



# **ADULT USE MARIJUANA PROGRAM RULE**

18-691 C.M.R., Chapter 1

**Office of Marijuana Policy  
Department of Administrative and Financial Services**

Major Substantive Rules Effective Date: December 5, 2019

Routine Technical Rules Effective Date: September 18, 2020

# Table of Contents

General	5
Section 1 - Adult Use Marijuana Program	5
1.1 - Statutory Authority	5
1.2 - Department Authority	5
1.3 - Communication with Department	5
1.4 - Definitions	5
Section 2 – Licenses and Licensing	16
2.1 - License Types	16
2.2 - Types of Marijuana Establishment Licenses	16
2.3 - Qualifications	20
2.4 - Application for Conditional License	25
2.5 - Application for Active Sample Collector License	33
2.6 - Department Review of Applications for Conditional Licenses and Active Sample Collector License	34
2.7 - Application for Active License of a Cultivation Facility, Testing Facility, Products Manufacturing Facility or Marijuana Store, Including Provisional Testing License	36
2.8 - Individual Identification Cards	39
2.9 - License Renewal Process	40
2.10 - Application for Relocation of Licensed Premises	42
2.11 - Transfer of Ownership Interests	43
Section 3 - General Compliance	43
3.1 - Reporting of Ownership, Financial, Management and Other Interests	43
3.2 - Premises	44
3.3 - Security	47
3.4 - General Conduct	49
3.5 - Adherence to Written Plans Approved by the Department	50
3.6 - Requirements Applicable to Cultivation Facilities	51
3.7 - Requirements Applicable to Testing Facilities	53
3.8 - Requirements Applicable to Products Manufacturing Facilities	56
3.9 - Requirements Applicable to Marijuana Stores and Nursery Cultivation Facilities	59
3.10 – Requirements Applicable to Sample Collectors	62

Section 3.11 – Recordkeeping Requirements for Sample Collection, Transport and Receipt	64
Section 4 - Tracking	66
4.1 - General Tracking Requirements	66
4.2 - Transportation	68
Section 5 - Advertising	71
5.1 - Definitions	71
5.2 - Prohibitions	71
5.3 - Websites	72
5.4 - Required Statements	72
5.5 - Objectionable and Non-Conforming Advertising	72
Section 6 - Licensee Samples	73
6.1 - Trade Samples	73
6.2 - Samples for Mandatory Testing or Research and Development	73
Section 7 - Authorized Transfers	74
Section 8 - Product Safety	75
8.1 - General Sanitary Requirements	75
8.2 - Marijuana Products Manufacturing Facility Product Safety	75
8.3 – Mandatory Testing	76
Section 9 - Waste Management	80
9.1 - Hazardous Waste	80
9.2 - Marijuana Waste	80
Section 10 - Wastewater	81
Section 11 - Packaging and Labeling	81
11.1 - General Packaging and Labeling Requirements for Retail Sale	81
11.2 - Packaging and Labeling of Trade Samples	83
11.3 - Packaging and Labeling for Retail Sale of Inhaled Marijuana Products	83
11.4 - Packaging and Labeling for Retail Sale of Edible Marijuana Products	84
11.5 - Packaging and Labeling for Retail Sale of Topical Marijuana Products	86
11.6 - Packaging and Labeling of Samples Collected by a Licensee	86
11.7 - Packaging and Labeling for Storage by a Marijuana Establishment	87
Section 12 - Enforcement	88
12.1 - Department Enforcement Authority	88
12.2 – Administrative Monetary Penalties	89

12.3 - License Restriction, Suspension, Revocation and Voluntary Surrender	91
12.4 - Destruction and Voluntary Surrender of Marijuana Plants, Marijuana and Marijuana Products	93
12.5 - Audit, Compliance and Random Testing	94
12.6 - Seizure or Confiscation of Marijuana, Marijuana Concentrate or Marijuana Products	94
12.7 - Marijuana Recalls	95
Section 13 - Fee Schedule	96
13.1 - Payment of Fees	96
13.2 - Return of Fees Prohibited	96
13.3 - Individual Identification Card Fees	96
13.4 - Fingerprinting and Criminal History Record Check Fee	96
13.5 - Tracking System Fees	96
13.6 - Cultivation Facility Application and License Fees	97
13.7 - Other Marijuana Establishment Application and License Fees	97
13.8 - Other Marijuana Establishment Fees	97
13.9 - Annual Renewal and Late Renewal Application and License Fees	97
Appendix A	98
<b>Section 1: Purpose</b>	98
<b>Section 2: Compliance Documents</b>	98
<b>Section 3: Applicable Matrix or Matrices</b>	98
<b>Section 4: Scope / Field of Application</b>	98
<b>Section 5: Summary of Procedure</b>	98
<b>Section 6: Definitions and Acronyms</b>	98
<b>Section 7: Safety</b>	100
<b>Section 8: Pre-Sample Collection Procedure</b>	100
<b>Section 9: Materials Required - Equipment and Supplies</b>	100
<b>Section 10: Reagents and Standards</b>	101
<b>Section 11: Sample collection, preservation, shipment and storage</b>	101
<b>Section 12: Sample Transportation and Receipt</b>	107
<b>Section 13: Recording Sampling Events in METRC Inventory Tracking System</b>	107
<b>Section 14: Quality Control</b>	107
<b>Section 15: Calibration and Standardization</b>	108
<b>Section 16: Waste Management</b>	108
<b>Section 17: Documentation</b>	108



## General

This Rule establishes the requirements for becoming a licensed marijuana establishment, including fees, application and licensing processes and procedures for cultivation, manufacture, sample collection, testing and retail sale of adult use marijuana and adult use marijuana products. The activities described in this Rule may be considered a violation of federal law. Persons cultivating, manufacturing, collecting samples of, testing, selling, purchasing or otherwise receiving adult use marijuana or adult use marijuana products may be subject to federal sanctions for what may otherwise be considered authorized conduct in the State of Maine, and compliance with the rule does not exempt licensees, their employees or customers from possible federal prosecution. The Department is not responsible or liable for the actions of licensed marijuana establishments under the Rule.

### Section 1 - Adult Use Marijuana Program

#### 1.1 - Statutory Authority

The Department of Administrative and Financial Services (referred heretofore as the Department), acting through its Office of Marijuana Policy, has developed the following Rule in accordance with the statutory authority provided in Title 28-B, § 104 and P.L. 2019, Ch. 676 (emergency, effective March 23, 2020), for the purpose of implementing, administering and enforcing the provisions of 28-B MRS, chapter 1.

#### 1.2 - Department Authority

The Department may enforce this Rule and any relevant provisions of 4 MRS, 5 MRS, 28-B MRS and other general statutes, laws, executive orders or subsequently passed legislation. The Department shall set licensing fees in accordance with 28-B MRS § 207. As applicable, the Department may delegate authority to appropriate state and local agencies. The Department, or an agent thereof, shall have the authority to inspect, during operating hours, times of apparent activity or other reasonable time, any marijuana establishment, vehicles used to transport marijuana or marijuana products or business records.

#### 1.3 - Communication with Department

**1.3.1 Written Communications.** If an applicant or licensee is required to or elects to submit anything in writing to the Department, unless otherwise prescribed by the Department, the applicant or licensee may submit the writing to the Department via:

- A. Mail;
- B. In-person delivery;
- C. Facsimile; or
- D. E-mail.

**1.3.2 Submission Deadline.** If a written notification must be submitted by a deadline it must be received by the Department, regardless of the method used to submit the writing, by 5:00 p.m. Eastern Time.

#### 1.4 - Definitions

1. **Action level:** “Action level” means the threshold value for determining whether a sample passes or fails an analytical test.

2. **Active license:** “Active license” means a license issued by the Department that authorizes cultivation, sample collection, testing, manufacture or sale of marijuana or marijuana products in accordance with 28-B MRS and this Rule.
3. **Adult use marijuana:** "Adult use marijuana" means marijuana cultivated, manufactured, tested, distributed or sold by a marijuana establishment.
4. **Adult use marijuana product:** "Adult use marijuana product" means a marijuana product that is manufactured, distributed or sold by a marijuana establishment.
5. **Analyst:** “Analyst” means the designated individual who tests the samples by performing the “hands-on” analytical methods and associated techniques. The analyst is responsible for applying required testing facility practices and other pertinent quality controls to meet the required level of quality.
6. **Analyte:** “Analyte” means a chemical, compound, element, bacteria, yeast, fungus or toxin that is identified or measured.
7. **Another jurisdiction:** "Another jurisdiction" means the Federal Government, the United States military, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the United States Virgin Islands, Guam, American Samoa and each of the several states of the United States except Maine.
8. **Apparent activity:** “Apparent activity” is any sights, sounds, smells or other indications that persons are present at a marijuana establishment.
9. **Applicant:** "Applicant" means a person who submits an application for a license under this Rule to the Department for review that the Department has not yet approved or denied.
10. **Batch:** “Batch” means:
  - a. A harvest batch; or
  - b. A production batch.
11. **Batch number:** "Batch number" means a distinct group of numbers, letters or symbols, or any combination thereof, assigned to a specific batch of adult use marijuana by a cultivation facility, sample collector, testing facility, or a marijuana store or to a specific batch of adult use marijuana or adult use marijuana products by a products manufacturing facility, sample collector, testing facility or a marijuana store.
12. **Best Practices Guide:** “Best Practices Guide” means the *Best Practices for the Sampling of Adult Use Marijuana*, Version 3.1, dated September 11, 2020, published by the Department available at: <https://www.maine.gov/dafs/omp/adult-use/applications-forms>; which is incorporated herein by reference. All licensees and any employee of a licensee collecting samples of marijuana, marijuana concentrate, or marijuana products for mandatory testing must collect samples in accordance with the best practices described in the guide.
13. **Business entity:** "Business entity" means a partnership, association, company, corporation, limited liability company or other entity incorporated or otherwise formed or organized by law. "Business entity" does not include a federal, state or municipal government organization.
14. **Cannabinoid:** “Cannabinoid” means a chemical compound that is unique to, and derived from, marijuana.
15. **Caregiver:** "Caregiver" has the same meaning as in 22 MRS§2422(8-A).
16. **Certificate of analysis:** “Certificate of analysis” means the report prepared for the party requesting testing and the Department about the analytical testing performed and results obtained by the marijuana testing facility.

17. **Certification:** “Certification” means the process by which an agency or organization evaluates and recognizes a marijuana testing facility as meeting certain predetermined qualifications or standards, thereby certifying the marijuana testing facility. The Department of Health and Human Services (DHHS), Center for Disease Control and Prevention (CDC), is responsible for certification of all marijuana testing facilities.
18. **Chain of custody form:** “Chain of custody form” means a record, either paper-based or electronic, that documents the possession of the samples at the time of receipt by the marijuana testing facility, in accordance with chain of custody protocol prescribed by the marijuana testing facility. This record, at a minimum, must include the sample location, the number and types of containers, the mode of collection, the authorized individual who collected the sample, the date and time of collection, preservation and requested analyses.
19. **Chain of custody protocols:** “Chain of custody protocols” means the procedures developed and employed by the marijuana testing facility to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a chain of custody form that documents the collection, transport and receipt of compliance samples by the marijuana testing facility. In addition, these protocols document all handling of the samples within the marijuana testing facility and, if applicable, by the sample collector or self-sampler.
20. **Child-resistant:** "Child-resistant" means, with respect to packaging or a container:
  - a. Specially designed or constructed to be significantly difficult for a typical child under 5 years of age to open and not to be significantly difficult for a typical adult to open and reseal; and
  - b. With respect to any product intended for more than a single use or that contains multiple servings, resealable.
21. **Conditional license:** “Conditional license” is a license issued by the Department that authorizes the licensee to seek local authorization to operate a cultivation facility, testing facility, products manufacturing facility or marijuana store. The conditional license does not authorize possession, transfer, cultivation, testing, manufacture or sale of marijuana or marijuana products.
22. **Contaminant:** “Contaminant” means an unacceptable level of an unwanted or objectionable substance, toxin, pollution or foreign material that causes impurity in a product. Contaminants include, but are not limited to, pesticides, microbiology, filth, heavy metals and residual chemical solvents.
23. **Container:** "Container" means a sealed package in which adult use marijuana or an adult use marijuana product is placed by a marijuana store prior to sale to a consumer and that meets all applicable packaging, labeling and health and safety requirements of this Rule.
24. **Criminal justice agency:** “Criminal justice agency" has the same meaning as in 16 MRS§803(4).
25. **Cultivation:** "Cultivation" or "cultivate" means the planting, propagation, growing, harvesting, drying, curing, grading, trimming or other processing of marijuana for use or sale. "Cultivation" or "cultivate" does not include manufacturing, testing or marijuana extraction.
26. **Cultivation facility:** "Cultivation facility" means a facility licensed under this Rule to purchase marijuana plants and seeds from other cultivation facilities; to cultivate, prepare and package adult use marijuana; to collect and transport samples of marijuana cultivated by that facility for mandatory testing; to sell adult use marijuana to products manufacturing facilities, to marijuana stores and to other cultivation facilities; and to sell marijuana plants and seeds to other cultivation facilities and immature marijuana plants and seedlings to marijuana stores. A cultivation facility includes a nursery cultivation facility. Licensees that cultivate marijuana in a nursery cultivation facility may sell an unlimited number of marijuana seeds and a sum total of 12 seedlings and immature plants to a consumer 21 years of age or older.
27. **Department:** “Department” means the Department of Administrative and Financial Services.



28. **Department of Health and Human Services (DHHS):** “Department of Health and Human Services (DHHS)” means the Maine Department of Health and Human Services. DHHS includes the Maine Center for Disease Control and Prevention (CDC), which certifies, through its Maine Marijuana Certification Program, the technology and testing methods used by marijuana testing facilities under this Rule.
29. **Direct or Indirect Financial Interest:** “Direct or Indirect Financial Interest” means any interest in a sole proprietorship or business entity that is applying for or holds a marijuana establishment license, including without limitation:
- a. **Equity Owners.** Proprietors, partners, shareholders, persons with membership interests, and persons with any other equity ownership interests such as purchase warrants or options, whether whole or partial.
  - b. **Other Equity Ownership.** Any employee, independent contractor, professional, or other person who/which has an agreement with the licensee that provides for their attaining any form of equity ownership.
  - c. **Royalty License Partners.** All person(s) who/which expect to receive financial payment, including without limitation, royalty payments, profit share or revenue share, in return for the licensing of an intellectual property asset or proprietary property, whether or not such assets or property be trademarked or patented, including without limitation, standard operating procedures, brand names, products, packaging, marketing materials, business plans or financial projections.
  - d. **Employee, Contractor and Other Profit Sharing Arrangements.** Any employee, independent contractor, professional, or other person who/which has an agreement with the licensee that provides for their attaining or receiving any form of profit sharing, commissions or the like.
  - e. **Capital Investors and Lenders.** All persons that invest in or lend money to a licensee with the expectation of receiving repayment, with or without additional interest and/or other financial payments or benefits as a condition of investing or lending. Lenders include persons that are holders of any negotiable instruments the licensee is indebted to. Except that state- or federally-chartered banks, credit unions or savings/loan institutions whose only financial interest constitutes a loan, need only provide a copy of the financial instrument recording the terms of the loan.
  - f. **Management Contractors and Consultants.** Persons that exert significant influence or decision-making authority over the licensee’s business plan, marketing strategy, operations or that otherwise control the business; and including any third-party contracted persons or other entities which provide ongoing management and/or consulting services to a licensee for a period longer than 6 months.
  - g. **Officers, Directors, Managers, and General Partners.** Any persons in these positions.
  - h. **Business Entities.** If any of the persons above are business entities, they shall list all persons which have the interests listed in (a), (b) and (g) in the business entity, until only individuals remain, excepting only individuals who own less than 5% of the total shares in a publicly traded company.
30. **Disqualifying drug offense:** “Disqualifying drug offense” means a conviction for a violation of a state or federal controlled substance law that is a crime punishable by imprisonment for one year or more, except that "disqualifying drug offense" does not include:
- a. An offense for which the sentence, including any term of probation, incarceration or supervised release, was completed 10 or more years prior to the submission of an application for a license under this Rule; or
  - b. An offense that consisted of conduct that is authorized under 28-B MRS, chapter 3.
31. **Edible marijuana product:** "Edible marijuana product" means a marijuana product intended to be consumed orally, including, but not limited to, any type of food, drink or pill containing marijuana or marijuana concentrate.
32. **Facility director:** “Facility director” means the individual who is legally authorized to direct the activities of a marijuana testing facility and who commits the appropriate resources to comply with this rule.

33. **Flowering:** "Flowering" means, with respect to a marijuana plant, the gametophytic or reproductive state of a female marijuana plant during which the plant is in a light cycle intended to produce flowers, trichomes and cannabinoids characteristic of marijuana.
34. **Full active license:** "Full active license" means a license issued by the Department to a marijuana testing facility that has received full certification from the CDC and ISO/IEC 17025:2017 accreditation for at least one technology and analyte, that authorizes testing of marijuana or marijuana products in accordance with 28-B MRS, Chapter 1, subchapters 2 and 6 and this Rule.
35. **Full certification:** "Full certification" means certification granted by the CDC pursuant to *Rules for the Certification of Marijuana Testing Facilities*, 18-691 CMR, ch. 5, to a marijuana testing facility that has received ISO/IEC 17025:2017 accreditation for at least one technology and analyte and meets all other requirements of this Rule. Full certification is a prerequisite for the issuance of a full active license by the Department pursuant to this Rule.
36. **Harvest batch:** "Harvest batch" means a specific quantity of adult use marijuana harvested from adult use marijuana plants of the same strain, grown under the same conditions, and harvested during a specified period of time from a specified cultivation area within a cultivation facility.
37. **Homogeneity:** "Homogeneity" means the amount of marijuana or marijuana concentrate and cannabinoids within the product being consistent and reasonably equally dispersed throughout the product or each portion of the product or concentrate, or a representative sample.
38. **Identity statement:** "Identity statement" means the name of a business entity as it is commonly known and used in any advertising or marketing by the business entity.
39. **Immature marijuana plant:** "Immature marijuana plant" means a marijuana plant that is not a mature marijuana plant or a seedling.
40. **Infused marijuana product:** "Infused marijuana product" means a product or compound that includes one or more marijuana concentrate along with other materials or ingredients, including without limitation, edible marijuana products and topical marijuana products.
41. **Inhaled marijuana product:** "Inhaled marijuana product" means marijuana, marijuana concentrate or marijuana products that are intended to be consumed by inhalation, including, without limitation: marijuana flower or trim, pre-rolled marijuana cigarettes, vaporizer cartridges and vaporizer pens.
42. **Inherently hazardous substance:** "Inherently hazardous substance" means a liquid chemical, compressed gas or commercial product that has a flash point at or lower than 38 degrees Celsius or 100 degrees Fahrenheit, including, but not limited to, butane, propane and diethyl ether. "Inherently hazardous substance" does not include any form of alcohol or ethanol.
43. **Intermediate packaging:** "Intermediate packaging" means packaging materials that are not part of the marketing layer or container, but are included inside an outer container layer, such as a marketing layer.
44. **Intoxication:** "Intoxication" means a substantial impairment of an individual's mental or physical faculties as a result of drug or alcohol use.
45. **ISO/IEC 17025:2017:** "ISO/IEC 17025:2017" means the general requirements for the competence of testing and calibration laboratories issued in 2017 joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission, and any subsequent revision or version thereof.
46. **Law enforcement officer:** "Law enforcement officer" has the same meaning as in 17-A MRS§2(17).
47. **Licensed premises:** "Licensed premises" means the premises specified in a license to operate a marijuana establishment within which the licensee is authorized under this Rule to cultivate, manufacture, distribute, sample, test or sell adult use marijuana or adult use marijuana products.

48. **Licensee:** "Licensee" means a natural person or business entity licensed pursuant to 28-B MRS to operate a marijuana establishment.
49. **Limited access area:** "Limited access area" means a building, room or other area within the licensed premises of a marijuana establishment where a licensee is authorized to cultivate, store, weigh, manufacture, sample, package or otherwise prepare for testing, transfer or retail sale, marijuana and marijuana products. A "limited access area" can only be accessed by authorized persons displaying individual identification cards or authorized contractors of the licensee aged 21 and older displaying a visitor identification badge.
50. **Liquid:** "Liquid" means a substance that flows freely but is of constant volume, having a consistency like that of water or oil.
51. **Local authorization:** "Local authorization" means authorization from a municipality in accordance with 28-B MRS§402 or authorization from the Maine Land Use Planning Commission and either a town, plantation, or county commission in accordance with 28-B MRS§403. Local authorization is not required for sample collector licenses.
52. **Manufacture:** "Manufacture" or "manufacturing" means the production, blending, infusing, compounding or other preparation of marijuana and marijuana products, including but not limited to marijuana extraction or preparation by means of chemical synthesis. "Manufacture" or "manufacturing" does not include cultivation or testing.
53. **Marijuana:** "Marijuana" means the leaves, stems, flowers and seeds of a marijuana plant, whether growing or not. "Marijuana" includes marijuana concentrate, except where context indicates otherwise, but does not include hemp as defined in 7 MRS §2231, or a marijuana product.
54. **Marijuana concentrate:** "Marijuana concentrate" means the resin extracted from any part of a marijuana plant and every compound, manufacture, salt, derivative, mixture or preparation from such resin, including, but not limited to, hashish. In determining the weight of marijuana concentrate in a marijuana product, the weight of any other ingredient combined with marijuana or marijuana concentrate to prepare the marijuana product may not be included.
55. **Marijuana drink:** "Marijuana drink" means a liquid edible marijuana product with a concentration of less than 1 mg of THC per ounce of liquid
56. **Marijuana establishment:** "Marijuana establishment" means a cultivation facility, a products manufacturing facility, a testing facility, a sample collector or a marijuana store licensed under 28-B MRS and this Rule.
57. **Marijuana extraction:** "Marijuana extraction" means the process of extracting marijuana concentrate from marijuana using water, lipids, gases, solvents or other chemicals or chemical processes.
58. **Marijuana flower:** "Marijuana flower" means the pistillate reproductive organs of a mature marijuana plant, whether processed or unprocessed, including the flowers and buds of the plant. "Marijuana flower" does not include marijuana trim or whole mature marijuana plants.
59. **Marijuana plant:** "Marijuana plant" means all species of the plant genus cannabis, including, but not limited to, a mother plant, a mature marijuana plant, an immature marijuana plant or a seedling but it does not include a marijuana product or "hemp" as defined in 7 MRS § 2231.
60. **Marijuana products:** "Marijuana products" means a product composed of marijuana or marijuana concentrate and other ingredients that is intended for use or consumption. "Marijuana product" includes, but is not limited to, an edible marijuana product, a marijuana ointment and a marijuana tincture. "Marijuana product" does not include marijuana concentrate.
61. **Marijuana store:** "Marijuana store" means a facility licensed under this Rule to purchase adult use marijuana, immature marijuana plants and seedlings from a cultivation facility, to purchase adult use

marijuana and adult use marijuana products from a products manufacturing facility, to collect and transport samples of marijuana, marijuana concentrate and marijuana products in that marijuana store's possession for mandatory testing, and to sell adult use marijuana, adult use marijuana products, immature marijuana plants and seedlings to consumers.

62. **Marijuana Testing Facility or Testing Facility:** "Marijuana testing facility" or "testing facility" means an entity licensed according to 28-B MRS §503, including those also registered as marijuana testing facilities in accordance with 22 MRS §2423-A, to test marijuana, marijuana products and other substances for research and development and to analyze contaminants in and the potency and cannabinoid profile of samples in an approved location. A marijuana testing facility is authorized to collect samples of marijuana, marijuana concentrate and marijuana products without a separate sample collector license in accordance with *Rules for the Certification of Marijuana Testing Facilities*, 18-691 CMR, ch. 5.
63. **Marijuana trim:** "Marijuana trim" means any part of a marijuana plant, whether processed or unprocessed, that is not marijuana flower or a marijuana seed.
64. **Marijuana waste** "Marijuana waste" means marijuana, marijuana plants or marijuana products that are unfit for retail sale for reasons including, without limitation, failed mandatory testing, expired products or crop failure.
65. **Marketing layer:** "Marketing layer" means the outermost layer of a retail sale container, which is most predominantly apparent and visible, such as a box or bag that another container containing marijuana, marijuana plants, marijuana concentrate, or marijuana products are within. If the retail sale container consists of only a single layer, then the outer surface of the retail sale container is the marketing layer.
66. **Matrix or matrices:** "Matrix" or "matrices" means the component or substrate that contains the analyte of interest (e.g. marijuana flower, trim, marijuana cigarettes, types of marijuana concentrate, types of marijuana products, etc.).
67. **Mature marijuana plant:** "Mature marijuana plant" means a marijuana plant that is flowering.
68. **Method:** "Method" means a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis or quantification), systematically presented in the order in which they are to be executed.
69. **Moisture content:** "Moisture content" means the percentage of water in a dry sample, by weight.
70. **Mother plant:** "Mother plant" means a mature marijuana plant that is used solely for the taking of seedling cuttings.
71. **Municipality:** "Municipality" means a city, town or plantation in this State that is not located within the unorganized and deorganized areas.
72. **Mycotoxin:** "Mycotoxin" means any toxic substance produced by a fungus and especially a mold.
73. **Opaque:** "Opaque" means, with respect to packaging or a container, that any product inside of the packaging or container cannot be seen from outside the packaging or container.
74. **Person:** "Person" means a natural person or a business entity.
75. **Plant canopy:** "Plant canopy" means the total surface area within the licensed premises of a cultivation facility that is authorized by the Department for use at any time by the cultivation facility licensee to cultivate mature marijuana plants. The surface area of the plant canopy must be calculated in square feet and measured using the outside boundaries of the area and must include all of the area within the boundaries. If the surface area of the plant canopy consists of noncontiguous areas, each component area must be separated by identifiable boundaries. If a tiered or shelving system is used by the cultivation

facility licensee, the surface area of each tier or shelf must be included in calculating the area of the plant canopy. Calculation of the area of the plant canopy may not include the areas within the licensed premises of cultivation facility that are used by the licensee to cultivate immature marijuana plants and seedlings and that are not used by the licensee at any time to cultivate mature marijuana plants.

76. **Plant regulator:** “Plant regulator” means any substance or mixture of substances intended through physiological action for accelerating or retarding the rate of growth or rate of maturation or for otherwise altering the behavior of plants or the produce thereof. “Plant regulator” does not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants or soil amendments.
77. **Premises:** “Premises” means the designated area within a structure or structures and land specified in a license application that is owned, leased or otherwise held under the control of the applicant or licensee where conduct related to the cultivation, manufacture, sampling, testing or sale of adult use marijuana and marijuana products occurs. The premises must be a contiguous area and may be occupied only by one establishment, unless otherwise permitted by statute or this Rule, except that nothing in this definition may be construed to prohibit the siting of multiple marijuana establishments in the same building or property so long as each establishment operates in a physically distinct space from any other establishment.
78. **Production batch:** “Production batch” means a specific quantity of marijuana concentrate or a marijuana product that is produced during a specified period of time using the same extraction and/or manufacturing method, formulation and/or recipe and standard operating procedure.
79. **Products manufacturing facility:** "Products manufacturing facility" means a facility licensed under this Rule to purchase adult use marijuana from a cultivation facility or another products manufacturing facility; to manufacture, label and package adult use marijuana and adult use marijuana products; to collect and transport samples of marijuana, marijuana concentrate and marijuana products manufactured by that facility for mandatory testing; and to sell adult use marijuana and adult use marijuana products to marijuana stores and to other products manufacturing facilities
80. **Propagation:** "Propagation" means the process of reproducing marijuana plants through the use of marijuana seeds, cuttings or grafting.
81. **Provisional active license:** “Provisional active license” means a license issued by the Department to a marijuana testing facility that has received provisional certification from the CDC and has applied for, but not yet received, ISO/IEC 17025:2017 accreditation for at least one technology and analyte, that authorizes testing of marijuana or marijuana products in accordance with 28-B MRS, Chapter 1, subchapter 2 and 6 and this Rule.
82. **Provisional certification:** “Provisional certification” means certification granted by the CDC pursuant to Rules for the Certification of Marijuana Testing Facilities, 18-691 CMR, ch. 5, to a marijuana testing facility that has not yet received ISO/IEC 17025 accreditation for at least one technology and analyte, but for which an application is pending, and that meets all other requirements of this Rule. Provisional certification is a prerequisite for the issuance of a provisional active license by the Department pursuant to this Rule.
83. **Qualifying patient:** “Qualifying patient” means a person who possesses a valid certification for the medical use of marijuana pursuant to 22 MRS § 2423-B.
84. **Quality assurance (QA):** “Quality assurance (QA)” means a set of operating principles that enable testing facilities to produce defensible data of known accuracy and precision. Quality assurance includes without limitation employee training, equipment preventative maintenance procedures, calibration procedures and quality control testing.
85. **Quality control (QC):** “Quality control (QC)” means the overall system of technical activities that measures the attributes and performance of a process, item or service against defined standards to verify that they meet the stated requirements established by the client; operational techniques and activities that

are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against “out of control” conditions and ensuring that the results are of acceptable quality.

86. **Quality assurance manual:** “Quality assurance manual” means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability and implementation of an agency, organization or a marijuana testing facility, to ensure the quality of its product and the utility of its product to its users.
87. **Quality system:** “Quality system” means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability and implementation plan of an organization for ensuring quality in its work processes, products (items) and services. The quality system provides the framework for planning, implementing and assessing work performed by the organization and for carrying out required QA and QC activities. A marijuana testing facility’s quality system must account for anomalies arising from the collection and transport of samples for mandatory testing conducted by a self-sampler or a sample collector licensee, including provisions regarding the use of blanks.
88. **Registered caregiver:** "Registered caregiver" means a caregiver who is registered by the department pursuant to 22 MRS §2425-A.
89. **Registered dispensary:** "Registered dispensary" or "dispensary" means an entity registered under 22 MRS §2425-A that acquires, possesses, cultivates, manufactures, delivers, transfers, transports, sells, supplies or dispenses marijuana or related supplies and educational materials to qualifying patients and the caregivers of those patients.
90. **Requester:** “Requester” means a person who submits a request to a licensed marijuana testing facility for State-mandated testing of marijuana or marijuana products.
91. **Resident:** “Resident” means a natural person who:
  - a. Has filed a resident individual income tax return in this State pursuant to Title 36, Part 8 in each of the 4 years prior to the year in which the person files an application for licensure under this Rule; this requirement does not apply after May 31, 2021;
  - b. Is domiciled in this State; and
  - c. Maintains a permanent place of abode in this State and spends in the aggregate more than 183 days of the taxable year in this State.
92. **Retail sale container:** “Retail sale container” means a container in which marijuana, marijuana plants, marijuana concentrate and marijuana products are conveyed during a retail sale which meets all applicable packaging and labeling requirements set forth in 28-B MRS and this Rule.
93. **Sale:** "Sale" or "sell" means a transfer of marijuana or marijuana products for consideration.
94. **Sample:** “Sample” means, as applicable, an amount of:
  - a. Marijuana, marijuana concentrate or marijuana product collected from an adult use marijuana establishment for mandatory testing:
    - i. By an employee of a testing facility in accordance with 28-B MRS § 604 and this Rule;
    - ii. By a sample collector, in accordance with 28-B MRS § 604 and this Rule; or
    - iii. By a self-sampler in accordance with 28-B MRS § 604-A and this Rule;

- b. Marijuana, marijuana concentrate or marijuana product provided to a testing facility by a marijuana establishment or other person for mandatory testing or testing for research and development purposes in accordance with 28-B MRS, chapter 1;
  - c. Adult use marijuana or adult use marijuana product collected from a licensee by the Department for the purposes of testing the marijuana or marijuana product for quality control purposes pursuant to 28-B MRS §512(2);
  - d. Adult use marijuana provided by a cultivation facility to another licensee for business or marketing purposes pursuant to 28-B MRS §501(8) (trade samples); or
  - e. Adult use marijuana or adult use marijuana product provided to another licensee by a products manufacturing facility for business or marketing purposes pursuant to 28-B MRS §502(6) (trade samples).
95. **Sample collection SOP:** “Sample collection SOP” means a standard operating procedure for the collection of samples of marijuana, marijuana concentrate and marijuana products for mandatory testing published by the Department that must be used by all licensees collecting, transporting and transferring samples for mandatory testing. The current sample collection SOP is Appendix A of this Rule
96. **Sample collector:** “Sample collector” means a person licensed pursuant to this Rule and 28-B MRS, ch. 1 to collect samples of marijuana and marijuana products for testing and to transport and deliver those samples to a testing facility. A sample collector must hold a valid individual identification card (“IIC”).
97. **Seedling:** “Seedling” means a marijuana plant that is:
- a. Not flowering;
  - b. Less than 6 inches in height; and
  - c. Less than 6 inches in width.
98. **Self-sampler or Self-sampling licensee:** “Self-sampler” or “self-sampling licensee” means a cultivation facility, products manufacturing facility or marijuana store licensee that collects samples of marijuana, marijuana concentrate and marijuana products for mandatory testing or an employee of a cultivation facility, products manufacturing facility or marijuana store licensee who collects samples of marijuana, marijuana concentrate and marijuana products for that licensee for mandatory testing. Any individual collecting samples for mandatory testing must hold a valid individual identification card (“IIC”).
99. **Standard operating procedure (SOP):** “Standard operating procedure (SOP)” means a written document that details the method for an operation, analysis or action, with thoroughly prescribed techniques and steps.
100. **Synthetic cannabinoid:** “Synthetic cannabinoid” means a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce psychoactive effects like those of marijuana.
101. **Tamper-evident:** “Tamper-evident” means, with respect to a device or process, bearing a seal, a label or a marking that makes unauthorized access to or tampering with a package, product or container easily detectable.
102. **Target organism:** “Target organism” means an organism that is being tested for in an analytical procedure or test method.
103. **Testing:** “Testing” or “test” means the research and analysis of marijuana, marijuana products or other substances for contaminants, safety or potency. “Testing” or “test” includes the collection of samples of marijuana and marijuana products for testing purposes but does not include cultivation or manufacturing. Nothing in this definition shall be construed to permit any licensee except a marijuana testing facility to perform analyses of marijuana, marijuana concentrate or marijuana products for mandatory testing without a separate marijuana testing facility license issued by the Department.

104. **Testing facility:** "Testing facility" means a facility licensed under this Rule to develop, research and test marijuana, marijuana products and other substances.
105. **Testing facility director:** "Testing facility director" means the marijuana testing facility director who is legally authorized to direct the activities of a marijuana testing facility and who commits the appropriate resources to comply with this Rule.
106. **THC:** "THC" means tetrahydrocannabinol.
107. **Tincture:** "Tincture" means a liquid edible marijuana product with a concentration of greater than 1 mg of THC per ounce of liquid.
108. **Topical marijuana product:** "Topical marijuana product" means non-edible marijuana or marijuana products that are intended to be applied topically and absorbed transdermal, including without limitation salves, creams, lotions, transdermal patches or balms.
109. **Transport manifest:** "Transport manifest" means a record, either paper or electronic, required by the Department for a licensed facility to document the possession of the marijuana or marijuana product on the premises, tracking all inventory, acquisition, sales, waste disposal and destruction, as well as the transfer of any marijuana or marijuana product to another facility, including for the purposes of testing or provision of trade samples to another licensee.
110. **Universal symbol:** "Universal symbol" means an image developed by the department, and made available to licensees, that indicates that a container, package or product contains marijuana or contains or is a marijuana product.
111. **Unorganized and deorganized areas:** "Unorganized and deorganized areas" has the same meaning as in 12 MRS§682(1).
112. **Unusable:** "Unusable" means that the Marijuana can no longer be smoked, eaten, ingested, topically applied or otherwise ingested. Nor can the marijuana be further manipulated in a manner to extract more than a trace amount of cannabinoid.
113. **Visibly intoxicated:** "Visibly intoxicated" means in a state of intoxication accompanied by a perceptible act, a series of acts or the appearance of an individual that clearly demonstrates the state of intoxication.
114. **Water activity:** "Water activity" means a measure of the quantity of water in a product that is available, and therefore capable of, supporting bacteria, yeasts and fungi. Water activity is reported in the unit  $A_w$ .
115. **Wholesale container:** "Wholesale container" means a sealed package in which adult use marijuana, marijuana concentrate and marijuana products are conveyed during an authorized transfer.



