowance requirements.

4. Regulated Marijuana Ongoing Contaminant Testing. After successfully achieving a Reduced Testing Allowance, once every 30 days a Regulated Marijuana Business shall subject at least one Harvest Batch to all contaminant testing required by Paragraph (C) of this Rule. If during any 30-day period the Regulated Marijuana Business does not possess a Harvest Batch that is ready for testing, The Regulated Marijuana Business must subject its first Harvest Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Regulated Marijuana. If a Harvest Batch subject to ongoing contaminant testing fails contaminant testing, the Regulated Marijuana Business shall follow the procedure in Paragraph (F)(2) of this Rule. Ongoing contaminant testing pursuant to this Rule 4-120 shall be subject to the requirements in Rule 4-110. *See* Rule 4-110(A) – Collection of Samples.

   a. The Division may reduce the frequency of ongoing contaminant testing required if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.

   b. If the Licensee fails to comply with paragraph (B)(4) of this Rule, the Regulated Marijuana Business is no longer authorized a Reduced Testing Allowance.

5. Regulated Marijuana Concentrate, Regulated Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana Ongoing Contaminant Testing. After successfully achieving a Reduced Testing Allowance, once every 30 days the Regulated Marijuana Business shall subject at least one Production Batch of each particular type of Regulated Marijuana Concentrate, Regulated Marijuana Product, Pre-Rolled Marijuana, or Infused Pre-Rolled Marijuana for which it has achieved a Reduced Testing Allowance to all contaminant testing required by Paragraph (C) of this Rule. If during any 30-day period the Regulated Marijuana Business does not possess a Production Batch that is ready for testing, the Regulated Marijuana Business must subject its first Production Batch that is ready for testing to the required contaminant testing prior to Transfer or processing of the Regulated Marijuana. If a Production Batch submitted for ongoing contaminant testing

fails contaminant testing, the Regulated Marijuana Business shall follow the procedure in Paragraph (F)(2) of this Rule.

a. The Division may reduce the frequency of ongoing contaminant testing required if the Division has reasonable grounds to believe Medical Marijuana Testing Facilities and Retail Marijuana Testing Facilities have reached maximum capacity to perform testing required by this Rule. The Division will provide notification of any reduction to the frequency of ongoing contaminant testing to the Licensee's last electronic mailing address provided to the Division.

b. If the Licensee fails to comply with paragraph (B)(5) of this Rule, the Regulated Marijuana Business is no longer authorized under a Reduced Testing Allowance.

6. Reduced Testing Allowance Certification Fee. Effective January 1, 2024, a Licensee seeking to obtain Reduced Testing Allowance must first pay the fee in Rule 2-205.

a. A Licensee who chooses to pay the Reduced Testing Allowance fee must also submit an attestation form that at a minimum requires the Licensee attest they understand these testing Rules and requirements.

b. Upon the Division's receipt of payment of the fee and submission of the attestation form, a Licensee may exercise the privileges of Reduced Testing Allowance for a 12-month period.

c. If a Licensee is required, under these Rules, to reauthorize the Reduced Testing Allowance within the 12-month period, the Licensee is not required to pay a new fee.

d. Reduced Testing Allowance Certification can be renewed annually.

C. Required Contaminant Tests.

1. Microbial Contaminant Testing. Harvest Batches of Regulated Marijuana, flower, shake, and trim, re-testing of Regulated Marijuana flower, shake, and/or trim that has undergone Decontamination, Production Batches of Physical Separation-, Heat/Pressure-, or Food-Based Medical Marijuana Concentrate, Production Batches of Physical Separation-, Heat/Pressure-, or Food-Based Retail Marijuana Concentrate, Solvent-Based Medical Marijuana Concentrate produced through Remediation, Solvent-Based Retail Marijuana Concentrate produced through Remediation, Regulated Marijuana Product, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, ~~Industrial~~ Hemp Products, Pressurized Metered Dose Inhalers, Vaporizer Delivery Devices, and Audited Product must be tested for microbial contamination by a Regulated Marijuana Testing Facility at the frequency established by Paragraphs (A) and (B) of this Rule. The microbial contamination test must include, but need not be limited to, testing to determine the presence of and/or amounts present of microbial contaminants listed in Rule 4-115(D)(1): Shiga-toxin producing Escherichia coli (STEC)*- Bacteria, *Aspergillus (A. fumigatus, A. flavus, A. niger, A. terreus),* Salmonella species* – Bacteria, Total Yeast and Mold, Total aerobic microbial count, *Staphylococcus Aureus, Pseudomonas aeruginosa, Bile tolerant gram negative bacteria and Candida albicans*.

a. Effective Date for Required *Aspergillus* Testing. Requirements for *Aspergillus* testing pursuant to this rule shall take effect on July 1, 2022.

1.5 Water Activity Testing. Harvest Batches of Regulated Marijuana, flower, shake, and trim (other than wet whole plant), re-testing of Regulated Marijuana flower, shake, and/or trim

that has undergone Decontamination, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana at the frequency established by Paragraphs (A) and (B) of this Rule.

2. Residual Solvent Contaminant Testing. Production Batches of Solvent-Based Medical Marijuana Concentrate, Solvent-Based Retail Marijuana Concentrate, and Audited Product that contains any Solvent-Based Medical Marijuana Concentrate or Solvent-Based Retail Marijuana Concentrate produced by a Regulated Marijuana Products Manufacturer must be tested by a Regulated Marijuana Testing Facility for residual solvent contamination at the frequency established by Paragraphs (A) and (B) of this Rule. The residual solvent contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of acetone, butane, ethanol, heptanes, isopropyl alcohol, propane, benzene*, toluene*, pentane, hexane*, methanol*, ethyl acetate, and total xylenes* (m, p, o – xylenes).

   * Note: These solvents are not approved for use. Testing is required for these solvents due to their possible presence in the solvents approved for use per Rule 5-315 and 6-315.

3. Mycotoxin Contaminant Testing. As part of Remediation, each Production Batch of Solvent-Based Medical Marijuana Concentrate produced by a Medical Marijuana Products Manufacturer or Solvent-Based Retail Marijuana Concentrate produced by a Regulated Marijuana Products Manufacturer from Regulated Marijuana that failed microbial contaminant testing produced must be tested by a Regulated Marijuana Testing Facility for mycotoxin contamination. Each failed Harvest Batch of Regulated Marijuana flower, shake, and/or trim and each failed Production Batch of Pre-Rolled Marijuana or Infused Pre-Rolled Marijuana that has undergone Decontamination must be tested by a Regulated Marijuana Testing Facility for mycotoxin contamination. Each Production Batch of Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contamination must be tested for mycotoxin contamination. The mycotoxin contaminant test must include, but need not be limited to, testing to determine the presence of, and amounts present of, aflatoxins (B1, B2, G1, and G2) and ochratoxin A. This is in addition to all other contaminant testing required by this Paragraph (C). This contaminant test cannot be exempt from testing by a Reduced Testing Allowance in accordance with subparagraph (B)(2) of this Rule, except Regulated Marijuana Concentrate produced from wet whole plant that was not tested for microbial contamination pursuant to Rule 4-121.

4. ~~p~~Pesticide Contaminant Testing. Harvest Batches of Regulated Marijuana, Production Batches of Regulated Marijuana Concentrate, Production Batches of Pre-Rolled Marijuana, and Production Batches of Infused Pre-Rolled Marijuana must be tested for Pesticide contamination by a Regulated Marijuana Testing Facility at the frequency established by this Rule 4-120(A) and (B). The Pesticide contamination test must include, but need not be limited to, testing to determine the presence of, and amounts present of, the Pesticides listed in Rule 4-115(D~~E~~)(5).

   a. Effective Date for Required Pesticide Contaminant Testing for Production Batches of Regulated Marijuana Concentrate: Requirements for Pesticide contaminant testing for Production Batches of Regulated Marijuana Concentrate pursuant to this rule shall take effect on July 1, 2021.

5. Elemental Impurities Testing.

   a. Each Harvest Batch and Production Batch of Regulated Marijuana must be tested for elemental impurities by a Regulated Marijuana Testing Facility at the frequency established in paragraphs (A) and (B) of this Rule. The elemental

impurities test must include, but need not be limited to, testing to determine the presence of, and amounts present of, arsenic, cadmium, lead, and mercury.

b. Emissions Testing. This subsection (C)(5)(b) is effective January 1, 2022. Each Harvest Batch and Production Batch of Regulated Marijuana Concentrate in a Vaporized Delivery Device must be tested for elemental impurities via emissions testing by a Regulated Marijuana Testing Facility at the frequency established in subparagraphs (A) and (B) of this Rule. The elemental impurities test must include, but need not be limited to, testing to determine the presence and amounts of arsenic, cadmium, lead, and mercury.

D. Additional Required Tests. The Division may require additional tests to be conducted on a Harvest Batch or Production Batch prior to a Regulated Marijuana Cultivation Facility or Regulated Marijuana Products Manufacturer Transferring or processing any Regulated Marijuana from that Harvest Batch or Production into a Regulated Marijuana Concentrate or Regulated Marijuana Product. Additional tests may include, but need not be limited to, screening for Pesticide, chemical contaminants, biological contaminants, or other types of microbials, molds, elemental impurities, or residual solvents.

E. Exemptions.

1. Medical Marijuana Concentrate.

a. A Medical Marijuana Products Manufacturer who combines multiple Production Batches of Solvent-Based Medical Marijuana Concentrate into a Production Batch of Solvent-Based Medical Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule only if all original Production Batches passed residual solvent testing. This does not apply if a solvent, Additive, or any other Ingredient was introduced during the combination of the Production Batches.

b. A Production Batch of Medical Marijuana Concentrate shall be considered exempt from contaminant testing requirements pursuant to this Rule if the Medical Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture Medical Marijuana Product, except that a Solvent-Based Medical Marijuana Concentrate must still be submitted for residual solvent contaminant testing and Medical Marijuana Concentrate must still be submitted for pesticide contaminant testing. The manufactured Medical Marijuana Product shall be subject to mandatory testing under this Rule.

2. Retail Marijuana Concentrate.

a. A Retail Marijuana Products Manufacturer or Accelerator Manufacturer who combines multiple Production Batches of Solvent-Based Retail Marijuana Concentrate into a Production Batch of Solvent-Based Retail Marijuana Concentrate shall be considered exempt from residual solvent testing pursuant to this Rule only if all original Production Batches passed residual solvent testing. This does not apply if a solvent, Additive or any other Ingredient was introduced during the combination of the Production Batches.

b. A Production Batch of Retail Marijuana Concentrate shall be considered exempt from contaminant testing requirements pursuant to this Rule if the Retail Marijuana Products Manufacturer that produced it does not Transfer any portion of the Production Batch and uses the entire Production Batch to manufacture

Retail Marijuana Product, except that a Solvent-Based Retail Marijuana Concentrate must still be submitted for residual solvent contaminant testing and Retail Marijuana Concentrate must still be submitted for pesticide contaminant testing. The manufactured Retail Marijuana Product shall be subject to testing under this Rule.

3. Regulated Marijuana Product. A Regulated Marijuana Business that produces Regulated Marijuana Products with intended use for oral consumption or skin and body products, is exempt from aspergillus testing as required by these 4-100 Series Rules.

F. Events Requiring Re-Authorization for a Reduced Testing Allowance - Contaminants.

1. Material Change. If a Licensee makes a Material Change to its cultivation or production process or its standard operating procedures , then it must have the first five Harvest Batches or Production Batches produced using the new procedures tested for all of the contaminants required by Paragraph (C) of this Rule regardless of whether its process has previously achieved a Reduced Testing Allowance regarding contaminants. If any of those tests fail, then the Regulated Marijuana Business's process must achieve a new Reduced Testing Allowance.

a. Pesticide or other Agricultural Substances. It is a Material Change if a Regulated Marijuana Cultivation Facility begins using a new or different Pesticide or other agricultural substances (e.g. nutrients, fertilizers) during its cultivation process.

b. Solvents. It is a Material Change if a Regulated Marijuana Products Manufacturer begins using a new or different solvent or combination of solvents or changes any parameters for equipment related to the solvent purging process, including but not limited to, time, temperature, or pressure.

c. Cultivation. It is a Material Change if a Regulated Marijuana Cultivation Facility begins using a new or different method for any material part of the cultivation process, including, but not limited to, changing from one growing medium to another.

d. Environmental Conditions. It is a Material Change if a Regulated Marijuana Cultivation Facility changes parameters associated with environmental conditions, including temperature, humidity, or lighting.

e. Cleaning and Sanitation. It is a Material Change if a Regulated Marijuana Cultivation Facility makes changes to cleaning or sanitation processes.

f. Inputs and Contact Surfaces. It is a Material Change if a Regulated Marijuana Cultivation Facility changes materials that have direct contact with product components, including but not limited to, ingredients, additives, or hardware such as Vaporizer Delivery Devices.

g. Testing Required Prior to Transfer or Processing. When a Harvest Batch or Production Batch is required to be submitted for testing pursuant to this Rule, the Licensee that produced it may not Transfer or process Regulated Marijuana, Pre-Rolled Marijuana, Infused Pre-Rolled Marijuana, Regulated Marijuana Concentrate or Regulated Marijuana Product unless the Harvest Batch or Production Batch passes all required testing.