## Section 2 – Licenses and Licensing

### 2.1 - License Types

The general types of licenses for adult use marijuana establishments are cultivation facility, testing facility, products manufacturing facility, marijuana store and sample collector.

### 2.2 - Types of Marijuana Establishment Licenses

#### 2.2.1 Cultivation Facility License.

- A. The Department may issue the following types of cultivation facility licenses:
- (1) **Tier 1 cultivation facility license.** The two subcategories of tier 1 cultivation facility license are plant-count-based tier 1 cultivation facility license and plant-canopy-based tier 1 cultivation facility license:
    - (a) Plant-count-based tier 1 cultivation facility license. Allows cultivation of a specified number (not more than 30) of mature marijuana plants and an unlimited number of immature marijuana plants and seedlings;
    - (b) Plant-canopy-based tier 1 cultivation facility license. Allows cultivation of not more than 500 square feet of plant canopy of mature plants.
  - (2) **Tier 2 cultivation facility license.** Allows cultivation by a licensee of not more than 2,000 square feet of plant canopy of mature plants;
  - (3) **Tier 3 cultivation facility license.** Allows cultivation by a licensee of not more than 7,000 square feet of plant canopy of mature plants;
  - (4) **Tier 4 cultivation facility license.** Allows cultivation by a licensee of not more than 20,000 square feet of plant canopy of mature plants, except as approved by the Department pursuant to 28-B MRS§304; or
  - (5) **Nursery cultivation facility license.** Allows cultivation by a licensee of not more than 1,000 square feet of plant canopy, subject to the requirements and restrictions of 28-B MRS§501(3).
- B. A tier 1, tier 2, tier 3 or tier 4 cultivation facility license permits the following activities, subject to all requirements of Maine Title 28-B and this Rule:
- (1) Planting and raising marijuana plants, subject to the limits associated with each tier of license described above;
  - (2) Harvesting and trimming marijuana plants;
  - (3) Storing harvested marijuana flower and marijuana trim;
  - (4) Packaging marijuana flower and marijuana trim into individual retail units for wholesale to a marijuana store;
  - (5) Collecting samples of marijuana for mandatory testing and delivering those samples to a testing facility, in compliance with:
    - (a) Applicable sample collection, transport and receipt recordkeeping requirements;
    - (b) The Department-required sampling standard operating procedures;
    - (c) The Department-required Best Practices Guide;
    - (d) The requirements and restrictions of 28-B MRS§604-A; and
    - (e) This Rule; and
  - (6) Selling and transporting as authorized marijuana flower and marijuana trim to testing facilities, products manufacturing facilities or marijuana stores.
- C. A tier 1, tier 2, tier 3, or tier 4 cultivation license does not exempt the licensee from electrical permitting and inspection requirements and does not authorize sales to consumers.
- D. A nursery cultivation facility license permits the following activities, subject to all requirements of 28-B MRS and this Rule:
- (1) Planting and raising immature marijuana plants, subject to the limits described above;
  - (2) Planting and raising mature marijuana plants, subject to the plant canopy square footage limits in Section 2.2.1 (A)(5) of this Rule, solely for the purpose of propagating seedlings or immature

marijuana plants or collecting seeds, in an area clearly delineated from areas used for planting and raising immature marijuana plants and seedlings;

- (3) Collection of marijuana seeds for sale;
  - (4) Preparation of marijuana seedlings and immature plants for sale;
  - (5) Selling marijuana seeds, seedlings and immature plants to cultivation facilities and marijuana stores;
  - (6) Selling unlimited marijuana seeds, and a sum total of 12 seedlings and immature plants to a consumer 21 years of age or older, provided the licensee has designated an area of premises for retail sales in compliance with Section 3.2.2 of this Rule;
  - (7) Collecting samples of marijuana for mandatory testing and delivering those samples to a testing facility, in compliance with:
    - (a) Applicable sample collection, transport and receipt recordkeeping requirements;
    - (b) The Department-required sampling standard operating procedures;
    - (c) The Department-required Best Practices Guide;
    - (d) The requirements and restrictions of 28-B MRS§604-A; and
    - (e) This Rule; and
  - (8) Selling agricultural or gardening supplies relating to the cultivation of marijuana to a consumer 21 years of age or older.
- E. A nursery cultivation facility license does not exempt the licensee from electrical permitting and inspection requirements.

### **2.2.2 Marijuana Testing Facility License.**

- A. A marijuana testing facility may purchase or otherwise obtain marijuana or marijuana products for the purposes of training staff, developing and validating protocols, and other purposes that directly support the operation of a marijuana testing facility.
- B. A marijuana testing facility license permits the following activities on behalf of cultivation facilities, products manufacturing facilities, and marijuana stores subject to all requirements of 28-B MRS and this Rule:
  - (1) Collecting and transporting, for the purpose of mandatory testing pursuant to 28-B MRS § 602, samples of:
    - (a) Marijuana from licensed cultivation facilities;
    - (b) Marijuana from licensed products manufacturing facilities;
    - (c) Marijuana products from licensed products manufacturing facilities;
    - (d) Marijuana sold at a marijuana store;
    - (e) Marijuana products sold at a marijuana store;
  - (2) Receiving, for the purpose of testing, samples of marijuana and marijuana products from sample collectors and self-samplers;
  - (3) Receiving, for the purpose of mandatory testing, samples collected by sample collectors and self-samplers in compliance with:
    - (a) Applicable sample collection, transport and receipt recordkeeping requirements;
    - (b) The Department-required sampling standard operating procedures;
    - (c) The Department-required Best Practices Guide;
    - (d) The requirements and restrictions of 28-B MRS§604-A; and
    - (e) This Rule;
  - (4) Performing laboratory analysis of such samples of marijuana and marijuana products following protocols approved by the Department;
  - (5) Providing reports on cannabinoid identity and content profiles and biological and chemical contaminants to cultivation facilities, products manufacturing facilities, and marijuana stores;
  - (6) Reporting testing results according to Section 8.3.3 of this Rule; and
  - (7) Destroying and disposing of samples, subject to all requirements of 28-B MRS and this Rule.
- C. A marijuana testing facility license permits the licensee, upon notification in writing to the Department, to:
  - (1) Accept, from a person 21 years of age or older, marijuana or marijuana products grown or possessed lawfully under 28-B MRS, chapter 3;
  - (2) Perform laboratory analysis of samples of marijuana or marijuana products following protocols approved by the Department; and

- (3) Issue, solely for the use of the person 21 years of age or older, a report on cannabinoid identity and content profiles and biological and chemical contaminants of the sample.
- D. A marijuana testing facility license permits, upon notification in writing to the Department, the following activities on behalf of qualifying patients, caregivers, registered caregivers or registered dispensaries, subject to all requirements of 28-B MRS, 22 MRS, chapter 558-C and this Rule:
- (1) Collecting and transporting, for testing purposes, samples of marijuana or marijuana products from a qualifying patient, a caregiver, a registered caregiver or a registered dispensary;
  - (2) Performing laboratory analysis of samples of marijuana and marijuana products following protocols approved by the Department;
  - (3) Providing reports to qualifying patients, caregivers, registered caregivers or dispensaries;
  - (4) Sharing the results of tests required of registered caregivers or registered dispensaries with the Department;
  - (5) Identifying marijuana or marijuana products that must be remediated before use;
  - (6) Identifying marijuana or marijuana products that cannot be remediated and must be destroyed; and
  - (7) Destroying and disposing of samples, subject to all requirements of 28-B MRS and this Rule.

### 2.2.3 Products Manufacturing Facility License.

- A. A products manufacturing facility license permits the following activities, subject to all requirements of 28-B MRS and this Rule:
  - (1) Purchasing adult use marijuana from licensed cultivation facilities;
  - (2) Purchasing adult use marijuana concentrate from other licensed products manufacturing facilities;
  - (3) Extracting cannabinoids from marijuana or marijuana plants;
  - (4) Preparing, weighing, packaging, labeling and storing inhaled marijuana products, edible marijuana products or tinctures and/or topical marijuana products using marijuana or marijuana concentrate;
  - (5) Collecting samples of marijuana or marijuana products for mandatory testing and delivering those samples to a testing facility, in compliance with:
    - (a) Applicable sample collection, transport and receipt recordkeeping requirements;
    - (b) The Department-required sampling standard operating procedures;
    - (c) The Department-required Best Practices Guide;
    - (d) The requirements and restrictions of 28-B MRS§604-A; and
    - (e) This Rule;
  - (6) Selling or authorized transport of marijuana concentrate to licensed products manufacturing facilities; and
  - (7) Selling or authorized transport of marijuana products to licensed marijuana stores.
- B. A products manufacturing facility license does not permit the manufacture or assembly of any goods other than marijuana products, including without limitation pipes, other smoking paraphernalia, reusable storage containers or any other items that do not contain marijuana and/or are not intended for consumption. A manufacturing facility may assemble packaging and labeling for use on their products if packaging and labeling is consistent with the requirements of governing statute and standards contained in this Rule.
- C. A products manufacturing facility shall comply with all generally applicable kitchen-related health and safety standards of the relevant local jurisdiction and of the State of Maine Food Code, Department of Health and Human Services (Chapter 200) and Agriculture, Conservation and Forestry (Chapter 331).
  - (1) Preparation of all edible marijuana products, unless otherwise specified, shall comply with all provisions of the State of Maine Food Code, including rules relating to potentially hazardous foods, food preparation areas and all other safety related provisions, unless otherwise specified.
  - (2) Per 22 MRS § 2158-B, the addition of adult use marijuana to food is not considered adulteration under the State of Maine Food Code.
- D. A products manufacturing facility licensee must meet applicable electrical codes and municipal, state, and federal environmental requirements.
- E. Adult use marijuana products shall comply with all other provisions of this Rule, including the use of solvents and inherently hazardous substances.

### 2.2.4 Marijuana Store License.

- A. A marijuana store license permits the following activities, subject to all requirements of 28-B MRS and this Rule:
  - (1) Purchase adult use marijuana, pre-packaged retail units of marijuana flower and marijuana trim, immature marijuana plants and seedlings from a licensed cultivation facility;
  - (2) Purchase packaged adult use marijuana and adult use marijuana products from a products manufacturing facility;
  - (3) Store adult use marijuana, adult use marijuana products, immature marijuana plants and seedlings;
  - (4) Collect, subject to the requirements and restrictions of 28-B MRS§604-A, samples of marijuana or marijuana products for mandatory testing;
  - (5) Conduct authorized transports of adult use marijuana, adult use marijuana products, immature marijuana plants and seedlings to another licensed marijuana store or licensed testing facility;
  - (6) Collecting samples of marijuana or marijuana products for mandatory testing and delivering those samples to a testing facility, in compliance with:
    - (a) Applicable sample collection, transport and receipt recordkeeping requirements;
    - (b) The Department-required sampling standard operating procedures;
    - (c) The Department-required Best Practices Guide;

- (d) The requirements and restrictions of 28-B MRS§604-A; and
    - (e) This Rule;
  - (7) Sell adult use marijuana, adult use marijuana products, immature marijuana plants and seedlings to consumers;
  - (8) Sell consumable products not containing marijuana, including, but not limited to: soft drinks, candies and baked goods.
- B. In addition to any other prohibitions and restrictions of 28-B MRS, this Rule, and any other applicable laws or rules, marijuana store licensee may not:
- (1) Give away adult use marijuana, adult use marijuana products or marijuana plants;
  - (2) Sell or give away:
    - (a) Mature marijuana plants; or
    - (b) Consumable products containing tobacco or alcohol that do not contain marijuana.
  - (3) Except for nonedible adult use marijuana products that do not contain THC, sell to any person in any individual sales transaction an amount of adult use marijuana, adult use marijuana products or immature marijuana plants or seedlings that exceeds the person adult use limitations of 28-B MRS § 1501(1);
  - (4) Sell adult use marijuana, adult use marijuana products, immature marijuana plants or marijuana seedlings using:
    - (a) An automated dispensing or vending machine;
    - (b) A drive-through sales window;
    - (c) An Internet-based sales platform; or
    - (d) A delivery service; or
  - (5) Sell adult use marijuana or adult use marijuana products to a person who is visibly intoxicated.
- C. A marijuana store license does not exempt the licensee from any state or local permitting and inspection requirements.

### **2.2.5 Sample Collector License.**

- A. A sample collector license permits the following activities, subject to all requirements of 28-B MRS and this Rule:
- (1) Collecting samples of marijuana and marijuana products from a marijuana establishment for the purposes of mandatory or other testing by a testing facility in compliance with:
    - (a) Applicable sample collection, transport and receipt recordkeeping requirements;
    - (b) The Department-required sampling standard operating procedures;
    - (c) The Department-required Best Practices Guide; and
    - (d) The requirements and restrictions of 28-B MRS § 604-A.
  - (2) Transporting and delivering those samples to a testing facility.
- B. A sample collector may not store any collected samples at the sample collector's home or place of business. Samples may not be held or stored overnight in the sample collector's vehicle except in the event of unforeseen exigent circumstances in accordance with Section 4.2.3 of this Rule.

## **2.3 - Qualifications**

**2.3.1 General Licensing Criteria.** An applicant for a license to operate a marijuana establishment must meet each of the following requirements, if applicable. Except as otherwise provided in this Section, if the applicant is a business entity, every officer, director, manager and general partner of the business entity must meet each of the requirements of this Section. An applicant shall disclose in or include with its application the names and addresses of the applicant and all natural persons and business entities having a direct or indirect financial interest in the

applied-for license and the nature and extent of the financial interest held by each person or entity and, if applicable, the nature and extent of any financial interest the person or entity has in any other license applied for or issued under this Rule.

- A. **Age.** The applicant must be at least 21 years of age. If the applicant is a business entity, every officer, director, manager and general partner of the business entity must be at least 21 years of age.
- B. **Resident.**
  - (1) If the applicant is a natural person, the applicant must certify that he or she is a resident of the State of Maine as defined by this Rule.
  - (2) If the applicant is a business entity:
    - (a) Every officer, director, manager and general partner of the business entity must be a natural person who is a resident of the State of Maine. The applicant shall demonstrate to the Department that every officer, director, manager and general partner of the business entity is a natural person who is a resident of the State of Maine; and
    - (b) A majority of the shares, membership interests, partnership interests or other equity ownership interests as applicable to the business entity must be held or owned by natural persons who are residents of the State of Maine or business entities whose owners are all natural persons who are residents of the State of Maine. The applicant shall demonstrate to the Department that a majority of the shares, membership interests, partnership interests and other equity ownership interests are held or owned by residents of the State of Maine.
  - (3) This subsection does not apply to an applicant for a testing facility license.
- C. **Incorporated in State.** If the applicant is a business entity, the business entity must be incorporated in the State of Maine or otherwise formed or organized under the laws of the State.
- D. **Prohibited persons.**
  - (1) Not employee of state agency. The applicant may not be employed by the Department or any other state agency with regulatory authority under this Rule. The applicant must disclose any current state employment.
  - (2) Not law enforcement officer or corrections officer. The applicant may not be a law enforcement officer; a corrections officer as defined in 25 MRS § 2801-A(2); or any other natural person subject to the certification requirements of 25 MRS, chapter 341.
- E. **Good conduct and character.**
  - (1) No disqualifying drug offense.
    - (a) Applicants are required to disclose all state and federal criminal convictions, as well as any pending prosecutions, for offenses punishable by imprisonment for one year or more and involving the possession, distribution, manufacturing, cultivation or use of a controlled substance.
    - (b) The Department may require supplemental information regarding any such convictions disclosed by the applicant or identified by a criminal background check.
  - (2) The Department may not grant a license to anyone convicted of such offenses, except that the Department may grant a license to an applicant if:
    - (a) The applicant completed his or her sentence, including any term of probation, incarceration or supervised release, 10 or more years prior to the submission of the application; or
    - (b) The conviction was based on conduct that is now authorized by 28-B MRS, chapter 3.
  - (3) Department consideration of other offenses.
    - (a) Applicants are required to disclose all state and federal criminal convictions for any offense involving dishonesty, deception, misappropriation or fraud, as well as any pending prosecutions for such offenses.
    - (b) The Department may require supplemental information regarding any such convictions disclosed by the applicant or identified by a criminal background check.
  - (4) The Department shall consider the following in determining whether to grant a license to an applicant convicted of offenses other than disqualifying drug offenses:
    - (a) The recency of the offense(s);
    - (b) The number and frequency of offenses;

- (c) Whether the offense(s) involved dishonesty, deception, misappropriation or fraud;
  - (d) Whether the offense(s) involved violence or threat of violence;
  - (e) Whether the offense(s) involved operation of a motor vehicle under the influence of drugs or alcohol;
  - (f) Evidence of rehabilitation, including employment and educational attainment; and
  - (g) Character references submitted by the applicant.
- (5) No license revocation. The applicant, or if the applicant is a business entity, any officer, director, manager or general partner of that entity, may not have had previously had revoked a license issued under this Rule.
  - (6) No medical registry identification card or registration certificate revocation. The applicant or any officer, director, manager and general partner if the applicant is a business entity, may not have had revoked a registry identification card or registration certificate previously issued pursuant to the Maine Medical Use of Marijuana Act.
  - (7) Departmental consideration of enforcement actions in other jurisdictions
    - (a) Applicants are required to disclose any violations or penalties imposed in another jurisdiction regarding the regulated cultivation, manufacture, testing or sale of marijuana or marijuana products.
  - (8) The Department may for good cause deny a license to an applicant if the applicant or any officer, director, manager or general partner if the applicant is a business entity, has had revoked a license, permit, certificate or other government-issued authorization issued in another jurisdiction allowing the cultivation, manufacture, testing or sale of marijuana or marijuana products or has faced significant penalties under such authorization.
  - (9) No outstanding court-ordered payments. A license may not be issued to an applicant if that applicant, or any business entity in which that applicant is an officer, director, manager or general partner, has any outstanding payments due on court-ordered fines, court-appointed attorney's fees or court-ordered restitution. Except that the Department may issue a license to an applicant if it is satisfied that the applicant has entered into, and is in compliance with, any agreement or payment plan for the remittance of any fines, fees, or restitution owed.
  - (10) Departmental consideration of past due taxes, interest, penalties or fees in Maine.
    - (a) Applicants are required to submit a detailed list of any pending past due taxes, interest, penalties or fees owed in Maine.
    - (b) The Department may for good cause deny a license to an applicant if the applicant, or if the applicant is a business entity, any officer, director, manager or general partner of that business entity, is currently delinquent in any payment of income tax, sales tax, excise tax or any other tax, interest, penalty or fee to the state or any municipality within the state. The Department will consider:
      - (i) The amount of the delinquency;
      - (ii) Whether deceit was involved; and
      - (iii) Whether the applicant, or if the applicant is a business entity, any officer, director, manager, or general partner of that business entity to whom this paragraph applies, has entered into, and is in compliance with, any agreement or payment plan with the relevant tax authority overseeing the tax liability for which the applicant is otherwise delinquent.
  - (11) Other mitigating circumstances.
  - (12) Departmental consideration of past tax delinquency.
    - (a) Applicants, and if the applicant is a business entity, every officer, director, manager and general partner of the business entity, are required to provide detailed tax history, covering Maine and all other jurisdictions in which taxes were owed, for the 5 years preceding the application.
  - (13) The Department shall consider an applicant's history, and if the applicant is a business entity, every officer's, director's, manager's and general partner's history of paying taxes to Maine and other jurisdictions in the previous 2 years, as well as any tax liens imposed in any jurisdiction in the previous 5 years, and may for good cause deny a license to an applicant with a recent history of tax delinquency.

- F. **Criminal history record check.** The applicant must have submitted to a criminal history record check in accordance with the requirements of 28-B MRS and this Rule.
- G. **Compliance with application process; no false statement of material fact.** The applicant must have completed all application forms required by the Department fully and truthfully and complied with all information requests of the department relating to the license application. A license may not be issued to an applicant that has knowingly or recklessly made any false statement of material fact to the Department in applying for a license under this Rule. The Department shall revoke the license of a licensee pursuant to 28-B MRS, chapter 1, subchapter 8 if, subsequent to the issuance of the license, the Department determines that the licensee knowingly or recklessly made a false statement of material fact to the Department in applying for the license.

**2.3.2 Required Forms and Supplemental Information for All Licenses.** All applicants for a marijuana establishment license shall include on forms supplied by the Department as well as attachments thereto, all information requested by the Department, including without limitation information described in this Section. The Department may collect this information as part of the application for conditional cultivation facility, testing facility, products manufacturing facility and marijuana store and active sample collector licenses.

- A. An applicant for a conditional license for a cultivation facility, testing facility, products manufacturing facility or marijuana store license or an applicant for an active sample collector license shall provide, on forms made available by the Department:
  - (1) The name of the applicant;
  - (2) An email account that is actively monitored;
  - (3) Date of application;
  - (4) The type of marijuana establishment license being applied for;
  - (5) Whether or not the licensee proposes to co-locate adult use and medical marijuana operations as permitted by this Rule and in accordance with rules governing the Maine Medical Use of Marijuana Program on the licensed premises;
  - (6) If a business entity, identification of every officer, director, manager and general partner of the business entity;
  - (7) Identification of all natural persons and business entities having a direct or indirect financial interest in the applied-for license and the nature and extent of the financial interest held by each person or entity and, if applicable, the nature and extent of any financial interest the person or entity has in any other license applied for or issued under this Rule;
  - (8) Identification of any other marijuana establishments, including those outside of Maine, in which the applicant, or if the applicant is a business entity, any officer, director, manager or general partner of the business entity, holds an ownership interest;
  - (9) Attestations that the applicant, or if the applicant is a business entity, every officer, director, manager and general partner of the business entity:
    - (a) Has read the licensing requirements;
    - (b) Is age 21 years or older and meets residency requirements; and
    - (c) Has disclosed any disqualifying drug convictions; convictions for any state or federal offense involving dishonesty, deception, misappropriation or fraud; and/or pending prosecutions for such offenses; and
  - (10) A notarized signature page, attesting under penalty of perjury to the accuracy of the information provided in the application.
- B. At a minimum, all applicants shall provide, at the time of application, the following information:
  - (1) Proof of lawful presence or citizenship and Maine residence, and as required by the current forms prescribed by the Department.
  - (2) A list of natural persons and business entities having a direct or indirect financial interest in the applied-for license and a description of the nature and extent of the financial interest held by each person or entity; except that with respect to banks, credit unions, or other state- or federally-chartered financial institutions, in order to satisfy the requirements of this subsection, the applicant shall disclose:
    - (a) The name of the institution;
    - (b) The address of the institution; and
    - (c) The terms of any financial instrument held by the bank, credit union, or other state- or federally-chartered financial institution.



- C. If the applicant for any license is a business entity it shall submit all Department-required forms, attachments and supplemental information for every officer, director, manager and general partner, along with the following additional information and supporting material:
- (1) If the business entity is a corporation, a copy of its articles of incorporation or articles of organization; evidence of incorporation within Maine; and proof of Maine residency for every officer, director, manager and general partner.
  - (2) If the business entity is a limited liability company, a copy of its articles of organization and its operating agreement; evidence of incorporation within Maine; proof of Maine residency for every officer, director, manager and general partner.
  - (3) If the business entity is a general partnership, limited partnership, limited liability partnership or limited liability limited partnership, a copy of the partnership agreement; evidence of incorporation in Maine; and proof of Maine residency for every officer, director, manager and general partner.
  - (4) The residency requirements of this subsection do not apply to an applicant for a testing facility license.
  - (5) Proof accounting for 100% of the equity ownership in the business entity sufficient to show that a majority of the applicant's shares, membership interests, partnership interests or other equity ownership interests as defined in Section 1.4(29)(a) and (b) meet the requirements of 28-B MRS § 202(2)(B). Such proof must include all the legally enforceable documents such as operating agreements, by-laws, partnership agreements, corporate governing documents and the like, with all schedules and amendments, that identify any person that owns or holds any equity ownership interest or part thereof in the business entity. The applicant will provide proof of Maine residency for each natural person included in the equity ownership majority.
- D. The Department shall require evidence of compliance with all tax obligations.
- (1) The Department shall require each applicant, or if the applicant is a business entity, every officer, director, manager or general partner of that business entity, to disclose the following information to Maine Revenue Services, on forms provided by the Department, for the purpose for providing evidence of compliance with all tax obligations:
    - (a) The applicant's, or if the applicant is a business entity, every officer, director, manager or general partner, Social Security Number for the Maine Revenue Service to provide an assessment of whether the person owes back taxes, interest, fees or penalties.
    - (b) A list of sales tax identification numbers and employer identification numbers for all entities licensed in the state in which the applicant, or if the applicant is a business entity, every officer, director, manager or general partner, has a management role or ownership interest of 10 percent or more for the Maine Revenue Service to provide an assessment of whether any of those entities owe back taxes, interest, fees or penalties.
  - (2) The Department shall require the disclosure of the following information to Maine Revenue Services for the purpose for providing evidence of compliance with all tax obligations:
    - (a) For each applicant that is a business entity, the business entity's employer identification number and any associated sales tax ID number for the Maine Revenue Service to provide an assessment of whether the business entity applying for a license to operate a marijuana establishment owes back taxes, interest, fees or penalties.
- E. It is the exclusive responsibility of the applicant to clearly indicate on any forms, attachments, and supplemental information supplied to the Department any content the applicant deems to be trade secrets or other information that would be within the scope of a privilege against discovery or use as evidence recognized by the courts of this State in civil or criminal trials if the records or inspection thereof were sought in the course of a court proceeding, which may otherwise be included as a "public record" pursuant to 1 MRS § 402(3) in a response to a request for records and information under the Maine Freedom of Access Act.

**2.3.3 Criminal History Record Check.** The Department shall require fingerprinting and state and federal criminal history record checks for every applicant.

- A. For applicants that are business entities, the Department shall require fingerprinting and criminal history record checks for all officers, directors, managers and general partners.

- B. The applicant is responsible for all costs associated with fingerprinting and criminal history record checks. The fee for the fingerprinting and criminal history record checks shall be set by the State Police and/or State Bureau of Identification, in accordance with its usual operations.
- C. The Department shall issue a fingerprinting and criminal history record check form or use forms specified by the Department of Public Safety, Bureau of State Police, State Bureau of Identification or Federal Bureau of investigation. Such forms shall obtain the applicant's consent and information needed to complete the check, including but not limited to:
  - (1) First, middle and last name;
  - (2) Any aliases and/or previous names;
  - (3) Date of birth;
  - (4) Place of birth;
  - (5) Identifying information such as gender, height, weight and eye color;
  - (6) Disclosure of previous convictions;
  - (7) Driver license information; and
  - (8) Address and recent residency information.
- D. The Department may request that an applicant disclose his or her Social Security Number if notice is provided that:
  - (1) Indicates the disclosure of the Social Security Number is voluntary; and
  - (2) That the Department requests the Social Security Number for the purpose of positively identifying the applicant during the criminal records check process.
- E. All applicants required to submit to a criminal history record check under this Section shall submit to having the individual's fingerprints taken. The State Police, upon payment by the individual of the required fee, shall take or cause to be taken the individual's fingerprints and shall forward the fingerprints to the Department of Public Safety, Bureau of State Police, State Bureau of Identification.
- F. The State Bureau of Identification shall conduct the state and national criminal history record checks, which shall include information from:
  - (1) The Maine Criminal Justice Information System, regarding records of offenses within the state; and
  - (2) The Federal Bureau of Investigation, regarding offenses in other jurisdictions
- G. Except for the portion of a payment, if any, that constitutes the processing fee for a criminal history record check charged by the Federal Bureau of Investigation, all money received by the State Police under this Section must be paid to the Treasurer of State, who shall apply the money to the expenses incurred by the Department of Public Safety in the administration of this Section.
- H. All criminal history record information obtained by the Department pursuant to this Section is confidential, is for the official use of the Department only and may not be disseminated outside of the Department or disclosed to any other person or entity.
- I. The subject of a Federal Bureau of Investigation criminal history record check may obtain a copy of the criminal history record check by following the procedures outlined in 28 Code of Federal Regulations (henceforth referred to C.F.R; the Code of Federal Regulations is available free online at multiple websites, including federal government websites, by searching the citation. All references are to the 2018 version) Sections 16.32 and 16.33. The subject of a state criminal history record check may inspect and review the criminal history record information pursuant to 16 MRS § 709.

## 2.4 - Application for Conditional License

**2.4.1 Conditional License.** The Department may issue a conditional license to applicants for any type of marijuana establishment license, except for a sample collector license.

The Department shall establish an application process for a conditional license for a cultivation facility, testing facility, products manufacturing facility and marijuana store.

- (1) Pursuant to 2.3 of this Rule, the application for a conditional license must meet all requirements applicable to all license types and include all information applicable to all license types.
- (2) The conditional license is valid for one year and is non-renewable.

- (3) The conditional license may be used to demonstrate that the applicant has met the Department's conditional licensing requirements under 28-B MRS §205(3), for the purpose of seeking local authorization.
  - (4) The conditional license does not grant any authority for cultivation, manufacturing, testing or sale of marijuana or marijuana products.
- B. Because an applicant for a sample collector license is not required to obtain local authorization, the Department will not issue a conditional sample collector license. Instead, the initial application is for an active license.

#### **2.4.2 Additional Requirements for Issuance of a Conditional Cultivation Facility License.**

- A. Each applicant for a conditional cultivation facility license shall designate in its operating plan and cultivation plan the tier (or designation as a nursery cultivation facility) for the proposed cultivation facility.
  - (1) Each applicant for a conditional tier 1 cultivation facility license must designate in its operating plan and cultivation plan whether the license sought is plant-count based or total plant canopy area based pursuant to 28-B MRS § 301.
  - (2) Each applicant for a conditional nursery cultivation facility license must designate in its operating plan and cultivation plan whether it intends to sell marijuana seeds, seedlings or immature plants to adults, 21 years of age or older, who are not licensees.
- B. Each applicant for a conditional cultivation facility license must submit a preliminary operating plan, accompanied by a fully completed cover form made available by the Department, along with all supplemental information and documentation specified by the Department. At minimum, the preliminary operating plan shall include:
  - (1) The proposed size of the cultivation facility;
  - (2) The proposed layout of the cultivation facility;
  - (3) Operating days and hours;
  - (4) Plans for wastewater and waste disposal for the cultivation facility, in compliance with all state and federal laws;
  - (5) The lights, irrigation, greenhouses and other equipment to be used and the approval listing;
  - (6) A list of all pesticides, fungicides, insecticides and fertilizers that will be present or used;
  - (7) Plans for providing electricity, water and other utilities necessary for the normal operation of the cultivation facility;
  - (8) Plans for ventilation and filtration systems that prevent marijuana plant odors from significantly altering the environmental odor outside, while addressing the potential for mold;
  - (9) A workplace safety plan consistent with 29 CFR Part 1910, covering personal protective equipment, hazard assessment, safe equipment operation, proper application of agricultural chemicals, ladder use, hazard communication and other state and federal workplace safety requirements;
  - (10) Plans for compliance with applicable building code, the National Fire Protection Association (NFPA) model fire code, the applicable electrical codes, and federal and state environmental requirements;
  - (11) A legal ingress onto property from the closest maintained public way;
  - (12) If the property is also used as a residence, the location of that residence within that property and plans for complete separation of the residence from the facility, including:
    - (a) Entirely separate entrances from the public right of way; and
    - (b) No solvent extraction using potentially hazardous extraction methods or inherently hazardous extraction methods in the same building or structure as the residence; and
  - (13) An indication whether the applicant intends to collect samples of marijuana and deliver them to testing facilities for mandatory testing pursuant to 28-B MRS §604-A, and if so, must submit an attestation that it will follow department-required sampling procedures, including:
    - (a) Compliance with applicable sample collection, transport and receipt recordkeeping requirements;
    - (b) The Department-required sampling standard operating procedures;
    - (c) The Department-required Best Practices Guide;

- (d) The requirements and restrictions of 28-B MRS§604-A; and
- (e) This Rule.

- C. Each applicant for a conditional cultivation facility license shall submit a preliminary cultivation plan, accompanied by a fully completed cover form made available by the Department, along with all supplemental information and documentation specified by the Department. The floor plan for a marijuana cultivation establishment must include the detail dimensions of all areas which the licensee is authorized to cultivate mature plants. At minimum, the cultivation plan shall cover:
  - (1) A floor plan showing the proposed size and layout of the cultivation areas where the licensee intends to cultivate mature marijuana plants, showing exterior dimensions of the areas, drawn in straight lines and clearly stating the square footage of each area;
  - (2) A sum total of the combined area within the premises in which the licensee is authorized to cultivate mature marijuana plants;
  - (3) The total amount of plant canopy (or, in the case of a plant-count-based tier 1 cultivation facility license, the number of mature marijuana plants);
  - (4) A floor plan showing the proposed size and layout of the cultivation areas where the licensee intends to cultivate mature marijuana plants solely for the purpose of propagating seedlings, immature marijuana plants or collecting seeds, seedlings and immature marijuana plants, showing exterior dimensions of the areas, drawn in straight lines and clearly stating the square footage of each area and whether this square footage is within or outside the plant canopy;
  - (5) Clear delineation of where mature marijuana plants, marijuana plants solely used for propagation, immature plants and seedlings will be grown; and
  - (6) Plans for physically separating areas where mature marijuana plants will be grown, from where marijuana plants solely used for propagation, seedlings and immature marijuana plants will be grown.
- D. Additional requirements apply to shared premises with a registered dispensary or registered caregiver.
  - (1) Each applicant for a conditional cultivation facility license to share premises with a registered dispensary or registered caregiver must address the following issues in its operating plan:
    - (a) A list of all equipment to be used for cultivating both marijuana for medical use and adult use marijuana;
    - (b) A description of how the licensee will ensure that each shared piece of cultivation equipment is not used simultaneously on marijuana for medical use and adult use marijuana, with the purpose of ensuring that marijuana for medical use remains separate from adult use marijuana.
  - (2) Each applicant for a conditional cultivation facility license to share premises with a registered dispensary or registered caregiver must address the following issues in its cultivation plan:
    - (a) Indication on the floor plan, with the same level of detail, areas to be used for cultivating marijuana for medical use, including which areas will be used to cultivate plants solely used for propagation, seedlings, immature plants and mature plants;
    - (b) Indication on the floor plan any areas that will support cultivation of both marijuana for medical use and adult use marijuana, including storage areas, office space, walkways, entryways, restrooms and utility rooms; and
    - (c) Plans for visually and physically separating cultivation of marijuana for medical use from cultivation of adult use marijuana.
  - (3) The licensee shall separately track marijuana for medical use and adult use marijuana and will otherwise ensure that they do not become intermixed.
- E. Additional requirements apply to issuance of a conditional nursery cultivation facility license authorizing sales to non-licensees. If an applicant intends to conduct sales to adults over the age of 21 who are not licensees, the applicant must submit an operating plan that meets all of the requirements for both a cultivation facility operating plan (as described in this subsection) and a marijuana store operating plan (as described in Subsection 2.4.7).

**2.4.3 Additional Requirements for Issuance of a Conditional Testing Facility License.** Each applicant for a marijuana testing facility license shall include, on forms supplied by the Department, and attachments thereto, all information required by the Department, including without limitation, the following information:

- A. A statement asserting whether the marijuana testing facility and/or other operational assets will be owned or leased by a person or entity other than the applicant.
- B. A statement as to whether the marijuana testing facility intends to offer, in addition to mandatory testing, testing services to persons 21 years of age or older under 28-B MRS §503(1)(C) and/or qualifying patients, caregivers, registered caregivers or registered dispensaries under 28-B MRS §503(1)(D).
- C. Each applicant for a conditional marijuana testing facility license shall submit sufficient information to enable the Department to determine the applicant's ability to operate a marijuana testing facility meeting the requirements of 28-B MRS and this Rule. This information shall be contained in a marijuana testing facility operating plan, which at minimum includes the following:
  - (1) A list of all mandatory tests, including technology and analyte, for which the applicant has received or is applying for ISO/IEC 17025 accreditation at the time of the application for a conditional license from the Department;
  - (2) A list of all mandatory tests, including technology and analyte, for which the applicant has received or is applying for full or provisional certification from the CDC;
  - (3) A list of all nonstandard test methods and technologies for which the applicant has received or requested CDC certification for any mandatory test;
  - (4) A premises diagram of the marijuana testing facility that includes a brief statement of the principal activity to be conducted in each room or partitioned area, including without limitation activities related to sample receiving, sample storage, record storage, microbiological and chemical analysis and office space;
  - (5) Operating days and hours;
  - (6) A description of the workplace safety plan consistent with 29 CFR 1910 as applicable; and
  - (7) Plans for disposal of marijuana waste and marijuana product waste.
- D. An applicant for a marijuana testing facility must submit the following additional documentation to obtain a conditional license:
  - (1) A written policy that, as indicated by signature, ensures management and personnel are free from any undue internal and external commercial, financial and other pressures, and influences that may adversely affect the quality of their work or diminish confidence in its competence, impartiality, judgement or operational integrity, as well as a signed disclosure by the owner(s) stating that there is no financial conflict with, interest in, investment in, landlord-tenant relationship with or loan to a cultivation facility, products manufacturing facility, marijuana store, registered caregiver or registered dispensary;
  - (2) A description of the organization and management structure of the marijuana testing facility, its place in any parent organization and the relationships between quality assurance, technical operations and support services;
  - (3) A management plan defining the responsibilities of key personnel in the organization who have any involvement or influence on the testing, and if the marijuana testing facility is part of an organization performing activities other than testing, identifying potential conflicts of interest;
  - (4) Written policies and procedures that ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
  - (5) A written policy defining legal chain of custody protocols and including procedures to control access to certificate of analysis data and other testing data to prevent it from being falsified or manipulated and
  - (6) Written procedures for the receipt of samples, including samples collected by:
    - (a) Sample collectors pursuant to 28-B MRS §503;
    - (b) Other marijuana establishments for mandatory testing pursuant to 28-B MRS §604-A or for voluntary testing;
    - (c) Qualifying patients, caregivers, registered caregivers or registered dispensaries pursuant to 22 MRS, chapter 558-C; and
    - (d) Other persons 21 years of age or older.

**2.4.4 Additional Requirements for Issuance of a Conditional Products Manufacturing Facility License.** Each applicant for a conditional products manufacturing facility license shall submit sufficient information to enable the Department to determine the applicant's ability to operate a marijuana products manufacturing facility meeting the requirements of 28-B MRS and this Rule. This information shall be contained in a products manufacturing facility operating plan, which at a minimum includes the following:

- A. A description of the classes of products such as edible, inhaled or topical that will be manufactured on the premises, along with a description of each specific product to be made;
- B. A description of the manufacturing processes that will occur on the premises;
- C. A diagram illustrating in which areas of the premises each manufacturing activity will occur;
- D. If the property is also used as a residence, the location of that residence within that property and plans for complete separation of that residence from the facility including:
  - (1) Entirely separate entrances from a public right of way; and
  - (2) No solvent extraction using potentially hazardous extraction methods or inherently hazardous extraction methods in the same building or structure as the residence;
- E. A diagram illustrating the areas of the premises where any solvent (excluding water), chemical or potentially hazardous substance will be stored;
- F. Operating days and hours;
- G. Education and relevant experience of the person in charge of food safety requirements;
- H. Education and relevant experience of any employee who will oversee day-to-day food safety procedures;
- I. Equipment to be used, including UL or other safety listing;
- J. Standard operating procedures for each process to be used to manufacture a marijuana product;
- K. Plans for ventilation and filtration systems that prevent marijuana odors from significantly altering the environmental odor outside, while reducing the risk of fire or respiratory harm within the facility;
- L. Any extraction methods and solvents to be used for extraction;
- M. Any inherently hazardous substances to be used for extraction, along with the process for use, certification by a certified industrial hygienist or professional engineer licensed in Maine that the manufacturing facility's storage, preparation, electrical, gas monitoring, fire suppression and exhaust systems are adequate;
- N. Status of licensure of any areas in which marijuana or marijuana concentrate is handled or combined with non-marijuana ingredients to form marijuana products as a commercial kitchen area;
- O. Status of licensure of any areas in which unwrapped marijuana products are stored, cooled, cut, packaged or otherwise handled as a commercial kitchen area;
- P. Plans for compliance with any other relevant sanitary standards;
- Q. Plans for compliance with packaging, labeling and other requirements;
- R. Plans for refrigerating any marijuana products or ingredients thereof requiring refrigeration;
- S. Plans for disposal of marijuana and marijuana product waste;
- T. A workplace safety plan consistent with 29 C.F.R. 1910, covering personal protective equipment, hazard assessment, safe equipment operation, proper application of agricultural chemicals, ladder use, hazard communication and other state and federal workplace safety requirements;
- U. Plans for compliance with applicable building and electrical codes and federal and state environmental requirements; and
- V. Whether it intends to collect samples of marijuana and marijuana products and deliver them to testing facilities for mandatory testing pursuant to 28-B MRS §604-A, and if so, must submit an attestation that it will follow department-required sampling procedure, including:
  - (1) Compliance with applicable sample collection, transport and receipt recordkeeping requirements;
  - (2) The Department-required sampling standard operating procedures;
  - (3) The Department-required Best Practices Guide;
  - (4) The requirements and restrictions of 28-B MRS§604-A; and
  - (5) This Rule.

It is the exclusive responsibility of the applicant to clearly indicate on any forms, attachments, and supplemental information supplied to the Department any content the applicant deems to be trade secrets or other information that would be within the scope of a privilege against discovery or use as evidence recognized by the courts of this State in civil or criminal trials if the records or inspection thereof were sought in the course of a court proceeding, which

may otherwise be included as a “public record” pursuant to 1 MRS § 402(3) in a response to a request for records and information under the Maine Freedom of Access Act.

**2.4.5 Additional Requirements for Issuance of a Conditional Marijuana Store License.** Each applicant for a conditional marijuana store license shall submit sufficient information to enable the Department to determine the applicant’s ability to comply with health and safety rules and operate a marijuana store meeting the requirements of 28-B MRS and this Rule. This information shall be contained in a marijuana store operating plan.

- A. A marijuana store operating plan must at a minimum include the following:
  - (1) Operating days and hours;
  - (2) Background screening process for employees and vendors;
  - (3) Plans for verifying identification of all customers and prevention of unauthorized sales to, or access to the premises by, persons under age 21;
  - (4) Layout of the store, indicating limited access areas and age-restricted areas;
  - (5) If the property is also used as a residence, the location of that residence within that property and plans for complete separation of the residence from the store, including:
    - (a) Entirely separate entrances from a public right of way; and
    - (b) No solvent extraction using potentially hazardous extraction methods or inherently hazardous extraction methods in the same building or structure as the residence;
  - (6) Descriptions or diagrams of displays indicating how they control customer access to marijuana and marijuana products;
  - (7) Descriptions of any electrical equipment and its UL or other safety listing;
  - (8) Plans for refrigerating any marijuana products requiring refrigeration;
  - (9) Plans for disposal of marijuana and marijuana product waste;
  - (10) Plans for compliance with applicable building and electrical codes and federal and state environmental requirements; and
  - (11) Plans for shipping and receiving of marijuana and marijuana products.
- B. If the operating plan for a nursery cultivation facility includes sales to consumers, the operating plan shall meet all requirements that are applicable to marijuana stores in addition to all requirements that are applicable to nursery cultivation facilities.
- C. The applicant must indicate whether it intends to collect samples of marijuana and marijuana products and deliver them to testing facilities for mandatory testing pursuant to 28-B MRS §604-A, and if so, must submit an attestation that it will follow department-required sampling procedure, including:
  - (1) Compliance with applicable sample collection, transport and receipt recordkeeping requirements;
  - (2) The Department-required sampling standard operating procedures;
  - (3) The Department-required Best Practices Guide;
  - (4) The requirements and restrictions of 28-B MRS§604-A; and
  - (5) This Rule.

**2.4.6 Co-location of Adult Use Marijuana Establishment with Registered Dispensary or Registered Caregiver.**

Licensees may co-locate an adult use marijuana establishment or establishments with a registered dispensary or registered caregiver registered with the Department pursuant to 22 MRS, chapter 558-C, only as provided in this Rule and 28-B MRS, chapter 1. Licensees are responsible for maintaining separate operations to ensure that adult use marijuana and marijuana products are not co-mingled marijuana and marijuana products for medical use.

- A. No licensee may sell or offer for sale to consumers adult use marijuana and adult use marijuana products within the same facility or building in which the licensee also sells or offers for sale to qualifying patients marijuana and marijuana products for medical use pursuant to 22 MRS, chapter 558-C.
- B. A cultivation facility may co-locate with a registered dispensary or a registered caregiver’s cultivation operation, except that if the cultivation facility is a nursery cultivation facility, no marijuana or marijuana products for medical use may be sold or offered for sale in the same facility or building where the nursery cultivation facility is located.
  - (1) The nursery cultivation facility must ensure that marijuana seeds, seedlings, immature plants or mature plants for medical use are not co-mingled with marijuana and marijuana products for adult use at any time.

- (2) The nursery cultivation facility must not conduct activities related to marijuana for medical use under a Sales Tax Identification Number or Excise Tax Identification Number associated with an adult use license.
  - (3) The nursery cultivation facility must have distinctly separate entrances from a public right of way for the area of the premises used for retail sales of adult use marijuana to consumers and for the distribution of marijuana and marijuana products for medical use. Under no circumstances can marijuana or marijuana products for medical use be sold in, transferred, transported or otherwise conveyed through any portion of the co-located premises designated for retail sales of adult use marijuana or marijuana products to consumers.
  - (4) The nursery cultivation facility must conduct all cultivation activities for adult use marijuana and marijuana for medical use in accordance with this Rule and 28-B MRS.
- C. A cultivation facility may co-locate with a registered dispensary or a registered caregiver's cultivation operation, except that if the cultivation facility is co-located with an adult use marijuana store, no marijuana or marijuana products for medical use may be sold or offered for sale in the same facility or building where the adult use marijuana store is located.
- (1) The cultivation facility must ensure that marijuana seeds, seedlings, immature plants, or mature plants for medical use are not co-mingled with marijuana or marijuana products for adult use at any time.
  - (2) The cultivation facility must not conduct activities related to marijuana for medical use under a Sales Tax Identification Number or Excise Tax Identification Number associated with an adult use license.
  - (3) The cultivation facility must have distinctly separate entrances from a public right of way for the area of the premises used for retail sales of adult use marijuana to consumers and for the distribution of marijuana and marijuana products for medical use. Under no circumstances can marijuana or marijuana products for medical use be sold in, transferred, transported or otherwise conveyed through any portion of the co-located premises designated for retail sales of adult use marijuana or marijuana products to consumers.
  - (4) The cultivation facility must conduct all cultivation activities for adult use marijuana and marijuana for medical use in accordance with this Rule and 28-B MRS.
- D. Any cultivation facility or products manufacturing facility that cultivates, manufactures, packages, stores, dispenses or otherwise handles marijuana or marijuana products for both adult use and medical use must clearly differentiate the two types of marijuana and marijuana products and prevent their co-mingling within the premises at all times. If a licensee proposes to co-locate adult use and medical use operations, the licensee must illustrate in its facility plan and security plan:
- (1) The areas of the premises that will contain adult use marijuana plants, marijuana, marijuana products or marijuana concentrate;
  - (2) The areas of the premises that will contain marijuana plants, marijuana, marijuana products or marijuana concentrate for medical use;
  - (3) The areas of the premises, if any, that will contain equipment, chemicals or other items that may be used for both adult use marijuana plants, marijuana or marijuana products and marijuana plants, marijuana or marijuana products for medical use;
  - (4) Plans for ensuring that all marijuana, finished marijuana concentrate and other marijuana products are correctly packaged and labeled for medical use or adult use; and
  - (5) A description of how the licensee will separately track, including input to the tracking system, marijuana, marijuana concentrate and marijuana products for medical use separately from adult use marijuana, marijuana concentrate and marijuana products and will otherwise keep them from becoming intermixed.
- E. Each applicant for a conditional cultivation facility license to share premises with a registered dispensary or registered caregiver, must address the following issues in its operating plan:
- (1) A list of all equipment to be used for cultivating both marijuana for medical use and adult use marijuana;
  - (2) A description of how the licensee will ensure that each shared piece of cultivation equipment is not used simultaneously or contemporaneously on marijuana for medical use and adult use marijuana, with the purpose of ensuring that marijuana flowers and trim for medical use remain separate from adult use marijuana flowers and trim; and



- (3) A description of how the licensee will separately track marijuana for medical use and adult use marijuana and will otherwise keep them from becoming intermixed.
- F. Each applicant for a conditional cultivation facility license to share premises with a registered dispensary or registered caregiver, must address the following issues in its cultivations plan:
- (1) Indication on the floor plan, with the same level of detail, areas to be used for cultivating marijuana plants solely used for propagation, seedlings, immature plants and mature plants for medical use;
  - (2) Indication on the floor plan any areas that will support cultivation of both marijuana for medical use and adult use marijuana, including storage areas for equipment and agricultural chemicals, office space, walkways, entryways, restrooms and utility rooms;
  - (3) Plans for visually and physically separating cultivation of marijuana for medical use from adult use marijuana cultivation;
  - (4) Plans for visually and physically separating the storage of harvested marijuana flower and trim for medical use from harvested adult use marijuana flower and trim; and
  - (5) A description of how the licensee will separately track, including input to the tracking system, marijuana, marijuana concentrate and marijuana products for medical use separately from adult use marijuana, marijuana concentrate and marijuana products and will otherwise keep them from becoming intermixed.
- G. Each applicant for a conditional products manufacturing facility license to share premises with a registered dispensary or registered caregiver, must address the following issues in its operating plan:
- (1) A list of all extraction equipment and other supplies to be used for extracting from both marijuana for medical use and adult use marijuana;
  - (2) A list of all manufacturing equipment and other supplies to be used for manufacturing both marijuana products for medical use and adult use marijuana products;
  - (3) A description of how the licensee will ensure that each shared piece of extraction or manufacturing equipment is not used simultaneously or contemporaneously on marijuana for medical use and adult use marijuana, with the purpose of ensuring that marijuana, marijuana concentrate and marijuana products for medical use remain separate from adult use marijuana, marijuana concentrate and marijuana products;
  - (4) A description of how the licensee will separately track marijuana for medical use, including input to the tracking system, marijuana concentrate and marijuana products separately from adult use marijuana, marijuana concentrate and marijuana products and will otherwise keep them from becoming intermixed;
  - (5) Plans for storage and refrigeration that keep medical marijuana, marijuana concentrate and marijuana products remain separate from adult use marijuana, marijuana concentrate and marijuana products;
  - (6) Plans for ensuring that all finished marijuana concentrate and other marijuana products are correctly packaged and labeled for medical use or adult use;
  - (7) A clear indication on floor plans of which areas house equipment used to manufacture both marijuana for medical use and adult use marijuana products; and
  - (8) A clear indication of any areas used to store equipment, supplies or non-marijuana ingredients used to produce, package or label both marijuana products for medical use and adult marijuana products.

**2.4.7 Co-Location of Adult Use Marijuana Establishments.** An applicant may propose the co-location of multiple adult use marijuana establishment types pursuant to the following Section.

- A. The Department may approve an application that would result in a testing facility being located adjacent to another type of adult use marijuana establishment or a registered dispensary, registered caregiver, or manufacturing facility registered in accordance with 22 MRS §2423-F, only if the following conditions are met:
- (1) The testing facility must have a distinctly separate entrance from a public right of way;
  - (2) The testing facility must demonstrate it has adequate environmental controls to protect against incidental contamination of testing equipment or samples as a result of its location adjacent to an

adult use marijuana establishment, registered dispensary, registered caregiver, or manufacturing facility registered in accordance with 22 MRS §2423-F;

- (3) Signage must not convey the impression that the two businesses are connected; and
  - (4) There must be no way that an employee of the testing facility or the other business may travel between the two businesses without returning to the public right of way. Public right of way shall be interpreted in this subsection to include private property that is generally open to the public during normal business hours, such as a shopping center or business park.
- B. The Department may approve an application that would result in a cultivation facility being co-located with a products manufacturing facility or marijuana store, only if the following conditions are met:
- (1) The cultivation facility area shall be clearly delineated from the other establishment in all written plans.
  - (2) The cultivation facility may connect to another type of establishment by a single, lockable door. Regardless of common ownership, excise tax is payable when any marijuana seedlings, immature plants, marijuana, or marijuana products pass out of the cultivation facility into another type of marijuana establishment. All marijuana to pass through a single, lockable door must be entered into the tracking system, and excise taxes shall be paid in accordance with this Rule and 28-B M.R.S. § 1001.
- C. The Department may approve an application that would result in a products manufacturing facility being co-located with a marijuana store, only if the following conditions are met:
- (1) The products manufacturing area shall be clearly delineated from the other establishment in all written plans.
  - (2) Any shared space must comply with all regulations applicable to products manufacturing facilities and all regulations applicable to marijuana stores.
  - (3) No manufacturing facility using inherently hazardous substances may be co-located with a marijuana store unless all inherently hazardous extraction activities are conducted in an entirely freestanding structure.

## 2.5 - Application for Active Sample Collector License

**2.5.1 Forms.** An applicant shall prepare an application on forms made available by the Department along with the appropriate application fee as determined by the Department pursuant to 28-B MRS § 207 and this Rule. In order for an application for an active sample collector license to be considered complete, the following must be true:

- A. An applicant for a sample collector license must meet all of the requirements in 2.3, 2.4 and 2.6 of this Rule, if applicable.
- B. An applicant for a sample collector license shall include on forms supplied by the Department, as well as attachments thereto, all information requested by the Department, including without limitation information described in the sections referenced in subsection A above and:
  - (1) An operating plan including hours of operation during which the applicant will be conducting business activities including without limitation:
    - (a) Collecting samples;
    - (b) Transporting samples;
    - (c) Training staff; or
    - (d) Using the inventory tracking system.
  - (2) Designation of a place of business or home office where records and equipment are appropriately and securely stored, including a description of where the Department can inspect all required records upon request. The applicant must ensure that an individual identification cardholder is authorized and able at all times during the hours of operation listed on the operating plan to produce all records upon the request of the Department;
  - (3) A statement asserting whether the sample collector's operational assets will be owned or leased by a person or entity other than the applicant;
  - (4) A written policy that, as indicated by signature, ensures management and personnel are free from any undue internal and external commercial, financial and other pressures, and influences that may adversely affect the quality of the sample collector's work, diminish confidence in the sample collector's competence, impartiality, judgment or operational

integrity, as well as a signed disclosure by the owner(s) stating that there is no financial conflict with, interest in, investment in, landlord-tenant relationship with or loan to a cultivation facility, products manufacturing facility, marijuana store, registered caregiver or registered dispensary;

- (5) A description of the organization and management structure of the sample collector, and its place in any parent organization;
  - (6) Written policies and procedures that ensure that protection of the sample collector's clients' confidential information and proprietary rights;
  - (7) Proof that the applicant has an inventory tracking system account activated and functional; and
  - (8) Evidence of proper registration with the State Tax Assessor. A sample collector licensee must obtain a Sales Tax Identification Number. A unique Sales Tax Identification Number is required for each active license, regardless of common ownership or co-location.
- C. All applications must be complete and accurate in every material detail.
  - D. A unique Sales Tax Identification Number is required for each active license, regardless of common ownership or co-location.
  - E. An application for an active sample collector license is considered incomplete until the Department is in possession of all required forms, supplemental information, criminal history record checks and any other requirements listed in Section 2 of this Rule.
  - F. A license issued to a marijuana establishment or an individual constitutes a revocable privilege. The burden of proving an Applicant's qualifications for licensure rests at all times with the applicant.

It is the exclusive responsibility of the applicant to clearly indicate on any forms, attachments, and supplemental information supplied to the Department any content the applicant deems to be trade secrets or other information that would be within the scope of a privilege against discovery or use as evidence recognized by the courts of this State in civil or criminal trials if the records or inspection thereof were sought in the course of a court proceeding, which may otherwise be included as a "public record" pursuant to 1 MRS § 402(3) in a response to a request for records and information under the Maine Freedom of Access Act.

**2.5.2 Vehicle requirements.** An applicant for an active sample collector licenses must provide the following information to the Department for each vehicle that will be used to transport samples:

- A. Proof of a valid insurance policy;
- B. A description, with photos as necessary, of the locked compartment to be used to secure samples; and
- C. A description of how the sample collector will maintain samples within the appropriate temperature range.

**2.5.3 Payment of Fees.** Before issuing an active license, the Department shall invoice the applicant for the applicable fee as determined by the Department pursuant to Title 28-B and this Rule. The Department shall not accept any license fees except pursuant to such invoice.

**2.5.4 Appeals.** An applicant may appeal an application denial pursuant to the Maine Administrative Procedure Act, 5 MRS, chapter 375.

## 2.6 - Department Review of Applications for Conditional Licenses and Active Sample Collector License

**2.6.1 Ownership interest.** Except for an applicant for a marijuana testing facility license, the Department shall verify that any applicant for a marijuana establishment license is either a natural person who is a resident of the state of Maine or is a business entity that meets the requirements of 28-B MRS § 202(2).

- A. The Department may require additional information to verify that business structures, loans, franchise agreements, royalty agreements and other legal arrangements are not being used to circumvent licensing

requirements including without limitation residency requirements, limits on common financial interests, and disqualifying drug offenses.

- B. The Department will ensure that issuance of both a conditional license or active license to the applicant will not result in any person having a direct or indirect financial interest in:
  - i. More than 3 cultivation facility licenses;
  - ii. Multiple cultivation facility licenses with a combined total licensed amount of plant canopy exceeding 30,000 square feet, except when that exceedance is solely attributable to approved increases in the maximum licensed area of plant canopy authorized under a tier 4 cultivation facility license pursuant to section 28-B MRS §304;
  - iii. A testing facility license or sample collector license if the applicant or licensee is a caregiver or a registered caregiver or has an equity ownership interest or a partial equity ownership interest or any other type of financial interest, including but not limited to, being an investor or serving in a management position in a registered dispensary, a cultivation facility license, a products manufacturing facility license or a marijuana store license; or
  - iv. More than 4 marijuana stores. The limit on direct or indirect financial interests in marijuana stores does not apply after December 31, 2021.
- C. An application for license will not be considered complete until the applicant satisfies all such information requests.
- D. The Department may refuse to issue a conditional license for a cultivation facility, products manufacturing facility or marijuana store license or active license for a sample collector to an applicant at its discretion until it is satisfied that the applicant has met the residency requirements of 28-B MRS §202(2) and this Rule.

**2.6.2 Application Processing.** An application for a conditional license or active license for a sample collector considered incomplete until the Department is in possession of all required forms, supplemental information, criminal history record checks and any other requirements listed in Section 2. If, in the course of processing the application, the Department discovers that any required forms, supplemental information or criminal history record checks are incomplete, the Department may ask the applicant to supply the missing information, and the Department has 90 days from the date the Department provides notice to the applicant that the application is complete to review and act upon the application. The Department shall, however, avoid unreasonable delays in the case of inadvertent omission of material that is not central to its review of the merits of the application for a conditional license or active license for a sample collector.

**2.6.3 Application Review.**

- A. For the purposes of processing applications for marijuana establishments, the Department, pursuant to 28-B MRS § 205, shall apply an objective standard to establishing whether an applicant has satisfied the marijuana establishment licensing requirements, specifically the satisfaction of general licensing criteria and the submission of all required documents, forms and fees and the subsequent issuance of provisional and active licenses.
- B. Within 90 days from the date the Department provides notice to the applicant that the application is complete, the Department shall, as applicable:
  - a. Deny the license application;
  - b. Issue a non-renewable conditional license for a cultivation facility, products manufacturing facility, testing facility or marijuana store valid for up to one year; or
  - c. Issue an active license for a sample collector valid for one year.

**2.6.4 Withdrawal.**

- A. The Department and the applicant for a conditional license for a cultivation facility, products manufacturing facility, testing facility or marijuana store or the applicant for an active license for a sample collector may mutually agree in writing to the voluntary withdrawal of an application.
- B. Applicants must first submit a notice to the Department requesting a voluntary withdrawal of the application.

- C. The Department will consider the request along with any circumstances at issue with the application in making a decision to accept the voluntary withdrawal. The Department may at its discretion grant the request with or without prejudice or deny the request.
- D. The Department will notify the applicant and relevant local jurisdiction of its acceptance of the voluntary withdrawal and the terms thereof.
- E. If the applicant agrees in writing to a voluntary withdrawal granted with prejudice, then the applicant is not eligible to apply again for licensing or approval until after expiration of one year from the date of such voluntary withdrawal.
- F. The Department may not refund any application or other fees, regardless of the circumstances of the withdrawal.

**2.6.5 Denial.** The Department may for good cause pursuant to 28-B MRS §206 deny an application for a conditional license or for an active sample collector license.

- A. The Department shall notify the applicant in writing of the denial and the good cause basis for the denial, including but not limited to:
  - (1) Disqualifying drug offenses;
  - (2) Other mandatory disqualifying factors;
  - (3) Serious concerns about the applicant’s character based on the applicant’s criminal record, disciplinary record with other government regulatory agencies or previous employment;
  - (4) Failure to meet residency requirements; or
  - (5) Any other reason constituting good cause.
- B. Denial of an application pursuant to 28-B MRS § 206 is final agency action as defined in 5 MRS § 8002(4). The Department shall notify the applicant in writing of the applicant’s right to appeal the denial to the Maine Superior Court in accordance with Rule 80C of the Maine Rules of Civil Procedure.

**2.6.6 Appeals.** An applicant may appeal an application denial pursuant to the Maine Administrative Procedure Act, 5 MRS, chapter 375.

## 2.7 - Application for Active License of a Cultivation Facility, Testing Facility, Products Manufacturing Facility or Marijuana Store, Including Provisional Testing License

**2.7.1 Forms.** An applicant shall prepare an application on forms made available by the Department for the type of license sought along with the appropriate application fee as determined by the Department pursuant to 28-B MRS § 207 and this Rule. In order for an application for a marijuana establishment to be considered complete, the following must be true:

- A. All applications must include all attachments or supplemental information required by the current forms supplied by the Department and all sections of this Rule.
- B. All applications must be complete and accurate in every material detail.
- C. A license issued to a marijuana establishment or an individual constitutes a revocable privilege. The burden of proving an Applicant’s qualifications for licensure rests at all times with the applicant.
- D. The Department may refuse to accept or consider an incomplete application.

### **2.7.2 Local Authorization.**

- A. In order for a cultivation facility, testing facility, products manufacturing facility or marijuana store conditional licensee to be eligible for a marijuana establishment active license, the municipality or the Maine Land Use Planning Commission, whichever has jurisdiction over the planned site, must have submitted a signed and notarized local authorization certification form prepared and furnished by the Department.
- B. Upon receipt of the local authorization certification form, the Department shall, within 10 calendar days, notify the applicant of any additional information needed for the issuance of an active license or, if applicable, a provisional active license.

- C. Nothing in this Rule shall be construed to prohibit local entities from implementing municipal or other local regulations further restricting the operation and siting of marijuana establishments, including, but not limited to regulations regarding the co-location of residences and marijuana establishments.
- D. Local authorization is not required for sample collector licenses.

**2.7.3 Tax Registration.** The Department may not issue an active license to a conditional licensee that is not properly registered with the State Tax Assessor.

- A. Any conditional licensee must obtain a Sales Tax Identification Number. A unique Sales Tax Identification Number is required for each active license, regardless of common ownership or co-location.
- B. A conditional cultivation facility licensee, including a nursery cultivation facility licensee, must additionally obtain an Excise Tax Identification Number. A unique Excise Tax Identification Number is required for each active cultivation facility license (including nursery cultivation facility), regardless of common ownership or co-location.

**2.7.4 Application Review.** For the purposes of processing applications for marijuana establishments, the Department, pursuant to 28-B MRS§205, shall apply an objective standard to establishing whether an applicant has satisfied the marijuana establishment licensing requirements, specifically the satisfaction of general licensing criteria and the submission of all required documents, forms and fees and the subsequent issuance of provisional and active licenses.

**2.7.5 Supplemental Information for Issuance of Active License.**

- A. All conditional licensees must submit the following forms and supplemental information:
  - (1) Evidence of compliance with all applicable electrical inspection and permitting requirements; which may include but is not limited to: a Certificate of Occupancy issued by the municipal code officer, or written clearance by the Electricians Examining Board, Department of Professional and Financial Regulations.
  - (2) Facility plan, covering the following elements:
    - (a) Location of the establishment within the municipality, town, township, plantation or county, and indicating its proximity to any school. A copy of a tax map showing an area in all directions from the premises of 1000 feet, or in cases where a municipality or the Maine Land Use Planning Commission has reduced the setback to no less than 500 feet, then showing the distance in all directions required by local authority, and indicating that the area around the premises does not include a pre-existing public or private school, as defined in 28-B MRS §§ 402(2)(A) and 403(2)(A), shall meet this requirement;
    - (b) Size and layout of the establishment, including limited access areas, display areas, commercial kitchen areas, sample receiving areas, and points of entry;
    - (c) Proof of ownership of the premises or proof the owner’s consent for the intended use of the premises;
    - (d) A legal ingress onto property from the closest maintained public way;
    - (e) If the property is also used as a residence, the location of that residence within that property and plans for complete separation of the residence from the facility, including:
      - (i) Entirely separate entrances from a public right of way; and
      - (ii) No solvent extraction in the same building or structure as the residence; and
    - (f) Any other elements required for inclusion in the facility plan by this Rule for the applied-for license type.
  - (3) Security plan, consistent with Section 3.3 of this rule.
  - (4) Operating plan, if any changes were made to the original operating plan submitted by the applicant.
  - (5) Proof that the marijuana establishment has a tracking system account activated and functional.
  - (6) Any material changes from the conditional license application, including but not limited to, any changes related to ownership or control, any changes in residency of the applicant or any officer,

- director, manager or general partner, and any new arrests or criminal charges of the applicant or any officer, director, manager or general partner.
- (7) Any information necessary to determine if the applicant continues to meet all requirements of conditional licensure; including any updates to information in the application or an attestation that there have not been any material changes to the conditional license application.
- B. All licensees engaging in manufacturing involving inherently hazardous substances shall also show proof of compliance with the requirements of Section 3.8.4 of this Rule.
- C. Cultivation facilities, including nursery cultivation facilities, must additionally submit the following documents before the Department may issue an active license:
- (1) An updated cultivation plan, if any changes were made to the original cultivation plan submitted by applicant, or certification that the municipality or entity/entities responsible for local authorization required no changes; and
  - (2) Excise Tax Identification Number and proof of registration with the State Tax Assessor.
- D. A marijuana testing facility must obtain full or provisional certification by the CDC as described in *Rules for the Certification of Marijuana Testing Facilities*, 18-691 CMR, ch. 5, before the Department will issue a provisional or full active testing facility license. A marijuana testing facility may test marijuana and marijuana products only if it holds a current provisional or full certification from the CDC. Initial certification will be for a period of 1 year, and annual recertification is required in compliance with 18-691 CMR, ch. 5. A marijuana testing facility must maintain its certification at all times to remain licensed by the Department. A marijuana testing facility must notify the Department within 1 business day if the CDC suspends or revokes its certification. If the CDC suspends or revokes its certification the marijuana testing facility must cease all testing for any analyte and technology covered by the suspension or revocation.
- (1) A marijuana testing facility must apply for ISO/IEC 17025:2017 accreditation before the Department will issue a provisional active testing facility license.
    - (a) The marijuana testing facility may apply for a Department-issued testing facility license to conduct testing only for those fields of testing included in the application for ISO/IEC 17025:2017 accreditation.
    - (b) Upon receipt of ISO/IEC 17025:2017 accreditation, a marijuana testing facility must demonstrate proof of accreditation to the Department and DHHS within 5 business days of receipt.
    - (c) Before the expiration of its provisional active license and any permitted one time renewal of the same, a marijuana testing facility must obtain ISO/IEC 17025:2017 accreditation; otherwise it must cease all operations in that field of testing until such accreditation is obtained if no other field of testing related to marijuana remains.
    - (d) If ISO/IEC 17025:2017 accreditation is denied to the marijuana testing facility holding provisional active licensure, the facility must notify the Department of the denial within one business day of receipt of the denial. The Department shall revoke the provisional active license, upon the marijuana testing facility's notification of denial of ISO/IEC 17025:2017 accreditation.
- E. The Department may request additional information or documentation to ensure that issuance of an active license will not result in any person having a direct or indirect financial interest in:
- (a) More than 3 cultivation facility licenses;
  - (b) Multiple cultivation facility licenses with a combined total licensed amount of plant canopy exceeding 30,000 square feet, except when that exceedance is solely attributable to approved increases in the maximum licensed area of plant canopy authorized under a tier 4 cultivation facility license pursuant to section 28-B MRS §304;
  - (c) A testing facility license or sample collector license if the applicant or licensee is a caregiver or a registered caregiver or has an equity ownership interest or a partial equity ownership interest or any other type of financial interest, including but not limited to, being an investor or serving in a management position in a registered dispensary, a cultivation facility license, a products manufacturing facility license or a marijuana store license; or

- (d) More than 4 marijuana stores. The limit on marijuana store common ownership does not apply after December 31, 2021.

**2.7.6 Payment of Fees.** Before issuing an active license, the Department shall invoice the conditional licensee for the applicable fee as determined by the Department pursuant to Title 28-B and this Rule. The Department shall not accept any license fees except pursuant to such invoice.

**2.7.7 Appeals.** An applicant may appeal an application denial pursuant to the Maine Administrative Procedure Act, 5 MRS, chapter 375.

## 2.8 - Individual Identification Cards

### 2.8.1 Individual Identification Cards Required.

- A. A valid individual identification card issued by the Department is required to be displayed by any individual working in or for a licensed marijuana establishment who:
  - (1) possesses, cultivates, manufactures, packages, tests, dispenses, transfers, serves, handles, transports or delivers marijuana or marijuana products; or
  - (2) has the authority to access or input data into the inventory tracking system or a marijuana establishment point of sale system.
- B. Licensees are responsible for verifying that each required person has a valid individual identification card and must report within 24 hours any attempt by an individual to use an individual identification card that is fake, altered or issued to a person other than the bearer.
- C. A contractor of the licensee, including, but not limited to, an electrician, a plumber, an engineer or an alarm technician, whose scope of work will not involve the handling of marijuana or marijuana products does not require an individual identification card, subject to the requirements of Section 3.2 of this Rule.
- D. The individual identification card requirement does not apply to employees or agents of the Department, law enforcement officers or employees or agents of other local or state agencies with regulatory authority, including but not limited to fire marshals, electrical inspectors, pesticide control staff and environmental inspectors, for the purpose of exercising such regulatory authority.