2. Failed Contaminant Testing and Reduced Testing Allowance. Failed contaminant testing may constitute a violation of these rules.

a. If a Test Batch is required to be tested by these Rules or required to be tested by the Division pursuant to Rule 4-120(A) and fails contaminant testing, the Licensee shall follow the procedures in Rule 4-135~~(B)~~ for any Inventory Tracking System package, Harvest Batch, or Production Batch from which the failed Sample was taken.

b. The Licensee shall also submit Test Batches from three new Harvest Batches or Production Batches of the Regulated Marijuana for contaminant testing by a Regulated Marijuana Testing Facility within no more than 30 days. If any one of the three submitted Test Batches fails contaminant testing, the Licensee shall achieve a new Reduced Testing Allowance for contaminants.

3. Failed Internal Audit or a Failed MED Inspection for Compliance with Rule 4-120(B)(1)(b). If a Regulated Marijuana Cultivation Facility fails an internal audit or a Division inspection evaluating compliance with the requirements referenced in Rule 4-120(B)(1)(b), then the Licensee must:

a. Correct the identified deficiencies. These activities to correct such deficiencies must follow Corrective Action Preventive Action procedures listed in Rule 6-120(D).

b. Complete a new internal audit to the Rules listed in Rule 4-120(B)(1)(b) and scored according to Rule 4-120(B)(1)(b).

c. Complete a new attestation of substantial compliance to the Rules referenced in Rule 4-120(B)(1)(b) signed by an authorized representative of the Regulated Marijuana Cultivation Facility.

d. Follow Re-Authorization procedures listed in paragraph (F)(2) of this Rule after paragraphs (i) – (iii) have been addressed.

In addition, regardless of completion of the steps above, the Regulated Marijuana Cultivation Facility may be required to submit additional Sample(s) or Test Batches pursuant to Rule 4-105 to address concerns from the failed internal audit or Division inspection.

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

Part 5 – Medical Marijuana Business License Types

5-100 Series – Medical Marijuana Stores

Basis and Purpose – 5-105

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(d)(I)-(VI), 44-10-313(7), 44-10-313(4), 44-10-313(14), 44-10-401(2)(a)(I), 44-10-501, and 44-10-505, C.R.S. The purpose of this rule is to establish a Medical Marijuana Store's license privileges. This Rule 5-105 was previously Rule M 401, 1 CCR 212-1.

Please Note: *The following proposed revisions seek to align Medical Marijuana Store license privileges with revised Retail Marijuana Store and Accelerator Store license privileges as amended in HB 23-1279.*

5-105 – Medical Marijuana Store: License Privileges

A. Licensed Premises. To the extent authorized by Rule 3-215 – Medical Marijuana Business and Retail Marijuana Business – Shared Licensed Premises and Operational Separation, a Medical Marijuana Store may share a Licensed Premises with a commonly-owned Retail Marijuana Store. However, a separate license is required for each specific business or business entity, regardless of geographical location.

B. Authorized Sources of Medical Marijuana. A Medical Marijuana Store may only Transfer Medical Marijuana that was obtained from a Medical Marijuana Business.

C. Authorized Transfers. A Medical Marijuana Store may only Transfer Medical Marijuana to a patient, a primary caregiver, another Medical Marijuana Store, a Medical Marijuana Cultivation Facility, a Medical Marijuana Products Manufacturer, or a Medical Marijuana Testing Facility.

D. Samples Provided for Testing. A Medical Marijuana Store may provide Samples of its products to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Store shall maintain the testing results as part of its business books and records. *See* Rule 3-905 – Business Records Required.

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

F. Authorized Marijuana Transport. A Medical Marijuana Store is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana so long as the place where transportation orders are taken and delivered is a licensed Medical Marijuana Business. Nothing in this Rule prevents a Medical Marijuana Store from transporting its own Medical Marijuana.

G. Performance-Based Incentives. A Medical Marijuana Store may compensate its employees using performance-based incentives, including sales-based performance-based incentives.

H. Authorized Transfers of ~~Industrial~~ Hemp Products. ~~This rule is effective July 1, 2020.~~ A Medical Marijuana Store may Transfer ~~Industrial~~ Hemp Product to a patient only after it has verified:

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

2. That the Person Transferring the ~~Industrial~~ Hemp Product to the Medical Marijuana Store is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

I. Medical Marijuana Store Delivery Permit. A Medical Marijuana Store with a valid delivery permit may accept delivery orders and deliver Medical Marijuana to a patient who is 21 years of age or older, or the patient's parent or guardian who is also the patient's primary caregiver pursuant to Rule 3-615. A Medical Marijuana Store that does not possess a valid delivery permit cannot deliver Medical Marijuana to a patient, parent, or guardian.

J. Automated Dispensing Machines. A Medical Marijuana Store may use an automated machine in the Restricted Access Area of its Licensed Premises to dispense Regulated Marijuana to patients without interaction with an Owner Licensee or Employee Licensee if the automated machine is reasonably monitored and complies with all requirements of these rules including but not limited to:

1. Health and safety standards,

2. Testing,

3. Packaging and labeling requirements,

4. Inventory tracking,

5. Identification requirements, and

6. Transfer limits to patients.

K. Walk-up or Drive-Up Window. A Medical Marijuana Store may serve patients through a walk-up window or drive-up window pursuant to the requirements of this rule.

1. Modification of Premises Required. Before accepting orders for sales of Medical Marijuana to a patient through either a walk-up window or a drive-up window, a Medical Marijuana Store shall apply for, and obtain approval of, an application for a modification of its Licensed Premises for the addition of a walk-up window or a drive-up window.

2. The area immediately outside the walk-up window or drive-up window must be under the Licensee's possession and control and cannot include any public property such as public streets, public sidewalks, or public parking lots.

3. Order and Identification Requirements.

   a. Prior to accepting an order or Transferring Medical Marijuana to a patient, the Employee Licensee or Owner Licensee must physically view and inspect the patient's identification and the patient's registry identification card.

   b. The Medical Marijuana Store may accept internet or telephone orders or may accept orders from the patient at the walk-up or drive-up window.

   c. All orders received through a walk-up window or drive-up window must be placed by the patient from a menu. The Medical Marijuana Store may not display Medical Marijuana at the walk-up window or drive-up window.

4. Payment Requirements. Cash, credit, debit, cashless ATM, or other payment methods are permitted for payment for Medical Marijuana at the walk-up window or drive-up window.

5. Video Surveillance Requirements. For every Transfer of Regulated Marijuana through either a walk-up window or drive-up window, the Medical Marijuana Store's video surveillance must enable the recording of the patient's identity (and patient's vehicle in the event of drive-up window), and must enable the recording of the Licensee verifying the patient's identification, registry identification card, and completion of the transaction through the Transfer of Regulated Marijuana.

6. Packaging and Labeling Requirements. A Medical Marijuana Store utilizing a walk-up or drive-up window must ensure that all Medical Marijuana is packaged and labeled in accordance with Rules 3-1010 and Rule 3-1015 prior to Transfer to the patient.

7. Local Restrictions. Transfers of Regulated Marijuana using a walk-up window or drive-up window are subject to requirements and restrictions imposed by the relevant Local Licensing Authority.

L. Sales over the Internet. A Medical Marijuana Store may accept orders and payment for Medical Marijuana over the internet.

1. Online Order Requirements.

a. Online orders must include the customer's name and date of birth.

b. Prior to accepting the order, the store must provide and the customer must acknowledge receipt of:

i. A digital copy of the pregnancy warning required in Rule 5-120; and

ii. If accepting an order for Medical Marijuana Concentrate, the Medical Marijuana Store must also provide the educational resource required in Rule 5-115(C.5).

c. Licensees must maintain standard operating procedures documenting their compliance with the requirements of this subparagraph (L).

2. Transfer of Medical Marijuana to the Patient.

a. The patient or primary caregiver must be physically present on the Licensed Premises to take possession of Medical Marijuana.

b. The Medical Marijuana Store must verify the patient's or primary caregiver's physical identification matches the name and date of birth the patient or primary caregiver provided at the time of the order.

3. Delivery. A Medical Marijuana Store that holds a valid delivery permit may make sales of Medical Marijuana over the internet in accordance with Rule 3-615.

4. Approved Sources of Payment. Medical Marijuana store may accept payment using any legal method of payment, gift card pre-payments, or pre-payment accounts established with a Medical Marijuana Store except that any payment with an Electronic Benefits Transfer Services Card is not permitted.

a. A Local Licensing Authority or Local Jurisdiction may further restrict legal methods of payment not expressly permitted by section 44-10-203(2)(dd)(XV), C.R.S.

5-200 Series – Medical Marijuana Cultivation Facilities~~y: License Privileges~~

Please Note: *The following proposed revisions seek to implement SB 23-271 statutory revisions in section 44-10-502.*

Basis and Purpose – 5-205

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-401(2)(a)(II), 44-10-313, 44-10-502, and 44-10-503, C.R.S. The purpose of this rule is to establish a Medical Marijuana Cultivation Facility's license privileges in addition to the privileges outlined in these rules. This Rule 5-205 was previously Rule M 501, 1 CCR 212-1.

5-205 – Medical Marijuana Cultivation Facility: License Privileges

A. Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Business – Shared Licensed Premises and Operational Separation, a Medical Marijuana Cultivation Facility may share a Licensed Premises with a commonly owned Retail Marijuana Cultivation Facility. However, a separate license is required for each specific business entity regardless of geographical location. In addition, a Medical Marijuana Cultivation Facility may share and operate at the same Licensed Premises as a Marijuana Research and Development Facility so long as:

1. Each business or business entity holds a separate license;

2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;

3. Both the Marijuana Research and Development Facility and the Medical Marijuana Cultivation Facility comply with all terms and conditions of the R&D Co-Location Permit; and

4. Both the Marijuana Research and Development Facility and the Medical Marijuana Cultivation Facility comply with all applicable rules. *See* 5-700 Series Rules.

B. Cultivation of Medical Marijuana and Production of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Medical Marijuana Concentrate Authorized. A Medical Marijuana Cultivation Facility may propagate, cultivate, harvest, prepare, cure, package, store, and label Medical Marijuana and Physical Separation-Based Medical Marijuana Concentrate. A Medical Marijuana Cultivation Facility may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Medical Marijuana Concentrate.

C. Authorized Transfers. A Medical Marijuana Cultivation Facility may Transfer Medical Marijuana and Physical Separation-Based Medical Marijuana Concentrate to another Medical Marijuana Cultivation Facility, a Medical Marijuana Store, a Medical Marijuana Products Manufacturer, a Medical Marijuana Testing Facility, a Marijuana Research and Development Facility, or a Pesticide Manufacturer.

1. A Medical Marijuana Cultivation Facility shall not Transfer Flowering plants. A Medical Marijuana Cultivation Facility may only Transfer Vegetative plants as authorized pursuant to Rule 3-605.

2. A Medical Marijuana Cultivation Facility may Transfer Sampling Units of Medical Marijuana or Medical Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-502(5), C.R.S., and Rule 5-230.

3. A Medical Marijuana Cultivation Facility may Transfer Medical Marijuana or Medical Marijuana Concentrate to another Medical Marijuana Cultivation Facility prior to testing required by these rules only if such Transfer is in accordance with one of the two options below.

   a. The Medical Marijuana Cultivation Facility may Transfer Medical Marijuana or Medical Marijuana Concentrate to another Medical Marijuana Cultivation Facility prior to testing if such Transfer is to perform a Microbial Control Step ~~for the purpose of Decontamination~~ and only after all other steps outlined in the Medical Marijuana Cultivation Facility's standard operating procedures have been completed, including but not limited to drying, curing, and trimming; or

   b. The Medical Marijuana Cultivation Facility may Transfer Medical Marijuana or Medical Marijuana Concentrate to another Medical Marijuana Cultivation Facility prior to testing, drying, curing, trimming, or completion of any other steps in the

Medical Marijuana Cultivation Facility's standard operating procedures, subject to the following additional requirements:

i. The Medical Marijuana Cultivation Facility receiving the Transfer is identified as a centralized processing hub in the Inventory Tracking System and must have identical Controlling Beneficial Owner(s) with the originating Medical Marijuana Cultivation Facility;

ii. An originating Medical Marijuana Cultivation Facility may only Transfer Medical Marijuana to one receiving Medical Marijuana Cultivation Facility that will be serving as a centralized processing hub.

iii. The Medical Marijuana or Medical Marijuana Concentrate is weighed prior to leaving the originating Medical Marijuana Cultivation Facility and immediately upon receipt at the receiving Medical Marijuana Cultivation Facility and in accordance with Rule 3-605;

iv. The Transfer, weighing and entry into the Inventory Tracking System are all completed within 24 hours from initiating the Transfer;

v. The receiving Medical Marijuana Cultivation Facility is responsible for compliance with all testing requirements regardless of any testing performed prior to Transfer. If the receiving Medical Marijuana Cultivation Facility is pursuing a Reduced Testing Allowance, a Reduced Testing Allowance must be achieved separately for Medical Marijuana received from each originating Medical Marijuana Cultivation Facility. A Medical Marijuana Cultivation Facility that has achieved a Reduced Testing Allowance must maintain and produce complete testing records that can verify that facility's compliance with testing and Reduced Testing Allowance requirements; and

vi. The standard operating procedures for the originating Medical Marijuana Cultivation Facility and receiving Medical Marijuana Cultivation Facility clearly reflect the steps taken by each facility to Transfer, transport, receive, process, and test Harvest Batches.

4. A Medical Marijuana Cultivation Facility may Transfer Medical Marijuana to a Retail Marijuana Cultivation Facility or Accelerator Cultivator in accordance with Rules 5-235, 6-230, and 6-730.

5. A Medical Marijuana Cultivation Facility may Transfer Immature Plants, Medical Marijuana seeds, and Genetic Material to a Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator. Transfers made under this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.

D. Packaging Processed Medical Marijuana. Processed Medical Marijuana plants shall be packaged in units of ten pounds or less and labeled pursuant to the 3-1000 Series Rules – Labeling, Packaging, and Product Safety, and securely sealed in a tamper-evident manner.

E. Authorized Marijuana Transport. A Medical Marijuana Cultivation Facility is authorized to utilize a licensed Medical Marijuana Transporter for transportation of its Medical Marijuana so long as the place where transportation orders are taken is a Medical Marijuana Business and the transportation order is delivered to a licensed Medical Marijuana Business or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana Cultivation Facility from transporting its own Medical Marijuana.

F. Performance-Based Incentives. A Medical Marijuana Cultivation Facility may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Medical Marijuana Cultivation Facility may not compensate a Sampling Manager using Sampling Units. *See* Rule 5-230 – Sampling Unit Protocols.

G. Authorized Sources of Medical Marijuana, Seeds, ~~and~~ Immature Plants, and Genetic Material.

1. A Medical Marijuana Cultivation Facility ~~shall only~~ may obtain Medical Marijuana seeds or Immature Plants from its own Medical Marijuana, properly Transferred Retail Marijuana cultivated at a Retail Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or properly Transferred from another Medical Marijuana Business pursuant to the inventory tracking requirements in the Rule 3-800 Series. A Medical Marijuana Cultivation Facility may also receive Transfers of Retail Marijuana from a Retail Marijuana Cultivation Facility or Accelerator Cultivator in compliance with Rules 5-235, 6-230, and 6-730. A Medical Marijuana Cultivation facility may not bring seeds, Immature Plants, or other marijuana that is not Regulated Marijuana onto the Licensed Premises at any time.

2. A Medical Marijuana Cultivation Facility may obtain Regulated Marijuana seeds, Immature Plants, and Genetic Material:

a. From another Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility;

b. A Retail Marijuana Testing Facility;

c. A marijuana cultivation or testing facility licensed or otherwise approved pursuant to a permit or registration issued by a government agency to operate in another state or territory of the United States;

d. An individual licensed as an Employee Licensee in Colorado, or holding a permit, registration, or license to work in cannabis in another state or territory of the United States; or

e. Pursuant to any federal legal authority allowing interstate commerce of Regulated Marijuana.

3. Transfers made under subparagraph (G)(2) of this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.

H. Centralized Distribution Permit. A Medical Marijuana Cultivation Facility may apply to the State Licensing Authority for a Centralized Distribution Permit for authorization to temporarily store Medical Marijuana Concentrate and Medical Marijuana Product received from a Medical Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Medical Marijuana Stores.

1. For purposes of a Centralized Distribution Permit only, the term “commonly owned” means at least one natural person who is disclosed to the Division who has a minimum of five percent ownership in both the Medical Marijuana Cultivation Facility possessing a Centralized Distribution Permit and the Medical Marijuana Store to which the Medical Marijuana Concentrate and Medical Marijuana Product will be Transferred.

2. To apply for a Centralized Distribution Permit, a Medical Marijuana Cultivation Facility may submit an addendum to its new or renewal application or a separate addendum prior to a renewal application on forms prepared by the Division to request a Centralized

Distribution Permit. The Medical Marijuana Cultivation Facility shall send a copy of its Centralized Distribution Permit addendum to the Local Licensing Authority in the jurisdiction in which the Centralized Distribution Permit is proposed at the same time it submits the addendum to the State Licensing Authority.

3. A Medical Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit and has obtained all required approvals from the local licensing jurisdiction where it is located, if any, may accept Transfers of Medical Marijuana Concentrate and Medical Marijuana Product from a Medical Marijuana Products Manufacturer for the sole purpose of temporary storage and Transfer to commonly owned Medical Marijuana Stores.

   a. A Medical Marijuana Cultivation Facility may only accept Medical Marijuana Concentrate and Medical Marijuana Product that is packaged and labeled for sale to a patient pursuant to the 3-1000 Series Rules.

   b. A Medical Marijuana Cultivation Facility storing Medical Marijuana Concentrate and Medical Marijuana Product pursuant to a Centralized Distribution Permit shall not store such Medical Marijuana Concentrate or Medical Marijuana Product on the Medical Marijuana Cultivation Facility's Licensed Premises for more than 90 days from the date of receipt.

   c. All Transfers of Medical Marijuana Concentrate and Medical Marijuana Product by a Medical Marijuana Cultivation Facility shall be without consideration.

4. All security and surveillance requirements that apply to a Medical Marijuana Cultivation Facility apply to activities conducted pursuant to the privileges of a Centralized Distribution Permit.

I. Transition Permit. A Medical Marijuana Cultivation Facility may only operate at two geographical locations pursuant to Rule 2-255(D).

5-300 Series – Medical Marijuana Products Manufacturer~~s~~ Facilities

Basis and Purpose – 5-305

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(k), 44-10-203(2)(d)(I)-(VI), 44-10-313(14), and 44-10-503, C.R.S. The purpose of this rule is to establish a Medical Marijuana Products Manufacturer's license privileges. This Rule 5-305 was previously Rule M 601, 1 CCR 212-1.

5-305 – Medical Marijuana Products Manufacturer: License Privileges

A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Products Manufacturer may share and operate at the same Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location. In addition, a Medical Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises as a Marijuana Research and Development Facility so long as:

1. Each business or business entity holds a separate license;

2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;

3. Both the Marijuana Research and Development Facility and the Medical Marijuana Products Manufacturer comply with all terms and conditions of the R&D Co-Location Permit; and

4. Both the Marijuana Research and Development Facility and the Medical Marijuana Products Manufacturer comply with all applicable rules. *See* 5-700 Series Rules.

B. Authorized Transfers. A Medical Marijuana Products Manufacturer is authorized to Transfer Medical Marijuana as follows:

1. Medical Marijuana Concentrate and Medical Marijuana Product.

a. A Medical Marijuana Products Manufacturer may Transfer its own Medical Marijuana Product and Medical Marijuana Concentrate to Medical Marijuana Stores, other Medical Marijuana Products Manufacturers, Medical Marijuana Testing Facility, Marijuana Research and Development Facility and Pesticide Manufactures.

b. A Medical Marijuana Products Manufacturer may Transfer Medical Marijuana Product and Medical Marijuana Concentrate to a Medical Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit.

i. Prior to any Transfer pursuant to this Rule 5-305(B)(1)(b), a Medical Marijuana Products Manufacturer shall verify Medical Marijuana Cultivation Facility possesses a valid Centralized Distribution Permit. *See* Rule 5-205 – Medical Marijuana Cultivation Facility: License Privileges.

ii. For any Transfer pursuant to this Rule 5-305(B)(1)(b), A Medical Marijuana Products Manufacturer shall only Transfer Medical Marijuana Product and Medical Marijuana Concentrate that is packaged and labeled for Transfer to a patient. *See* 3-1000 Series Rules.

2. Medical Marijuana.

a. A Medical Marijuana Products Manufacturer may Transfer Medical Marijuana to another Medical Marijuana Products Manufacturer, a Medical Marijuana Store, a Marijuana Research and Development Facility or a Pesticide Manufacturer.

3. Sampling Units. A Medical Marijuana Products Manufacturer may also Transfer Sampling Units of its own Medical Marijuana Products and Medical Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-503(10), C.R.S., and Rule 5-320.

C. Manufacture of Medical Marijuana Concentrate, Medical Marijuana Product, Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana Authorized. A Medical Marijuana Products Manufacturer may manufacture, prepare, package, and label Medical Marijuana Concentrate Medical Marijuana Product comprised of Medical Marijuana and other Ingredients intended for use or consumption, such as Edible Medical Marijuana Products, ointments, or tinctures. A Medical Marijuana Products Manufacturer may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana.

1. ~~Industrial~~ Hemp Product Authorized. ~~This subparagraph (C)(1) is effective July 1, 2020.~~ A Medical Marijuana Products Manufacturer that uses ~~Industrial~~ Hemp Product as an Ingredient in the manufacture and preparation of Medical Marijuana Product must comply with this subparagraph (C)(1) of this Rule.

a. Prior to accepting and taking possession of any ~~Industrial~~ Hemp Product for use as an Ingredient in a Medical Marijuana Product the Medical Marijuana Products Manufacturer shall verify the following:

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

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

D. Location Prohibited. A Medical Marijuana Products Manufacturer may not manufacture, prepare, package, store, or label Medical Marijuana Product in a location that is operating as a retail food establishment.

E. Samples Provided for Testing.

1. A Medical Marijuana Products Manufacturer may provide samples of its Medical Marijuana Concentrate or Medical Marijuana Product to a Medical Marijuana Testing Facility for testing and research purposes. The Medical Marijuana Products Manufacturer shall maintain the testing results as part of its business books and records. *See* Rule 3-905 – Business Records Required.

F. Authorized Marijuana Transport. A Medical Marijuana Products Manufacturer is authorized to utilize a Medical Marijuana Transporter for transportation of its Medical Marijuana Product or Medical Marijuana Concentrate so long as the place where transportation orders are taken is a licensed Medical Marijuana Business and the transportation order is delivered to a Medical Marijuana Business, or Pesticide Manufacturer. Nothing in this Rule prevents a Medical Marijuana Products Manufacturer from transporting its own Medical Marijuana or Medical Marijuana Concentrate.

G. Performance-Based Incentives. A Medical Marijuana Products Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Medical Marijuana Products Manufacturer may not compensate a Sampling Manager using Sampling Units. *See* Rule 5-320 – Sampling Unit Protocols.

H. Receipt of Retail Marijuana Concentrate. A Medical Marijuana Products Manufacturer may receive a Transfer of Retail Marijuana Concentrate in compliance with Rules 5-335, 6-335, and 6-730.

5-400 Series – Medical Marijuana Testing Facilities

Basis and Purpose – 5-405

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-313(14), 44-10-401(2)(a)(IV), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1), and 44-10-504(2), C.R.S. The purpose of this rule is to establish the license privileges of a Medical Marijuana Testing Facility. This Rule 5-405 was previously Rule M 701.5, 1 CCR 212-1.

5-405 - Medical Marijuana Testing Facilities: License Privileges

A. Licensed Premises. A separate License is required for each specific Medical Marijuana Testing Facility and only those privileges granted by the Marijuana Code and any rules promulgated pursuant to it may be exercised on the Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Medical Marijuana Testing Facility may share and operate at the same Licensed Premises with a Retail Marijuana Testing Facility with identical ownership.

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

C. Testing of ~~Industrial~~ Hemp Product Authorized.

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

2. Before a Medical Marijuana Testing Facility accepts a sample of ~~Industrial~~ Hemp Product, the Medical Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

3. A Medical Marijuana Testing Facility is responsible for entering and tracking samples of ~~Industrial~~ Hemp Product in the inventory tracking system pursuant to the 3-800 Series Rules.