### 2.8.2 Issuance of Individual Identification Cards.

- A. The Department shall issue individual identification cards to natural persons licensed under Title 28-B.
- B. Upon request, the Department shall issue an individual identification card to an officer, director, manager or general partner who has participated in the license application process and has had fingerprinting and criminal history record checks approved by the Department within the past year, subject to the reporting of any arrests subsequent to the criminal history record check.
- C. Upon request, the Department shall issue an individual identification card for the purpose of employment to an applicant who:
  - (1) Submits to fingerprinting and criminal history record checks following procedures applicable to Licensees under this Rule;
  - (2) Submits proof of being of age 21 or older in a form satisfactory to the Department;
  - (3) Submits any other information required by the Department on its individual identification card application form, including history of enforcement actions in the adult use or medical use of marijuana programs; and
  - (4) Satisfies all requirements for the issuance of an individual identification card.
- D. The Department shall deny an application for individual identification card by any person who has been convicted of a disqualifying drug offense.
- E. The Department may for good cause deny an application for individual identification card by any person who:
  - (1) Has been convicted, or currently faces prosecution for, any state or federal offense involving dishonesty, deception, misappropriation or fraud;
  - (2) Has faced penalties under the adult use marijuana program;



- (3) Has been subject to revocation of a registry identification card or registration certificate issued pursuant to 22 MRS, chapter 558-C;
  - (4) Has outstanding court-ordered payments, past due taxes or fees or other tax delinquency;
  - (5) Has had an individual identification card revoked within the previous 2 years; or
  - (6) Has had been subject to 2 or more individual identification card revocations.
- F. Each licensee shall provide to the Department annually, and upon request of the Department at any other time, a list of all individual identification card numbers used by any owners, officers, managers, contractors, employees or other support staff of the licensee.
  - G. A licensee shall timely notify the Department if it terminates for cause an individual identification cardholder.
  - H. The Department shall maintain a list of all individual identification cards that have been issued to individuals and any licensees that have reported an affiliation with the cardholder.

### **2.8.3 Format and Use of Individual Identification Cards.**

- A. The Department shall charge fees for the issuance, reissuance and renewal of an individual identification card in accordance with the fee schedule located in Section 13 of this Rule.
- B. The individual identification card shall include a current photograph, full name, date of birth, expiration date and a unique identification number.
- C. Individual identification cards are valid for one year from the date of issue. The individual identification card shall be renewed on forms provided by the Department in accordance with the fee schedule located in Section 13 of this Rule; at the time of renewal of an individual identification card, the applicant shall inform the Department of all criminal convictions and other issues that could affect their eligibility since the original issuance of the individual identification card.
- D. All individual identification cards shall remain the property of the Department and shall be returned to the Department upon demand of the Department.
- E. No person shall alter, obscure, damage or deface an individual identification card in any manner. To be valid, all individual identification cards must be in good condition, with all original markings and information clearly legible.
- F. The holder of an identification card must notify the Department immediately if the individual identification card is lost, stolen or damaged. A fee, in accordance with the fee schedule located in Section 13 of this Rule, will be charged for the issuance of a reissued individual identification card, which will not extend the expiration date of the individual identification card it replaces.

**2.8.4 Appeals.** An applicant may appeal an application denial pursuant to the Maine Administrative Procedure Act, 5 MRS, chapter 375.

## **2.9 - License Renewal Process**

### **2.9.1 Annual Renewal.**

- A. Active licenses must be renewed on an annual basis. At the time of renewal the licensee must demonstrate continued compliance with all applicable licensing criteria in accordance with 28-B MRS and this Rule.
- B. An annual inspection by the Department may be required for renewal of a marijuana establishment license.
- C. A license shall not be renewed by the Department if:
  - (1) Outstanding fines or penalties are owed to the Department, unless a plan for payment of those fines has been agreed to and approved, in writing, by the Department, prior to the expiration of an active license;
  - (2) The licensee has not engaged in licensed activity at the licensed premises for a period of 1 year or more, unless the licensee submits evidence of reasonable justification, including without limitation death, illness, natural disaster, or other circumstances beyond the licensee's control;
  - (3) Renewal will result in any person having a direct or indirect financial interest in:
    - (a) More than 3 cultivation facility licenses;
    - (b) Multiple cultivation facility licenses with a combined total licensed amount of plant canopy exceeding 30,000 square feet, except when that exceedance is solely attributable to approved increases in the maximum licensed area of plant canopy

authorized under a tier 4 cultivation facility license pursuant to section 28-B MRS §304;

- (c) A testing facility license or sample collector license if the applicant or licensee is a caregiver or a registered caregiver or has an equity ownership interest or a partial equity ownership interest or any other type of financial interest, including but not limited to, being an investor or serving in a management position in a registered dispensary, a cultivation facility license, a products manufacturing facility license or a marijuana store license; or
  - (d) More than 4 marijuana stores. The limit on direct or indirect financial interests in marijuana stores does not apply after December 31, 2021.
- D. The Department shall notify all licensees of the duty to renew no later than 90 days prior to the expiration date of an active license.
- E. In conjunction with license renewal, a tier 1, tier 2 or tier 3 cultivation facility licensee may apply for a tier of cultivation facility license authorizing a greater area of plant canopy.
- (1) The Department may approve the application, subject to:
    - (a) Submission of revised operation plan and cultivation plan;
    - (b) Payment of any requisite fee(s) in accordance with Section 13 of this Rule;
    - (c) Demonstration that 85% of adult use marijuana cultivated by the licensee at its cultivation facility was sold over the current period of licensure; and
    - (d) Compliance with total canopy limits.
  - (2) If the licensee does not meet the criteria for a tier of cultivation facility license authorizing a greater area of plant canopy, but otherwise meets the requirements for renewal, the Department may renew the license at the existing tier.
- F. In conjunction with license renewal and no more frequently than once in a 2 year period, a tier 4 cultivation facility licensee may apply for an increase of up to 7,000 square feet in plant canopy area.
- (1) The Department may approve the application, subject to:
    - (a) Submission of revised operation plan and cultivation plan;
    - (b) Payment of any requisite fee(s) in accordance with Section 13 of this Rule;
    - (c) Licensee demonstration that 85% of adult use marijuana cultivated by licensee at its cultivation facility was sold over the past 2-year period of licensure; and
    - (d) Compliance with total canopy limits.
  - (2) If the licensee does not meet the criteria for a greater plant canopy, but otherwise meets the requirements for renewal, the Department may renew the license with the existing plant canopy area.
- G. At the time of renewal, the licensee shall ensure that all material changes to the required plans have been communicated in writing to the Department pursuant to Section 3.5 of this Rule.
- H. The licensee shall submit proof that the licensee is still in good standing with MRS.
- (1) For all licensees, an active Sales Tax Identification Number, and no tax delinquencies associated with that Sales Tax Identification Number.
  - (2) For cultivation facility licensees, an active Excise Tax Identification Number, and no tax delinquencies associated with that Excise Tax Identification Number.
  - (3) For all licensees, a list of all Sales Tax Identification Numbers and Excise Tax Identification Numbers associated with any related marijuana establishment in Maine and no tax delinquencies associated with those numbers.
- I. The licensee shall submit proof, through a renewed local authorization certification form, that the licensee is still in compliance with all requisite local permits and licenses and is in good standing with the municipality or other local entity wherein the licensee's facility is located.

### **2.9.2 Continued Authority.**

- A. The Department shall make every effort to approve license renewals in a timely manner.
- B. A licensee that has submitted a timely renewal application by the deadline given by the Department shall be permitted to continue operations if the licensee is not required, or if the licensee is a business entity, no officer, director, manager or general partner is required, pursuant to this Rule and 28-B MRS, to report information, including criminal convictions or enforcement actions, that could affect continued eligibility.

- C. A cultivation facility may not increase its mature plant canopy beyond the limits of its type of license before receiving approval from the Department.
- D. Any application for change in ownership or control must be approved by the Department and is not considered a renewal application.

**2.9.3 Appeals.** An applicant may appeal an application denial pursuant to the Maine Administrative Procedure Act, 5 MRS, chapter 375.

## 2.10 - Application for Relocation of Licensed Premises

The Department must approve any relocation of any marijuana establishment for which local authorization is required, even if the move is entirely within a premise in the control of the licensee. This includes, but is not limited to: expansion, movement of a greenhouse or changes to co-location of multiple establishment types. Nothing in this section shall be interpreted to require prior approval of the relocation of an establishment not requiring local authorization, including a sample collector.

### **2.10.1 Conditional Relocation of Licensed Premises Approval.**

- A. Before seeking local authorization, the licensee must inform the Department, in writing, of its application for relocation of licensed premises.
  - a. All licensees must submit an updated facility plan, security plan, operating plan and proof of compliance with all applicable electrical inspection and permitting requirements.
  - b. All cultivation facilities must submit a revised cultivation plan.
- B. The Department shall, within 30 days, issue a decision, in writing, on the application for relocation of licensed premises.
- C. All licensees must then obtain, as applicable, local authorization.
- D. The relevant authority must submit a local authorization form to the Department.

### **2.10.2 Updated License.**

- A. Within 10 days of receiving authorization on the local authorization form, the Department shall notify the licensee and issue an updated license with the new address. The license shall have the same expiration date as the one it replaces.
- B. A marijuana establishment may operate at the new location only after receiving the updated license from the Department.
- C. After receiving the updated license, the marijuana establishment may conduct activity concurrently at both locations, subject to the following limitations:
  - (1) The licensee shall provide the department with timeline of planned relocation not to exceed 90 days;
  - (2) From the moment the licensee transfers any marijuana or marijuana products in any form to the new location, the licensee has no more than 90 days to cease all activities at the old location. During the period of transfer, the licensee may not begin any new operations in the old location;
  - (3) From the moment the licensee sells or otherwise transfers marijuana or marijuana products in any form to the new location, the licensee may no longer sell or transfer marijuana or marijuana products in any form at the old location, except to transfer the marijuana or marijuana products to the new location;
  - (4) The licensee shall notify the Department in writing when it has ceased operations at the old location; and
  - (5) During the period of transfer, limits of the number of plants or size of the plant canopy shall be calculated by combining the total amount of plants at both the old and new location.

**2.10.3 Relocation with Any Change in Ownership Interests.** When a licensee proposes both a relocation and any change in ownership interests, the licensee shall be required to fulfill all requirements of an application for a new license, and the Department shall evaluate the application de novo.

**2.10.4 Appeals.** An applicant may appeal an application denial pursuant to the Maine Administrative Procedure Act, 5 MRS, chapter 375.

## 2.11 - Transfer of Ownership Interests

**2.11.1 Department Approval Required.** A licensee may transfer ownership interests, including without limitation partial ownership, only after the application for a transfer of ownership interests has been approved by the Department. Ownership interests include all equity ownership interests as defined in Section 1.4(29)(a) and (b), and officers, directors, managers and general partners as defined in Section 1.4(29)(g). This section applies, without limitation, to any change in officers, directors, managers or general partners.

- A. An application for the transfer of ownership interests must:
  - (1) Be completed on forms made available by the Department;
  - (2) Be submitted to the Department;
  - (3) Be accompanied by any applicable fees described on the application form; and
  - (4) Be accompanied by all required forms and supplemental information, provided by the person or entity seeking to assume an ownership interest, similar to that required in an application for a marijuana establishment license, to demonstrate compliance with all applicable requirements for licensure.
- B. Fingerprinting and criminal history record checks in accordance with Section 2.4.3 of the Rule as described above are required for anyone proposed as an officer, director, manager or general partner.
- C. The municipality or the Maine Land Use Planning Commission, as applicable, must submit the local authorization form.

**2.11.2 Temporary Appointee.** Ownership or operations generally may not be transferred to a person or business entity prior to the approval of an application for transfer of ownership interests. However, in cases of death, disability, bankruptcy or other exceptional circumstances, a court may appoint a receiver, personal representative, executor, administrator, guardian, conservator, trustee or similarly situated person to take possession of, operate, manage or control a licensed marijuana establishment. Under such circumstances:

- A. The court appointee may assert a financial and management interest in a marijuana establishment upon certification to the Department that the person is 21 years of age and has no disqualifying drug offenses.
- B. No person appointed by the court may enter a limited access area, sell or otherwise transfer marijuana or marijuana products without a valid individual identification card.
- C. No person may use the tracking system until authorized by the Department.
- D. The person shall submit application for transfer of ownership interests as soon as practical, and in no case more than 45 days after a qualifying event.

**2.10.3 License Invalidation.** The Department may revoke or otherwise make void a license immediately upon discovery of any effort to transfer an ownership interest in a license without complying with the requirements of this subsection.

**2.10.4 Appeals.** An applicant may appeal an application denial pursuant to the Maine Administrative Procedure Act, 5 MRS, chapter 375

## Section 3 - General Compliance

### 3.1 - Reporting of Ownership, Financial, Management and Other Interests

Licensees shall not attempt to conceal or disguise ownership or other control over their operations. The Department retains discretion to determine when a transfer of ownership interests has occurred. Licensees must comply with all

reporting requirements regarding ownership, financial, management and other interests as required by this Rule. Natural persons with indirect financial interests as defined in Section 1.4(29)(h) shall be included in the same category as those with a like direct financial interest. It is the exclusive responsibility of the applicant to clearly indicate on any forms, attachments, and supplemental information supplied to the Department any content the applicant deems to be trade secrets or other information that would be within the scope of a privilege against discovery or use as evidence recognized by the courts of this State in civil or criminal trials if the records or inspection thereof were sought in the course of a court proceeding, which may otherwise be included as a “public record” pursuant to 1 MRS § 402(3) in a response to a request for records and information under the Maine Freedom of Access Act.

**3.1.1 Notice and Department Approval Required.** Any change in ownership interests, including those in Section 1.4(29)(a), (b), and (g), requires Departmental approval under Section 2.10 prior to anyone with a new ownership interest associating with the licensee.

**3.1.2 Notice and Individual Identification Cardholders.** Before any new employee, contractor or other persons defined in Section 1.4(29)(d) or any new manager, contractor or consultant as defined in Section 1.4(29)(f) may associate with a licensee, the licensee shall comply with 28-B MRS § 213 and this Rule in regards to that person.

**3.1.3 Notice and Assessment.** For any financial interest that does not require prior approval or notice as above, such as Section 1.4(29)(c) and (e), the licensee shall notify the Department prior to the beginning of that association and the Department will consider whether the interest has been appropriately characterized and whether 28-B MRS § 205(2) is implicated.

**3.1.4 Notice of Termination and Changes.** The licensee shall notify the Department within 5 business days of the termination of any direct or indirect financial interest, and of any significant change to the nature or extent of that interest.

**3.1.5 No Prior Notice Required.** Without prior notice to and approval by the Department, licensees may employ and contract with any persons who clearly do not fall within the definition of those with direct or indirect financial interests in the licensee, for the operation of a marijuana establishment, so long as each such person has a valid individual identification card. Compensation for such persons must not be structured as a means of evading the provisions of this Rule. As employers, licensees are required to follow all applicable local, state and federal employment laws, including, without limitation, laws pertaining to workplace safety, hours and wages, and all other laws pertaining to the employment of persons in the State of Maine. Nothing in this Rule shall be misconstrued to exempt a marijuana establishment from the rights and responsibilities associated with being an employer.

## 3.2 - Premises

Only activities authorized by this Rule and 28-B MRS may be conducted on the licensed premises. No other activities besides those authorized by this Rule and 28-B MRS may be conducted at any time on the licensed premises, including without limitation: sampling events, catered events or parties.

### 3.2.1 Controlling Entry to Marijuana Establishments.

- A. Marijuana establishments must design entry points so that no person under 21 years of age is allowed entry to the premises.
  - (1) All establishment types must designate specific places at which an employee or licensee will:
    - (a) Verify the age and identity of all persons entering the premises;
    - (b) Require authorized contractors to sign the visitor entry log before entering limited access areas; and
    - (c) Receive mail and other deliveries.

- (2) Nursery cultivation facilities and marijuana stores must designate a specific place at which an employee or licensee will check for a valid government-issued form of identification and controlling access to areas of the premises designated for retail sales, in compliance with section 3.9.4 of this Rule.
- B. Entry points must be designed so as not to enable a person under 21 years of age to handle marijuana or marijuana products.

### **3.2.2 Access to Adults Aged 21 or Older.**

- A. Marijuana stores and nursery cultivation may allow access to adults aged 21 or older, after verifying their age on a valid government-issued form of identification, for the following purposes:
  - (1) Consultations between employees and adult customers;
  - (2) Distribution of printed materials about marijuana;
  - (3) Sales or returns of products that may be legally sold by the licensee; and
  - (4) Customer restrooms, if provided.
- B. A marijuana establishment may not allow the purchaser of marijuana or marijuana products to consume them on the premises.
- C. A marijuana testing facility may designate on its facility plan a portion of the premises where it will receive samples for non-mandatory testing from licensees, persons 21 years of age or older, and/or qualifying patients, caregivers, registered caregivers or registered dispensaries in accordance with 28-B MRS §§ 503 and 503-A and this Rule.

### **3.2.3 Limited Access Areas.**

- A. Limited access areas include, but are not limited to:
  - (1) Areas in cultivation facilities in which marijuana plants, immature plants or seedlings are grown; or marijuana is cut, stored, trimmed, cured or otherwise cultivated; marijuana is packaged for transfer; or marijuana waste is stored or processed.
  - (2) Areas in testing facilities in which marijuana or marijuana products are received, stored, handled, tested, transferred or discarded.
  - (3) Areas in marijuana product manufacturing facilities in which marijuana or marijuana concentrate is received, stored, combined with other ingredients or otherwise manufactured; marijuana products are stored, cooled, cut, packaged or labeled; marijuana or marijuana products are refrigerated; or marijuana waste is discarded or destroyed.
  - (4) Areas in marijuana stores in which a person would be able to touch or handle marijuana or marijuana products, including point of sale areas intended for employees only.
- B. Any other area that is used to cultivate, store, weigh, manufacture, package or otherwise prepare for sale adult use marijuana and adult use marijuana products is also considered a limited access area.
- C. It is the sole responsibility of the licensee to control access to limited access areas and limit access only to the following persons:
  - (1) The establishment's owners, managers or employees who are displaying a valid individual identification card issued to that person;
  - (2) Sample collectors who are displaying a valid individual identification card issued to that person;
  - (3) Employees of a testing facility who are displaying a valid individual identification card issued to that person;
  - (4) Contractors aged 21 or older (including, but not limited to, electricians, plumbers, engineers or alarm technicians) who will not handle marijuana plants, marijuana or marijuana products, in compliance with this subsection;
  - (5) Staff or agents of the Department;
  - (6) Law enforcement officers; and
  - (7) Employees or agents of other local or state agencies with regulatory authority, including but not limited to fire marshals, electrical inspectors, pesticide control staff, and environmental inspectors.
- D. Staff or agents of the Department, law enforcement officers and employees or agents of local or state agencies with regulatory authority shall provide proof of identification but shall not be considered visitors and shall not be denied entry to any area of the premises.
- E. Security.

- (1) Licensees that admit persons 21 years of age or older for the purpose of purchasing marijuana plants, marijuana, or marijuana products shall use identification checks, locked doors, video surveillance, counters, and locked displays, in accordance with their Department-approved security plan, to prevent unauthorized entry to limited access areas
  - (2) Other licensees shall use identification checks, locked doors, and video surveillance, in accordance with their Department-approved security plan, to prevent unauthorized entry to limited access areas.
  - (3) Any security breaches must be reported within 24 hours, in writing, to the Department.
- F. Required Signage.
- (1) All areas of ingress and egress to limited access areas on the premises shall be clearly identified by posting a sign which shall be no smaller than 8.5 inches high and 11 inches wide, composed of letters not less than a half inch in height, which shall state: "Pursuant to State Law: Do Not Enter – Authorized Persons Only."
  - (2) If a person must pass through a limited access area to reach other limited access areas, and there is no other route through which a person can gain access to the subsequent limited access areas, then signage must only be posted on the first limited access area through which a person must pass.
- G. Contractors and other authorized visitors.
- (1) Contractors and other authorized who will not handle marijuana plants, marijuana or marijuana products, including but not limited to electricians, plumbers, engineers and alarm technicians, do not require an individual identification card.
  - (2) A contractor may enter a limited access area only if wearing a visitor identification badge, signed in and recorded on a visitor entry log and prevented from accessing marijuana plants, marijuana or marijuana products.
    - (a) If the contractor is working in an area with immediate access to marijuana plants, marijuana or marijuana products, a licensee or employee must supervise the contractor at all times.
    - (b) If the contractor is working in an area in which locked doors, compartments or other physical security measures prevent the contractor from accessing marijuana plants, marijuana or marijuana products, a licensee or employee must take reasonable precautions to ensure that the contractor remains in such areas and does not attempt to gain access to marijuana plants, marijuana or marijuana products.
  - (3) At all times while in a limited access area, the contractor shall display in a conspicuous place on their person a visitor identification badge.
    - (a) The visitor identification badge must display an identifying mark, which may be a clearly identifiable letter, number or symbol or combination thereof.
    - (b) The visitor identification badge may be displayed on a sticker, a card on a lanyard, a card pinned to the clothing of the visitor, or by other effective means.
  - (4) A visitor entry log must include, at a minimum:
    - (a) The date and time of the visitor's entry;
    - (b) The date and time of the visitor's departure;
    - (c) The full name of the visitor;
    - (d) The identifying number of the visitor's state- or federally-issued identification;
    - (e) The identifying mark on the visitor identification badge;
    - (f) The individual identification card number of the person who will accompany the contractor, if required, while the contractor is in the limited access areas of the premises; and
    - (g) The purpose for which the contractor is accessing the limited access area[s].
  - (5) Any incident not compliant with the marijuana establishment licensee's authorized conduct that occurred while the contractor or visitor was in a limited access area of the premises must be reported in writing to the Department within 24 hours, including all information required by the visitor entry log.

### 3.3 - Security

Cultivation facilities, testing facilities, products manufacturing facilities, and marijuana stores must provide adequate security at the licensed premises. This section does not apply to sample collectors.

**3.3.1 Mandatory Requirements for Cultivation Facilities, Testing Facilities, Products Manufacturing Facilities, and Marijuana Stores.** As applicable, marijuana establishments must enact security measures to prevent the diversion of marijuana or marijuana products that are being cultivated, manufactured, tested, packaged, stored, displayed or transported.

- A. Lighting
  - (1) Any gate or perimeter entry point of a marijuana establishment must have lighting sufficient for observers to see, and cameras to record, any activity within 10 feet of the gate or entry.
  - (2) A motion detection lighting system may be employed to light required areas in low-light conditions.
- B. Doors and windows
  - (1) Commercial grade locks, appropriate for facilities requiring high levels of physical security, are required on all perimeter entry doors and on all doors separating limited access areas from areas open to visitors and customers.
  - (2) All external entrances to indoor facilities on the licensed premises must be able to be locked.
  - (3) All perimeter windows must be in good condition and lockable.
- C. Alarm system
  - (1) Monitored sensors are required on all perimeter entry points and perimeter windows.
  - (2) Alarm systems must be monitored by a licensed security company capable of contacting the licensee and, if necessary, law enforcement.
  - (3) The system must include an audible alarm, which must be capable of being disabled remotely by the security company.
- D. Video surveillance
  - (1) Placement and coverage of cameras shall be sufficient:
    - (a) Cameras must be permanently fixed inside each entry/exit point (perimeter and limited access area) to allow identification of persons entering the premises and limited access areas.
    - (b) Cameras must be permanently fixed outside each entry/exit point (perimeter and limited access area) to allow identification of persons exiting the premises and limited access areas.
    - (c) A sufficient number of cameras must be permanently fixed to allow the viewing, in its entirety, of any area where marijuana, marijuana plants, immature marijuana plants, seedlings, seeds, marijuana concentrate or marijuana products are cultivated, manufactured, stored or prepared for transfer or sale or where samples for mandatory testing are collected, and prepared and sealed for transport to a marijuana testing facility.
    - (d) A sufficient number of cameras must be permanently fixed to allow the viewing, in its entirety, of any area where marijuana waste is stored before being made unusable, or where marijuana waste is made unusable.
    - (e) A camera must be permanently fixed at each point of sale to monitor the identity of the purchaser and ensure facial identity.
    - (f) A sufficient number of cameras shall be permanently fixed to allow recording of all areas outside of the premises within 10 feet of the exterior fence and gates of a cultivation facility with outdoor growing.
  - (2) Video surveillance shall meet the following minimum requirements:
    - (a) Minimum camera resolution is 720p.
    - (b) System storage and cameras are internet protocol (IP) compatible.
    - (c) All cameras must record continuously twenty-four hours per day and at a minimum of 15 frames per second.
    - (d) All recorded images must clearly and accurately display the time and date. Time is to be measured in accordance with the U.S. National Institute Standards and Technology standards.



- (e) The surveillance system storage device must be secured on the premises in a lockbox, cabinet or closet, or must be on a third-party server or secured in another manner to protect from employee tampering or criminal theft.
- (3) All surveillance recordings must be kept for a minimum of 45 days on the licensee's recording device.
- (4) All videos are subject to inspection by any Department employee or law enforcement officer and must be copied and provided to the Department or law enforcement officer upon request.
- (5) Licensees shall maintain a list of all persons with access to video surveillance recording and procedures for controlling access to recordings.

**3.3.2 Fencing and Lighting Requirements for Cultivation Facilities.** A cultivation facility that cultivates seedlings, immature plants or mature plants in outdoor areas or in greenhouses or other structures that do not meet all security requirements for buildings must secure such cultivation areas with fencing and lighting.

- A. Any cultivation facility with cultivation areas that do not meet the requirements for building security shall erect secure fencing around such areas. Fencing and all gates must be secure, at least 6 feet high and obscure, or have a cover that obscures, the Limited Access Area from being readily viewed from outside of the fenced in area.
- B. Lighting shall be designed to illuminate a perimeter of at least 10 feet around any point of entry, whether it is a gate or access from a building.

**3.3.3 Additional Security Measures.** The licensee may choose to enact additional security measures to enhance the safety of the marijuana establishment.

- A. Measures to prevent employee theft:
  - (1) Licensees may designate areas for employee storage of bags, overcoats and other belongings.
  - (2) Licensees may place limits on the size of bags to be brought to the marijuana establishment.
  - (3) Licensees may institute other reasonable procedures for checking for stolen marijuana or marijuana products when an employee leaves the premises.
- B. Security guards:
  - (1) Security guards are permitted but not required at marijuana establishments.
  - (2) Security guards employed or contracted by a licensee must:
    - (a) Meet all qualifications of 32 MRS, chapter 93;
    - (b) Be at least 21 years of age;
    - (c) Comply with all requirements of 32 MRS, chapter 93; and
    - (d) Obtain and display individual identification cards if they will be in limited access areas or in a vehicle that is transporting marijuana plants, marijuana or marijuana products.
  - (3) Security guards must not consume marijuana or marijuana products or be intoxicated while performing any duties for a licensee.
  - (4) Licensees, employees and security guards must comply with all laws and regulations related to firearms and other weapons.

**3.3.4 Written Security Plan.** Before cultivating, manufacturing, testing, selling, storing or transporting marijuana or marijuana products, each licensee shall receive Department approval of a written security plan, demonstrating compliance with all requirements of this Rule.

- A. At a minimum, the security plan shall provide sufficient detail so that the Department may determine whether the following requirements are met:
  - (1) Lighting adequately illuminates entry and exit points;
  - (2) All doors and windows are lockable;
  - (3) Fences (if present) meet height and other requirements;
  - (4) Alarm sensors are present on all entry points and windows and are remotely monitored;
  - (5) Video cameras are present in all required locations;
  - (6) Video cameras and storage meet all required specifications; and

- (7) In areas of the premises (if any) designated for retail sales, lockable and secure display cases or counters of sufficient height to prevent the public from handling marijuana plants, marijuana or marijuana products without direct supervision of a licensee or employee.
- B. Each licensee shall adhere to the security plan and submit in writing to the Department a revised security plan within 14 days any time a material change is made to security measures. The Department may, but is not required, to approve revised security plans. The Department may determine at any time that the revised security plan does not meet minimum requirements.
- C. Material changes include, but are not limited to, the addition or removal of sensors or cameras, changing of monitoring companies, additions of points of entry and changes to lighting.

### 3.4 - General Conduct

#### 3.4.1. General Requirements.

- A. Marijuana licensees are responsible for the operation of their licensed business in compliance with Maine Revised Statutes, Titles 28-B, 17-A, 36; this Rule; and any other applicable state laws and rules.
- B. Licensees and their employees must conduct business and maintain the licensed premises, surrounding area, and vehicles transporting product, in compliance with the following laws, as they now exist or may later be amended:
  - (1) Falsification in Official Matters, 17-A MRS, chapter 19;
  - (2) Offenses against Public Order, 17-A MRS, chapter 21;
  - (3) Drugs, 17-A MRS, chapter 45; and
  - (4) Motor Vehicles and Traffic, 29-A MRS.
- C. Licensees have the responsibility to control their conduct and the conduct of employees, customers, contractors and visitors on the licensed premises at all times. Licensees shall ensure that at all times during operating hours and hours of apparent activity that there is, on-site, an individual identification cardholder authorized to cooperate with Department inspection of the premises and business records. Except as otherwise provided by law, licensees or employees may not:
  - (1) Be disorderly or visibly intoxicated by liquor, marijuana or controlled substances on the licensed premises;
  - (2) Permit any disorderly or visibly intoxicated person to remain on the licensed premises;
  - (3) Engage in or allow behavior on the licensed premises that provokes conduct which presents a threat to public safety;
  - (4) Engage in, or permit any employee or other person to engage in, conduct on the licensed premises that is prohibited by any portion of 28-B MRS, 17-A MRS or 36 MRS; any part of this Rule; or any other applicable state laws and rules; or
  - (5) Engage in or permit any employee or other person to engage in the consumption of any type of marijuana, marijuana concentrate or marijuana product on the premises, except:
    - (a) A licensee may allow an employee who is a qualifying patient to consume legally obtained medical marijuana or marijuana products, so long as no customer or visitor sees, smells, hears or otherwise observes the consumption of medical marijuana. Pursuant to 22 MRS§2426(2)(B), no employer is required to accommodate the ingestion of medical marijuana in any workplace or any employee working while under the influence of marijuana.
    - (b) A products manufacturing facility licensee or employee may ingest, consume or apply products for quality control, research or development purposes, so long as the licensee does not allow any products to be smoked on the premises and the licensee ensures that the person conducting the testing does not operate any equipment or machinery or a motor vehicle while under the influence of the marijuana product.
- D. Licensees are prohibited by this Rule from manufacturing, selling or offering for sale any marijuana product intended for intravenous delivery or that involves any type of injection involving piercing of the skin of a human or animal.

### 3.5 - Adherence to Written Plans Approved by the Department

Marijuana establishment licensees are required to conduct operations in accordance with all written plans submitted by the licensee as an applicant, conditional licensee or active licensee and approved by the Department as indicated by the issuance of a marijuana establishment license.

**3.5.1 Covered Plans.** As applicable, a licensee is responsible for developing, obtaining approval for and adhering to any plans that the Department may require to promote public health, public safety and orderly operation of the adult use marijuana program in accordance with the 28-B MRS and this rule. At minimum:

- A. All marijuana establishments must develop, receive approval for and operate in accordance with:
  - (1) An operating plan;
  - (2) A facility plan; and
  - (3) A security plan.
- B. All cultivation facilities must additionally develop, receive approval for, and operate in accordance with a cultivation plan.
- C. All marijuana establishments must operate in accordance with:
  - (1) Any other written assurances regarding operations to the Department for the purposes of ensuring health and safety;
  - (2) Local ordinances, land use standards and/or warrant articles;
  - (3) Any permits issued, or conditions imposed by a municipality, town, plantation, county commission or the Maine Land Use Planning Commission in connection with local authorization; and
  - (4) Any plans required by any other state agency or regulatory authority.
- D. Licensees collecting their own samples for mandatory testing must comply with all Department-required forms, SOPs and guidance,

**3.5.2 Plans of Record.** The Department shall keep on file a copy of all facility plans, security plans, operating plans and cultivation plans, as well as copies of certifications of testing facilities. The most recent plan, whether submitted with the issuance of the marijuana establishment license, or by the subsequent approval of an application to change, shall be the plan of record with which the licensee must comply.

**3.5.3 Licensee Responsibility.** A marijuana establishment licensee is solely responsible for the operation of the marijuana establishment in accordance with the marijuana establishment operating plan of record on file with the Department.

**3.5.4 Changes to Operating Plan or Cultivation Plan.** Any significant changes to the operating plan of record of any marijuana establishment or the cultivation plan of a cultivation facility must be approved by the Department.

- A. An application to significantly change the operating plan of a marijuana establishment must be:
  - (1) Submitted on forms made available by the Department;
  - (2) Accompanied by all required fees associated with a change of operating plan; and
  - (3) Consistent with 28-B MRS, this Rule and any other applicable laws and rules.
- B. No licensee shall make changes to operations until the application for changes to the operating plan have been approved by the Department.
- C. Within 30 days of receiving an application for changes to the operating plan, the Department shall:
  - (1) Approve the application for changes to the operating plan and update the operating plan of record on file with the Department; or
  - (2) Deny the application for changes to the operating plan only if the changes requested are in violation of 28-B MRS, this Rule, conditions required for local approval or other applicable laws or rules.
- D. The Department may place an application for changes to an operating plan on hold if the marijuana establishment applying for the change of operating plan is currently under investigation for a violation of 28-B MRS, this Rule or other related laws or rules.
- E. The same procedures apply for changing a cultivation plan.

- F. For purposes of this section, a licensee proposing to co-locate a medical marijuana operation not currently operating on the premises shall constitute a change in the operating plan.

**3.5.5 Changes to Facility Plan.** Any changes to the facility plan must be approved. The licensee shall submit a revised facility plan to the Department 14 days prior to any material change. The Department may deny the application for changes to the facility plan if the changes requested are in violation of 28-B MRS, this Rule, conditions required for local approval or other applicable laws or rules

### 3.6 - Requirements Applicable to Cultivation Facilities

**3.6.1 General Compliance.** In addition to the general compliance requirements pursuant to this Rule, including without limitation Section 3, and all requirements pursuant to 28-B MRS, 36 MRS and all other applicable laws and rules, a marijuana cultivation licensee must comply with the requirements of this subsection.

**3.6.2 Privileges Granted.** A marijuana cultivation licensee shall only exercise those privileges granted to it by the Department. In accordance with 28-B MRS, this Rule and all other applicable laws and rules, a marijuana cultivation licensee may within limited access areas of the premises as described in the marijuana establishment operating plan of record:

- A. Propagate and cultivate marijuana plants;
- B. Trim, dry, cure and store marijuana;
- C. Prepare marijuana plants and marijuana for authorized transfer and participate in authorized transfers of marijuana plants and marijuana;
- D. Package marijuana for retail sale:
  - (1) A marijuana cultivation establishment may package marijuana flower and trim for retail sale; and
  - (2) A marijuana cultivation establishment may produce pre-rolled marijuana cigarettes, so long as the pre-rolled marijuana cigarettes contain only marijuana flower or trim.
- E. Prepare marijuana waste for disposal and dispose of marijuana waste;
- F. Transfer marijuana samples to products manufacturing and marijuana store licensees pursuant to 28-B MRS and this Rule;
- G. Collect samples for mandatory testing in compliance with this Rule;
- H. Transfer marijuana testing samples to a licensed marijuana testing facility; and
- I. Performed authorized transfer of marijuana plants and marijuana.

**3.6.3 Authorized Sources of Marijuana Plants and Seeds.** A cultivation facility licensee may acquire marijuana plants and seeds by the following processes:

- A. By lawful purchase from another marijuana establishment, including a nursery cultivation facility.
- B. By gift from an individual person, who must be a resident of the State of Maine:
  - (1) A marijuana cultivation licensee may receive, by gift from an individual, only plants that qualify as marijuana seedling pursuant to this Rule;
  - (2) If a marijuana cultivation licensee receives a marijuana plant or plants as a gift from an individual, the marijuana cultivation licensee shall record, on forms made available by the Department, the full name, contact telephone number and the identification number of a valid state identification belonging to the individual;
  - (3) The individual gifting the marijuana seedling to the licensee may not receive remuneration of any kind in return; and
  - (4) The gift of the marijuana seedling must not be conditional or contingent upon any other terms or requirements of the licensee.
- C. By way of limited authorization for the sale of marijuana plants (including seedlings, immature plants and mature plants) and marijuana seeds by registered caregiver or registered dispensary to marijuana cultivation licensee, pursuant to 28-B MRS§501(6):
  - (1) A cultivation facility licensee may not make such purchases unless the cultivation facility licensee is:
    - (a) A natural person who is also a registered caregiver or registered dispensary;
    - (b) A business entity that is also a registered caregiver or registered dispensary; or

- (c) A business entity with identical ownership and ownership shares as registered caregiver or registered dispensary.
- (2) A cultivation facility may not make such purchases more than 1 year after it is first issued a cultivation facility license.
- (3) A cultivation facility may not make such purchases more than 2 years after the Department first issues a cultivation facility license to any other licensee.
- (4) A cultivation facility must enter all marijuana seedlings, immature plants, and mature marijuana plants acquired through such purchases into the tracking system.
- (5) A cultivation facility must report such purchases on a form supplied by the Department.
- (6) A cultivation facility must pay any excise tax that would have been owed if the same amount of marijuana plants or seeds had been sold by a cultivation facility.
- (7) Any marijuana seeds and marijuana must be transported in accordance with all requirements relevant to transfers between licensees.
- (8) A cultivation facility may not make such a purchase from a registered caregiver or registered dispensary that previously has made a sale of marijuana or marijuana seeds under this provision.
- (9) Any marijuana or marijuana seeds obtained in violation of this paragraph, and any marijuana derived therefrom, are subject to seizure and destruction by the Department, in addition to any administrative penalties that the Department may impose.