4. A Medical Marijuana Testing Facility shall be permitted to test ~~Industrial~~ Hemp Product only in the category(ies) that the Medical Marijuana Testing Facility is certified to perform testing in pursuant to Rule 5-415 – Medical Marijuana Testing Facilities: Certification Requirements.

5. A Medical Marijuana Testing Facility may provide the results of any testing performed on ~~Industrial~~ Hemp Product to the Person submitting the sample of ~~Industrial~~ Hemp Product.

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

D. Testing Medical Marijuana for Patients in Research Project. A Medical Marijuana Testing Facility is authorized to accept Samples of Medical Marijuana from an individual person for testing under only the following conditions:

1. The individual person is:

a. A currently registered patient pursuant to section 25-1.5-106, C.R.S.; and

b. A participant in an approved clinical or observational study conducted by a Marijuana Research and Development Facility.

2. The Medical Marijuana Testing Facility shall require the patient to produce a valid patient registry card and a current and valid photo identification. *See* Rule 3-405(A) – Acceptable Forms of Identification.

3. The Medical Marijuana Testing Facility shall require the patient to produce verification on a form approved by the Division from the Marijuana Research and Development Facility that the patient is a participant in an approved clinical or observational Research Project conducted by the Marijuana Research and Development Facility and that the testing will be in furtherance of the approved Research Project.

4. A primary caregiver may transport Medical Marijuana on behalf of a patient to the Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility shall require the following documentation before accepting Medical Marijuana from a primary caregiver:

   a. A copy of the patient registry card and valid photo identification for the patient;

   b. A copy of the caregiver's registration with the State Department of Health pursuant to section 25-1.5-106, C.R.S. and a current and valid photo identification, *see* Rule 3-405 – Acceptable Forms of Identification; and

   c. A copy of the Marijuana Research and Development Facility's verification on a form approved by the Division that the patient is participating in an approved clinical or observational Research Project being conducted by the Marijuana Research and Development Facility and that the testing will be in furtherance of the approved Research Project.

5. The Medical Marijuana Testing Facility shall report all results of testing performed pursuant to this Paragraph (C.5) to the Marijuana Research and Development Facility identified in the verification form submitted pursuant to Paragraph (D)(3) or (4)(c), or as otherwise directed by the approved Research Project being conducted by the Marijuana Research and Development Facility. Testing result reporting shall conform with the requirements under these Rules.

E. Product Development Authorized. A Medical Marijuana Testing Facility may develop Medical Marijuana Product, but is not authorized to engage in the manufacturing privileges described in section 44-10-503, C.R.S. and Rule 5-305 – Medical Marijuana Products Manufacturer: License Privileges.

F. Transferring Samples to Another Licensed and Certified Medical Marijuana Testing Facility. A Medical Marijuana Testing Facility may Transfer Samples to another Medical Marijuana Testing Facility for testing. All laboratory reports provided to or by a Medical Marijuana Business, or to a patient or primary caregiver must identify the Medical Marijuana Testing Facility that actually conducted the test.

G. Authorized Medical Marijuana Transport. A Medical Marijuana Testing Facility is authorized to utilize a licensed Medical Marijuana Transporter to transport Samples of Medical Marijuana for testing, in accordance with the Marijuana Code and the rules adopted pursuant thereto, between the originating Medical Marijuana Business requesting testing services and the destination Medical Marijuana Testing Facility performing testing services. Nothing in this Rule requires a Medical Marijuana Business to utilize a Medical Marijuana Transporter to transport Samples of Medical Marijuana for testing.

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

Basis and Purpose – 5-410

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(2)(h), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-203(2)(f)(II), 44-10-

203(2)(f)(IV), 44-10-203(3)(d), 44-10-203(3)(e), 44-10-313(8)(a), 44-10-401(2)(a)(IV), 44-10-501(6), 44-10-502(3), 44-10-503(8), 44-10-504(1), and 44-10-504(2), 44-10-701, and 35-61-105.5, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Medical Marijuana Testing Facility. This Rule 5-410 was previously Rule M 702, 1 CCR 212-1.

5-410 – Medical Marijuana Testing Facilities: General Limitations or Prohibited Acts

A. Prohibited Financial Interest. A Person who is a Controlling Beneficial Owner or Passive Beneficial Owner of a Medical Marijuana Cultivation Facility, Medical Marijuana Products Manufacturing Facility, Medical Marijuana Store, Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, or a Retail Marijuana Store shall not be a Controlling Beneficial Owner or Passive Beneficial Owner of a Medical Marijuana Testing Facility.

B. Conflicts of Interest. The Medical Marijuana Testing Facility shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the Medical Marijuana Testing Facility's testing processes or results, or that may diminish public confidence in the competency, impartiality, and integrity of the Medical Marijuana Testing Facility's testing processes or results. At a minimum, employees, owners or agents of a Medical Marijuana Testing Facility who participate in any aspect of the analysis and results of a Sample are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any on-going financial, employment, personal or business relationship with the Medical Marijuana Business that provided the Sample.

C. Transfer of Medical Marijuana Prohibited. A Medical Marijuana Testing Facility shall not Transfer Medical Marijuana to a Medical Marijuana Business, a consumer, a patient, or primary caregiver, except that a Medical Marijuana Testing Facility may Transfer a Sample to another Medical Marijuana Testing Facility.

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

E. Sample Rejection. A Medical Marijuana Testing Facility shall reject any Sample where the condition of the Sample at receipt indicates that that the Sample may have been tampered with.

F. Medical Marijuana Business Requirements Applicable. A Medical Marijuana Testing Facility shall be considered a Licensed Premises. A Medical Marijuana Testing Facility shall be subject to all requirements applicable to Medical Marijuana Businesses.

G. Medical Marijuana Testing Facility – Inventory Tracking System Required. A Medical Marijuana Testing Facility must use the Inventory Tracking System to ensure all Test Batches or Samples containing Medical Marijuana are identified and tracked from the point they are Transferred from a Medical Marijuana Business, a patient, or a patient's primary caregiver through the point of Transfer, destruction, or disposal. The Inventory Tracking System reporting shall include the results of any tests that are conducted on Medical Marijuana. *See* Rule 3-805 – Regulated Marijuana Business: Inventory Tracking System, Rule 3-825 – Reporting and Inventory Tracking System, and Rule 5-405(D)(5). The Medical Marijuana Testing Facility must have the ability to reconcile its Sample records with the Inventory Tracking System and the associated transaction history. *See* Rule 3-905 – Business Records Required and Rule 3-825 Reporting and Inventory Tracking

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

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

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

Basis and Purpose – 5-430

The statutory authority for this rule includes but is not limited to sections 44-10-203(2)(d), 44-10-401(2)(a)(IV), and 44-10-504, C.R.S. The purpose of this rule is to establish analytical processes standards for the operation of a Medical Marijuana Testing Facility. This Rule 5-430 was previously Rule M 706, 1 CCR 212-1.

5-430 – Medical Marijuana Testing Facilities: Analytical Processes

A. Gas Chromatography ("GC"). A Medical Marijuana Testing Facility using GC must:

1. Document the conditions of the gas chromatograph, including the detector response;

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

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

4. Document the performance of new columns before use;

5. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;

6. Establish criteria of acceptability for variances between different aliquots and different columns; and

7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.

B. Gas Chromatography Mass Spectrometry ("GC/MS"). A Medical Marijuana Testing Facility using GC/MS must:

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

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

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

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

5. Maintain records of mass spectrometric tuning;

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

7. Document corrective actions if a mass-spectrometric tune is unacceptable;

8. Monitor analytic analyses to check for contamination and carry-over;

9. Use selected ion monitoring within each run to assure that the laboratory compares ion ratios and retention times between calibrators, controls and samples for identification of an analyte;

10. Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

11. Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;

12. Define the criteria for designating qualitative results as positive;

13. When a library is used to qualitatively identify an analyte, the identity of the analyte must be confirmed before reporting results by comparing the relative retention time and mass spectrum to that of a known standard or control run on the same system; and

14. Evaluate the performance of the instrument after routine and preventive maintenance (*e.g.* clipping or replacing the column or cleaning the source) prior to analyzing subject Samples.

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

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

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

3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a sample is not included within the types of samples approved by the manufacturer; and

4. Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.

D. Thin Layer Chromatography ("TLC"). A Medical Marijuana Testing Facility using TLC must:

1. Apply unextracted standards to each thin layer chromatographic plate;

2. Include in their written procedure the preparation of mixed solvent systems, spray reagents and designation of lifetime;

3. Include in their written procedure the storage of unused thin layer chromatographic plates;

4. Evaluate, establish, and document acceptable performance for new thin layer chromatographic plates before placing them into service;

5. Verify that the spotting technique used precludes the possibility of contamination and carry-over;

6. Measure all appropriate RF values for qualitative identification purposes;

7. Use and record sequential color reactions, when applicable;

8. Maintain records of thin layer chromatographic plates; and

9. Analyze an appropriate matrix blank with each batch of samples analyzed.

E. High Performance Liquid Chromatography ("HPLC"). A Medical Marijuana Testing Facility using HPLC must:

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

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

3. Monitor and document the performance of the HPLC instrument each day of testing;

4. Evaluate the performance of new columns before use;

5. Create written standards for acceptability when eluting solvents are recycled;

6. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay; and

7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.

F. Liquid Chromatography Mass Spectroscopy ("LC/MS"). A Medical Marijuana Testing Facility using LC/MS must:

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

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

3. Maintain records of mass spectrometric tuning;

4. Document corrective actions if a mass-spectrometric tune is unacceptable;

5. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

6. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;

7. Compare two transitions and retention times between calibrators, controls and samples within each run;

8. Document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument; and

9. Evaluate the performance of the instrument when changes in: source, source conditions, eluent, or column are made prior to reporting test results.

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

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

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

3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a test sample submitted for testing is not included within the types of Test Batches approved by the manufacturer;

4. Verify the method at the action levels for each analyte. Verification at the qualitative presence/absence limit shall include a fractional recovery study unless otherwise completed by the manufacturer and approved by an independent scientific body.

5. Include controls for each batch of test samples. Quantitative microbial methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;

6. For molecular methods, the Medical Marijuana Testing Facility shall include controls for each individual analytical run. Quantitative molecular methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;

7. PCR-based and qPCR-based methods must include validated internal amplification controls;

8. Microbial methods must include steps to confirm presumptive positive results; confirmation methods may be molecular or cultural or both. Confirmation methods must include quality controls that match the organism which is being confirmed.

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

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

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

3. Specify all unique method parameters, such as temperature, test sample surface area, volatile compound interferences, including but not limited to temperature;

4. Evaluate the performance of the method after routine and preventive maintenance prior to analyzing the Test Batch;

5. Establish criteria for acceptable instrument performance.

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

1. Implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices prior to reporting results. Validation of other or new methodology must include when applicable, but is not limited to:

    a. Verification of Accuracy

    b. Verification of Precision

    c. Verification of Analytical Sensitivity

    d. Verification of Analytical Specificity

    e. Verification of the LOD

    f. Verification of the LOQ

    g. Verification of the Reportable Range

    h. Identification of Interfering Substances

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

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

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

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

J. Testing and Validation of Complex Matrices. A Medical Marijuana Testing Facility must include a variety of matrices as part of the validation/verification process. During method validation/verification, a Medical Marijuana Testing Facility must:

1. Select matrices which best represent each category of products to be tested as listed in Rule 4-115(D). The laboratory shall independently determine the category of matrix a product falls within; properties to consider include fat content, cannabinoid content, pH, salt content, sugar content, water activity, the presence of know chemical compounds, microbial flora and antimicrobial compounds.

2. Perform a new matrix validation, prior to reporting results, on matrices which are either a new category of matrix or are considerably different from the original matrix validated within the category.

    a. For example, the Medical Marijuana Testing Facility intends to receive the topical product “bath bombs” for testing, but previous validation studies for topical product included lotion and massage oil. A new validation should be performed for the product prior to testing since salt content and other properties differ vastly from the original matrices validated.

3. Perform a matrix verification (a client matrix spike or similar consisting of the target analyte(s) at the time of analysis) on matrices submitted for testing which differ slightly from those initially validated but which fall within a category already validated.

a. For example, the Medical Marijuana Testing Facility laboratory receives a new edible type matrix for testing (snickerdoodle cookies) but previous validation included gummies and hard candy. A spike of a portion of the submitted material must be analyzed prior to, or at the time of, sample analysis.

K. All Test Batches and ~~Industrial~~ Hemp Product must be tested as received, must not be manipulated, and tested in a manner that ensures results are representative of sample as received.