#### **3.6.4 Marijuana Cultivation Establishment Premises.**

- A. The premises of a marijuana cultivation establishment must comply with all security requirements described in Section 3.3.
- B. All electrical equipment, including but not limited to growing lights, cultivation equipment and packaging equipment, must be agency approved including UL, ETL, and CSA.
- C. Any cultivation of seedlings, immature plants or mature plants must take place in:
  - (1) A fully enclosed secure indoor facility or secure greenhouse with walls, a roof, lockable doors, and secure windows as described in Section 3.3 that prevent entry by unauthorized persons; or
  - (2) Within a secured fenced area, as described in Section 3.3, structures, or an expanse of open or cleared ground.
- D. The entire area within the fence surrounding non-secure greenhouses, other structures or expanse of open or cleared ground shall be considered a limited access area.
  - (1) An outdoor or greenhouse marijuana cultivation facility must provide sufficient security measures to demonstrate that outdoor areas are not readily accessible by unauthorized individuals.
  - (2) It shall be the responsibility of the licensee to maintain physical security in a manner similar to a cultivation facility located in an indoor licensed premise so it can be fully secured and alarmed.
- E. A nursery cultivation facility or a cultivation facility that also holds a marijuana store license on the same premises must use a fence or other adequate security measures to separate areas of the premises designated for retail sales from limited access areas, including any area where samples for mandatory testing are collected, packaged, and sealed for transport to a marijuana testing facility.

**3.6.5 Authorized Mature Plant Canopy.** At no time may a marijuana cultivation licensee cultivate mature marijuana plants in an area not clearly illustrated on the operating plan of record or cultivation plan of record, previously filed and approved by the Department. At no time may the total area in square feet in which mature marijuana plants are cultivated exceed the total area for which the marijuana cultivation licensee has been approved as indicated on the license issued to the licensee by the Department.

#### **3.6.6 Hours of Operation.**

A marijuana cultivation licensee may not, outside of the hours of operation stated on the operating plan of record, conduct the following activities:

- A. Harvest mature marijuana plants;
- B. Move immature and mature marijuana plants from one area of the premises to another;
- C. Transfer marijuana to or from a drying or curing area;
- D. Otherwise cultivate marijuana;
- E. Create, change or combine a batch of marijuana or marijuana products;

- F. Transfer or transport of any material tracked in the tracking system;
- G. Prepare marijuana waste to be unusable; or
- H. Dispose of marijuana waste.

Except that, in the event of an emergency due to unforeseen or otherwise unavoidable circumstances, the licensee may conduct the enumerated activities outside the hours of operation stated on the operating plan of record, for the purposes of protecting the licensee's marijuana inventory, provided that the licensee first provides notice to the Department regarding the character of the emergent circumstances, the activities to be conducted and the hours during which such activities will occur.

**3.6.7 Cultivation of Medical and Adult Use Marijuana on the Same Premises.** A cultivation facility may cultivate both medical marijuana and adult use marijuana only if: (1) it has received the Department's approval of an operating plan to cultivate both, and (2) it is a validly registered dispensary or caregiver. The cultivation facility must:

- A. Cultivate medical marijuana in an area physically and visually separated from the area used to cultivate adult use marijuana;
- B. Track all medical marijuana separately from adult use marijuana;
- C. Store all medical marijuana separately from adult use marijuana;
- D. Ensure that medical marijuana is never cultivated simultaneously or contemporaneously with adult use marijuana on the same piece of equipment;
- E. Keep a log of the following information for all equipment used to cultivate both medical marijuana and adult use marijuana:
  - (1) The name of the licensee or employee who operated the equipment;
  - (2) The tracking information for the marijuana or marijuana concentrate that was processed using the equipment;
  - (3) The exact date, time and duration the equipment was used; and
  - (4) The tracking information for the resulting marijuana concentrate or marijuana product; and
- F. Make the log for any piece of equipment available to the Department, the Maine Revenue Service or any law enforcement officer for inspection.

### 3.7 - Requirements Applicable to Testing Facilities

**3.7.1 General Requirements.** Before accepting any marijuana or marijuana products for mandatory testing pursuant to 28-B MRS § 602, a marijuana testing facility must:

- A. Obtain certification from the Department of Health and Human Services, Maine Center for Disease Control and Prevention, in accordance with 18-691 CMR, Ch. 5, at any point during the licensure process, but prior to the issuance of a full or provisional active license by the Department. Approval by the CDC of plans, standard operating procedures, financial and business arrangements, or other documents and information provided for certification by the CDC pursuant to the *Rules for the Certification of Marijuana Testing Facilities*, 18-691 CMR, ch. 5 does not constitute approval by DAFS for the purposes of licensure pursuant to this Rule; and
- B. Obtain a conditional license from the Department, in accordance with Section 2.4; obtain local authorization to operate a marijuana testing facility, in accordance with Section 2.6; and a provisional or full active license from the Department, in accordance with Section 2.6.

**3.7.2 Prohibited Conduct.** In addition to any other restrictions or prohibitions contained in this Rule, 28-B MRS, 18-691 CMR, Ch. 5, any other applicable Federal, State or Local rules or laws or any accreditation requirements, marijuana testing facilities are subject to the following prohibitions.

- (1) No testing facility or owner, officer, director, manager, general partner, or employee of a marijuana testing facility may have a direct or indirect financial interest in a cultivation facility, products manufacturing facility, manufacturing facility, marijuana store, registered caregiver or registered dispensary.
- (2) No owner, officer, director, manager or general partner of a marijuana testing facility may be a registered caregiver.

- (3) No testing facility may conduct testing on behalf of a registered caregiver who is an employee of that testing facility.
- (4) Marijuana or marijuana products may not be collected, accepted, transported, purchased, transferred or destroyed without entering the marijuana or marijuana products into the tracking system required by the Department by 11:59 pm that same day.
- (5) A marijuana testing facility may not transfer any marijuana or marijuana products or samples to any person or entity other than the person or entity who provided the sample, a law enforcement officer authorized to collect the marijuana or marijuana product, another licensed marijuana testing facility with a valid license to perform the testing requested, or the Department.
- (6) No owner, officer, director, manager, general partner, contractor or employee of a marijuana testing facility may accept any gifts of goods, services, or money from a cultivation facility, products manufacturing facility, marijuana store, registered caregiver or registered dispensary or a person or an organization representing such entities.
- (7) A marijuana testing facility shall maintain the confidentiality of test results and may not report test results with any identifying information to anyone other than the person or entity who submitted the sample, law enforcement officers authorized to collect the information, the CDC, or the Department.
- (8) No employee of a marijuana testing facility may alter the results of any test. In cases in which a sample was retested in accordance with Section 8.3 of this Rule, both test results shall be maintained.
- (9) No employee of a marijuana testing facility may conceal from the Department the results of any mandatory test for cannabinoid content or contamination.
- (10) No testing facility may fail to operate within the requirements of this Rule, any term of certification or any order, or any request or other directive made under authority of or under the statutory authority vested in the Department.
- (11) No testing facility may engage in, aid, abet, cause or permit any action prohibited under this Rule.
- (12) No testing facility may fail to provide timely and accurate data reporting.
- (13) No testing facility may engage in false or deceptive advertising.
- (14) A marijuana testing facility must maintain its certification at all times for at least one analyte and technology required as part of mandatory testing to remain licensed by the Department.
- (15) No testing facility may continue to operate after a municipality or the Maine Land Use Planning Commission informs the Department that it has revoked, suspended or not renewed local authorization.

**3.7.3 Personnel Qualifications.** A marijuana testing facility must employ at all times qualified staff who meet the requirements of certification by the CDC.

- A. A marijuana testing facility must ensure that a marijuana testing facility director meeting CDC certification requirement is onsite and available during on average, at least 60% of the hours of operation indicated on the facility's operating plan.
- B. A marijuana testing facility must keep a current record of all individual identification cards, the individual identification card number and date of issuance and expiration for every officer, director, manager, general partner, employee, or any other individual identification card holder of the marijuana testing facility.

**3.7.4 Written SOPs are requirements of licensing and must be followed.**

- A. Actual practice must conform to the written procedures required under 18-691 CMR ch.5.
  - (1) The marijuana testing facility must maintain copies of the methods from which the procedures are developed and must ensure that the applicable requirements are incorporated into each procedure.
  - (2) A copy of each procedure must be available to all personnel that engage in that activity.
  - (3) An analyst must use the marijuana testing facility's SOP beginning on its effective date.
- B. It is the exclusive responsibility of the marijuana testing facility to clearly indicate on any SOPs supplied to the Department any content the marijuana testing facility deems to be trade secrets or other information that would be within the scope of a privilege against discovery or use as evidence recognized by the courts of this State in civil or criminal trials if the records or inspection thereof were sought in the course of a court

proceeding, which may otherwise be included as a “public record” pursuant to 1 MRS § 402(3) in a response to a request for records and information under the Maine Freedom of Access Act.

- C. The marijuana testing facility must make the SOPs available to the Department and the CDC upon request.

### **3.7.5 A marijuana testing facility must comply with all recordkeeping requirements of 18-691 CMR, Ch. 5 and this Rule.**

- A. The marijuana testing facility must maintain analytical records to demonstrate to the Department and the CDC the following: the analyst’s name; date of analysis; approver of the certificate of analysis and relevant data package; the test method; and the materials used.
  - (1) Marijuana testing facility records may be on paper or on electronic, magnetic or optical media and must be stored in such a way that the records are readily retrieved when requested by the Department or the CDC.
  - (2) If the marijuana testing facility records are not on paper, the marijuana testing facility must be able to produce the records in hard copy for the Department or the CDC, upon request.
  - (3) All marijuana testing facility records must be kept for a minimum of five years.
  - (4) The Department and the CDC must be allowed access to all electronic data, including standards records, calibration records, extraction logs, marijuana testing facility notebooks and all other marijuana testing facility-related documents as required by this Rule and 18-691 CMR, Ch. 5.
- B. The marijuana testing facility must maintain all analytical records and documents, forms, records and standard operating procedures associated with the marijuana testing facility’s methods as required by this Rule and 18-691 CMR, Ch. 5.
- C. If records are missing or incomplete, or if the marijuana testing facility does not produce records for the Department or the CDC upon request, the Department may take disciplinary or enforcement action against the marijuana testing facility. A marijuana testing facility shall have 7 calendar days from the request to respond.

### **3.7.6 Electronic data storage and security.**

- A. A marijuana testing facility must store all raw unprocessed instrument output data files and processed quantitation output files on some form of electronic, magnetic or optical media. The marijuana testing facility must allow access to these records for inspection and audit by the Department or the CDC.
- B. A marijuana testing facility must install, manage and maintain password-protection for electronically stored data, including any certificate of analysis.

### **3.7.7 Test waste disposal.**

- A. A marijuana testing facility must dispose of all unused test samples and waste generated by the testing of samples of marijuana, marijuana concentrate and marijuana products in accordance with the facility’s SOPs and this Rule.
- B. The marijuana testing facility must discard hazardous waste in accordance with Section 9.1 of this Rule.
- C. The marijuana testing facility must discard marijuana waste in accordance with Section 9.2 of this Rule.

### **3.7.8 Security**

- A. All marijuana on the premises must be tracked using the chain-of-custody forms and the inventory tracking system in accordance with this Rule and 18-691 CMR, Ch. 5.
- B. The marijuana testing facility must install key-card doors, alarms or other means of detecting entrance and exit to limited access areas and during times that are outside of the operating hours of the facility.
- C. The marijuana testing facility must develop and implement security protocols that can prevent diversion, theft and loss of samples.
- D. The security protocol must be documented in writing and available to all testing facility personnel during normal business hours and must be included in training materials. The marijuana testing facility must ensure that personnel have a thorough understanding of the security protocol.
- E. The marijuana testing facility must deter the unauthorized entrance into areas within the marijuana testing facility where samples are present by controlling access to those areas through the following means:



- (1) Limiting access to specific personnel, in order for them to execute their specific job function and duties;
  - (2) Implementing an access-control-card system capable of preventing unauthorized access through access control points and recording the transaction history of all entrants;
  - (3) Using a monitored security alarm system;
  - (4) Maintaining a visitor arrival and departure log, which must contain, at a minimum, the name of the visitor, date and time of arrival and departure, and the purpose of the visit; and
  - (5) Installing security cameras at all access points to the premises, in storage areas for samples and where marijuana waste will be destroyed.
- F. The marijuana testing facility must store and secure marijuana with a commercial-grade lock in a room or cabinet capable of preventing diversion, theft, and loss. Secured areas must be locked at all times, except when managing or retrieving a secured item or items. The marijuana testing facility must store marijuana and marijuana product samples apart and away from non-marijuana samples and items. The marijuana testing facility must designate secured areas for storage of the following:
- (1) Test samples of marijuana and marijuana products;
  - (2) Waste containing marijuana;
  - (3) Reference standards for analysis of cannabinoids; and
  - (4) Any controlled substances related to cannabinoids.
- G. Testing facilities must notify the Department within one business day of discovering any of the following:
- (1) An unexplained loss of 5% or more of the inventory of unpackaged and unused production batch samples held at the marijuana testing facility;
  - (2) An unexplained loss of one or more units of packaged batch samples held at the marijuana testing facility; or
  - (3) Diversion or theft of marijuana, unauthorized or prohibited conduct, or any other criminal activity pertaining to the operation of the marijuana testing facility.
- H. The marijuana testing facility must also comply with security requirements of Section 3.3 of this Rule.
- I. In addition to any samples collected for mandatory testing by the marijuana testing facility, a marijuana testing facility may only accept samples for mandatory testing from:
- (1) Licensed sample collectors; or
  - (2) A self-sampler in compliance with this Rule.

### 3.8 - Requirements Applicable to Products Manufacturing Facilities

**3.8.1 General Product Safety.** In addition to other provisions in this Rule, 28-B MRS and all other applicable rules and laws, a marijuana products manufacturing facility must:

- A. Ensure that all equipment and surfaces that come into contact with any marijuana or other ingredients are food grade and made of materials that do not react adversely with marijuana, any ingredient, chemical or solvent being used;
- B. Construct, install and maintain all counters and surface areas in a manner that reduces the potential for development of microbials, molds, mildew, fungi and other contaminants, and that can be easily cleaned;
- C. Maintain the premises in a manner that is:
  - (1) Free from conditions that may result in contamination; and
  - (2) Suitable to facilitate safe and sanitary operations;
- D. Provide adequate refrigeration for perishable marijuana products that will be consumed and utilize adequate storage facilities and transport methods;
- E. Ensure that all electrical equipment, including but not limited to equipment used for extraction, mixing, cutting and packaging; refrigerators; ventilation; and lights, is agency approved including UL, ETL, and CSA;
- F. Ensure that all chemicals and substances used in the manufacturing process are stored in a safe location on the premises and in a manner to prevent contamination of any marijuana or marijuana products; and

- G. Collect and submit samples of marijuana concentrate and marijuana products for mandatory testing in accordance with all requirements of this rule.

**3.8.2 Prohibited Conduct.** In addition to any other restrictions or prohibitions contained in this Rule, 28-B MRS and any other applicable rules or laws, a marijuana products manufacturing establishment may not:

- A. Manufacture a marijuana product that by its shape or design is likely to appeal to persons under 21 years of age, including without limitation:
  - (1) Products that are modeled after non-marijuana products commonly consumed by and marketed to children; or
  - (2) Products in the distinct shape of a human, animal or fruit.
- B. Manufacture a marijuana product by adding or infusing marijuana into a commercially available non-marijuana end product;
- C. Manufacture any product that does not contain marijuana;
- D. Manufacture any edible marijuana product that has more than 10 milligrams of THC per serving;
- E. Package together for sale an edible marijuana product that has more than 100 milligrams of total THC; or
- F. Engage in the sale of marijuana, if required testing is not verified/verifiable with certificate of analysis, or if testing reports unsafe levels of potentially harmful substances.

**3.8.3 Tracking.** A marijuana products manufacturing facility must enter into the tracking system all required information each time a batch is created.

**3.8.4 Extraction.** A marijuana products manufacturing facility must conform with the standard operating procedures for extraction methods described in its operating plan of record for any extraction to be performed on the premises.

- A. **Generally safe extraction methods.** The Department permits the following generally safe extraction methods, so long as they are listed in the operating plan of record:
  - (1) Mechanical extraction using:
    - (a) Potable water and ice made from potable water;
    - (b) Dry screening or sieving;
    - (c) Cryogenic or subzero processing not involving a solvent; or
    - (d) Pressure and temperature.
  - (2) Infusion of marijuana in food grade fats or synthetic food additives:
    - (a) Propylene glycol;
    - (b) Glycerin;
    - (c) Butter;
    - (d) Olive Oil; or
    - (e) Other typical cooking fats.
- B. **Potentially hazardous extraction methods.** The Department will permit potentially hazardous solvent extraction using a 99 percent or greater purity of the following solvents, using storage, preparation, electrical, gas monitoring, fire suppression and exhaust systems methods approved in the operating plan of record, so long as the solvents are listed in the operating plan of record and the end result does not exceed allowable limits specified by the Department:
  - (a) CO<sub>2</sub>;
  - (b) Ethanol, including solutions of ethanol and potable water;
  - (c) A liquid chemical, compressed gas or commercial product that has a flashpoint above 38 degrees Celsius or 100 degrees Fahrenheit
- C. **Inherently hazardous extraction methods.** Upon certification by a certified industrial hygienist or professional engineer licensed in Maine that the manufacturing facility's storage, preparation, electrical, gas monitoring, fire suppression and exhaust systems are adequate, the Department will permit inherently hazardous solvent extraction using a 99 percent or greater purity of the following solvents, so long as the solvents are listed in the operating plan of record and the end result does not exceed allowable limits specified by the Department:
  - (a) Butane;
  - (b) Propane;
  - (c) Acetone;

- (d) Heptane;
  - (e) Pentane; or
  - (f) Any other chemicals approved by the Department in writing.
- D. All flammable gas must be odorized in compliance with state and federal regulations.
- E. Pressurized canned flammable fuel, including without limitation butane or propane in containers intended for camp stoves, handheld torch devices, refillable cigarette lighters and similar consumer products are prohibited for use in extraction.
- F. As applicable, all licensees and employees must:
  - (1) Work in an environment with proper ventilation, controlling all sources of ignition where a flammable atmosphere is or may be present;
  - (2) Use proper eye protection, respiratory protection and gloves;
  - (3) Use only potable water and ice made from potable water in processing; and
  - (4) Undergo safety training on fire prevention and safe operation of equipment used for manufacturing.
- G. A marijuana products manufacturing facility performing extraction may be subject to inspection by the state fire marshal, local fire department, building inspector or code enforcement officer to confirm that no health or safety concerns are present, and that the facility is in compliance with all applicable standards contained in the NFPA model fire code.

**3.8.5 Edible Marijuana Products Manufacturing.** In addition to all other provisions of this Rule, 28-B MRS and all other applicable rules or laws, a marijuana products manufacturing facility that has declared edible marijuana products as part of their operating plan of record may manufacturer edible marijuana products in accordance with the following:

- A. Must obtain a food establishment license from the State of Maine pursuant to 22 MRS § 2167.
- B. Must employ a Certified Food Protection Manager, pursuant to State of Maine Food Code Section 2-102.12, who has attained certification by a program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs;
- C. May not:
  - (1) Manufacture edible marijuana products intended for non-human consumption;
  - (2) Manufacture edible marijuana products within the same licensed food establishment that operates as a restaurant or that prepares non-marijuana food to be served to order;
  - (3) Share a food establishment with a person or entity not licensed as a marijuana products manufacturing establishment; or
  - (4) Process or prepare food intended for commercial sale that does not contain marijuana;
- D. Shall be subject to inspection by state or local regulatory authorities including but not limited to the local fire department, building inspector or code enforcement officer to confirm that no health, safety or threats to the public welfare are present; and
- E. Shall comply with all applicable standards of the relevant local jurisdiction and the Maine Food Code.
  - (1) The addition of marijuana to food is not considered adulteration as provided in 22 MRS §2158-B.
  - (2) In the event of a conflict between this Rule and the Maine Food Code, this Rule shall control.

**3.8.6 Manufacturing of Medical Marijuana Products and Adult Use Marijuana Products on Same Premises.**

- A. A products manufacturing facility may possess medical marijuana or medical marijuana concentrate only if it has received the Department’s approval of an operating plan to extract from medical marijuana or produce medical marijuana products. The products manufacturing facility must:
  - (1) Track all medical marijuana, medical marijuana concentrate and medical marijuana products separately from adult use marijuana, adult use marijuana concentrate and adult use marijuana products in the tracking system.
  - (2) Store all medical marijuana, medical marijuana concentrate and medical marijuana products separately from adult use marijuana, medical marijuana concentrate and medical marijuana products.

- (3) Ensure that medical marijuana or medical marijuana concentrate is never manufactured simultaneously or contemporaneously with adult use marijuana or marijuana concentrate on the same piece of equipment.
- (4) Keep a log of the following information for all equipment used to extract from both medical marijuana and adult use marijuana or to manufacture both medical marijuana products and adult use marijuana products:
  - (a) The name of the licensee or employee who operated the equipment;
  - (b) The tracking information for the marijuana or marijuana concentrate that was manufactured using the equipment;
  - (c) The exact date, time and duration the equipment was used; and
  - (d) The tracking information for the resulting marijuana concentrate or marijuana product.
- B. A log for any piece of equipment used to manufacture marijuana must be made available to the Department, the Maine Revenue Service or any law enforcement officer for inspection.

### 3.9 - Requirements Applicable to Marijuana Stores and Nursery Cultivation Facilities

**3.9.1 Authorized Conduct.** In accordance with the requirements and restrictions of 28-B MRS, this Rule and any other applicable laws or rules, a marijuana store licensee or nursery cultivation facility may:

- A. Between the hours of 7:00 AM and 10:00 PM local time or the hours approved in its operating plan:
  - (1) Sell or transfer permitted items on the licensed premises to consumers age 21 or older, within the limits described in this Section:
    - (a) Marijuana stores may sell marijuana seedlings, immature marijuana plants, marijuana or marijuana products, along with marijuana paraphernalia, non-marijuana food and non-alcoholic beverages, clothing and other generally permissible retail items.
    - (b) Nursery cultivation facilities may sell marijuana seeds, marijuana seedlings, immature marijuana plants and agricultural or gardening supplies relating to the cultivation of marijuana.
  - (2) Accept returns of products sold by the licensee at the same premises to the person making the return and offer a refund or exchange of equal or lesser value;
  - (3) Refuse to sell any item to any person; or
  - (4) Provide consultations between employees and adult consumers
- B. During the hours stated on the operating plan:
  - (1) Prepare and transport permitted items to another licensee;
  - (2) Accept deliveries of permitted items and manage its inventory;
  - (3) Enter transfers or deliveries into the tracking system;
  - (4) Dispose of marijuana waste;
  - (5) Conduct employee training; or
  - (6) Perform administrative work, cleaning or maintenance.

#### 3.9.2 Sales Limits.

- A. A marijuana store may not knowingly sell more than the following amounts to an individual at any one time or within one day:
  - (1) Two and one-half ounces of marijuana; or
  - (2) Two and one-half ounces of marijuana and marijuana concentrate that includes no more than five grams of marijuana concentrate, whether sold alone, contained in an inhalant delivery system, or contained in edible marijuana products.
- B. A nursery cultivation facility may not sell more than a sum total of 12 seedlings or immature plants to an individual at any one time or within one day.
- C. A marijuana store or nursery cultivation facility is required to report to law enforcement the identity of any individual who explicitly communicates the intent to divert adult use marijuana to individuals under the age of 21, across state lines or to be engaging in the unlicensed sale of marijuana.

- D. A licensee shall report any criminal activity of which it is aware related to the unlicensed sale or diversion of marijuana, marijuana products or marijuana plants. Failure to report such activity to appropriate law enforcement entities may result in penalties up to and including license revocation and monetary fines.
- E. A licensee shall report all transactions into the tracking system.

**3.9.3 Prohibited Conduct.** In addition to any other prohibitions and restrictions of 28-B MRS, this Rule or any other applicable laws or rules, a marijuana store or nursery cultivation facility must not:

- A. Conduct any transaction without face-to-face verification of the purchaser's identity and age of 21 or older on an approved form of government-issued identification;
- B. Sell marijuana or a marijuana product that has not passed mandatory testing;
- C. Sell a marijuana or marijuana product that is not properly packaged or labeled in accordance with Section 11 of this Rule;
- D. Give away adult use marijuana, adult use marijuana products, immature marijuana plants or marijuana seedlings;
- E. Sell or give away:
  - (1) Mature marijuana plants; or
  - (2) Consumable products containing tobacco or alcohol that do not contain marijuana.
- F. Except for nonedible adult use marijuana products that do not contain THC, sell to any person in any individual sales transaction an amount of adult use marijuana, adult use marijuana products or immature marijuana plants or seedlings that exceeds the personal adult use limitations of 28-B MRS §1501(1);
- G. Sell adult use marijuana, adult use marijuana products, immature marijuana plants or marijuana seedlings using:
  - (1) An automated dispensing or vending machine;
  - (2) A drive-through sales window;
  - (3) An Internet-based sales platform; or
  - (4) A delivery service.
- H. Sell adult use marijuana or adult use marijuana products to a person who is visibly intoxicated;
- I. Sell or offer for sale to consumers adult use marijuana and adult use marijuana products within the same facility or building in which the licensee also sells or offers for sale to qualifying patients marijuana and marijuana products for medical use pursuant to 22 MRS, chapter 558-C.
- J. Sell or give away pressurized containers of butane or other materials that could be used in the home production of marijuana concentrate, except that a marijuana store or nursery cultivation facility may sell or give away disposable butane lighters;
- K. Sell or give away any items that are attractive to persons under 21 years of age as defined in Section 3.8.2 of this Rule;
- L. Sell an edible marijuana product that according to its label, exceeds 10 milligrams of THC per serving and 100 milligrams of THC in the total product;
- M. Discount marijuana or a marijuana product if the retail sale is made in conjunction with the retail sale of any other items, including other marijuana or marijuana products;
- N. Sell marijuana or marijuana products at a nominal price for promotional purposes;
- O. Permit consumers to be present on the licensed premises or sell to a consumer between the hours of 10:00 p.m. and 7:00 a.m. local time the following day or any hours not permitted on the operating plan;
- P. Conduct any activities during hours or on days not authorized in the licensee's operating plan;
- Q. Sell or transfer returned marijuana or marijuana products to another consumer;
- R. Permit a consumer to open or alter a package containing marijuana or a marijuana product or otherwise remove marijuana or a marijuana product from packaging required by this Rule within the premises or in an area that the licensee controls;
- S. Permit a consumer to bring marijuana or marijuana products onto the premises except for marijuana or marijuana products being returned for refund or exchange as allowed by this Rule;
- T. Sell any item not allowed under this Rule or any of the following items:
  - (1) Pet or animal food, treats or other pet or animal products containing marijuana;
  - (2) Injectable marijuana; or
  - (3) Any other marijuana products not meant for human consumption or use;
- U. Sell mature marijuana plants or tissue cultures;

- V. Use any electrical equipment, including but not limited to display lighting, not listed as approved by a nationally recognized testing laboratory or not approved by the authority having jurisdiction; or
- W. Engage in the sale of marijuana seeds, marijuana plants, marijuana or marijuana products if mandatory testing is not verified or verifiable with certificate of analysis, or if testing reports unsafe levels of potentially harmful substances.

**3.9.4 Controlling Access to Areas of the Premises Designated for Retail Sales.** The marijuana store or nursery cultivation facility shall maintain control of areas of the premises designated for retail sales, using one of the following arrangements:

- A. **Stationing a licensee or employee at the entry door during all hours of public operation.** The licensee or employee shall check for valid identification and control entry to the premises; or
- B. **Keeping entry doors locked.** The establishment shall use a door buzzer or other means to alert employees that a person wants to enter the premises. A licensee or employee shall check for valid identification before allowing entry.

**3.9.5 Display of Seeds, Seedlings, Immature Marijuana Plants, Marijuana and Marijuana Products.**

Marijuana seeds, seedlings, immature marijuana plants, marijuana and marijuana products may only be displayed in such a way that prevents access to persons who are not licensees or employees.

- A. As permitted under the type of license, marijuana seeds, marijuana seedlings, immature marijuana plants, marijuana and marijuana products may be displayed in such ways that prevents access to persons who are not licensees or employees.
- B. As permitted under the type of license, displays accessible by persons other than licensees and employees may include packaging and marketing materials for marijuana seeds, marijuana seedlings, immature marijuana plants, marijuana or marijuana products and mock examples, provided that no actual marijuana seedlings, immature marijuana plants, marijuana or marijuana products are present.

**3.9.6 Point of Sale Areas.** A marijuana store or nursery cultivation facility must keep all permitted marijuana seeds, marijuana seedlings, immature marijuana plants, marijuana and marijuana products in limited access areas where access is restricted to licensees and employees.

- A. No person 21 years of age or older who is not a licensee or employee may handle marijuana seeds, marijuana seedlings, immature marijuana plants, marijuana and marijuana products in the point of sale area unless a licensee or its employee supervises the person at all times.
- B. A person 21 years of age or older who is not a licensee or employee may only handle marijuana seeds, marijuana seedlings, immature marijuana plants, marijuana or marijuana products without the supervision of a licensee or employee only following the completion of a sale and once the purchased items are placed into exit packaging are no longer within the premises or within an area that the licensee controls.

**3.9.7 Exit Packaging.** A marijuana store or nursery cultivation facility, after a retail sale, must place all items purchased fully within appropriate exit packaging prior to a customer leaving the premises.

- A. All exit packaging must be opaque.
- B. All marijuana and marijuana products other than seedlings or immature plants must leave the premises in child-resistant, tamper-evident packaging.
  - (1) Marijuana or marijuana products that are not prepackaged in child-resistant containers must be placed into child-resistant exit packaging.
  - (2) Marijuana or marijuana products that are not prepackaged in tamper-evident containers must be placed into tamper-evident exit packaging.
  - (3) The packaging must be enclosed and sealed.
- C. A licensee may charge a fee to consumers for exit packaging.
- D. A licensee may sell reusable exit packaging that is child-resistant and opaque but not tamper-evident.
- E. A customer may supply reusable exit packaging, so long as:
  - (1) The reusable packaging is of a type sold by the licensee, and the licensee or employee verifies that it is legal exit packaging;
  - (2) The licensee or employee verifies that the reusable exit packaging is in sound condition; and

- (3) The reusable packaging is used only for marijuana or marijuana products that are prepackaged in tamper-evident packaging and that such sale otherwise meets applicable packaging requirements of 28-B MRS §701(2).
- F. The exit packaging must be free of any words, images, markings or design that in anyway indicate or suggest that its contents are of the exit package are marijuana, marijuana concentrate or marijuana products.
- G. A licensee shall maintain a copy of the certificate showing that all types of exit packaging required to be child-resistant meet the requirements of 16 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995).

**3.9.8 Sales Tax.** A marijuana store or marijuana nursery cultivation facility must track sales and remit sales taxes according to 36 MRS and the rules of the Maine Revenue Service.

### 3.10 – Requirements Applicable to Sample Collectors

**3.10.1 General Requirements.** Before collecting samples of marijuana, marijuana concentrate and marijuana products for mandatory testing, a sample collector must:

- A. Obtain an active sample collector license from the Department;
- B. Ensure that all individuals employed by the sample collector who will be collecting samples of marijuana, marijuana concentrate or marijuana products are in possession of a valid IIC issued by the Department;
- C. Ensure that each individual employed by the sample collector who will be collecting samples of marijuana, marijuana concentrate or marijuana products:
  - a. Is physically able to perform the duties of a sample collector, with or without reasonable accommodations;
  - b. Is trained and able to pass initial and ongoing demonstrations of sample collection in compliance with the Sample Collection SOP;
  - c. Completes, when available, 8 hours of initial training on various sampling techniques; and
  - d. Completes, when available, 8 hours of periodic refresher training annually; and
- D. Prior to every sample collection for mandatory testing, and in accordance with the sample collection recordkeeping requirements and sample collection SOP published by the Department, contact the marijuana testing facility(ies) conducting the mandatory analyses for instructions regarding the sample collection event, including without limitation:
  - a. Sample collection tools to be used by the sample collector based upon the matrices to be sampled;
  - b. Sample collection containers necessary to store the samples collected based on the analyses to be conducted;
  - c. Sample storage and transportation requirements based upon the matrices sampled and analyses to be conducted; and
  - d. Any additional considerations regarding sample collection, transportation, storage or receipt of the samples by the marijuana testing facility(ies) conducting the mandatory analyses.

**3.10.2 Prohibited Conduct.** In addition to any other restrictions or prohibitions contained in this Rule, 28-B MRS and any other applicable Federal, State or Local rules or laws, sample collectors are subject to the following prohibitions:

- A. No sample collector or owner, officer, director, manager, general partner or employee of a sample collector may have a direct or indirect financial interest in a cultivation facility, products manufacturing facility, manufacturing facility, marijuana store, registered caregiver or registered dispensary.
- B. No owner, officer, director, manager or general partner of a sample collector may be a registered caregiver.
- C. No sample collector may collect samples for a registered caregiver that is an employee of that sample collector.

- D. Samples of marijuana, marijuana concentrate and marijuana products may not be collected, transported, transferred or destroyed without entering the samples of marijuana, marijuana concentrate or marijuana products into the tracking system required by the Department by 11:59 that same day.
- E. Samples of marijuana, marijuana concentrate and marijuana products may not be stored by the sample collector except during transport from the site where the samples were collected to the marijuana testing facility(ies) conducting mandatory analyses.
- F. Samples of marijuana, marijuana concentrate and marijuana products may not be stored overnight by a sample collector except in exigent circumstances as described in Section 4.2.3 of this Rule.

**3.10.3 Use of Sample Collection SOP and Best Practices Guide Published by the Department Required.** A sample collector must collect samples of marijuana, marijuana concentrate and marijuana products using the Sample Collection SOP and Best Practices Guide published by the Department when collecting samples of marijuana, marijuana concentrate or marijuana products for mandatory testing. A sample collector must document the sample collection event in accordance with the requirements of Section 3.11 of this Rule

- A. The sample collector must keep complete records for each sample collection event conducted.
- B. The sample collector must collect samples in accordance with the Sample Collection SOP published by the Department. The Department may require a sample collector to demonstrate to the Department proper sample collection technique in accordance with the Sample Collection SOP at the request of the Department.
- C. The sample collector must collect samples in accordance with the Best Practices Guide published by the Department.
- D. The sample collector must ensure that at all times the sample collector and its employees are using the correct version of the Sample Collection SOP (Appendix A of this Rule) and Best Practices Guide available on the Department’s website at: <https://www.maine.gov/dafs/omp/adult-use/applications-forms>.

**3.10.4 Record Keeping.** A sample collector must maintain records in accordance with this Rule.

- A. A sample collector must track all samples collected in the inventory tracking system required by the Department.
- B. A sample collector must keep for five years from the date of a sample collection event a copy all records generated by sample collection event conducted by the sample collector and its employees in accordance with Section 3.11 of this Rule.
- C. A sample collector must keep personnel records that include information on any training on sample collection received by its employees and a copy of the Department’s *Sample Collection Standard Operating Procedure for Mandatory Testing* (Appendix A) signed by each IIC holder who will be collecting samples.
- D. A sample collector must keep an up-to-date list of all personnel and vehicles used to conduct sample collection or the transport of samples from the site where the samples are collected to marijuana testing facilities for analyses.
- E. A sample collector must make all required records available to the Department at its request. A sample collector must allow access to the Department to any premises where records are kept, including without limitation all vehicles used to transport samples of marijuana, marijuana concentrate and marijuana products and any physical or electronic location used to store all documents required by this Rule.

**3.10.5 Waste Disposal.** A sample collector may not dispose of waste generated by the collection, storage or transport of samples.

- A. Waste generated by the collection, storage or transport of samples must be disposed of by the licensee from which the samples were collected.
- B. If samples of marijuana, marijuana concentrate or marijuana products collected and transported by a sample collector are rejected by a marijuana testing facility, the sample collector will return the samples of



marijuana, marijuana concentrate or marijuana products to the licensee from which the samples were collected.

**3.10.6 Security.** A sample collector will employ security measures adequate to ensure that samples of marijuana, marijuana concentrate and marijuana products are not stolen or otherwise diverted during the course of sample collection, transport and as necessary due to exigent circumstances, storage.

### Section 3.11 – Recordkeeping Requirements for Sample Collection, Transport and Receipt

**3.11.1 Sample Collection Records.** Licensees collecting samples for mandatory testing, including self-sampling licensees, sample collectors, and marijuana testing facility staff collecting samples for mandatory testing must retain records of every sample collection event in accordance with this section. Licensees may use their own sample collection form, a form provided by the marijuana testing facility conducting the mandatory analyses or a sample collection log or any other format that the licensee can make available to the Department upon request, so long as such records include all information required by this Rule. A licensee who is not a self-sampling licensee shall provide the licensee for whom the licensee is collecting samples for mandatory testing with a copy of all sample collection records generated by the sample collection event.

All sample collection records must include, for every sample collection event, all information required by this Rule and the Sample Collection SOP in Appendix A herein, including without limitation:

- A. The name and individual identification card number of the individual identification cardholder collecting samples for mandatory testing;
- B. Instructions, if any, provided to the self-sampling licensee or sample collector licensee by the marijuana testing facility conducting the mandatory analyses regarding the following:
  - a. Sample collection tools to be used to collect samples of marijuana, marijuana concentrate or marijuana products, based upon matrix type sampled and mandatory analyses required;
  - b. Sample storage containers to be used to collect and store the samples of marijuana, concentrate or marijuana products, based upon matrix type sample and mandatory analyses required;
  - c. Special instructions regarding sample storage and transport, including without limitation:
    - i. The temperature at which the samples should be stored and transported;
    - ii. The environmental humidity at which the samples should be stored and transported;
    - iii. Any instructions regarding sample storage and transport required to maintain the integrity of the samples during storage and transport; and
    - iv. Any other instructions regarding sample receipt by the marijuana testing facility;
- C. Any anomalies noted by the sample collector in the batch sampled at the time of the sample collection event;
- D. The type, number and weight of each sample storage container used to store sample increments collected;
- E. The total weight of the composite sample and the weight of any additional sample increments collected for homogeneity testing;
- F. The seal numbers for every tamper evident seal affixed to a sample container used in the sample collection event;
- G. An attestation signed by the individual identification cardholder who collected the samples for mandatory testing and affixed tamper evident seals to every sample container in accordance with the Department's Sample Collection SOP, that is also signed by an individual identification cardholder who witnessed the tamper evident seals being affixed to the sample containers. All signatures must be either wet or digital. The attestation must include, without limitation, the following:
  - a. A statement attesting that the self-sampler or sample collector:

- i. Collected all samples in accordance with the Department’s Sample Collection SOP, Best Practices Guide and any instructions provided by the marijuana testing facility conducting the mandatory analyses;
  - ii. Collected all sample increments randomly and that the self-sampler or sample collector did not intentionally enrich, alter, tamper with, degrade or otherwise alter the sample increments collected;
  - iii. Was not asked by, nor allowed, another individual identification cardholder to enrich, alter, tamper with, degrade or otherwise alter the sample increments collected;
  - iv. Sealed the sample collection containers with tamper evident seals in the presence of the witness countersigning the attestation; and
  - v. Acknowledges that any intentional misrepresentation in the sample collection records or any attempt at tampering with the samples collected is grounds for revocation of the individual’s individual identification card and/or revocation, suspension or limitation of the sampling licensee’s license; and
- b. A statement attesting that the witness:
- i. Was present for the sealing of the sample containers with the tamper evident seal;
  - ii. Did not witness the sample collector enrich, alter, tamper with, degrade or otherwise alter the sample increments when affixing the tamper evident seals to the sample containers;
  - iii. Did not enrich, alter, tamper with, degrade or otherwise alter the sample increments when the tamper evident seals were affixed to the sample containers; and
  - iv. Acknowledges that any intentional misrepresentation by the witness is grounds for revocation of the witness’ individual identification card and/or revocation, suspension or limitation of the sampling licensee’s license.

**3.11.2 Sample Transportation Records.** Except as permitted by this rule, the licensee that collected samples of marijuana, marijuana concentrate and marijuana products for mandatory testing must transport those samples to the marijuana testing facility conducting the mandatory analyses. A marijuana testing facility that did not collect the samples for mandatory testing, but that offers a service to transport samples collected by self-sampling licensees to its testing facility for mandatory testing, may offer to transport samples from self-sampling licensees to the marijuana testing facility for mandatory analyses. A marijuana testing facility may not transport samples to any other licensee unless otherwise authorized by this Rule or 18-691 CMR, ch. 5. All samples of marijuana, marijuana concentrate and marijuana products must be appropriately tracked in the Department’s inventory tracking system and accompanied by a transport manifest in accordance with this Rule.

**3.11.3 Sample Receipt Records.** A marijuana testing facility must maintain sample receipt records in accordance with the marijuana testing facility’s quality system and must at all times maintain chain-of-custody records for all samples of marijuana, marijuana concentrate and marijuana products received by the marijuana testing facility from the time of receipt through storage, analysis and destruction. A marijuana testing facility may require any licensee delivering samples to the marijuana testing facility to record sample information on a form created by or in a database maintained by the marijuana testing facility, in addition to any sample collection records maintained by the licensee. The marijuana testing facility conducting mandatory analyses is responsible for maintaining all sample receipt records and must make those records available to the Department upon request.

## Section 4 - Tracking

### 4.1 - General Tracking Requirements

In addition to any requirements specific to tracking within each license type, all licensees of marijuana establishments must meet minimum requirements.

- A. Marijuana establishment licensees must track, using the inventory tracking system specified by the Department, marijuana, marijuana concentrates and marijuana products from immature plant to point of sale.
- B. In addition to any tracking requirements specific to license type, a licensee must record the following data in the tracking system:
  - (1) A complete inventory of all marijuana, marijuana concentrate and marijuana products in the possession, control or ownership of the licensee;
  - (2) Any changes to the marijuana establishment's inventory of any marijuana;
  - (3) When plants are partially or fully harvested or destroyed;
  - (4) When marijuana waste is destroyed;
  - (5) When an authorized transfer occurs;
  - (6) Any theft of marijuana;
  - (7) All sales records;
  - (8) Marijuana excise tax records;
  - (9) Marijuana sales tax records;
  - (10) All mandatory testing results;
  - (11) The municipality or municipalities where the product was harvested, otherwise cultivated, manufactured, tested, sold to other licensees, sold to consumers and disposed of or destroyed; and
  - (12) Other information required by the tracking system or specified by the Department.

#### 4.1.1 Implementation and Administration of Tracking System.

- A. Unless excused by the Department, in writing, a marijuana establishment must have an inventory tracking system account activated and functional prior to operating or exercising any privileges of a license. The licensee shall keep and maintain comprehensive records to ensure adequate inventory tracking of any marijuana, marijuana concentrates and marijuana products during the period the licensee is not otherwise using the inventory tracking system.
- B. Each licensee must designate at least one individual identification cardholder as an inventory tracking system administrator.
- C. In order to obtain an inventory tracking system administrator account, a licensee or its designee must attend and successfully complete all required inventory tracking system training. A licensee may apply for an account and training once they receive a conditional license from the Department.
- D. The Department may also require additional ongoing, continuing education for the inventory tracking system administrator to retain his or her inventory tracking system administrator account.
- E. Each licensee is responsible for all costs associated with its use of the tracking system and any associated vendor fees.
- F. A marijuana establishment may designate additional employees or staff who are individual identification cardholders as inventory tracking system users. The establishment shall ensure that all individuals who are granted inventory tracking system user account access for the purposes of conducting inventory tracking functions in the system are trained by inventory tracking system administrators in the proper and lawful use of the inventory tracking system.

#### 4.1.2 General Inventory Tracking System Use.

- A. All inventory tracking activities at a marijuana establishment licensee must be tracked through use of the inventory tracking system. A licensee must reconcile all on-premises and in-transit marijuana, marijuana concentrates and marijuana product inventories each day in the inventory tracking system by 11:59 p.m. that same day.

- B. A marijuana establishment must utilize a standard of weights and measures that is supported by the inventory tracking system to track all marijuana, concentrate and marijuana product. A scale used to weigh product prior to entry into the inventory tracking system shall be tested and approved in accordance with 10 MRS, chapter 501.
- C. A licensee shall maintain the security of the inventory tracking system, as follows:
  - (1) A marijuana establishment licensee shall maintain and provide to the Department an accurate and complete list of all inventory tracking system administrators and inventory tracking system users for each licensed premises.
  - (2) A marijuana establishment licensee shall update this list and provide the updated list to the Department when a new inventory tracking system user is trained or when an existing user is removed.
  - (3) A marijuana establishment licensee must train and authorize any new inventory tracking system users before they may access inventory tracking system or input, modify or delete any information in the inventory tracking system.
  - (4) A marijuana establishment licensee must cancel any inventory tracking system administrators and inventory tracking system users from their associated inventory tracking system accounts once any such individuals are no longer employed by the licensee or at the licensed premises.
  - (5) A marijuana establishment licensee is accountable for all actions employees take while logged into the inventory tracking system or otherwise conducting marijuana, marijuana concentrates and marijuana product inventory tracking activities.
  - (6) Each individual user is also accountable for all of his or her actions while logged into the inventory tracking system or otherwise conducting marijuana, marijuana concentrates or marijuana product inventory tracking activities, and shall maintain compliance with all relevant laws.
  - (7) Each individual user shall only log activities in the inventory tracking system under the user's own unique inventory tracking system user account.
- D. A marijuana establishment may use separate software applications to collect information to be used by the business, including secondary inventory tracking or point of sale systems.
  - (1) A licensee must ensure that all relevant inventory tracking system data is accurately transferred to and from the inventory tracking system for the purposes of reconciliations with any secondary systems.
  - (2) A marijuana establishment must preserve original inventory tracking system data when transferred to and from a secondary application(s). Secondary software applications must use the inventory tracking system data as the primary source of data and must be compatible with updating to the inventory tracking system.

#### **4.1.3 Conduct While Using Inventory Tracking System.**

- A. A marijuana establishment and its designated inventory tracking system administrator(s) and inventory tracking system user(s) shall enter data into the inventory tracking system that fully and transparently accounts for all inventory tracking activities and authorized transfers. Both the marijuana establishment and the individuals using the inventory tracking system are responsible for the accuracy of all information entered into the inventory tracking system. Any misstatements or omissions may be considered a license violation affecting public safety.
- B. Individuals entering data into the inventory tracking system shall only use that individual's inventory tracking system account.
- C. If at any point a marijuana establishment loses access to the inventory tracking system for any reason:
  - (1) The marijuana establishment shall immediately notify the Department and shall keep and maintain comprehensive records detailing all marijuana, marijuana concentrates and marijuana product tracking inventory activities that were conducted during the loss of access;
  - (2) Once access is restored, all marijuana, marijuana concentrates and marijuana product inventory tracking activities that occurred during the loss of access must be entered into the inventory tracking system and the Department shall be notified that access has been restored;
  - (3) A marijuana establishment must document when access to the system was lost, the cause of system loss and when it was restored; and

- (4) A marijuana establishment shall not transport or receive any marijuana, or marijuana product to or from another marijuana establishment until such time as access is restored and all information is recorded into the inventory tracking system.

#### **4.1.4 System Notifications.**

- A. A marijuana establishment must monitor all compliance notifications from the inventory tracking system. The licensee must resolve the issues detailed in the compliance notification in a timely fashion. Compliance notifications shall not be dismissed in the inventory tracking system until the marijuana establishment resolves the compliance issues detailed in the notification.
- B. A marijuana establishment must take appropriate action in response to informational notifications received through the inventory tracking system including but not limited to notifications related to enforcement alerts and other pertinent information.

**4.1.5 Lawful Activity Required.** Proper use of the inventory tracking system does not relieve a licensee of its responsibility to maintain compliance with all laws, rules and other requirements at all times.

**4.1.6 Inventory Tracking System Procedures Must Be Followed.** A marijuana establishment must utilize the inventory tracking system in conformance with this Rule and inventory tracking system procedures, including but not limited to:

- A. Properly indicating the creation of a harvest batch or production batch including the assigned harvest batch or production batch number;
- B. Accurately identifying the cultivation rooms where each plant is located on the licensed premises;
- C. Accurately identifying when inventory is no longer on the licensed premises or is part of an authorized transfer;
- D. Properly indicating that a test batch is being used as part of achieving process validation;
- E. Properly indicate test results from a marijuana testing facility;
- F. Accurately indicating the inventory tracking system category for all marijuana and marijuana products; and
- G. Accurately including a note explaining the reason for any destruction of marijuana and/or marijuana products, and reason for any adjustment of weights to inventory tracking system packages.

## 4.2 - Transportation

**4.2.1 Transport Manifest.** A transport manifest, generated by the tracking system, is required for all authorized transfer of marijuana or marijuana products, including samples of marijuana, marijuana concentrate and marijuana products for mandatory and other testing. The transport manifest does not take the place of a chain-of-custody form that may be required of the licensee. Transport authorized by this Rule shall be by motor vehicle only.

- A. The licensee transporting marijuana or marijuana products including samples is responsible for entering all required information in the tracking system for the generation of a transport manifest, including without limitation, the following information:
  - (1) The name, contact information, licensed premises address and license number of the licensee transporting the marijuana or marijuana products;
  - (2) The name, contact information, licensed premises address and license number of the licensee receiving the transported marijuana;
  - (3) Product name and quantities (by weight or unit) of all marijuana and/or marijuana product, including samples, contained in each transport;
  - (4) The date of transport and approximate time of departure;
  - (5) Arrival date and estimated time of arrival;
  - (6) Delivery vehicle make and model and license plate number;
  - (7) Name and signature of the licensee or individual identification card holder and their identification card number accompanying the transport;
  - (8) Name and signature of the licensee or individual identification card holder and their identification card number receiving the authorized transfer;
  - (9) The correct Sales Tax Identification Number or Excise Tax Identification Number for the transferor and the transferee;

- (10) Damaged or refused marijuana or marijuana products being returned to the original seller, in the case of samples of marijuana, marijuana concentrate or marijuana products for mandatory testing collected by a sample collector, the sample collector will return any samples rejected by a marijuana testing facility to the licensee from which the samples were collected;
- B. A transport manifest must be prepared for each marijuana establishment that will receive marijuana or marijuana products.
- C. A licensee may not void or change a transport manifest after departing from the originating premises.
- D. A licensee must accept returns of any marijuana or marijuana products, including samples, that are refused by the intended recipient and appropriately track and dispose of the same.

**4.2.2 Transport Manifest Exception.** When marijuana or marijuana products are transferred by way of authorized transfer between two licenses controlled by the same licensee, and which do not require the transport of the marijuana or marijuana products outside the boundaries of the premises, then a transport manifest is not required. In these cases, the licensee must still follow all requirements of the tracking system.

**4.2.3 Transportation of Marijuana and Marijuana Products.** Marijuana and marijuana products, including samples, must be transported subject to the following requirements:

- A. Marijuana or marijuana products may be transported only from one licensed marijuana establishment to another licensed marijuana establishment;
- B. Samples of marijuana, marijuana concentrate and marijuana products for mandatory testing must be transported by the licensee that collected the samples for mandatory testing from the site where the samples were collected to the marijuana testing facility(ies) performing the mandatory analyses, except that a marijuana testing facility may, at its discretion, offer a service to retrieve samples collected by self-samplers from the marijuana establishment where the samples were collected and transport those samples to the marijuana testing facility conducting the mandatory analyses;
- C. All marijuana or marijuana products being transported must be included in and accompanied by a transport manifest generated by the tracking system;
- D. All marijuana or marijuana products being transported must be contained within an enclosed, locked area in the transport vehicle;
- E. A marijuana products manufacturing facility must provide adequate refrigeration for perishable marijuana product that will be consumed and shall utilize adequate storage facilities and transport methods. This shall include, but not be limited to, potentially hazardous food as defined under the State of Maine Food Code.
- F. The licensee transporting the marijuana or marijuana products must:
  - (1) Keep marijuana or marijuana products in transit shielded from public view;
  - (2) Use a vehicle for transport that is:
    - (a) Insured at or above the legal requirements in Maine; and
    - (b) Equipped with, at a minimum, a functional, manufacturer-installed alarm system.
  - (3) Ensure that only IIC holders are in any vehicle, including trailers, used in transport.
- G. All marijuana or marijuana products must be contained within wholesale containers in the transport vehicle.
- H. Samples of marijuana, marijuana concentrate and marijuana products for mandatory testing must be transported in appropriately labeled sample collection containers with tamper evident seals affixed.
- I. A licensee or individual identification card holder transporting marijuana or marijuana products must carry three copies of each transport manifest during the transportation of marijuana or marijuana products and must:
  - (1) Give one copy to the receiving licensee following the verification of the transport manifest and transfer of the marijuana or marijuana products;
  - (2) Possess one copy that is to be provided to a law enforcement officer or government agent upon request, as follows:
    - (a) A licensee or individual identification card holder who has given a transport manifest to a law enforcement officer or government agent shall obtain the name, rank and agency of the law enforcement officer;
    - (b) The licensee or individual identification card holder who has given a transport manifest to a law enforcement officer or government agent must retain the name and

- identification number of the law enforcement officer or government agent for the duration of the transport; and
- (3) Maintain a copy of the transport manifest that must be returned to the marijuana establishment for record-keeping purposes, except that a sample collector licensee will retain this copy of the transport manifest for the sample collector licensee's records and is not required to return this copy to the marijuana establishment from which the samples were collected;
- J. A licensee must notify law enforcement and the Department immediately, or as soon as possible given the circumstances, if a vehicle transporting marijuana or marijuana products, including samples of marijuana, marijuana concentrate or marijuana products for mandatory testing, is involved in a vehicular accident or theft resulting in the loss of marijuana or marijuana products;
  - K. In the event of unforeseen exigent circumstances, a sample collector licensee that needs to store samples of marijuana, marijuana concentrate or marijuana products for mandatory testing overnight must store those samples:
    - (1) Securely in a locked container or locked compartment in the locked vehicle;
    - (2) In a manner that maintains at all times the recommended temperature range; and
    - (3) The sample collector must provide contemporaneous written notice via e-mail to the Department's Compliance Division regarding the nature of the exigent circumstances, the amount of marijuana or marijuana products being stored, the location, the license and IIC number of the person in possession of the marijuana or marijuana products and the expected duration of the circumstances necessitating storage in a vehicle.
  - L. Any vehicle transporting marijuana or marijuana products must travel directly from the shipping licensee to the receiving licensee and the licensee or individual identification card holder transporting marijuana or marijuana products must not:
    - (1) Make any stops in between except:
      - (a) to other licensed premises listed on a transport manifest;
      - (b) to accommodate meal and rest periods required by law, or refueling; or
      - (c) in the case of an emergency, in which case the shipping licensee shall promptly report, or cause to be reported, the stop and the reasons for the stop to the Department and note the same on the transport manifest;
    - (2) Remove the marijuana or marijuana products from the vehicle until arrival at the destination;
    - (3) Transfer marijuana or marijuana products to, nor store marijuana or marijuana products in any unlicensed premises; or
    - (4) Travel with any persons not listed on the transport manifest.
  - M. A licensee must notify the Department in advance of the location of every stop at an unlicensed location that exceeds two hours in duration.
  - N. A licensee or individual identification card holder must make a vehicle used for the transport of marijuana or marijuana products immediately available for inspection upon request of the Department.
  - O. Upon law enforcement stop or other contact all persons in the vehicle shall identify themselves with their Department-issued individual identification card and all transport manifests.

**4.2.4 Receiving Party.** The marijuana establishment receiving marijuana or marijuana products pursuant to an authorized transfer must:

- A. Verify the condition and quantity of marijuana or marijuana products included in the transport manifest;
- B. Record in the tracking system and any other relevant business records any damaged or refused marijuana or marijuana products, or other discrepancies found between the marijuana or marijuana products delivered and the marijuana or marijuana products stated on the transport manifest;
- C. Enter the received marijuana or marijuana products in the tracking system of the receiving party prior to end of business on the day that they are received; and
- D. Provide an authorized signature and individual identification card number of the person receiving the authorized transport on the transport manifest belonging to the party transporting the marijuana or marijuana products, which must be kept by the transporting party for their records.

## Section 5 - Advertising

### 5.1 - Definitions

For the purposes of this subsection, the following terms are defined as:

- A. "Advertising" means publicizing the trade name of a licensee together with words or symbols referring to marijuana or publicizing the brand name of marijuana or marijuana products.
- B. "Handbill" is a flyer, leaflet or sheet that advertises marijuana.
- C. "Radio" means a system for transmitting sound without visual images, and includes broadcast, cable, on-demand, satellite or internet programming. Radio includes any audio programming downloaded or streamed via the internet.
- D. "Television" means a system for transmitting visual images and sound that are reproduced on screens, and includes broadcast, cable, on-demand, satellite, or internet programming. Television includes any video programming downloaded or streamed via the internet.

### 5.2 - Prohibitions

- A. In the course of promoting its brand, marijuana or marijuana products, a marijuana establishment or licensee may not advertise in a manner:
  - (1) That is attractive to persons under 21 years of age;
  - (2) That promotes irresponsible use;
  - (3) That promotes activity that is illegal under Maine law;
  - (4) That is contrary to or in direct violation of state or federal consumer protections; or
  - (5) That otherwise presents a significant risk to public health and safety.
- B. Advertising for a marijuana establishment may not:
  - (1) Contain statements that are deceptive, false or misleading;
  - (2) Display consumption of marijuana or marijuana products;
  - (3) Include claims related to potency (beyond listing of cannabinoid content);
  - (4) Depict activities or conditions considered risky when under the influence of marijuana, such as operating a motorized vehicle, boat or machinery, being pregnant or breastfeeding;
  - (5) Contain any content that can reasonably be considered to target or is designed to appeal particularly to individuals under the age of 21, including but not limited to images of persons under 21 years of age, cartoons, toys or similar images and items typically marketed towards persons under 21 years of age or references to products that are commonly associated with persons under 21 years of age or marketed by persons under 21 years of age;
  - (6) Contain any imitation of candy advertising;
  - (7) Include the term "candy" or "candies";
  - (8) Encourage the transportation of marijuana or marijuana products across state lines or otherwise encourage illegal activity;
  - (9) Assert that marijuana or marijuana products are safe because they are regulated by the Department or have been tested by a testing facility or otherwise make claims that any government agency endorses or supports marijuana;
  - (10) Make claims that marijuana has curative or therapeutic effects;
  - (11) Contain any health or physical benefit claims, including but not limited to health or physical benefit claims on labels or packaging; or
  - (12) Contain material that encourages excessive or rapid consumption.
- C. No licensee or agent of a licensee may:
  - (1) Make any deceptive, false or misleading assertions or statements on any informational material, any sign or any document provided to a consumer;
  - (2) Distribute handbills in public areas or on publicly owned property;
  - (3) Utilize television, radio, print media or internet advertising in cases where there is a high likelihood it will reach person under the age of 21. Licensees or an agent of a licensee must take reasonable steps to ensure that any mass marketing or advertising does not reach persons under the age of 21, including, for example, using marketing information from the vendor or employing age



verification techniques commonly used in internet advertising to avoid reaching persons under the age of 21;

- (4) Advertise within a prohibited distance of the property line of an existing public or private school, which shall be:
    - (a) A distance of 500 feet or more as established by the municipality in which the advertising is located;
    - (b) A distance of 500 feet or more as established by the Maine Land Use Planning Commission for advertising located in unorganized or deorganized areas; or
    - (c) A distance of 1,000 feet if no other distance has been set by a municipality or the Maine Land Use Planning Commission.
  - (5) Engage in advertising via marketing directed towards location-based devices, including but not limited to cellular phones, unless the marketing is a mobile device application installed on the device by the owner of the device who is 21 years of age or older and includes a permanent and easy opt-out feature; or
  - (6) Permit use of the licensee's trademarks, brands, names, locations or other distinguishing characteristics for third-party use on advertising in a manner that does not comply with this Section or any other statute, rule or regulation.
- D. In the event a third-party has used licensee brand, trademarks, brands, names, locations or other distinguishing characteristics in an advertisement that does not comply with this Section or any other statute, rule or regulation, the licensee must immediately notify the Department, issue a cease-and-desist order to the third-party and pursue appropriate legal action.

### 5.3 - Websites

In addition to complying with the advertisement criteria and prohibitions outlined in Section 5.2, a marijuana establishment advertising on a website must:

- A. Utilize appropriate measures to ensure that individuals visiting the web page are over 21 years of age;
- B. Not utilize unsolicited pop-up or banner advertising on the internet other than on age-restricted websites for people 21 and over who consent to view marijuana-related material.

### 5.4 - Required Statements

A licensee must include the following statements, either in print or audio, on all print, television, radio and internet advertising in font size legible to the viewer or at a volume and speed that is readily understandable by the average listener:

- A. "For use only by adults twenty-one years of age and older."
- B. The license number of the marijuana establishment.

### 5.5 - Objectionable and Non-Conforming Advertising

The Department reserves the right to take action, including the use of punitive measures, against any licensee who fails to comply with the advertising provisions of this Rule, including, without limitation, specifying a period of time by which the licensee shall cease the non-compliant advertising and remove any advertising still being published or displayed.

## Section 6 - Licensee Samples

### 6.1 - Trade Samples

**6.1.1 Regulation of Trade Samples.** Licensees may not provide samples of seeds, seedlings, immature marijuana plants or mature marijuana plants to other licensees. As authorized in this section, trade samples may be provided only by cultivation facilities, with the exception of nursery cultivation facilities, and product manufacturing facilities and:

- A. Must be provided solely for the purposes of business to business marketing;
- B. May not be sold or otherwise provided for payment or consideration, including swapping samples among licensees;
- C. Must be conveyed by way of authorized transfer in accordance with all tracking requirements;
- D. Must be packaged and labeled in accordance with Section 11 of this Rule;
- E. Must be placed in exit packaging in accordance with Section 11 of this Rule;
- F. May not be consumed on the premises of the licensee providing or receiving the sample;
- G. May not be sold or conveyed to another licensee or consumer; and
- H. May not be provided for any payment or consideration in contravention of sales and excise tax requirements.

**6.1.2 Cultivation Facilities.** Cultivation facilities, with the exception of nursery cultivation facilities, may provide trade samples of marijuana grown at the facility to licensed products manufacturing facilities or marijuana stores.

**6.1.3 Products Manufacturing Facilities.** Products manufacturing facilities may provide trade samples of marijuana products to licensed marijuana stores in accordance with this subsection.

**6.1.4 Trade Sample Limits.** No samples of marijuana or marijuana products shall be permitted to be sold or otherwise transferred or conveyed consumers or to other licensees, except as outlined in Section 6.1.1. A licensee is limited to providing the following aggregate amounts of trade samples to an authorized individual recipient licensee in a calendar month period:

- A. Edible containing products containing less than five grams of THC, which is easily divisible into servings of 10 mg of THC per serving;
- B. Marijuana concentrate containing five grams of THC; and
- C. Two- and one-half ounces of marijuana.

### 6.2 - Samples for Mandatory Testing or Research and Development

**6.2.1. Authorized collection of samples.** In accordance with 28-B MRS §§604 and 604-A, all samples for mandatory testing under this Rule must be collected by:

- A. An employee of the testing facility;
- B. A licensed sample collector; or
- C. A self-sampling licensee, collecting samples of marijuana or marijuana products cultivated, manufactured or otherwise produced by that licensee in compliance with all requirements of this Rule.

**6.2.2. Collection by marijuana testing facilities or sample collectors.** An employee of a marijuana testing facility or a sample collector must collect samples of marijuana or marijuana products in compliance with:

- A. Sample collection, transport and receipt recordkeeping requirements;
- B. The Department-required sampling standard operating procedures;
- C. The Department-required Best Practices Guide;
- D. The requirements and restrictions of 28-B MRS § 604; and
- E. This Rule.

**6.2.3. Collection by self-sampling licensees.** A self-sampling licensee may collect samples of marijuana or marijuana products cultivated, manufactured, or otherwise produced or sold by that licensee if the licensee has submitted all required documentation to the Department and in compliance with:

- A. Sample collection, transport and receipt recordkeeping requirements;
- B. The Department-required sampling standard operating procedures;
- C. The Department-required Best Practices Guide;
- D. The requirements and restrictions of 28-B MRS§604-A; and
- E. This Rule.

**6.2.4. Required documentation and record keeping.** An adult use marijuana cultivation, manufacturing, or marijuana store licensee requesting testing by a marijuana testing facility must indicate in its request for testing whether the requested testing is for mandatory testing purposes as required by this Rule or for research and development purposes. The licensee must indicate in writing, prior to collection of the samples for testing, whether such testing is for mandatory testing purposes or for research and development purposes.

- A. Pursuant to 28-B MRS § 602(2), a licensee must maintain a record of all mandatory testing conducted at the request of the licensee that includes at a minimum:
  - (1) A description of the marijuana, marijuana concentrate or marijuana product submitted for mandatory testing;
  - (2) The identity of the testing facility conducting the mandatory testing; and
  - (3) The results of any and all mandatory testing conducted at the request of the licensee.

## Section 7 - Authorized Transfers

A licensee may transfer, within its licensed authority, marijuana seeds, seedlings, immature plants; marijuana; marijuana concentrate; other marijuana products; marijuana trade samples or marijuana samples for testing to other licensees pursuant to the tracking system requirements described in 28-B MRS, this Rule and all other applicable laws and rules.

**7.1.1 Compliance with Tracking System Requirements.** A licensee must enter any marijuana seeds, seedlings or immature plants; marijuana; marijuana concentrate; other marijuana products; marijuana trade samples or marijuana samples for testing into the tracking system.

- A. The correct Excise Tax Identification Number or Sales Tax Identification Number for the transferor and the transferee must be entered into the tracking system.
- B. Tracking requirements apply to any transfer between two licensees, regardless of common ownership or co-location.
- C. Tracking requirements apply to any transfer between the designated cultivation area of a nursery cultivation facility to the area of a nursery cultivation facility designated for consumer sales.
- D. The tracking information must include the municipality or municipalities between which the transfer takes place.

**7.1.2 Compliance with Transportation Requirements.** All authorized transfers shall be by motor vehicle only and comply with the transportation requirements of Section 4.2 and 29-A MRS.

## Section 8 - Product Safety

In an effort to assure the safety of all marijuana, marijuana concentrate and marijuana products, marijuana establishment licensees must follow, and the Department may act in accordance with, in addition to all other applicable laws and rules, the following provisions in this Section.

### 8.1 - General Sanitary Requirements

In addition to the requirements found in Maine Food Code Chapter 33, this Rule and all other applicable rules and laws, a marijuana establishment licensee must:

- A. Prohibit an individual from working on a licensed premise, until the condition is corrected, who has or appears to have:
  - (1) An open or draining skin lesion unless the individual wears an absorbent dressing and protective gloves; or
  - (2) Any illness accompanied by diarrhea or vomiting if the individual has a reasonable possibility of contact with marijuana or marijuana products on the licensed premises;
- B. Require all persons who work in direct contact with marijuana or marijuana products conform to hygienic practices while on duty, including but not limited to:
  - (1) Maintaining adequate personal cleanliness; and
  - (2) Washing hands thoroughly in an adequate hand-washing area before starting work, prior to having contact with marijuana or marijuana products and at any other time when the hands may have become soiled or contaminated;
- C. Provide adequate and convenient hand-washing facilities, furnished with potable running water at a suitable temperature, effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying device;
- D. Properly remove all litter and waste from the licensed premises and maintain the operating systems for waste disposal in an adequate manner so that they do not constitute a source of contamination in areas where marijuana or marijuana products are exposed;
- E. Provide employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
- F. Hold marijuana or marijuana products in a manner that prevents pathogenic microorganism growth or toxin formation.

### 8.2 - Marijuana Products Manufacturing Facility Product Safety

- A. A marijuana products manufacturing facility that manufactures edible marijuana products must create and maintain standard production procedures and detailed manufacturing processes for each edible marijuana product it manufactures. These procedures and processes must be documented and made available on the licensed premises for inspection by the Department and local authorities.
- B. The following information must be documented in the standard production procedures for each edible marijuana product:
  - (1) The amount in milligrams of a standardized serving of marijuana;
  - (2) The total number of a standardized serving of marijuana per package; and
  - (3) The total amount of active THC contained within the product.
- C. Marijuana and cannabinoid content must be homogeneous throughout:
  - (1) The product, or that portion of the product that contains THC; and
  - (2) Each serving.
- D. Serving sizes must be standardized.
  - (1) The size of a standardized serving of marijuana shall be no more than 10mg of active THC.
  - (2) A marijuana products manufacturing facility that manufactures edible marijuana product shall determine the total number of standardized servings per package of marijuana for each product that it manufactures.

- (3) No individual edible marijuana product unit for sale shall contain more than 100 milligrams of active THC, which must be readily divisible into individual servings containing no more than 10 milligrams of THC per serving.
- (4) Determinations of cannabinoid content must comply with the testing requirements of this Rule.
- E. Unless impracticable, each single standardized serving of marijuana shall be marked, stamped or otherwise imprinted with the Department-approved universal symbol directly on at least one side of the edible marijuana product in a manner to cause the universal symbol to be distinguishable and easily recognizable. The universal symbol marking shall:
  - (1) Be centered either horizontally or vertically on each standardized serving of marijuana; and
  - (2) If centered horizontally on a serving, the height and width of the universal symbol shall be of a size that is at least 25% of the serving's width, but not less than ¼ inch by ¼ inch; or
  - (3) If centered vertically on a serving, the height and width of the universal symbol shall be of a size that is at least 25% of the serving's height, but not less than ¼ inch by ¼ inch.
- F. The following categories of edible marijuana products are considered to be per se practicable to mark with the universal symbol:
  - (1) Chocolate;
  - (2) Soft confections;
  - (3) Hard confections or lozenges;
  - (4) Consolidated baked goods (including without limitation cookies, brownies, cupcakes, and granola bars); and
  - (5) Pressed pills and capsules.

## 8.3 – Mandatory Testing

A licensee may not sell or transfer adult use marijuana or an adult use marijuana product to a consumer or to another licensee under 28-B MRS, chapter 1 and this Rule unless the marijuana or marijuana product has been tested pursuant to this Rule and 18-691 CMR, Ch. 5, and mandatory testing has demonstrated that the marijuana or marijuana product does not exceed the maximum level of allowable contamination for any contaminant that is injurious to health and for which testing is required. The Department may temporarily waive mandatory testing requirements under this section for any contaminant or factor for which the Department has determined that there exists no licensed testing facility in the State capable of and certified to perform such testing.