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

5-700 Series – Marijuana Research and Development Facilities

Basis and Purpose – 5-705

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(j), 44-10-203(1)(k), 44-10-203(2)(s), 44-10-401(1)(a)(VII), and 44-10-507, C.R.S. The purpose of this rule is to establish and clarify the distinct license privilege granted to Marijuana Research and Development Facilities by the State Licensing Authority. This Rule 5-705 was previously Rule M 1901, 1 CCR 212-1.

5-705 – Marijuana Research and Development Facilities: License Privileges

A. License Privileges.

1. Licensed Premises. A Marijuana Research and Development Facility may share a Licensed Premises with a commonly owned Medical Marijuana Testing Facility. Additionally, a Marijuana Research and Development Facility with an R&D Co-Location Permit may share a Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility.

a. If a Marijuana Research and Development Facility shares its Licensed Premises with a commonly owned Medical Marijuana Testing Facility, the Licensees shall physically segregate all Medical Marijuana used for research purposes in order to prevent contamination or any other effect on Medical Marijuana submitted to the Medical Marijuana Testing Facility for testing.

b. If a Marijuana Research and Development Facility shares its Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility, the Marijuana Research and Development Facility must first obtain an R&D Co Location Permit for that Licensed Premises and must comply with all terms and conditions of the R&D Co-Location Permit.

2. Authorized Sources of Medical Marijuana. A Medical Marijuana Cultivation Facility and Medical Marijuana Products Manufacturer may Transfer Medical Marijuana to a Marijuana Research and Development Facility.

a. A Marijuana Research and Development Facility may also accept and possess Regulated Marijuana obtained in accordance with an approved Research Project.

b. Upon receipt of Regulated Marijuana pursuant to Rule 5-705(A)(2)(a), a Marijuana Research and Development Facility shall immediately enter the

Regulated Marijuana as Medical Marijuana in its Inventory Tracking System and shall follow all requirements of the Marijuana Code and these Rules including but not limited to inventory tracking and packaging and labeling. As part of and in compliance with the conditions of an approved Research Project, a Marijuana Research and Development Facility may Transfer the Medical Marijuana to another Marijuana Research and Development Facility or to a Medical or Retail Marijuana Testing Facility. In no event shall any marijuana obtained or Transferred pursuant to this Rule be consumed by humans or utilized in human subject research.

3. Cultivation of Marijuana Authorized. A Marijuana Research and Development Facility may grow, cultivate, possess, and Transfer Medical Marijuana for use in research only.

4. Production of Marijuana Concentrate. A Marijuana Research and Development Facility and a Medical Marijuana Cultivation Facility are subject to the same restrictions concerning Medical Marijuana Concentrate production. Therefore, a Marijuana Research and Development Facility may produce Medical Marijuana Concentrate only as allowed by, and in conformance with, Rule 5-220(A)-(B).

5. Production of Marijuana Products. A Marijuana Research and Development Facility and a Medical Marijuana Products Manufacturer are subject to the same restrictions concerning Medical Marijuana Product manufacturing. Therefore, a Marijuana Research and Development Facility may manufacture Medical Marijuana Product only as allowed by, and in conformance with, Rule 5-305.

5.5. Production of Semi-Synthetic Cannabinoids. A Marijuana Research and Development Facility may manufacture semi-synthetic cannabinoids derived from Medical Marijuana.

6. Authorized Marijuana Transport. A Marijuana Research and Development Facility is authorized to utilize a licensed Medical Marijuana Transporter for transportation of Medical Marijuana to other Marijuana Research and Development Facility Licensees so long as the place where transportation orders are taken and delivered is a Marijuana Research and Development Facility. Nothing in this Rule prevents a Marijuana Research and Development Facility from transporting its own Medical Marijuana to other Marijuana Research and Development Facilities.

B. R&D Co-Location Permit. A Marijuana Research and Development Facility may obtain an R&D Co-Location Permit to operate at the same Licensed Premises as a commonly owned Medical Marijuana Products Manufacturer, Retail Marijuana Products Manufacturer, Medical Marijuana Cultivation Facility, or Retail Marijuana Cultivation Facility under the following circumstances:

1. The Marijuana Research and Development Facility must apply on current Division forms and pay any applicable fees.

2. A Marijuana Research and Development Facility may only apply for and hold an R&D Co-Location Permit if the Local Licensing Authority or Local Jurisdiction allow for Marijuana Research and Development Facility to operate at the same location as the specified Regulated Marijuana Business. Any R&D Co-Location Permit issued by the Division is conditioned upon the Marijuana Research and Development Facility's receipt of all required Local Licensing Authority or Local Jurisdiction approvals or acknowledgements.

3. The Marijuana Research and Development Facility and the specified Regulated Marijuana Business shall be commonly owned.

4. Prior to operating in the same Licensed Premises pursuant to an R&D Co-Location Permit, the Marijuana Research and Development Facility shall submit a co-location plan and standard operating procedures to the Division. The co-location plan and standard operating procedures shall demonstrate protocols to prevent cross-contamination and protect public health and safety, including but not limited to:

    a. Standards and controls for maintaining physical separation between the Marijuana Research and Development Facility's research activities and the cultivating or manufacturing activities of the co-located Regulated Marijuana Business; and

    b. Standards and controls for maintaining physical separation between the Marijuana Research and Development Facility's Medical Marijuana and the co-located Regulated Marijuana Business's Regulated Marijuana.

5. The Division may request the assistance of the Colorado Department of Public Health and Environment or any other state or local agency in reviewing the co-location plan and standard operating procedures, and in determining whether the co-location plan and standard operating procedures demonstrate protocols to prevent cross-contamination and protect public health and safety.

6. Modifying the co-location plan and standard operating procedures shall be considered a significant change to the Licensed Premises. *See* Rule 2-260 – Changing, Altering, or Modifying the Licensed Premises.

7. Record keeping, inventory tracking, packaging and labeling for the Marijuana Research and Development Facility and co-located Regulated Marijuana Business must enable the Division, Local Licensing Authority, or Local Jurisdiction to clearly distinguish the inventory, transactions, and activities of the Marijuana Research and Development Facility from the inventory, transactions, and activities of the co-located Regulated Marijuana Business.

Part 6 – Retail Marijuana Business License Types

6-200 Series – Retail Marijuana Cultivation Facilities

Please Note: *The following proposed revisions seek to implement SB 23-271 statutory revisions in section 44-10-602.*

Basis and Purpose – 6-205

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(j), 44-10-203(2)(r), 44-10-203(3)(c), 44-10-313(14), 44-10-401(2)(b)(II), and 44-10-602, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to a Retail Marijuana Cultivation Facility. This Rule 6-205 was previously Rule R 501, 1 CCR 212-2.

6-205 – Retail Marijuana Cultivation Facility: License Privileges

A. Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Cultivation Facility may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Cultivation Facility. However, a separate license is required for each specific business or business entity, regardless of geographical location. In addition, a Retail Marijuana Cultivation

Facility may share, and operate at, the same Licensed Premises as a Marijuana Research and Development Facility so long as:

1. Each business or business entity holds a separate license;

2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;

3. Both the Marijuana Research and Development Facility and the Retail Marijuana Cultivation Facility comply with all terms and conditions of the R&D Co-Location Permit; and

4. Both the Marijuana Research and Development Facility and the Retail Marijuana Cultivation Facility comply with all applicable rules. *See* 5-700 Series Rules.

B. Cultivation of Retail Marijuana and Production of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Retail Marijuana Concentrate Authorized. A Retail Marijuana Cultivation Facility may propagate, cultivate, harvest, prepare, cure, package, store, and label Retail Marijuana and Physical Separation-Based Retail Marijuana Concentrate. A Retail Marijuana Cultivation Facility may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Retail Marijuana Concentrate.

C. Authorized Transfers. A Retail Marijuana Cultivation Facility may only Transfer Retail Marijuana and Physical Separation-Based Retail Marijuana Concentrate to another Retail Marijuana Business. A Retail Marijuana Cultivation Facility and an Accelerator Cultivator may also Transfer to a Medical Marijuana Cultivation Facility in compliance with Rules 6-230 and 6-730.

1. A Retail Marijuana Cultivation Facility shall not Transfer Flowering plants. A Retail Marijuana Cultivation Facility may only Transfer Vegetative plants as authorized pursuant to Rule 3-605.

2. A Retail Marijuana Cultivation Facility may Transfer Sampling Units of Retail Marijuana or Retail Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-602(6), C.R.S., and Rule 6-225.

3. A Retail Marijuana Cultivation Facility may Transfer Retail Marijuana or Retail Marijuana Concentrate to another Retail Marijuana Cultivation Facility prior to testing required by these rules only if such Transfer is in accordance with one of the two options below.

   a. The Retail Marijuana Cultivation Facility may Transfer Retail Marijuana or Retail Marijuana Concentrate to another Retail Marijuana Cultivation Facility prior to testing if such Transfer is to perform a Microbial Control Step ~~for the purpose of Decontamination~~ and only after all other steps outlined in the Retail Marijuana Cultivation Facility's standard operating procedures have been completed, including but not limited to drying, curing, and trimming; or

   b. The Retail Marijuana Cultivation Facility may Transfer Retail Marijuana or Retail Marijuana Concentrate to another Retail Marijuana Cultivation Facility prior to testing, drying, curing, trimming, or completion of any other steps in the Retail Marijuana Cultivation Facility's standard operating procedures, subject to the following additional requirements:

      i. The Retail Marijuana Cultivation Facility receiving the Transfer is identified as a centralized processing hub in the Inventory Tracking System and must have identical Controlling Beneficial Owner(s) with the originating Retail Marijuana Cultivation Facility;

ii. An originating Retail Marijuana Cultivation Facility may only Transfer Retail Marijuana to one receiving Retail Marijuana Cultivation Facility that will be serving as a centralized processing hub;

iii. The Retail Marijuana or Retail Marijuana Concentrate is weighed prior to leaving the originating Retail Marijuana Cultivation Facility and immediately upon receipt at the receiving Retail Marijuana Cultivation Facility and in accordance with Rule 3-605;

iv. The Transfer, weighing and entry into the Inventory Tracking System are all completed within 24 hours from initiating the Transfer;

v. The receiving Retail Marijuana Cultivation Facility is responsible for compliance with all testing requirements regardless of any testing performed prior to Transfer. If the receiving Retail Marijuana Cultivation Facility is pursuing a Reduced Testing Allowance, a Reduced Testing Allowance must be achieved separately for marijuana received from each originating Retail Marijuana Cultivation Facility. A Retail Marijuana Cultivation Facility that has achieved a Reduced Testing Allowance must maintain and produce complete testing records that can verify that facility's compliance with testing and Reduced Testing Allowance requirements; and

vi. The standard operating procedures for the originating Retail Marijuana Cultivation Facility and receiving Retail Marijuana Cultivation Facility clearly reflect the steps taken by each facility to Transfer, transport, receive, process, and test Harvest Batches.

4. A Retail Marijuana Cultivation Facility may transfer Retail Marijuana to a Pesticide Manufacturer.

5. A Retail Marijuana Cultivation Facility may Transfer Retail Marijuana to a Medical Marijuana Cultivation Facility in accordance with Rules 5-235 and 6-230.

6. A Retail Marijuana Cultivation Facility may Transfer Immature Plants, Retail Marijuana seeds, and Genetic Material to a Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator. Transfers made under this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.

D. Authorized On-Premises Storage. A Retail Marijuana Cultivation Facility is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area and tracked consistently with the inventory tracking rules.

E. Samples Provided for Testing. A Retail Marijuana Cultivation Facility may provide Samples of its Retail Marijuana to a Retail Marijuana Testing Facility for testing and research purposes. The Retail Marijuana Cultivation Facility shall maintain the testing results as part of its business books and records. *See* Rule 3-905 – Business Records Required.

F. Authorized Marijuana Transport. A Retail Marijuana Cultivation Facility is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents a Retail Marijuana Cultivation Facility from transporting its own Retail Marijuana.

G. Performance-Based Incentives. A Retail Marijuana Cultivation Facility may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Retail Marijuana Cultivation Facility may not compensate a Sampling Manager using Sampling Units. *See* Rule 6-225 – Sampling Unit Protocols.

H. Authorized Sources of Retail Marijuana, Seeds, ~~and~~ Immature Plants, and Genetic Material.

1. A Retail Marijuana Cultivation Facility ~~shall only~~may obtain Retail Marijuana seeds or Immature Plants from its own Retail Marijuana, properly Transferred Medical Marijuana cultivated at a Medical Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or properly Transferred from another Retail Marijuana Business pursuant to the inventory tracking requirements in the 3-800 Series Rules. A Retail Marijuana Cultivation facility may not bring seeds, Immature Plants, or other marijuana that is not Regulated Marijuana onto the Licensed Premises at any time.

2. A Retail Marijuana Cultivation Facility may obtain Regulated Marijuana seeds, Immature Plants, and Genetic Material from:

a. Another Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility;

b. A Retail Marijuana Testing Facility;

c. A marijuana cultivation or testing facility licensed or otherwise approved pursuant to a permit or registration issued by a government agency to operate in another state or territory of the United States;

d. An individual licensed as an Employee Licensee in Colorado, or holding a permit, registration, or license to work in cannabis in another state or territory of the United States; or

e. Pursuant to any federal legal authority allowing interstate commerce of Regulated Marijuana.

3. Transfers made under subparagraph (H)(2) of this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.

I. Centralized Distribution Permit. A Retail Marijuana Cultivation Facility may apply to the State Licensing Authority for a Centralized Distribution Permit for authorization to temporarily store Retail Marijuana Concentrate and Retail Marijuana Product received from a Retail Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Retail Marijuana Stores.

1. For purposes of a Centralized Distribution Permit only, the term “commonly owned” means at least one natural person has a minimum of five percent ownership in both the Retail Marijuana Cultivation Facility possessing a Centralized Distribution Permit and the Retail Marijuana Store to which the Retail Marijuana Concentrate and Retail Marijuana Product will be Transferred.

2. To apply for a Centralized Distribution Permit, a Retail Marijuana Cultivation Facility may submit an addendum to its new or renewal application or a separate addendum prior to a renewal application on forms prepared by the Division to request a Centralized Distribution Permit. The Retail Marijuana Cultivation Facility shall send a copy of its Centralized Distribution Permit addendum to the Local Licensing Authority in the

jurisdiction in which the Centralized Distribution Permit is proposed at the same time it submits the addendum to the State Licensing Authority.

3. A Retail Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit and has obtained all required approvals from the local licensing jurisdiction where it is located, if any, may accept Transfers of Retail Marijuana Concentrate and Retail Marijuana Product from a Retail Marijuana Products Manufacturer for the sole purpose of temporary storage and Transfer to commonly owned Retail Marijuana Stores.

   a. A Retail Marijuana Cultivation Facility may only accept Retail Marijuana Concentrate and Retail Marijuana Product that is packaged and labeled for sale to a consumer pursuant to the 3-1000 Series Rules.

   b. A Retail Marijuana Cultivation Facility storing Retail Marijuana Concentrate and Retail Marijuana Product pursuant to a Centralized Distribution Permit shall not store such Retail Marijuana Concentrate or Retail Marijuana Product on the Retail Marijuana Cultivation Facility's Licensed Premises for more than 90 days from the date of receipt.

   c. All Transfers of Retail Marijuana Concentrate and Retail Marijuana Product by a Retail Marijuana Cultivation Facility shall be without consideration.

4. All security and surveillance requirements that apply to a Retail Marijuana Cultivation Facility apply to activities conducted pursuant to the privileges of a Centralized Distribution Permit.

J. Transition Permit. A Retail Marijuana Cultivation Facility may only operate at two geographical locations pursuant to Rule 2-255(D).

6-300 Series – Retail Marijuana Products Manufacturing Facilities

Basis and Purpose – 6-305

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-307(1)(j), 44-10-313(14), 44-10-401(2)(b)(III), and 44-10-603, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to a Retail Marijuana Products Manufacturer. This Rule 6-305 was previously Rule R 601, 1 CCR 212-2.

6-305 – Retail Marijuana Products Manufacturer: License Privileges

A. Licensed Premises. A separate license is required for each specific business or business entity and geographical location. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer. However, a separate license is required for each specific business or business entity, regardless of geographical location. In addition, a Retail Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises as a Marijuana Research and Development Facility so long as:

1. Each business or business entity holds a separate license;

2. The Marijuana Research and Development Facility obtains an R&D Co-Location Permit;

3. Both the Marijuana Research and Development Facility and the Retail Marijuana Products Manufacturer comply with all terms and conditions of the R&D Co-Location Permit; and

4. Both the Marijuana Research and Development Facility and the Retail Marijuana Products Manufacturer comply with all applicable rules. *See* 5-700 Series Rules.

B. Authorized Transfers. A Retail Marijuana Products Manufacturer is authorized to Transfer Retail Marijuana as follows:

1. Retail Marijuana Concentrate and Retail Marijuana Product.

a. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana Concentrate or Retail Marijuana Product to Retail Marijuana Stores, other Retail Marijuana Products Manufacturers, Retail Marijuana Testing Facilities, Retail Marijuana Hospitality and Sales Businesses, and Pesticide Manufacturers.

b. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana Product and Retail Marijuana Concentrate to a Retail Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit.

i. Prior to any Transfer pursuant to this Rule 6-305(B)(1)(b), a Retail Marijuana Products Manufacturer shall verify the Retail Marijuana Cultivation Facility possesses a valid Centralized Distribution Permit. *See* Rule 6-205 – Retail Marijuana Cultivation Facility: License Privileges.

ii. For any Transfer pursuant to this Rule 6-305(B)(1)(b), a Retail Marijuana Products Manufacturer shall only Transfer Retail Marijuana Product and Retail Marijuana Concentrate that is packaged and labeled for Transfer to a consumer. *See* 3-1000 Series Rules.

c. A Retail Marijuana Products Manufacturer and Accelerator Manufacturer may Transfer Retail Marijuana Concentrate to a Medical Marijuana Products Manufacturer in compliance with Rules 6-335 and 6-830.

2. Retail Marijuana. A Retail Marijuana Products Manufacturer may Transfer Retail Marijuana to other Retail Marijuana Products Manufacturer, Retail Marijuana Testing Facilities, and Retail Marijuana Stores.

3. Sampling Units. A Retail Marijuana Products Manufacturer may also Transfer Sampling Units of its own Retail Marijuana Concentrate or Retail Marijuana Product to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-603(10), C.R.S., and Rule 6-320.

C. Manufacture of Retail Marijuana Concentrate, Retail Marijuana Product, Pre-Rolled Marijuana, and Infused Pre-Rolled Marijuana Authorized. A Retail Marijuana Products Manufacturer may manufacture, prepare, package, store, and label Retail Marijuana Concentrate and Retail Marijuana Product comprised of Retail Marijuana and other Ingredients intended for use or consumption, such as Edible Retail Marijuana Products, ointments, or tinctures. A Retail Marijuana Products Manufacturer may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana.

1. ~~Industrial~~ Hemp Product Authorized. ~~This subparagraph (C)(1) is effective July 1, 2020.~~ A Retail Marijuana Products Manufacturer that uses ~~Industrial~~ Hemp Product as an

Ingredient in the manufacture and preparation of Retail Marijuana Product must comply with this subparagraph (C)(1) of this Rule.

a. Prior to accepting and taking possession of any ~~Industrial~~ Hemp Product for use as an Ingredient in a Retail Marijuana Product the Retail Marijuana Products Manufacturer shall verify the following:

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

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

D. Location Prohibited. A Retail Marijuana Products Manufacturer may not manufacture, prepare, package, store, or label Retail Marijuana Concentrate or Retail Marijuana Product in a location that is operating as a retail food establishment.

E. Samples Provided for Testing. A Retail Marijuana Products Manufacturer may provide samples of its Retail Marijuana Concentrate or Retail Marijuana Product to a Retail Marijuana Testing Facility for testing and research purposes. The Retail Marijuana Products Manufacturer shall maintain the testing results as part of its business books and records. *See* Rule 3-905 – Business Records Required.

F. Authorized Marijuana Transport. A Retail Marijuana Products Manufacturer is authorized to utilize a Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken is a Retail Marijuana Business and the transportation order is delivered to a Retail Marijuana Business, or Pesticide Manufacturer. Nothing in this Rule prevents a Retail Marijuana Products Manufacturer from transporting its own Retail Marijuana.

G. Performance-Based Incentives. A Retail Marijuana Products Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, a Retail Marijuana Products Manufacturer may not compensate a Sampling Manager using Sampling Units. *See* Rule 6-320 – Sampling Unit Protocols.

6-400 Series – Retail Marijuana Testing Facilities

Basis and Purpose – 6-405

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-202(4), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-203(2)(h), 44-10-203(2)(y), 44-10-203(3)(c), 44-10-203(3)(d), 44-10-313(8)(a), 44-10-313(14), 44-10-401(2)(b)(IV), 44-10-604, 35-61-104, and 35-61-105.5, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to Retail Marijuana Testing Facilities. This Rule 6-405 was previously Rule R 701.

***Please Note:** The following proposed revisions seek to implement SB 23-271 statutory revisions in section 44-10-602*

6-405 – Retail Marijuana Testing Facilities: License Privileges

A. Licensed Premises. A separate License is required for each specific Retail Marijuana Testing Facility and only those privileges granted by the Marijuana Code and any rules promulgated

pursuant to it may be exercised on the Licensed Premises. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Testing Facility may share and operate at the same Licensed Premises with a Medical Marijuana Testing Facility with identical ownership.

B. Testing of Retail Marijuana Authorized. A Retail Marijuana Testing Facility may accept Samples of Retail Marijuana from Retail Marijuana Businesses for testing and research purposes only. The Division may require a Retail Marijuana Business to submit a Sample of Retail Marijuana to a Retail Marijuana Testing Facility upon demand.

C. Product Development Authorized. A Retail Marijuana Testing Facility may develop Retail Marijuana Product, but is not authorized to engage in the manufacturing privileges described in section 44-10-603, C.R.S., and Rule 6-305 – Retail Marijuana Manufacturing Facilities: License Privileges.

D. Transferring Samples to Another Licensed and Certified Retail Marijuana Testing Facility. A Retail Marijuana Testing Facility may Transfer Samples to another Retail Marijuana Testing Facility for testing. All laboratory reports provided to or by a Retail Marijuana Business must identify the Retail Marijuana Testing Facility that actually conducted the test.

E. Testing of Registered and Tracked ~~Industrial~~ Hemp Authorized.

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

2. Before a Retail Marijuana Testing Facility accepts a sample of ~~Industrial~~ Hemp, the Retail Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-104, C.R.S.

3. A Retail Marijuana Testing Facility is responsible for entering ~~tracking~~ samples of ~~Industrial~~ Hemp in the Inventory Tracking System pursuant to the 3-800 Series Rules.

4. A Retail Marijuana Testing Facility shall be permitted to test ~~Industrial~~ Hemp only in the category(ies) that the Retail Marijuana Testing Facility is certified to perform testing in pursuant to Rule 6-415 – Retail Marijuana Testing Facilities: Certification Requirements.

5. In accordance with section 35-61-105.5, C.R.S., a Retail Marijuana Testing Facility shall provide the results of any testing performed on ~~Industrial~~ Hemp to the Person submitting the sample of ~~Industrial~~ Hemp and to the Colorado Department of Agriculture.

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

F. Testing of ~~Industrial~~ Hemp Product Authorized.

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

2. Before a Retail Marijuana Testing Facility accepts a sample of ~~Industrial~~ Hemp Product, the Retail Marijuana Testing Facility shall verify that the Person submitting the sample is registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S.

3. A Retail Marijuana Testing Facility is responsible for entering and tracking samples of ~~Industrial~~ Hemp Product in the inventory tracking system pursuant to the 3-800 Series Rules.

4. A Retail Marijuana Testing Facility shall be permitted to test ~~Industrial~~ Hemp Product only in the category(ies) that the Retail Marijuana Testing Facility is certified to perform testing in pursuant to Rule 6-415 – Retail Marijuana Testing Facilities: Certification Requirements.

5. A Retail Marijuana Testing Facility may provide the results of any testing performed on ~~Industrial~~ Hemp Product to the Person submitting the sample of ~~Industrial~~ Hemp Product.

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

G. Authorized Retail Marijuana Transport. A Retail Marijuana Testing Facility is authorized to utilize a licensed Retail Marijuana Transporter to transport Samples of Retail Marijuana for testing, in accordance with the Marijuana Code and Marijuana Rules, between the originating Retail Marijuana Business requesting testing services and the destination Retail Marijuana Testing Facility performing testing services. Nothing in this Rule requires a Retail Marijuana Business to utilize a Retail Marijuana Transporter to transport Samples of Retail Marijuana for testing.

H. Authorized Transfers.

1. A Retail Marijuana Testing Facility may Transfer Immature Plants, Regulated Marijuana seeds, and Genetic Material to a Regulated Marijuana Cultivation Facility. Any Transfers made under this Rule must be in compliance with the 3-800 and the 3-900 Series Rules.

2. It shall be considered a conflict of interest and a Retail Marijuana Testing Facility shall not perform testing required under the 4-100 Series Rules for a Regulated Marijuana Business Licensee that the Retail Marijuana Testing Facility has Transferred Immature Plants, Regulated Marijuana seeds, or Genetic Material to.