### 8.3.1 Commencement of Mandatory Testing.

The Department will not be requiring mandatory testing for every contaminant and factor listed in this Rule at the time this Rule becomes effective. On December 31, 2019, the Department published a list of the initial analytes for which mandatory testing is required.<sup>1</sup> The Department shall provide notice via its website and other appropriate means to licensees prior to requiring mandatory testing for any of the contaminants or factors listed in this Rule. The Department may, at any time, require immediate mandatory testing for any analyte required by this Rule or any other analyte reasonably suspected to be a health hazard or safety threat, to ensure public health and safety.

### 8.3.2 Mandatory Testing and Additional Analysis.

- A. Upon notice from the Department as described in Section 8.3.1, the following tests are mandatory for all marijuana or marijuana products prior to being sold or transferred to a consumer or another licensee in accordance with Table 8.3.2-A:

---

<sup>1</sup> Office of Marijuana Policy, *Guidance Documents*, OMP Website: Resources, <https://www.maine.gov/dafs/omp/resources/guidance-documents/mandatory-testing> (accessed April 15, 2020). As of April 1, 2020, the Department requires mandatory testing for the following analyte categories: filth and foreign materials, dangerous molds and mildews, harmful microbes, THC potency, homogeneity, cannabinoid profiles, water activity and moisture content.

- (1) **Filth and foreign material.** Any visible contaminant, including without limitation, hair, insects, feces, mold, sand, soil, cinders, dirt, packaging contaminants and manufacturing waste and by-products.
  - (2) **Residual solvents, poisons and toxins.** Acetone, acetonitrile, butanes, ethanol, ethyl acetate, ethyl ether, heptanes, hexane, isopropyl alcohol, methanol, pentane, propane, toluene, total xylenes (m, p, o-xylenes), 1,2-dichloroethane, benzene, chloroform, ethylene oxide, methylene chloride, trichloroethylene and any others used. A marijuana testing facility is not required analyze for residual solvents and processing chemicals in dried flower, kief, hashish or marijuana products manufactured without chemical solvents. A marijuana testing facility is not required to analyze an orally-consumed tincture containing alcohol for residual ethanol.
  - (3) **Pesticides, fungicides, insecticides, and growth regulators.** Bifenthrin, cyfluthrin, daminozide, etoxazole, imazalil, myclobutanil, spiromesifen, trifloxystrobin and any others used. MTFs must also report any pesticides that appear on testing and which are on the list of 195 pesticides federally prohibited on organic produce. (Appendix A to 18-691 CMR Ch. 5)
  - (4) **Other harmful chemicals (Metals).** Cadmium (Cd), lead (Pb), arsenic (As), mercury (Hg)
  - (5) **Dangerous molds and mildew.** Total yeast and mold, and for any marijuana or marijuana product that is further manufactured after failure of such test, mycotoxins including aflatoxins (B1, B2, G1, and G2) and ochratoxin A.
  - (6) **Harmful microbes.** Total viable aerobic bacteria, total coliforms, bile tolerant gram (-) bacteria, enterobacter, E. coli (pathogenic strains) and Salmonella (spp.).
  - (7) **THC potency, homogeneity and cannabinoid profiles.** THC and any other cannabinoid to be referenced in labeling or marketing materials.
  - (8) **Water activity and moisture content.** Testing for water activity is mandatory for solid and semi-solid edible marijuana products that do not require preservation by other means (e.g. refrigeration) and for marijuana plant material that is dried and prepared as a product in its final form of intended use and that is to be sold or transferred by a cultivation facility, products manufacturing facility, marijuana store, registered caregiver or registered dispensary. Testing for moisture content is mandatory for flower and trim and other plant material that has been dried, cured or otherwise prepared in any manner to reduce or eliminate moisture from the plant material.
- B. A licensed or registered cultivation facility, licensed or registered manufacturing facility, licensed marijuana store, registered or exempt caregiver, or registered dispensary may submit for additional analysis samples of marijuana for research and development purposes, but such testing shall not be considered mandatory, and marijuana that is further manufactured must then undergo mandatory testing.
  - C. The Department shall publish a Best Practices Guide that includes a sampling plan and preservation instructions appropriate to each matrix type. All marijuana testing facilities, all sample collectors and any self-sampling licensee collecting samples for mandatory testing must comply with the Department-required Best Practices Guide.
  - D. A licensee collecting and transporting samples for mandatory testing must comply with all recordkeeping requirements regarding sample collection, sample transport and sample receipt in accordance with this Rule and any instructions regarding sample collection, sample transport and sample receipt provided to the licensee by the marijuana testing facility(ies) conducting the mandatory analyses.
  - E. The Department shall publish standard operating procedures for sample collection which must be used by any licensee collecting samples for mandatory testing.
  - F. A licensee may sell or furnish to a consumer or to another licensee marijuana or marijuana product without submitting it for testing if:
    - (1) The marijuana or marijuana product has previously undergone all required testing at the direction of another licensee as evidenced by a certificate of analysis;
    - (2) The previous testing demonstrated that the marijuana or marijuana product does not exceed the maximum level of allowable contamination for any contaminant that is injurious to health and for which testing is required;
    - (3) The mandatory testing process and the test results for the marijuana or marijuana product are documented in a certificate of analysis issued pursuant to a request for mandatory testing. A certificate of analysis for non-mandatory testing for research or development purposes does not satisfy this requirement; and

- (4) The marijuana or marijuana product has been appropriately tracked in the inventory tracking system, and the marijuana or marijuana product has not been altered in any way, including any further processing or manufacturing, other than packaging and labeling of the marijuana or marijuana product for retail sale, following the issuance of the certificate of analysis indicated in subsection 1 above.

**Table 8.3.2-A**

**Maine Mandatory Testing Requirements for Adult Use Marijuana Products Based Upon Production Stage**

Production Stage/Product	Mandatory Testing Required
<p style="text-align: center;">Marijuana (Including marijuana seedlings, immature marijuana plants, marijuana trim, finished plant material, pre-rolled marijuana cigarettes, kief)</p>	<p>All Harvest Batches:</p> <ul style="list-style-type: none"> <li>● Pesticides</li> <li>● Metals</li> <li>● Water Activity and Moisture Content*</li> </ul> <p>Additional Testing Required for Production Batches to be packaged and transferred for sale to consumers:</p> <ul style="list-style-type: none"> <li>● Residual solvents*</li> <li>● Microbiological Impurities (Bacteria, Yeasts and Mold)</li> <li>● Filth and Foreign Material</li> <li>● Cannabinoid Profile*</li> </ul>
<p style="text-align: center;">Marijuana Concentrate</p>	<p>All Production Batches:</p> <ul style="list-style-type: none"> <li>● Residual Solvents</li> <li>● Pesticides</li> <li>● Metals</li> </ul> <p>Additional Testing Required for Production Batches to be packaged and transferred for sale to consumers:</p> <ul style="list-style-type: none"> <li>● Microbiological Impurities (Bacteria, Yeasts and Mold)</li> <li>● Filth and Foreign Material</li> <li>● Cannabinoid Profile</li> <li>● Homogeneity</li> </ul>
<p style="text-align: center;">Marijuana Product*</p>	<p>All Production Batches to be packaged and transferred for sale to consumers:</p> <ul style="list-style-type: none"> <li>● Microbiological Impurities (Bacteria, Yeasts and Mold)</li> <li>● Filth and Foreign Material</li> <li>● Cannabinoid Profile</li> <li>● Water Activity</li> <li>● Homogeneity</li> <li>● Metals</li> </ul>

\*Testing for water activity and moisture content is not required for marijuana flower or marijuana trim that has not been dried, cured, or otherwise prepared in any manner to reduce or eliminate water weight (e.g. “fresh frozen” marijuana flower or trim). Testing for water activity, moisture content, residual solvents, and cannabinoids is not mandatory for marijuana seedlings and immature marijuana plants for sale to consumers. Testing for residual solvents is not required for marijuana flower, trim, kief, hashish, or marijuana products that have not been

manufactured using chemical solvents. Testing for residual ethanol is not required for orally-consumed tinctures that contain alcohol.

### **8.3.3 Reporting.**

- A. If a sample's result exceeds an action level as required by 18-691 CMR, Ch. 5, the marijuana testing facility must report in the inventory tracking system and the certificate of analysis that the sample failed the mandatory test for which the result exceeds the action level, and the marijuana testing facility must report that the sample failed mandatory testing in general unless otherwise provided for in this Rule or 18-691 CMR, Ch. 5.
  - (1) In the event a marijuana testing facility determines that a sample has failed testing, the entity that submitted the sample may request from the Department an opportunity to remediate the batch before requesting the batch be re-tested.
  - (2) The entity that submitted the sample that is requesting an opportunity for remediation must demonstrate to the Department that the issues identified by the marijuana testing facility are of the kind that can be remediated.
  - (3) When deciding if remediation is appropriate, the Department shall consider the public health and safety consequences of remediation, as well as the frequency and history of failed tests from the requestor.
  - (4) Any testing of a remediated batch must be conducted by the marijuana testing facility that originally determined that the sample failed testing.
  - (5) The results of failed mandatory tests must be reported to both the Department and the entity that submitted the sample.
  - (6) The marijuana testing facility is not required to report to the Department the results of any tests if the requester notifies the marijuana testing facility in advance that the testing is solely for research development purposes and agrees not to use the results to satisfy any mandatory testing requirements.
- B. If a sample passes testing, the marijuana testing facility must, within one business day from issuance of final QC review, enter "pass" into the inventory tracking system for the batch from which the sample came. The batch is then released for transfer or distribution to another licensee or consumer.
- C. In the event that a sample fails any test, the marijuana testing facility may retest the product, provided that the entity that submitted the sample requests and pays for retesting; the following protocol shall be followed:
  - (1) If there is enough remaining material from the initial sample to retest, the marijuana testing facility may use that sample material.
  - (2) If there is not enough material from the initial sample, a sampler will collect another sample from the same batch using the same collection process. Unless the entity that submitted the sample requests an opportunity to remediate the batch pursuant to Section 8.3.3(A), the licensee may not alter in any way any portion of the batch from which the failed sample was collected.
  - (3) If a sample fails mandatory testing initially, the entity that submitted the sample may request that the batch be retested. Two subsequent successive tests must both indicate a passing result for any previous failed tested sample to be deemed to have passed the mandatory test.
- D. If a sample fails mandatory testing or retesting, the marijuana testing facility must, within two business days from issuance of final QC review, send to the Department a copy of the certificate of analysis.
- E. Upon a determination by the marijuana testing facility that a sample has failed any mandatory test, and that sample failed any subsequent retesting allowed by the Department as described above, the marijuana testing facility shall issue to the Department and the licensee a Notice of Failure on forms provided by the Department.

### **8.3.4 Department action following issuance of a Notice of Failure by a marijuana testing facility.**

Upon receipt of a Notice of Failure from a marijuana testing facility, the Department shall, within 3 business days, issue an Order of Destruction to the licensee. Unless otherwise indicated by the Department, an Order of Destruction under this subsection shall be considered final agency action and notice will be given to the licensee of the licensee's right to appeal, consistent with the Maine Administrative Procedures Act, 5 MRS, Chapter 375. The notice shall contain:



- A. The batch number of the marijuana or marijuana products to be destroyed;
- B. Notice about whether the Department will be taking any samples from the batch for its own testing, and if so when that will occur;
- C. The method of destruction directed by the Department, if any;
- D. A HOLD – DO NOT DESTROY order for any marijuana or marijuana products subject to an investigation by a criminal justice agency;
- E. Any proof of destruction required by the Department; and
- F. The date by which destruction must occur and the Department must receive notice.

## Section 9 - Waste Management

All wastes must be managed in accordance with federal, state and local requirements. Applicants should contact the Department of Environmental Protection for guidance on applicable regulations.

### 9.1 - Hazardous Waste

Discharges of hazardous waste or other matter in any quantity and under any circumstances must be reported to the Department and in accordance with this Section.

- A. Licensees must immediately report discharges to the Department of Public Safety (State Police) unless exempted pursuant to Chapters 800 and 850 of the Department of Environmental Protection’s regulations:
  - (1) Licensees must call 1-800-452-4664 or 207-624-7000 to notify the Department of Public Safety of a discharge.
  - (2) Licensees are not required to notify the Department of Environmental Protection.
- B. Licensees must also report any discharges of hazardous matter exceeding the federal reportable quantities in Appendix A to Chapters 800 and 850 of the Department of Environmental Protection’s regulations as follows:
  - (1) The licensee must call the National Response Center at 1-800-424-8802; and
  - (2) If the spill goes beyond the boundary of the facility, the licensee must call the local fire department and the local community emergency coordinator.

### 9.2 - Marijuana Waste

In addition to any other provisions of 28-B MRS, this Rule or other applicable laws or rules, non-hazardous marijuana wastes shall be managed in accordance with the following:

- A. A marijuana plant, marijuana, trim and other plant material in itself is not considered hazardous waste unless it is toxic, flammable or a listed waste subject to regulation under Department of Environmental Protection Rule Chapter 850.
- B. Non-hazardous marijuana waste that is to be disposed of must be rendered unusable prior to leaving a marijuana establishment by one of the following methods:
  - (1) Grinding and incorporating the marijuana waste with other ground materials so the resulting mixture is at least fifty percent non-marijuana waste by volume, including:
    - (a) Food waste;
    - (b) Yard waste; or
    - (c) Other wastes approved by the Department; or
  - (2) Using another method approved by the Department and recorded in the licensee’s operating plan of record before implementation.
  - (3) Sample collector licensees may not dispose of marijuana waste. A sample collector licensee who is in possession of samples of marijuana or marijuana products to be wasted must return such samples of marijuana, marijuana concentrate or marijuana products to the licensee from which the samples were collected.

- C. Composting of marijuana wastes may be subject to the Department of Environmental Protection's Solid Waste Management Rules: Composting Facilities rule, 06-096 C.M.R., chapter 410.

**9.2.1 Marijuana Waste Exceptions.** The following materials shall not be considered to be marijuana waste requiring treatment to be rendered unusable, provided that they are completely free of all marijuana flowers and leaves with any visible trichomes, and may be disposed of, provided that they are non-hazardous, in accordance with standard waste disposal regulations:

- A. Root balls, soil or growing media;
- B. Stalks of marijuana plants; and
- C. Leaves and branches removed from marijuana clones, seedlings and marijuana plants.

## Section 10 - Wastewater

Wastewater generated during the cultivation or manufacturing of marijuana must be disposed of in compliance with all applicable state and local laws and regulations.

## Section 11 - Packaging and Labeling

All marijuana, marijuana concentrate and marijuana products received by a marijuana store from an authorized transfer, and offered for retail sale at a marijuana store must be packaged and labeled, including all required health and safety warnings, in accordance with the following section, in addition to any other provisions of this Rule, 28-B MRS and any other applicable laws and rules.

A licensee may not label or package for sale adult use marijuana or an adult use marijuana product under this Rule unless the marijuana or marijuana product has been analyzed by a testing facility for minimally the following test matrices:

- A. Residual solvents, poisons and toxins;
- B. Harmful chemicals;
- C. Dangerous molds and mildew;
- D. Harmful microbes, including, but not limited to, Escherichia coli and salmonella;
- E. Pesticides, fungicides and insecticides; and
- F. THC potency, homogeneity and cannabinoid profiles to ensure correct labeling.

The Department may waive testing requirements specified above, for any contaminant or factor for which the Department has determined that there exists no licensed testing facility in Maine certified to perform such testing.

### 11.1 - General Packaging and Labeling Requirements for Retail Sale

**11.1.1 General Packaging for Retail Sale Requirements.** All marijuana or marijuana products must be packaged in containers that:

- A. Are fully enclosable;
- B. Are resealable;
- C. Protect the packaged item from contamination; and
- D. Do not impart any toxic or deleterious substance to the packaged item.

**11.1.2 General Labeling for Retail Sale Requirements.** In addition to any other requirements pursuant to this Rule and 28-B MRS, all marijuana or marijuana product labels must comply with the following:

- A. All required information must be printed directly on, or on a label or sticker affixed directly to, the marketing layer.
- B. Labeling text on any marketing layer must be no smaller than size 6 font or 1/12 inch.
- C. All information included in the labeling requirements, or any other provision of this Rule, must be clearly written or printed and in the English language. In addition to the required English label,

licensees may include an additional, accurate foreign language translation on the label that otherwise complies with this Rule.

- D. All information included in the labeling requirements, or any other provision of this Rule, must be displayed on the marketing layer and must be unobstructed and conspicuous. A marijuana establishment licensee may affix multiple labels to the marketing layer, provided that none of the information required by this Rule is obstructed.
- E. The marijuana store that conducted the retail sale of the marijuana, marijuana concentrate or marijuana product must affix its license number to the marketing layer of the marijuana, marijuana concentrate or marijuana product on a separate label or sticker that may be applied following the retail sale but before placing the marijuana, marijuana concentrate or marijuana product in an exit package.
- F. The label must include:
  - (1) The licensee's identification statement;
  - (2) The unique identification number of the final batch from which the testing sample for the mandatory testing of the contents of the marijuana or marijuana product was taken;
  - (3) Mandatory testing results from the licensed testing facility that tested the sample of the batch from which the marijuana or marijuana product was taken; and
  - (4) The license numbers of the cultivation facility and, if applicable, the products manufacturing facility involved with the cultivation and manufacture of the marijuana or marijuana product.
- G. The label's statement of net contents must identify the net weight of the marijuana, marijuana concentrate or marijuana product prior to its placement in the container, using a standard of measure compatible with the tracking system.
- H. The Department-approved universal symbol, as made available by the department, must appear on the front or most predominantly displayed area of the marketing layer, no smaller than  $\frac{1}{2}$  inch by  $\frac{1}{2}$  inch.
- I. The label must include, as a production date:
  - (1) For marijuana and marijuana products consisting in whole or in part of marijuana flower or marijuana trim, the date of the harvest batch; or
  - (2) For marijuana concentrate or marijuana products that were manufactured, the date on which the production batch was created.
- J. Required information may be stated in a peel-back accordion style, expandable, extendable or layered label, so long as the label can be easily identified by a consumer as containing important information.
- K. The label must state cannabinoid content, and, if applicable, gases, solvents and chemicals used in marijuana extraction. Statements regarding contaminants and use of solvents or absence thereof may not conflict with results reported in an approved marijuana testing facility's Certificate of Analysis.
- L. In addition to any other warning statements required for specific categories of marijuana products, all marijuana and marijuana products must carry the following warning statement in no smaller than 6-point font: "There may be health risks associated with the use of this product. There may be additional health risks associated with the use of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant. Do not drive a motor vehicle or operate heavy machinery while using this product."

**11.1.3 General Labeling Prohibitions.** The label for retail sale of marijuana, marijuana concentrate or marijuana products may not:

- A. Depict a human, animal or fruit or the word "candy" or "candies" on the label of any marketing layer, container holding marijuana, marijuana concentrate or marijuana product or intermediate packaging;
- B. Display any content on a container, marketing layer or intermediate packaging making any claims regarding health or physical benefits to the consumer;
- C. Cause a reasonable consumer confusion as to whether the marijuana, marijuana concentrate or marijuana product is a trademarked product;
- D. Violate any state or federal trademark law or regulation;
- E. Include any false or misleading statements;
- F. Obscure identifying information or warning statements;
- G. Reasonably appear to target or appeal to individuals under the age of 21, including but not limited to, cartoon characters or similar images; or

- H. Report information regarding the quality or potency of the enclosed product, except as reported by a testing facility, unless the label clearly indicates that testing regarding the claim is not required or conducted by a testing facility.

## 11.2 - Packaging and Labeling of Trade Samples

Along with all requirements pursuant to this Rule and 28-B MRS, marijuana cultivation and marijuana products manufacturing establishments shall comply with the following minimum packaging and labeling requirements prior to authorized transfer of any trade sample to a licensed marijuana establishment.

- A. Prior to authorized transfer, a trade sample must be placed in a container that is compliant with the packaging for retail sale requirements of this Rule.
- B. Prior to authorized transfer to a licensed marijuana establishment, every container containing a trade sample shall be affixed with a label that includes at least the following information:
  - (1) The license number for the marijuana cultivation or marijuana products manufacturing establishment transferring the trade sample;
  - (2) The relevant batch from which the trade sample was selected;
  - (3) The universal symbol on the front of the marketing layer, no smaller than  $\frac{1}{2}$  of an inch by  $\frac{1}{2}$  of an inch;
  - (4) A potency statement, either in a font that is bold and enclosed within an outlined shape such as a circle or square or highlighted with a bright color such as yellow:
    - (a) For a sampling unit composed of marijuana or marijuana concentrate, the potency of the sampling unit's active THC and CBD expressed as a percentage;
    - (b) For a sampling unit composed of marijuana product, the potency of the sampling unit's active THC and CBD expressed in milligrams; and
  - (5) The date and identification number of the transport manifest pursuant to which the trade sample was transferred.
- C. Any statement as to cannabinoid profile or the presence or absence of contaminants requires testing and label verification by a testing facility
- D. Either the label affixed to the container or the marketing layer shall include the statement: "Trade Sample. Not for Sale."

## 11.3 - Packaging and Labeling for Retail Sale of Inhaled Marijuana Products

**11.3.1 Retail Sale Packaging for Inhaled Marijuana Products.** Prior to authorized transfer to a marijuana store, all inhaled marijuana products shall be packaged in accordance with the following:

- A. The container must be fully enclosed on all sides, as follows:
  - (1) If container is soft sided, it must be four mil or greater in thickness; or
  - (2) If container has rigid sides, it must have a lid or enclosure that can be placed tightly and securely on the container.
  - (3) The container must be child-resistant or must be placed into child-resistant exit packaging by the marijuana store at time of sale.
  - (4) The container must be opaque or must be placed into opaque exit packaging by the marijuana store at time of sale.
- B. The container must be tamper-evident:
  - (1) If the container is soft sided, the opening must be sealed by some means in a manner which would indicate if the container had been opened or tampered with. The tamper evident indicating feature of the opening must not be resealable, and once opened must remain clearly evident that the package has previously been opened; or
  - (2) If the container is rigid, the opening must contain a tamper evident seal, or the lid or enclosure must have an adhesive band or seal that once opened must remain clearly evident that the package has previously been opened.
- C. The packaging must contain a marketing layer, on which required labeling information can be printed.

**11.3.2 Labeling for Retail Sale Requirements for Inhaled Marijuana Products.** In addition to Section 11.1.2 any other provisions of this Rule and 28-B MRS, all inhaled marijuana products must clearly display the following information on the marketing layer of the package for retail sale:

- A. A statement, if applicable, that the packaging is not child-resistant;
- B. The applicable license number as follows:
  - (1) For inhaled marijuana products consisting in whole or in part of marijuana flower or trim, the license number of marijuana cultivation establishment that most recently cultivated or processed the inhaled marijuana product; or
  - (2) For inhaled marijuana products consisting in whole or in part of marijuana concentrate, or products manufactured by a marijuana products manufacturing establishment, the license number of the marijuana products manufacturing establishment which manufactured the inhaled marijuana products;
- C. The potency of inhaled marijuana products, expressed as the percentage total of THC and CBD and based on the results of analysis reported by a testing facility and as:
  - (1) A range of percentages of total THC and CBD that extends from the lowest percentage to the highest percentage for each cannabinoid listed that may be found in the inhaled marijuana product, so long as the lowest percentage and the highest percentage of total THC and CBD do not differ by more than 20% of the lowest percentage stated; or
  - (2) The average percentage total of THC and CBD found in the inhaled marijuana product, so long as the actual percentage totals of the inhaled marijuana product does not vary by more than 15% higher or 15% lower than the potency statement stated on the label;
- D. If applicable, a list of any solvent(s) used to produce any marijuana concentrate that was used in the manufacturing of the inhaled marijuana product;
- E. If applicable, a list of all ingredients used to manufacture the inhaled marijuana products, including identification of any major allergens contained in the marijuana concentrate in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010), specifically milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans; and
- F. Net content, according to the following:
  - (1) For inhaled marijuana products, net contents shall be stated in grams, except that inhaled marijuana products containing less than one gram of net content may state the net contents in milligrams.
  - (2) Variance is allowed as follows:
    - (a) For inhaled marijuana products composed primarily of marijuana flower or trim, the actual net contents by weight may be as much as 0.1 grams less or 0.5 grams greater than the statement of net content on the label;
    - (b) For inhaled marijuana products that are pre-rolled marijuana cigarettes, the actual net contents by weight may be as much as 5% less than or 15% greater than the statement of net content;
    - (c) For inhaled marijuana products composed primarily of marijuana extract, the actual net contents by weight may be as much as 5% less or 10% more than the statement of net content.
  - (3) Inhaled marijuana product labels may state the net contents in ounces in addition to stating the net contents in grams.
  - (4) In determining the weight of marijuana concentrate in a marijuana product, the weight of any other ingredients combined with marijuana or marijuana concentrate to prepare the marijuana products may not be included.

#### 11.4 - Packaging and Labeling for Retail Sale of Edible Marijuana Products

**11.4.1 Retail Sale Packaging Requirements for Edible Marijuana Products.** Prior to authorized transfer to a marijuana store, all edible marijuana products shall, unless otherwise specified, be packaged in child-resistant containers in accordance with 16 C.F.R. Part 1700 (2018) as follows:

- A. For single-serving edible marijuana products:
  - (1) Single-serving edible marijuana products must be placed into a child-resistant container that may or may not be resealable.

- (2) Single-serving edible marijuana products that are placed into a child-resistant container may be bundled into a larger marketing layer so long as the total amount of active THC per marketing layer does not exceed 100 milligrams.
- B. For multiple-serving edible marijuana products:
  - (1) Every multiple-serving edible marijuana product must be placed into a child-resistant container that is resealable or made of plastic four mil or greater in thickness and heat sealed with no easy-open tab, dimple, corner or flap, as to make it difficult for a child to open.
  - (2) A multiple-serving edible marijuana product must not exceed 100 milligrams of total THC per multiple-serving container.
  - (3) The packaging shall clearly indicate the size of a serving if the edible product is not in a form that indicates a serving.
- C. A single-serving tincture may contain no more than 10 milligrams of THC and must be placed into a child-resistant container that may or may not be resealable.
- D. Single-serving marijuana drinks that do not contain more than 10 milligrams of THC may be packaged in:
  - (1) A child-resistant container; or
  - (2) An aluminum or metal can with a stay tab mechanism opening; or
  - (3) A bottle with a metal crown cork style bottle cap.
- E. Multiple-serving marijuana drinks that contain more than 10 milligrams of THC but no more than 100 milligrams of THC must:
  - (1) Be packaged in a child-resistant container compliant with 16 C.F.R. Part 1700 (2018) that has a resealing cap or closure; and
  - (2) Include a measuring device such as a measuring cap or dropper with the package containing the marijuana-infused liquid edible product; hash marks on the bottle or package do not qualify as a measuring device.
- F. Marijuana drinks packaged according to this section may be bundled into a larger marketing layer so long as the total amount of THC per marketing layer does not exceed 100 milligrams.
- G. The container must be tamper-evident or must be placed into tamper-evident exit packaging by the marijuana store at time of sale.
- H. The container must be opaque or must be placed into opaque exit packaging by the marijuana store at time of sale.

**11.4.2 Labeling for Retail Sale Requirements for Edible Marijuana Products.** In addition to Section 11.1.2, any other provisions of this Rule and Maine Title 28-B, all edible marijuana products must clearly display the following information on the marketing layer of the package for retail sale:

- A. Total contents of THC and CBD, stated in milligrams and not more than 10% less or 10% greater than the actual THC and CBD content, including:
  - (1) The total contents of THC and CBD per serving unit; and
  - (2) If the label is on the marketing layer of a package containing more than one serving unit, the total contents of THC and CBD contained within the entire package;
- B. The serving size, which may contain no more than 10 milligrams of THC;
- C. The number of servings per container or marketing layer;
- D. Total net weight of the edible marijuana product separate from the package and label;
- E. A statement in font no smaller than 6 point: “This product contains marijuana. Keep away from children”;
- F. If applicable, a list of all ingredients used to manufacture the Edible Marijuana Product, including identification of any major allergens contained in the product in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. § 343 (2010), specifically milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans;
- G. A nutritional fact panel in accordance with 21 C.F.R. Part 101 (2018);
- H. A statement in font no smaller than 6 point: “Effects of this product may not be felt for up to 4 hours.”; and
- I. If applicable, a statement that the packaging is not tamper-evident.

## 11.5 - Packaging and Labeling for Retail Sale of Topical Marijuana Products

**11.5.1 Retail Sale Packaging for Topical Marijuana Products.** Prior to authorized transfer to a marijuana store, all topical marijuana products shall be packaged in a child-resistant container in accordance with the following:

- A. Salves, creams, lotions and balms shall be packaged in a child-resistant container that has a resealing cap or closure compliant with 16 C.F.R. 1700 (2018).
- B. Transdermal patches shall be packaged in a plastic four mil or greater in thickness and be heat sealed with no easy-open tab, dimple, corner or flap, as to make it difficult for a child to open.
- C. The packing must be tamper-evident or must be placed into tamper-evident exit packaging by the marijuana store at time of sale.
- D. The container must be opaque or must be placed into opaque exit packaging by the marijuana store at time of sale.

**11.5.2 Labeling for Retail Sale of Topical Marijuana Products.** In addition to Section 11.1.1, any other provisions of this Rule and Maine Title 28-B, all topical marijuana products must clearly display the following information on the marketing layer of the package for retail sale:

- A. A potency statement for topical marijuana products stating the total content of THC and CBD in milligrams in the container, and for transdermal products the total content of THC and CBD in milligrams contained in each transdermal product;
- B. A list of all ingredients in descending order of predominance by weight or volume as applicable;
- C. The amount recommended for use at any one time; and
- D. The following warning statement: “For Topical Application – Do Not Eat or Smoke.”
- E. If applicable, a statement that the packaging is not tamper-evident.

## 11.6 - Packaging and Labeling of Samples Collected by a Licensee

**11.6.1 Self-samplers and Sample Collectors Must Contact Marijuana Testing Facility.** Any licensee collecting samples for mandatory testing in accordance with 28-B MRS, subchapter 6, and Section 8.3 of this Rule must contact the marijuana testing facility that will conduct the mandatory testing and comply with the marijuana testing facility’s specific recommendations regarding, without limitation:

- A. Required sample collection tools and equipment based upon sample matrix type and mandatory tests required;
- B. Required sample collection containers based upon sample matrix type and mandatory tests required;
- C. Required sample transportation conditions based upon sample matrix and mandatory tests required;
- D. A plan for sample receipt which includes any limitations on days or times when samples will be accepted by the marijuana testing facility; and
- E. Any additional quality measures required by the marijuana testing facility to ensure sample integrity and prevent contamination of the licensee’s samples or the samples of other licensees.

All marijuana testing facility recommendations regarding sample collection will be recorded for every sampling event in the licensee’s sample collection records in accordance with Section 3.11 of this Rule. Marijuana testing facility recommendations must align with the Department’s Best Practice Guide as applicable.

**11.6.2 Self-samplers and Sample Collectors must use sample collection containers required by Marijuana Testing Facility.** A licensee collecting samples for mandatory testing must collect samples in accordance with the Department’s sample collection SOP and deposit the required sample increments in the sample collection containers required by the marijuana testing facility analyzing the samples. When all required sample increments are collected, the person collecting the samples must:

- A. Affix a tamper evident seal to each sample container and must initial the seal. The seal must be initialed by another individual identification cardholder witnessing the sealing of the sample containers;

- B. Ensure that the universal symbol is on every sample collection container, no smaller than  $\frac{1}{2}$  of an inch by  $\frac{1}{2}$  of an inch;
- C. Ensure that each sample collection container has the following notice: “FOR TESTING PURPOSES ONLY”; and
- D. Ensure that each sample collection container is accompanied by the appropriate label generated by the inventory tracking system required by the Department.

**11.6.3 Self-samplers, Sample Collectors and Marijuana Testing Facilities must Comply with All Sample Collection Recordkeeping Requirements and Use the Department-required Sample collection SOP and Best Practices Guide.** A licensee must conduct all sample collection in accordance with the Department’s sample collection SOP and Best Practices Guide and must submit to the marijuana testing facility all information required by the marijuana testing facility’s quality system for each batch of marijuana or marijuana product sampled for mandatory testing. A licensee conducting sample collection for mandatory testing must comply with the sample collection recordkeeping requirements of this Rule.

## 11.7 - Packaging and Labeling for Storage by a Marijuana Establishment

**11.7.1 Storage Prior to Testing.** Following samples being taken from a batch of marijuana, a licensee must:

- A. Store the batch in one or more sealed containers enclosed on all sides, so as to:
  - (1) Prevent the product from being tampered with or transferred or sold prior to test results being reported; and
  - (2) Be able to be easily located.
- B. Affix to the container(s) in which the marijuana is stored a label including the following information:
  - (1) The marijuana establishment license number;
  - (2) The batch number;
  - (3) Name and number of the individual identification card holder number of the person who took the samples;
  - (4) Name and license number of the testing facility that will perform the tests;
  - (5) The test sample(s) unique identification number;
  - (6) The date the samples were taken; and
  - (7) In bold, capital letters, no smaller than 12-point font, “PRODUCT NOT TESTED”;
- C. Report the transfer of the sample into the tracking system and the batch number being sampled.

**11.7.2 Storage of Marijuana Not Labeled for Retail Sale.** All marijuana or marijuana products stored on the licensed premise must be secured in a limited access area and tracked consistently with the inventory tracking rules.

**11.7.3 Health and Safety Standards for Storage.** Storage of marijuana and marijuana products shall be under conditions that will protect products against physical, chemical and microbial contamination, as well as against deterioration of any container.



## Section 12 - Enforcement

### 12.1 - Department Enforcement Authority

**12.1.1 Inspection of Marijuana Establishments and Premises.** A marijuana establishment licensee must provide the Department, or agent thereof, access to inspect a marijuana establishment and premises at any time during the operating hours stated on the operating plan of record of the marijuana establishment or during apparent activity. Licensees shall not deny entrance for inspection, upon demand and without notice required, during any operating hours and other times of apparent activity, or at any other time upon reasonable notice. In any case, the licensee shall ensure there is an individual identification card holder at the marijuana establishment to accompany the agent of the Department during the inspection. Licensees shall permit staff or agents of the Department, law enforcement officers and employees or agents of local or state agencies with regulatory authority access to inspect the marijuana establishment and premises in accordance with the statutes, regulations and operating procedures employed by those regulatory bodies.

- A. If a licensee denies the agent of the Department access to a licensed premise, the Department may put an administrative hold on the marijuana establishment license and may impose fines, suspensions or revocation of that license.
- B. If the Department seizes marijuana, the Department shall not cultivate nor preserve any seized marijuana, marijuana plants or marijuana products.
- C. Unless notified by a criminal justice agency of pending investigation of the licensee, the Department may, in its final order, specify the destruction of the seized marijuana, marijuana plants or marijuana products.

**12.1.2 Routine or random inspection or audit of sample collection by licensees.** The Department may, with or without suspicion of infractions, conduct inspection or audit of any licensee's sample collection practices, including without limitation:

1. Reviewing video footage;
2. Reviewing sample collection and chain-of-custody forms;
3. Inspecting any samples, including sample collection containers, for compliance with all packaging and labeling requirements of this Rule;
4. Reviewing tracking system data and transportation manifests;
5. Reviewing any business-related documents, including personnel records, deemed necessary by the Department to determine compliance with all sample collection requirements of this Rule; and
6. Requiring testing of batches, at the licensee's expense. Samples collected for testing pursuant to this paragraph must be collected by or in the presence of Department employees.