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

***Please Note:** The following proposed revisions seek to implement SB 23-271 statutory revisions in section 44-10-602.*

Basis and Purpose – 6-410

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(a), 44-10-202(1)(b), 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(c), 44-10-203(2)(d), 44-10-202(4), 44-10-203(2)(h), 44-10-203(2)(y), 44-10-203(3)(c), 44-10-203(2)(d), 44-10-401(2)(b)(IV), 44-10-604, 44-10-701, 35-61-104, and 35-61-105.5, C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion, or prohibited, by a Retail Marijuana Testing Facility. This Rule 6-410 was previously Rule R 702, 1 CCR 212-2.

6-410 – Retail Marijuana Testing Facilities: General Limitations or Prohibited Acts

A. Prohibited Financial Interest. A Person who is Controlling Beneficial Owner or Passive Beneficial of a Retail Marijuana Cultivation Facility, Retail Marijuana Products Manufacturer, Retail Marijuana Store, Medical Marijuana Store, Medical Marijuana Cultivation Facility, or a Medical Marijuana Products Manufacturer shall not be a Controlling Beneficial Owner or Passive Beneficial Owner of a Retail Marijuana Testing Facility.

B. Conflicts of Interest. The Retail Marijuana Testing Facility shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the Retail Marijuana Testing Facility's testing processes or results, or that may diminish public confidence in the competency, impartiality and integrity of the Retail Marijuana Testing Facility's testing processes or results. At a minimum, employees, owners or agents of a Retail Marijuana Testing Facility who participate in any aspect of the analysis and results of a Sample or Test Batch are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any on-going financial, employment, personal or business relationship with the Retail Marijuana Business that provided the Sample.

C. Transfer of Retail Marijuana Prohibited. A Retail Marijuana Testing Facility shall not Transfer Retail Marijuana to another Retail Marijuana Business or a consumer, except that a Retail Marijuana Testing Facility may Transfer a Sample to another Retail Marijuana Testing Facility.

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

E. Sample Rejection. A Retail Marijuana Testing Facility shall reject any Sample where the condition of the Sample at receipt indicates that the Sample may have been tampered with.

F. Retail Marijuana Business Requirements Applicable. A Retail Marijuana Testing Facility shall be considered a Licensed Premises. A Retail Marijuana Testing Facility shall be subject to all requirements applicable to Retail Marijuana Businesses.

G. Retail Marijuana Testing Facility – Inventory Tracking System Required. A Retail Marijuana Testing Facility must use the Inventory Tracking System to ensure all Test Batches or Samples containing Retail Marijuana are identified and tracked from the point they are Transferred from a Retail Marijuana Business through the point of Transfer or destruction or disposal. A Retail Marijuana Testing Facility that performs testing on ~~Industrial~~ Hemp must use the Inventory Tracking System to ensure all samples of ~~Industrial~~ Hemp are identified and tracked from the point they are Transferred from a cultivator registered with the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-104, C.R.S., to the point of Transfer or destruction or disposal. The Inventory Tracking System reporting shall include the results of any tests that are conducted on Retail Marijuana or ~~Industrial~~ Hemp. *See also* Rule 3-805 – Regulated Marijuana Businesses: Inventory Tracking System and Rule 3-825 – Reporting and Inventory Tracking System. The Retail Marijuana Testing Facility must have the ability to reconcile its Sample records with the Inventory Tracking System and the associated transaction history. *See also* Rule 3-905 – Business Records Required and Rule 3-825.

H. Testing of Unregistered or Untracked ~~Industrial~~ Hemp or ~~Industrial~~ Hemp Products Prohibited.

1. A Retail Marijuana Testing Facility is authorized to accept or test ~~Industrial~~ Hemp only if (1) the entity providing the Samples of ~~Industrial~~ Hemp is regulated by Article 61 of Title 35, C.R.S., (2) the ~~Industrial~~ Hemp is submitted by a registered cultivator, and (3) the ~~Industrial~~ Hemp is tracked in the Inventory Tracking System.

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

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

Basis and Purpose – 6-425

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-202(4), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish standard operating procedure manual standards for the operation of a Retail Marijuana Testing Facility. This Rule 6-425 was previously Rule R 705, 1 CCR 212-2.

6-425 –Retail Marijuana Testing Facilities: Standard Operating Procedure Manual

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

1. Test Batch receiving;

2. Test Batch accessioning;

3. Test Batch storage;

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

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

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

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

8. Test Batch preparation, including but not limited to, sub-sampling for testing, homogenization, and aliquoting Test Batches to avoid contamination and carry-over;

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

   a. For Test Batches submitted for testing other than Pesticide contaminant testing, Test Batch retention for 14 days;

   b. For Test Batch submitted for Pesticide contaminant testing, Test Batch retention for 90 days.

10. Disposal of Test Batches;

11. The theory and principles behind each assay;

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

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

14. Frequency and number of control and calibration materials;

15. Recording and reporting assay results;

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

17. Pertinent literature references for each method;

18. Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;

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

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

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

22. Testing ~~Industrial~~ Hemp, if the Retail Marijuana Testing Facility tests ~~Industrial~~ Hemp;

23. Investigating and documenting existing or potential Nonconformances and implementing Corrective Actions and/or Preventive Actions;

24. Contacting the requesting entity about existing Nonconformances; and

25. Retesting or additional analyses of Test Batches, including but need not be limited to, when it is appropriate to retest or perform an additional analysis of the Test Batch, when it is appropriate to request a new Test Batch from the requesting entity, and when it is appropriate for the requesting entity to request retesting (e.g., after failing Pesticide testing or elemental impurity testing on Regulated Marijuana flower, trim, shake, or wet whole plant as permitted by Rule 4-135(d) and 4-135(D.1));

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

Basis and Purpose – 6-430

The statutory authority for this rule includes but is not limited to sections 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(d), 44-10-202(4), 44-10-401(2)(b)(IV), and 44-10-604, C.R.S. The purpose of this rule is to establish analytical processes standards for the operation of a Retail Marijuana Testing Facility. This Rule 6-430 was previously Rule R 706, 1 CCR 212-2.

6-430 –Retail Marijuana Testing Facilities: Analytical Processes

A. Gas Chromatography ("GC"). A Retail Marijuana Testing Facility using GC must:

1. Document the conditions of the gas chromatograph, including the detector response;

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

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

4. Document the performance of new columns before use;

5. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;

6. Establish criteria of acceptability for variances between different aliquots and different columns; and

7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.

B. Gas Chromatography Mass Spectrometry ("GC/MS"). A Retail Marijuana Testing Facility using GC/MS must:

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

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

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

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

5. Maintain records of mass spectrometric tuning;

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

7. Document corrective actions if a mass-spectrometric tune is unacceptable;

8. Monitor analytic analyses to check for contamination and carry-over;

9. Use selected ion monitoring within each run to assure that the laboratory compares ion ratios and retention times between calibrators, controls and samples for identification of an analyte;

10. Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

11. Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system;

12. Define the criteria for designating qualitative results as positive;

13. When a library is used to qualitatively identify an analyte, the identity of the analyte must be confirmed before reporting results by comparing the relative retention time and mass spectrum to that of a known standard or control run on the same system; and

14. Evaluate the performance of the instrument after routine and preventive maintenance (*e.g.* clipping or replacing the column or cleaning the source) prior to analyzing subject samples.

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

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

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

3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a sample is not included within the types of samples approved by the manufacturer; and

4. Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.

D. Thin Layer Chromatography ("TLC"). A Retail Marijuana Testing Facility using TLC must:

1. Apply unextracted standards to each thin layer chromatographic plate;

2. Include in their written procedure the preparation of mixed solvent systems, spray reagents and designation of lifetime;

3. Include in their written procedure the storage of unused thin layer chromatographic plates;

4. Evaluate, establish, and document acceptable performance for new thin layer chromatographic plates before placing them into service;

5. Verify that the spotting technique used precludes the possibility of contamination and carry-over;

6. Measure all appropriate RF values for qualitative identification purposes;

7. Use and record sequential color reactions, when applicable;

8. Maintain records of thin layer chromatographic plates; and

9. Analyze an appropriate matrix blank with each batch of Samples analyzed.

E. High Performance Liquid Chromatography ("HPLC"). A Retail Marijuana Testing Facility using HPLC must:

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

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

3. Monitor and document the performance of the HPLC instrument each day of testing;

4. Evaluate the performance of new columns before use;

5. Create written standards for acceptability when eluting solvents are recycled;

6. Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay; and

7. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system.

F. Liquid Chromatography Mass Spectroscopy ("LC/MS"). A Retail Marijuana Testing Facility using LC/MS must:

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

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

3. Maintain records of mass spectrometric tuning;

4. Document corrective actions if a mass-spectrometric tune is unacceptable;

5. Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

6. Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system;

7. Compare two transitions and retention times between calibrators, controls and samples within each run;

8. Document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument; and

9. Evaluate the performance of the instrument when changes in: source, source conditions, eluent, or column are made prior to reporting test results.

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

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

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

3. Validate any changes or modifications to a manufacturer's approved assays or testing methods when a test sample is not included within the types of Test Batches approved by the manufacturer;

4. Verify the method at the action levels for each analyte. Verification at the qualitative presence/absence limit shall include a fractional recovery study unless otherwise completed by the manufacturer and approved by an independent scientific body.

5. Include controls for each batch of test samples. Quantitative microbial methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;

6. For molecular methods, the Retail Marijuana Testing Facility shall include controls for each individual analytical run. Quantitative molecular methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;

7. PCR-based and qPCR-based methods must include validated internal amplification controls;

8. Microbial methods must include steps to confirm presumptive positive results; confirmation methods may be molecular or cultural or both. Confirmation methods must include quality controls that match the organism which is being confirmed.

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

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

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

3. Specify all unique method parameters, such as temperature, sample surface area, volatile compound interferences, including but not limited to temperature;

4. Evaluate the performance of the method after routine and preventive maintenance prior to analyzing the Test Batch;

5. Establish criteria for acceptable instrument performance.

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

1. Implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices prior to reporting results. Validation of other or new methodology must include when applicable, but is not limited to:

a. Verification of Accuracy

b. Verification of Precision

c. Verification of Analytical Sensitivity

d. Verification of Analytical Specificity

e. Verification of the LOD

f. Verification of the LOQ

g. Verification of the Reportable Range

h. Identification of Interfering Substances

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

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

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

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

J. Testing Validation of Complex Matrices. A Retail Marijuana Testing Facility must include a variety of matrices as part of the validation/verification process. During method validation/verification, a Retail Marijuana Testing Facility must:

1. Select matrices which best represent each category of products to be tested as listed in Rule 4-115(D). The laboratory shall independently determine the category of matrix a product falls within; properties to consider include fat content, cannabinoid content, pH, salt content, sugar content, water activity, the presence of know chemical compounds, microbial flora and antimicrobial compounds.

2. Perform a new matrix validation, prior to reporting results, on matrices which are either A) a new category of matrix or B) considerably different from the original matrix validated within the category.

a. For example, the Retail Marijuana Testing Facility intends to receive the topical product "bath bombs" for testing, but previous validation studies for topical product included lotion and massage oil. A new validation should be performed for the product prior to testing since salt content and other properties differ vastly from the original matrices validated.

3. Perform a matrix verification (a client matrix spike or similar consisting of the target analyte(s) at the time of analysis) on matrices submitted for testing which differ slightly from those initially validated but which fall within a category already validated.

a. For example, the Retail Marijuana Testing Facility receives a new edible type matrix for testing (snickerdoodle cookies) but previous validation included gummies and hard candy. A spike of a portion of the submitted material must be analyzed prior to, or at the time of, sample analysis.

K. All Test Batches and ~~Industrial~~ Hemp Product must be tested as received, must not be manipulated, and tested in a manner that ensures results are representative of sample as received.

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

6-700 Series – Accelerator Cultivator Licenses

Please Note: *The following proposed revisions seek to implement SB 23-271 statutory revisions in section 44-10-602.*

Basis and Purpose – 6-705

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(h), 44-10-203(2)(j), 44-10-203(2)(r), 44-10-203(2)(aa), 44-10-203(3)(c), 44-10-401(2)(b)(VII), 44-10-602, and 44-10-607 C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to an Accelerator Cultivator licensee.

6-705 – Accelerator Cultivator: License Privileges

A. Licensed Premises.

1. Shared Licensed Premises. An Accelerator Cultivator may operate on the same Licensed Premises as a Retail Marijuana Cultivation Facility that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.

2. Separate Licensed Premises. An Accelerator Cultivator may operate on a separate premises in the possession of a Retail Marijuana Cultivation Facility that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.

3. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Cultivation Facility may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Cultivation Facility. However, a separate license is required for each specific business or business entity, regardless of geographical location. A Regulated Marijuana Business that is operating at the same premises as a commonly owned Medical Marijuana Business may become an Accelerator-Endorsed Licensee. An Accelerator Cultivator may operate at the premises where the Accelerator-Endorsed Licensee operates along with the commonly owned Medical Marijuana Cultivation Facility.

B. Cultivation of Retail Marijuana and Production of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Retail Marijuana Concentrate Authorized. An Accelerator Cultivator may propagate, cultivate, harvest, prepare, cure, package, store, and label Retail Marijuana and Physical Separation-Based Retail Marijuana Concentrate. An Accelerator Cultivator may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana from Physical Separation-Based Retail Marijuana Concentrate.

C. Authorized Transfers. An Accelerator Cultivator may only Transfer Retail Marijuana and Physical Separation-Based Retail Marijuana Concentrate to another Retail Marijuana Business or to a Medical Marijuana Cultivation Facility in compliance with Rule 6-230.

1. An Accelerator Cultivator shall not Transfer Flowering plants. An Accelerator Cultivator may only Transfer Vegetative plants as authorized pursuant to Rule 3-605.

2. An Accelerator Cultivator may Transfer Sampling Units of Retail Marijuana or Retail Marijuana Concentrate to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-602(6), C.R.S., and Rule 6-725.

3. An Accelerator Cultivator may Transfer Retail Marijuana or Retail Marijuana Concentrate to another Accelerator Cultivator or Retail Marijuana Cultivation Facility prior to testing required by these rules to perform a Microbial Control Step ~~for the purpose of Decontamination~~ only after all other steps outlined in the Accelerator Cultivator's standard operating procedures have been completed, including but not limited to drying, curing, and trimming.

4. An Accelerator Cultivator may Transfer Immature Plants, Retail Marijuana seeds, and Genetic Material to a Medical Marijuana Cultivation Facility, a Retail Marijuana Cultivation Facility, or an Accelerator Cultivator. Transfers made under this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.

D. Authorized On-Premises Storage. An Accelerator Cultivator is authorized to store inventory on the Licensed Premises. All inventory stored on the Licensed Premises must be secured in a Limited Access Area and tracked consistently with the inventory tracking rules.

E. Samples Provided for Testing. An Accelerator Cultivator may provide Samples of its Retail Marijuana to a Retail Marijuana Testing Facility for testing and research purposes. The

Accelerator Cultivator shall maintain the testing results as part of its business books and records. *See* Rule 3-905 – Business Records Required.

F. Authorized Marijuana Transport. An Accelerator Cultivator is authorized to utilize a licensed Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken and delivered is a licensed Retail Marijuana Business. Nothing in this Rule prevents an Accelerator Cultivator from transporting its own Retail Marijuana.

G. Performance-Based Incentives. An Accelerator Cultivator may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, an Accelerator Cultivator may not compensate a Sampling Manager using Sampling Units. *See* Rule 6-725 – Sampling Unit Protocols.

H. Authorized Sources of Retail Marijuana, Seeds, ~~and~~ Immature Plants, and Genetic Material.

1. An Accelerator Cultivator ~~shall only~~may obtain Retail Marijuana seeds or Immature Plants from its own Retail Marijuana, properly Transferred Medical Marijuana cultivated at a Medical Marijuana Cultivation Facility with at least one identical Controlling Beneficial Owner, or properly Transferred from another Retail Marijuana Business pursuant to the inventory tracking requirements in the 3-800 Series Rules. An Accelerator Cultivator may not bring seeds, Immature Plants, or other marijuana that is not Regulated Marijuana onto the Licensed Premises at any time.

2. An Accelerator Cultivator may obtain Retail Marijuana seeds, Immature Plants, and Genetic Material from:

   a. Another Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility;

   b. A Retail Marijuana Testing Facility;

   c. A marijuana cultivation or testing facility licensed or otherwise approved pursuant to a permit or registration issued by a government agency to operate in another state or territory of the United States;

   d. An individual licensed as an Employee Licensee in Colorado, or holding a permit, registration, or license to work in cannabis in another state or territory of the United States; or

   e. Pursuant to any federal legal authority allowing interstate commerce of Regulated Marijuana.

3. Transfers made under subparagraph (H)(2) of this Rule must be in compliance with the 3-800 and the 3-900 Rules Series.

I. Centralized Distribution Permit. An Accelerator Cultivator may apply to the State Licensing Authority for a Centralized Distribution Permit for authorization to temporarily store Retail Marijuana Concentrate and Retail Marijuana Product received from a Retail Marijuana Products Manufacturer for the sole purpose of Transfer to commonly owned Accelerator Stores.

1. For purposes of a Centralized Distribution Permit only, the term “commonly owned” means at least one natural person has a minimum of five percent ownership in both the Accelerator Cultivator possessing a Centralized Distribution Permit and the Accelerator Store to which the Retail Marijuana Concentrate and Retail Marijuana Product will be Transferred.

2. To apply for a Centralized Distribution Permit, an Accelerator Cultivator may submit an addendum to its new or renewal application or a separate addendum prior to a renewal application on forms prepared by the Division to request a Centralized Distribution Permit. The Accelerator Cultivator shall send a copy of its Centralized Distribution Permit addendum to the Local Licensing Authority in the jurisdiction in which the Centralized Distribution Permit is proposed at the same time it submits the addendum to the State Licensing Authority.

3. An Accelerator Cultivator that has been issued a Centralized Distribution Permit and has obtained all required approvals from the local licensing jurisdiction where it is located, if any, may accept Transfers of Retail Marijuana Concentrate and Retail Marijuana Product from a Retail Marijuana Products Manufacturer for the sole purpose of temporary storage and Transfer to commonly owned Accelerator Stores.

   a. An Accelerator Cultivator may only accept Retail Marijuana Concentrate and Retail Marijuana Product that is packaged and labeled for sale to a consumer pursuant to the 3-1000 Series Rules.

   b. An Accelerator Cultivator storing Retail Marijuana Concentrate and Retail Marijuana Product pursuant to a Centralized Distribution Permit shall not store such Retail Marijuana Concentrate or Retail Marijuana Product on the Accelerator Cultivator's Licensed Premises for more than 90 days from the date of receipt.

   c. All Transfers of Retail Marijuana Concentrate and Retail Marijuana Product by an Accelerator Cultivator pursuant to a Centralized Distribution Permit shall be without consideration.

4. All security and surveillance requirements that apply to an Accelerator Cultivator apply to activities conducted pursuant to the privileges of a Centralized Distribution Permit.

J. Transition Permit. An Accelerator Cultivator may only operate at two geographical locations pursuant to Rule 2-255(D).

6-800 Series – Accelerator Manufacturer Licenses

Basis and Purpose – 6-805

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(2)(d), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-203(2)(aa), 44-10-307(1)(j), 44-10-401(2)(b)(VIII), 44-10-603 and 44-10-608, C.R.S. The purpose of this rule is to establish the license privileges granted by the State Licensing Authority to an Accelerator Manufacturer.

6-805 – Accelerator Manufacturer: License Privileges

A. Licensed Premises.

1. Shared Licensed Premises. An Accelerator Manufacturer may operate on the same Licensed Premises as a Retail Marijuana Products Manufacturer that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.

2. Separate Licensed Premises. An Accelerator Manufacturer may operate on a separate premises in the possession of a Retail Marijuana Products Manufacturer that is an Accelerator-Endorsed Licensee pursuant to the 3-1100 Series Rules.

3. To the extent authorized by Rule 3-215 – Regulated Marijuana Businesses: Shared Licensed Premises and Operational Separation, a Retail Marijuana Products Manufacturer may share, and operate at, the same Licensed Premises with a commonly owned Medical Marijuana Products Manufacturer Facility. However, a separate license is required for each specific business or business entity, regardless of geographical location. A Regulated Marijuana Business that is operating at the same premises as a commonly owned Medical Marijuana Business may become an Accelerator-Endorsed Licensee. An Accelerator Manufacturer may operate at the premises where the Accelerator-Endorsed Licensee operates along with the commonly owned Medical Marijuana Products Manufacturer.

B. Authorized Transfers. An Accelerator Manufacturer is authorized to Transfer Retail Marijuana as follows:

1. Retail Marijuana Concentrate and Retail Marijuana Product.

a. An Accelerator Manufacturer may Transfer Retail Marijuana Concentrate or Retail Marijuana Product to Retail Marijuana Stores, Accelerator Stores, other Accelerator Manufacturers, Retail Marijuana Products Manufacturers, Retail Marijuana Testing Facilities, Retail Marijuana Hospitality and Sales Businesses, and Pesticide Manufacturers.

b. An Accelerator Manufacturer may Transfer Retail Marijuana Product and Retail Marijuana Concentrate to a Retail Marijuana Cultivation Facility that has been issued a Centralized Distribution Permit.

i. Prior to any Transfer pursuant to this Rule 6-805(B)(1)(b), an Accelerator Manufacturer shall verify the Retail Marijuana Cultivation Facility possesses a valid Centralized Distribution Permit. *See* Rule 6-205 – Retail Marijuana Cultivation Facility: License Privileges.

ii. For any Transfer pursuant to this Rule 6-805(B)(1)(b), an Accelerator Manufacturer shall only Transfer Retail Marijuana Product and Retail Marijuana Concentrate that is packaged and labeled for Transfer to a consumer. *See* 3-1000 Series Rules.

c. An Accelerator Manufacturer may Transfer Retail Marijuana Concentrate to a Medical Marijuana Products Manufacturer in compliance with Rule 6-335.

2. Retail Marijuana. An Accelerator Manufacturer may Transfer Retail Marijuana to other Accelerator Manufacturers, Retail Marijuana Products Manufacturer, Retail Marijuana Testing Facilities, Accelerator Stores, and Retail Marijuana Stores.

3. Sampling Units. An Accelerator Manufacturer may also Transfer Sampling Units of its own Retail Marijuana Concentrate or Retail Marijuana Product to a designated Sampling Manager in accordance with the restrictions set forth in section 44-10-603(10), C.R.S., and Rule 6-820.

C. Manufacture of Retail Marijuana Concentrate and Retail Marijuana Product and Production of Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana Authorized. An Accelerator Manufacturer may manufacture, prepare, package, store, and label Retail Marijuana Concentrate and Retail Marijuana Product comprised of Retail Marijuana and other Ingredients intended for use or consumption, such as Edible Retail Marijuana Products, ointments, or tinctures. An Accelerator Manufacturer may also produce Pre-Rolled Marijuana and Infused Pre-Rolled Marijuana.

1. ~~Industrial~~ Hemp Product Authorized. An Accelerator Manufacturer that uses ~~Industrial~~ Hemp Product as an Ingredient in the manufacture and preparation of Retail Marijuana Product must comply with this subparagraph (C)(1) of this Rule.

    a. Prior to accepting and taking possession of any ~~Industrial~~ Hemp Product for use as an Ingredient in a Retail Marijuana Product the Accelerator Manufacturer shall verify the following:

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

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

D. Location Prohibited. An Accelerator Manufacturer may not manufacture, prepare, package, store, or label Retail Marijuana Concentrate or Retail Marijuana Product in a location that is operating as a retail food establishment.

E. Samples Provided for Testing. An Accelerator Manufacturer may provide samples of its Retail Marijuana Concentrate or Retail Marijuana Product to a Retail Marijuana Testing Facility for testing and research purposes. The Accelerator Manufacturer shall maintain the testing results as part of its business books and records. *See* Rule 3-905 – Business Records Required.

F. Authorized Marijuana Transport. An Accelerator Manufacturer is authorized to utilize a Retail Marijuana Transporter for transportation of its Retail Marijuana so long as the place where transportation orders are taken is a Retail Marijuana Business and the transportation order is delivered to a Retail Marijuana Business or Pesticide Manufacturer. Nothing in this Rule prevents an Accelerator Manufacturer from transporting its own Retail Marijuana.

G. Performance-Based Incentives An Accelerator Manufacturer may compensate its employees using performance-based incentives, including sales-based performance-based incentives. However, an Accelerator Manufacturer may not compensate a Sampling Manager using Sampling Units. *See* Rule 6-820 – Sampling Unit Protocols.

Basis and Purpose – 6-810

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-203(1)(a), 44-10-203(1)(c), 44-10-203(1)(k), 44-10-203(2)(f), 44-10-203(2)(g), 44-10-203(2)(h), 44-10-203(2)(i), 44-10-203(2)(y), 44-10-203(2)(aa), 44-10-203(3)(d), 44-10-401(2)(b)(VIII), 44-10-603, 44-10-608 and 44-10-701(2)(a), C.R.S. The purpose of this rule is to clarify those acts that are limited in some fashion or prohibited by an Accelerator Manufacturer.