**12.1.3 Investigation.** The Department may, as a result of a complaint filed with the Department, or as a result of its administration of the program, investigate suspected infractions by licensees to any provision of 28-B MRS or this Rule. Infractions that may be investigated include, without limitation:

- A. Failure to comply with operating plan of record;
- B. Failure to properly report inventory in the inventory tracking system;
- C. Unauthorized transfers of marijuana;
- D. Failure to disclose or properly report changes to the record of officers, directors, managers, general partners or natural persons or business entities having a direct or indirect financial interest in the licensee or the nature of such direct or indirect financial interests;
- E. Failure to report and submit tax payments;
- F. Failure to comply with the applicable electrical codes;
- G. Failure to comply with any conditions required by a municipality, town, plantation, township or county commission for approval of the license;
- H. Any violation of the rules and regulations as set forth by the Department; or
- I. Any conduct by a marijuana establishment licensee not authorized by 28-B MRS or this Rule.

#### **12.1.4 Enforcement Actions.**

- A. The Department may take the following actions against licensees, alone or in combination, subject to the requirements of this Section:
  - (1) Impose monetary penalties;
  - (2) Restrict a license;
  - (3) Suspend a license;
  - (4) Revoke a license;
  - (5) Accept the voluntary surrender of a license;
  - (6) Confiscate or seize marijuana plants, marijuana or marijuana products;
  - (7) Destroy marijuana plants, marijuana or marijuana products;
  - (8) Recall marijuana or marijuana products; or
  - (9) Accept the voluntary surrender of marijuana plants, marijuana or marijuana products.
- B. The Department may revoke an individual identification card for any violation of 28-B MRS or this Rule

#### **12.1.5 Procedures for Enforcement Actions.**

- A. The Department may, on its own initiative or on complaint and after investigation, initiate enforcement actions, notwithstanding any other criminal, civil or administrative proceedings against the licensee.
- B. Enforcement actions require a finding of the following:
  - (1) Any false or misleading statements to the Department;
  - (2) Other violations by the licensee or by an agent or employee of the licensee of 28-B MRS or this Rule;
  - (3) Violations by the licensee or by an agent or employee of the licensee of the terms, conditions or provisions of the licensee's license, including all licensing criteria required to be granted a conditional or active license; or
  - (4) Inactivity at the licensed premises for a period of 1 year or more without reasonable justification, including without limitation death or illness of a licensee, fire, natural disaster, or building conditions outside of the licensee's control.
- C. Any enforcement action by the Department shall be made only on the basis of relevant evidence and shall be communicated in writing to the licensee, along with a notice of the licensee's right to appeal, consistent with the Maine Administrative Procedures Act, 5 MRS, chapter 375.

### **12.2 – Administrative Monetary Penalties**

A monetary penalty imposed by the Department on a licensee pursuant to this subchapter may not exceed \$100,000 per license violation. Penalties to be imposed on a licensee based upon specific categories of unauthorized conduct by the licensee, including major and minor license violations, as follows:

- A. Not more than \$100,000 per major license violation affecting public safety
- B. Not more than \$50,000 per other major license violation; and
- C. Not more than \$10,000 per minor license violation.

#### **12.2.1 Major License Violations Affecting Public Safety**

- A. The Department may impose a fine of up to \$100,000 for each major license violation affecting public safety.
- B. Such violations include, but are not limited to:
  - (1) Intentionally or recklessly selling marijuana or marijuana products containing any other federally controlled substance, including but not limited to opioids, stimulants or hallucinogens;
  - (2) Intentionally or recklessly using prohibited agricultural chemicals that pose a threat to public health and concealing their use from the Department, other licensees or consumers;
  - (3) Engaging in a deliberate pattern of 2 or more instances of marketing or selling marijuana plants, marijuana or marijuana products to individuals who are younger than 21 years old;

- (4) Intentionally destroying, damaging, altering, removing or concealing potential evidence of a violation under this subsection, attempting to do so or asking or encouraging another person to do so;
- (5) Misleading the Department for the purposes of involving a person with a disqualifying drug offense in the operation of a marijuana establishment;
- (6) Knowingly diverting marijuana or marijuana products to the illicit market;
- (7) Three or more instances of a licensee failing to have on the premises, at all times during the hours of operation and periods of apparent activity, an individual identification card holder who is authorized to allow and cooperate with Department requests to inspect the premises;
- (8) Two or more instances of a licensee refusing to permit the Department to inspect the premises during hours of operation or periods of apparent activity;
- (9) Intentionally tampering with or interfering with mandatory testing processes, including sample collection, or the auditing thereof; or
- (10) Other conduct that shows willful or reckless disregard for health and safety.

### **12.2.2 Major License Violations**

- A. The Department may impose a fine of up to \$50,000 for each other major license violation.
- B. Such violations include, but are not limited to:
  - (1) Deliberately making a false statement to the Department, the Maine Revenue Service, the Maine Land Use Planning Commission, or any law enforcement officer for the purpose of evading responsibility for any requirements of Titles 28-B or 36 of the Maine Revised Statutes, this Rule, or the license;
  - (2) Deliberately purchasing marijuana plants, marijuana or marijuana products from out of state or outside of the licensed and tracked adult use system;
  - (3) Engaging in a pattern of reporting adult use marijuana plants, marijuana or marijuana products as medical marijuana for the purposes of avoiding taxation or regulation;
  - (4) Selling marijuana plants, marijuana or marijuana products to anyone under the age of 18 by failing to take all necessary steps to verify age;
  - (5) Allowing any individual under the age of 21 to engage in any marijuana-related activity.
  - (6) Engaging in a pattern of selling or transferring marijuana plants, marijuana or marijuana products outside of the tracking system;
  - (7) Supporting, facilitating or willfully or recklessly ignoring suspicious purchasing patterns that suggest a customer is in possession of illegal amounts of marijuana plants, marijuana or marijuana products or is diverting marijuana or marijuana products them to persons under 21 years of age or out of state;
  - (8) Engaging in a deliberate pattern of minor license violations;
  - (9) Intentionally destroying, damaging, altering, removing or concealing potential evidence of a violation that does not threaten public safety, attempting to do so or asking or encouraging another person to do so;
  - (10) Two instances of a licensee failing to have on the premises, at all times during the hours of operation and periods of apparent activity, an individual identification card holder who is authorized to allow and cooperate with Department requests to inspect the premises;
  - (11) Refusal to permit the Department to inspect the premises during hours of operation or periods of apparent activity; and
  - (12) Other conduct that shows a pattern of willful or reckless disregard for the tracking system requirements, sales tax obligations, excise tax obligations, mandatory testing obligations, facility requirements or other provisions of 28-B MRS, 36 MRS, this Rule or other laws or rules.

### **12.2.3 Minor License Violations**

- C. The Department may impose a fine of up to \$10,000 for each minor license violation.
- D. Such violations include, but are not limited to:
  - (1) Knowingly buying, selling, transferring or receiving any marijuana, marijuana plant or marijuana product that was illegally entered into the tracking system;

- (2) Allowing anyone without a valid individual identification card to engage in any marijuana-related activity;
- (3) Selling marijuana plants, marijuana or marijuana products to anyone under the age of 21, but over the age of 18, by failing to take all necessary steps to verify age;
- (4) Misrepresenting any marijuana product to a consumer, licensee or the public, including:
  - (a) Its contents;
  - (b) Its testing results; or
  - (c) Its potency.
- (5) Making representations or claims that the marijuana or marijuana product has curative or therapeutic effects;
- (6) Treating or otherwise adulterating marijuana with any chemical (excluding a controlled substance or prohibited agricultural chemical but including nicotine) that has the effect or intent of altering the marijuana's color, appearance, weight or smell or that has the effect or intent of increasing potency, toxicity or addictiveness;
- (7) Supplying adulterated marijuana or marijuana products;
- (8) Failing to report suspicious purchasing patterns that suggest a customer is in possession of illegal amounts of marijuana plants, marijuana or marijuana products or is diverting marijuana or marijuana products to persons under 21 years of age or out of state;
- (9) Refusing to give, or failing to promptly give, a Department regulatory specialist, representative of the State Tax Assessor, or law enforcement officer evidence when lawfully requested to do so.
- (10) Subletting any portion of the premises;
- (11) Except by way of authorized transfer of trade samples or testing samples, giving away or otherwise transferring marijuana in exchange for a monetary sum less than the licensee has paid for the marijuana by way of authorized transfer or less than the value the licensee has invested, in labor and materials, in the marijuana;
- (12) Allowing consumption of marijuana on a marijuana establishment premises, except as allowed by this Rule;
- (13) Failure to have on the premises, at all times during the hours of operation and periods of apparent activity, an individual identification card holder who is authorized to allow and cooperate with Department requests to inspect the premises;
- (14) Not operating in accordance with the current operations, cultivation or facility plan of record with the Department; or
- (15) Any other violation of 28-B MRS or this Rule.

### 12.3 - License Restriction, Suspension, Revocation and Voluntary Surrender

The Department shall have the authority to suspend or revoke licenses subject to Title 28-B, Section 802.

**12.3.1 Certain Restrictions.** The Department may place certain restrictions on licenses in cases where the restrictions may, in addition to other civil or administrative penalties, prevent recurring violations or conflicts with this Rule.

- A. The Department will provide written notice to a licensee if a license is to be restricted and a licensee will be given an opportunity to appeal pursuant to the Maine Administrative Procedure Act, 5 MRS, chapter 375.
- B. A marijuana establishment with a restricted license may only exercise license privileges in compliance with the restrictions of the license.
- C. Failure to comply with restrictions is a violation of this Rule.
- D. A restriction remains in effect until the Department removes it.

#### 12.3.2 Suspension.

- A. Upon the finding of any license violation described in subsection 12.2, in addition to any monetary penalties, the Department may suspend for a period of up to one year, any or all marijuana establishment licenses held by the licensee found in violation, including any other licenses with a common officer, director, manager or general partner.

- B. The Department may suspend a license based upon the Department’s determination that the licensee has failed at least two audits of a licensee’s sample collection process.
- C. A licensee whose license has been suspended pursuant to this subchapter may not, for the duration of the period of suspension, engage in any activities relating to the operation of the marijuana establishment the licensee is licensed to operate.
- D. The Department retains discretion as to whether to allow a transfer of license for a suspended license and shall be permitted but not required to allow new owners to begin some or all operations prior to the end of the suspension.

**12.3.3 Summary Suspension.**

- A. The Department may order summary suspension of a marijuana establishment license for up to 30 days under the following circumstances:
  - (1) The Department concludes, based upon a physical test, inspection or examination conducted by a state-certified inspector, that allowing the licensee to continue operations would not adequately protect public health or public safety; or
  - (2) The Department has other objective and reasonable grounds to believe that public health, public safety or significant natural resources are in immediate jeopardy.
- B. The Department may order summary suspension of a marijuana establishment license if a court issues a ruling that indicates the licensee has committed a major license violation.

**12.3.4 Revocation.**

- A. Upon the finding of any license violation described in subsection 12.2, in addition to any monetary penalties, the Department may permanently revoke, any or all marijuana establishment licenses held by the licensee found in violation, including any other licenses with a common officer, director, manager or general partner.
- B. The Department may permanently revoke a license based upon the Department’s determination that the licensee has failed at least two audits of a licensee’s sample collection process.
- C. The Department may also permanently revoke for inactivity, a marijuana establishment license, when it determines that the licensed premises have been inactive for a period of one year or more without reasonable justification.
- D. A licensee whose license has been revoked pursuant to this subchapter shall cease all activities relating to the operation of the marijuana establishment, following the procedure described in subsection 12.3.6 of this Rule.
- E. A license that is revoked may not be transferred or renewed.

**12.3.5 Voluntary Surrender of License.**

- A. A licensee facing penalties under this Section may offer to voluntarily surrender its license, meaning that the licensee must cease operations and may not renew or transfer the license. In such cases, the Department has the discretion:
  - (1) To reject voluntary surrender of license and pursue penalties under this Section;
  - (2) To accept the voluntary surrender of license made without conditions; or
  - (3) To negotiate conditions of a voluntary surrender, including but not limited to the following:
    - (a) The amount of monetary penalties, if any are to be imposed;
    - (b) The effect of the voluntary surrender on any other adult use marijuana licenses or medical marijuana registrations with which the licensee is associated;
    - (c) The amount of time before which the licensee or any officer, director, manager or general partner of the licensee may apply for an adult use marijuana license or medical marijuana registration; and
    - (d) The waiver of appeal.
- B. A licensee who voluntarily surrenders its license must follow the procedure described in subsection 12.3.6 of this Rule.

**12.3.6. Procedure for Termination of License.** Licensees who permanently abandon the licensed premises or otherwise permanently cease all activities relating to the operation of the marijuana establishment under its license, whether a result of revocation, voluntary surrender or other reasons, must follow the procedures for terminating a license prescribed by 28-B MRS §212. The licensee must:

- A. Provide written notice of abandoning the licensed premises or ceasing operations at least 48 hours in advance to the Department and the municipality in which the licensed premises are located, which shall mean notifying:
  - (1) The county commissioners of the county in which the township is located, for licensed premises located in townships;
  - (2) The Maine Land Use Planning Commission and the town or plantation, for licensed premises located in unorganized areas; or
  - (3) The city, town or plantation in which the licensed premises are located;
- B. Provide the department and the municipality in which the licensed premises are located with a full accounting of all adult use marijuana and adult use marijuana products located within the licensed premises; and
- C. Forfeit the marijuana and marijuana products to the department for destruction in accordance with 28-B MRS §803.

## 12.4 - Destruction and Voluntary Surrender of Marijuana Plants, Marijuana and Marijuana Products

### 12.4.1 Order by the Department.

- A. If the Department issues a final order imposing a monetary penalty on or a license suspension or revocation against a licensee pursuant to this subchapter, the Department may specify in the order, in addition to any other penalties imposed in the order, that all or a portion of the marijuana or marijuana products in the possession of the licensee are not authorized under this Rule and are subject to destruction. A licensee subject to a final order directing the destruction of marijuana or marijuana products in its possession shall forfeit the marijuana and marijuana products described in the order to the Department for destruction.
- B. If the Department is notified by a criminal justice agency that there is a pending investigation of a licensee subject to an order imposed under subsection A, as set forth in 28-B MRS§803, the Department may not destroy any marijuana or marijuana products of that licensee until the destruction is approved by the criminal justice agency.

### 12.4.2 Voluntary Surrender of Marijuana Plants, Marijuana or Marijuana Products

- A. A licensee may elect, upon mutual agreement with the Department, to voluntarily surrender any marijuana plants, marijuana or marijuana products to the Department. Such voluntary surrender:
  - (1) Must be made on a form supplied by the Department;
  - (2) Must be signed by an individual who certifies that he or she has authority to represent and bind the licensee; and
  - (3) May require destruction of any marijuana plants, marijuana or marijuana products in the presence of a Department employee or agent and at the licensee's expense; except that no marijuana plants, marijuana or marijuana products may be destroyed until the Department confirms with law enforcement that the marijuana plants, marijuana or marijuana products to be destroyed are not necessary to any ongoing investigation or prosecution.
- B. Such a voluntary surrender may be made:
  - (1) Prior to a final order and upon mutual agreement with the Department;
  - (2) In connection with a stipulated order through which the licensee waives the right to hearing and any associated rights;
  - (3) In conjunction with a pending action even if the licensee does not waive the right to hearing and any associated rights, with the understanding that the outcome of the hearing does not impact the validity of the voluntary surrender; or

- (4) After a final order.
- C. If a voluntary surrender is made in conjunction with a final order, including a stipulated order, the licensee must complete and return the Department's voluntary surrender form within 15 calendar days of the date of the final order.

## 12.5 - Audit, Compliance and Random Testing

**12.5.1 Department may require audits and random testing.** The Department may require a marijuana establishment licensee to submit samples identified by the Department to a testing facility of the licensee's choosing to be tested in order to determine whether a licensee is in compliance with mandatory testing standards and may require additional testing that is conducted at a testing facility of the Department's choosing.

- A. A testing facility doing audit testing must comply with applicable provisions of this Rule, and if conducting testing not required by this Rule, may only use Department approved methods.
- B. The Department may require a licensee to submit samples to the Department for any mandatory or additional testing to be conducted by a testing facility.
- C. The Department may order the removal from retail sale of any marijuana or marijuana products for which a licensee has intentionally misrepresented testing results.
- D. The Department may exempt a product at its sole discretion.

**12.5.2 Routine or random audits of sampling by licensees.** The Department may, with or without suspicion of infractions, conduct routine audits of any licensee's sample collection practices, including without limitation:

- A. Reviewing video footage;
- B. Reviewing sample collection and chain-of-custody forms;
- C. Inspecting any samples, including sample collection containers, for compliance with all packaging and labeling requirements of this Rule;
- D. Reviewing tracking system data and transportation manifests;
- E. Requiring a demonstration of the licensee's sample collection practices; and
- F. Requiring testing of batches, at the licensee's expense. Samples collected for testing pursuant to this paragraph must be collected by or in the presence of Department employees.

## 12.6 - Seizure or Confiscation of Marijuana, Marijuana Concentrate or Marijuana Products

**12.6.1. Authority.** The Department may seize, destroy, confiscate or place an administrative hold on any marijuana or marijuana products under, but not limited to, the following circumstances:

- A. Any marijuana or marijuana products not properly logged in inventory records or the tracking system;
- B. Any marijuana or marijuana products that are altered or not properly packaged and labeled in accordance with this Rule in general and Section 11 specifically;
- C. Any marijuana or marijuana products that has been cultivated, harvested, manufactured or transferred in a manner, or otherwise in a form, not compliant with 28-B MRS, this Rule or rules governing the Maine Medical Use of Marijuana Program; or
- D. Improper use, handling, storage, transport, transfer or other possession of samples of marijuana, marijuana concentrate or marijuana products.

**12.6.2. Administrative Holds.** Department officers may order an administrative hold of marijuana or marijuana products to prevent destruction of evidence, diversion or other threats to public safety, while permitting a licensee to retain its inventory pending further investigation, pursuant to the following procedure:

- A. If during an investigation or inspection of a licensee, an employee or agent of the Department develops reasonable grounds to believe certain marijuana plants, marijuana or marijuana products constitute evidence of acts in violation of 28-B MRS or this Rule or constitute a threat to the public health or safety, the employee or agent may issue a notice of administrative hold of any such marijuana plants, marijuana or marijuana products. The notice of administrative hold shall provide a documented description of the marijuana plants, marijuana or marijuana products to be subject to the administrative hold and a concise statement that is promptly issued and approved by the director of the Office of Marijuana Policy or a designee regarding the reasons for issuing the administrative hold.

- B. Following the issuance of a notice of administrative hold, the Department will identify the marijuana plants, marijuana or marijuana products subject to the administrative hold in the tracking system. The licensee shall continue to comply with all tracking requirements.
- C. The licensee shall completely and physically segregate the marijuana plants, marijuana or marijuana products subject to the administrative hold in a limited access area of the licensed premises under investigation, where it shall be safeguarded by the licensee.
- D. While the administrative hold is in effect, the licensee is prohibited from selling, giving away, transferring, transporting or destroying the marijuana plants, marijuana or marijuana products subject to the administrative hold, except as otherwise authorized by this Rule.
- E. While the administrative hold is in effect, the licensee must safeguard the marijuana plants, marijuana or marijuana products subject to the administrative hold, must maintain the licensed premises in reasonable condition according to health, safety and sanitary standards, and must fully comply with all security requirements, including but not limited to all surveillance, lock and alarm requirements detailed in the security plans, 28-B MRS or this Rule.
- F. Nothing herein shall prevent a licensee from voluntarily surrendering marijuana plants, marijuana or marijuana products that is subject to an administrative hold, except that the licensee must follow the procedures set forth in Section 12.4.
- G. Nothing herein shall prevent a licensee from the continued possession, cultivation or harvesting of the marijuana plants, marijuana or marijuana products subject to the administrative hold.
- H. At any time within 30 days after the initiation of the administrative hold, the Department may lift the administrative hold or seek other appropriate relief.

## 12.7 - Marijuana Recalls

The Department may require a licensee to recall any marijuana and marijuana product that the licensee has sold or transferred upon a finding that circumstances exist that pose a risk to public health and safety.

- A. A recall may be based on, without limitation, evidence that:
  - (1) Marijuana or marijuana product contains an unauthorized pesticide(s);
  - (2) Marijuana or marijuana product failed a mandatory test and was not mitigated pursuant to testing protocols;
  - (3) Marijuana or marijuana product is contaminated or otherwise unfit for human use, consumption or application;
  - (4) Marijuana or marijuana product is not properly packaged or labeled; or
  - (5) Marijuana or marijuana product was not cultivated or manufactured by a marijuana establishment.
- B. If the Department finds that a recall is required, the Department:
  - (1) Must notify the public and licensees of the recall;
  - (2) Must administratively hold all affected marijuana or marijuana products in the tracking system;
  - (3) May require a licensee to notify an individual to whom marijuana or a marijuana product was sold; and
  - (4) May require that the licensee destroy the recalled product.



## Section 13 - Fee Schedule

### 13.1 - Payment of Fees

**13.1.1 Application Fees.** An applicant shall pay the application fee required by the Department at the time that the applicant submits an application for licensure to the Department for processing.

**13.1.2 License Fees.** Before issuing an active license, the Department shall invoice the conditional licensee for the applicable fee as determined by the Department pursuant to Title 28-B and this Rule. The Department shall not accept any license fees except pursuant to such invoice.

### 13.2 - Return of Fees Prohibited

Pursuant to 28-B MRS§207(5), the Department may not return to an applicant or licensee or reimburse an applicant or licensee for any portion of an application or license fee paid by the applicant or licensee, regardless of whether the applicant withdraws its application prior to a final decision of the Department on the application, the licensee voluntarily terminates its license pursuant to 28-B MRS and this Rule or the Department suspends or revokes the licensee's license in accordance with the provisions of 28-B MRS and this Rule.

### 13.3 - Individual Identification Card Fees

<u>Card Type</u>	<u>Fee</u>
Original Issuance	\$50.00 plus cost of fingerprinting and criminal history record check
Annual Renewal	\$50.00
Reissuance (lost, stolen, damaged, info change)	\$50.00

### 13.4 - Fingerprinting and Criminal History Record Check Fee

The fee for the fingerprinting and criminal history record checks shall be set by the State Police and/or State Bureau of Identification, in accordance with its usual operations.

### 13.5 - Tracking System Fees

Each licensee is responsible for all costs associated with its use of the tracking system and any associated vendor fees.

### 13.6 - Cultivation Facility Application and License Fees

<u>License Type</u>	<u>Application Fee</u>	<u>Annual License Fee</u> <u>Outdoor Only</u>	<u>Indoor/Both</u>
Tier 1 Cultivation Facility			
Plant-Count-Based	\$100.00	\$9.00/mature plant	\$17/mature plant
Plant-Canopy-Based	\$100.00	\$250.00	\$500.00
Tier 2 Cultivation Facility	\$500.00	\$1,500.00	\$3,000.00
Tier 3 Cultivation Facility	\$500.00	\$5,000.00	\$10,000.00
Tier 4 Cultivation Facility	\$500.00	\$15,000.00	\$30,000.00
For each increase in canopy size		+\$5,000	+\$10,000
Nursery Cultivation Facility	\$60.00	\$350.00	\$350.00

### 13.7 - Other Marijuana Establishment Application and License Fees

<u>License Type</u>	<u>Application Fee</u>	<u>License Fee</u>
Products Manufacturing Facility	\$250.00	\$2,500.00
Marijuana Store	\$250.00	\$2,500.00
Testing Facility	\$250.00	\$1,000.00
Sample Collector	\$100.00	\$250.00

### 13.8 - Other Marijuana Establishment Fees

<u>Fee Type</u>	<u>Application Fee</u>
Transfer of Ownership	\$250.00
Relocation	\$250.00

### 13.9 - Annual Renewal and Late Renewal Application and License Fees

All renewal application and license fees shall be due annually in the amounts listed above in Section 13 of this Rule and submitted in accordance with Section 13.1 of this Rule, except that the Department may require payment of \$2,500.00 in addition to the relevant application fee for renewal applications received less than 30 days prior to the date of expiration of the license. The Department may not accept an application for renewal of a license after the date of expiration of that license.

## Appendix A

### Maine Adult Use Marijuana Program Sample Collection Standard Operating Procedure for Mandatory Testing

#### **Section 1: Purpose**

To explain and standardize the process by which Adult Use Marijuana Program licensees (including without limitation, cultivation facility, products manufacturing facility, marijuana store, sample collector and marijuana testing facility licensees) must collect and transport samples of marijuana, marijuana concentrate and marijuana products for mandatory testing.

#### **Section 2: Compliance Documents**

Sample collection must be done in compliance with this standard operating procedure (SOP), *Adult Use Marijuana Program Rule*, 18-691 CMR, ch. 1 and *Rules for the Certification of Marijuana Testing Facilities*, 18-691 CMR, ch. 5, using techniques described in the Best Practices Guide published by the Department. All licensees collecting samples for mandatory testing must comply with the recordkeeping requirements of Section 3.11 of 18-691, ch.1.

#### **Section 3: Applicable Matrix or Matrices**

This SOP applies to sample collection of marijuana, marijuana concentrate and marijuana products.

#### **Section 4: Scope / Field of Application**

This SOP covers the requirements for sample collection and transportation for mandatory testing under Maine's Adult Use Marijuana Program. All licensees collecting samples of marijuana, marijuana concentrate and/or marijuana products for mandatory testing must collect samples in accordance with this SOP.

#### **Section 5: Summary of Procedure**

This SOP describes sample collection procedures for licensees collecting samples for mandatory testing.

#### **Section 6: Definitions and Acronyms**

1. **Aliquot** is a portion of a sample that is used in an analysis performed by a testing facility.
2. **Analytical Method** is a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.
3. **Best Practices Guide** means the *Best Practices for the Sampling of Adult Use Marijuana* published by the Department available at: <https://www.maine.gov/dafs/omp/adult-use/applications-forms>. All licensees and any employee of a licensee collecting samples of marijuana, marijuana concentrate, or marijuana products for mandatory testing must collect samples in accordance with the best practices described in the Guide.
4. **CDC** means the Maine Center for Disease Control and Prevention, Marijuana Testing Facility Certification Program.
5. **Chain of Custody Form** means a record, either paper-based or electronic, that documents the possession of the samples at the time of receipt by the marijuana testing facility, in accordance with chain of custody protocol prescribed by the marijuana testing facility. This record, at a minimum, must include the sample location, the number and types of containers, the mode of collection, the authorized individual who collected the sample, the date and time of collection, preservation and requested analyses.

6. **Cultivar** means a specific variety of marijuana produced by selective breeding. Also commonly referred to as a “strain” of marijuana.
7. **Decontaminate** or **decontamination** means cleaning tools, equipment, sample preparation areas and any other required areas or surfaces to neutralize or otherwise remove any analyte of interest, filth and any other material that may be reasonably expected to interfere with the integrity of mandatory test results.
8. **Department** means Department of Administrative and Financial Services, Office of Marijuana Policy.
9. **Harvest Batch** means a specific quantity of adult use marijuana harvested from adult use marijuana plants of the same strain, grown under the same conditions, and harvested during a specified period of time from a specified cultivation area within a cultivation facility.
10. **Homogeneity** means the amount of marijuana or marijuana concentrate and cannabinoids within the product being consistent and reasonably equally dispersed throughout the product or each portion of the product or concentrate, or a representative sample. Sample increments for homogeneity testing must be stored and transported in a separate sample collection container from the larger, combined primary sample.
11. **Increment or Sample Increment** means a smaller sample that, together with other increments, makes up the primary sample.
12. **Licensee** means a natural person or business entity licensed pursuant to 28-B MRS, Chapter 1, subchapters 2 and 5 to operate an adult use marijuana establishment.
13. **Primary Sample** means a portion of marijuana or marijuana products collected from a harvest or production batch for testing. Also referred to as a “composite sample”.
14. **Production Batch** means a specific quantity of marijuana concentrate or a marijuana product that is produced during a specified period of time using the same extraction and/or manufacturing method, formulation and/or recipe and standard operating procedure.
15. **Random Sampling** is a procedure in which the selection of sample increments from a batch of marijuana product is based on chance, and every element of the batch has a probability of being selected. Random sampling helps produce representative marijuana samples by eliminating certain types of biases.
16. **Representative Sample** is a sample that accurately reflects the characteristics of the larger batch of marijuana product.
17. **Requester** means a person who submits a request to a licensed marijuana testing facility for State-mandated testing of marijuana or marijuana products.
18. **Sample** means, as applicable, an amount of:
  - a. Marijuana, marijuana concentrate or marijuana product collected from an adult use marijuana establishment for mandatory testing:
    - i. By an employee of a testing facility in accordance with 28-B MRS § 604 and this Rule;
    - ii. By a sample collector, in accordance with 28-B MRS § 604 and this Rule; or
    - iii. By a self-sampler in accordance with 28-B MRS § 604-A and this Rule;
  - b. Marijuana, marijuana concentrate or marijuana product provided to a testing facility by a marijuana establishment or other person for mandatory testing or testing for research and development purposes in accordance with 28-B MRS, chapter 1; or
  - c. Adult use marijuana or adult use marijuana product collected from a licensee by the Department for the purposes of testing the marijuana or marijuana product for quality control purposes pursuant to 28-B MRS §512(2).
19. **Sample Collector** means a person licensed pursuant to this Rule and 28-B MRS, ch. 1 to collect samples of marijuana and marijuana products for testing and to transport and deliver those samples to a testing facility. A sample collector must hold a valid individual identification card (“IIC”).
20. **Self-sampler** or **Self-sampling licensee** means a cultivation facility, products manufacturing facility or marijuana store licensee that collects samples of marijuana, marijuana concentrate and marijuana products for mandatory testing or an employee of a cultivation facility, products manufacturing facility or marijuana store licensee who collects samples of marijuana, marijuana concentrate and marijuana products for that licensee for

mandatory testing. Any individual collecting samples for mandatory testing must hold a valid individual identification card (“IIC”).

21. **Sterilization** or **Sterilize** means cleaning tools, equipment, sample preparation areas and any other required areas or surfaces to destroy and remove all forms of life present in those areas which may be reasonably expected to interfere with the integrity of mandatory test results, specifically, microbiological impurities. In the context of this guide, areas and surfaces that have been cleaned in this manner are “sterile”.

## **Section 7: Safety**

The safety rules of each facility to be sampled will be followed with no exceptions.

Each facility will be responsible for educating any sample collector or employee of a marijuana testing facility collecting samples for mandatory testing of the rules and safety requirements of the facility where samples for mandatory testing are collected.

All safety rules will be followed as dictated by Maine motor vehicle and traffic laws.

Cross-contamination from site to site must be considered during every step of the sample collection process. A sample collector or employee of a marijuana testing facility collecting samples for mandatory testing must decontaminate any reusable tools or equipment used for sample collection at more than one facility or sampling site between sample collection events.

## **Section 8: Pre-Sample Collection Procedure**

The following pre-sample collection procedure applies to self-sampling licensees or sample collector licensees collecting samples for mandatory testing:

- 1) The requester, and if applicable, the sample collector, must keep records of the sample collection information required in Section 3.11 of 18-691, ch. 1.
- 2) The self-sampler or sample collector must contact the marijuana testing facility(ies) conducting analyses for mandatory testing prior to collecting any samples.
- 3) The self-sampler or sample collector licensee must keep records of the instructions given to the self-sampler or sample collector licensee by the marijuana testing facility conducting the analyses.
- 4) The self-sampler or sample collector must collect samples for mandatory testing in accordance with this SOP, the Department’s Best Practices Guide, and instructions given to the licensee by the marijuana testing facility conducting the mandatory analyses.

The following pre-sample collection procedure applies to a marijuana testing facility licensee collecting samples for mandatory testing:

- 1) A marijuana testing facility collecting samples for mandatory testing from an adult use licensee must keep records of the sample collection event in accordance with its site-specific sample collection SOP, if any, and this rule.
- 2) A marijuana testing facility collecting samples for mandatory testing must conduct its sample collection and sample transport in accordance with this SOP, the Department’s Best Practices Guide, and any other requirements of the marijuana testing facility’s quality system.

## **Section 9: Materials Required - Equipment and Supplies**

The following equipment and supplies must be used for sample collection as applicable:

NOTE: Images and examples of the sample collection equipment and supplies listed below are included in the Department’s Best Practices Guide.

- Spatulas (disposable or stainless steel).
- Forceps (disposable or stainless steel).

- Field balance (capable of 0.01g measurements).
- Calibrated verification weights appropriate to verify accuracy of field balance.
- Mylar bags / amber jars / or equivalent, certified clean (for metals, water activity and moisture content, filth and foreign matter analyses).
- Amber jars or equivalent, certified clean (for pesticide and potency analyses).
- Borosilicate VOA vials or equivalent, certified clean (for residual solvent analysis).
- Sterile Amber Bottles/ Whirl-Pak bags/ or equivalent (for microbial analyses).
- NIST traceable thermometer or infrared thermometer gun calibrated every 6 months.
- Coolers and ice packs or other appropriate refrigeration to maintain collected samples at required temperature, as appropriate.
- A transport manifest generated by the inventory tracking system for tracking all collected samples from the sample collection site to the marijuana testing facility.
- Pens with indelible ink.
- Security tamper evident tape labeled with “For Testing Purposes Only.”
- Sample labels.
- Equipment logbook.
- Disposable 1mL (or larger) syringes or pipettes (for liquid transfer).
- Sterile/sanitized nitrile, latex, or rubber gloves.
- Teri-Wipes, Clorox wipes or equivalent.
- Transport container for marijuana material that is stored at room temperature.
- Transport container that meets any matrix-specific storage requirements.

NOTE: For sample collectors or employees of marijuana testing facilities, sample collection tools and supplies *may* be provided by the requester at the location to be sampled; this will minimize the possibility of outside contamination. The requester may also supply all necessary sample collection equipment and sample containers. The requester should receive guidance from the testing facility regarding what types and sizes of sample collection containers should be used. The testing facility may also ship or drop off sample collection containers to the requester in preparation of the sampling event.

Any self-sampler, sample collector or employee of a marijuana testing facility that uses re-usable sample collection tools and equipment must keep a log of cleaning and sterilization for every re-usable sample collection tool and equipment used.

#### **Section 10: Reagents and Standards**

The following reagents or standards may be used to clean reusable sample collection tools and equipment:

- Cleaning supplies – solvent, bleach, 70% ethanol, etc.
- Deionized Water

The self-sampler, sample collector or employee of a marijuana testing facility that cleans reusable sample collection tools and equipment will be responsible for keeping a log of cleaning and supplies used.

NOTE: Some cleaning supplies, such as alcohol or ethanol, are solvents which are tested for pursuant to Maine’s mandatory testing requirements. To that end, it is important that reusable sample collection tools that are used to collect sample increments for residual solvent testing are not cleaned using alcohol or ethanol.

#### **Section 11: Sample collection, preservation, shipment and storage**

Further guidance on how to perform the sample collection procedures outlined below, including selection of appropriate sample collection equipment and tools based upon matrix type, collection of random sample increments, etc. is included in the Department’s Best Practice Guide.

### **Representative Sampling**

When sampling a batch, the self-sampler, sample collector, or employee of a marijuana testing facility collecting samples for mandatory testing shall check for any signs of non-uniformity. Some obvious indicators may be different types or sizes of containers, variations in marks and labels, or mixed batch numbers. During sample collection, the self-sampler, sample collector, or employee of a marijuana testing facility shall look for differences in the usable marijuana being sampled such as color, shape, size, and treatment. The batch must be uniform for all factors that appear on the label; hence, variations in the product may indicate nonuniformity in the batch and any sample collected may not be representative for testing. The self-sampler, sample collector, or employee of a marijuana testing facility shall note these anomalies in the sample collection records kept by the licensee in accordance with Section 3.11 of 18-691 CMR, ch.1.

General procedural guidelines that apply to all sample collection include:

- a. The self-sampler, sample collector or employee of a marijuana testing facility must be given access to the entire batch.
- b. The self-sampler, sample collector or employee of a marijuana testing facility must use of appropriate sampling equipment.
- c. The self-sampler, sample collector or employee of a marijuana testing facility must consistently follow sample collection procedures based upon matrix type.
- d. The self-sampler, sample collector or employee of a marijuana testing facility must take equal portions for each sample increment.
- e. The self-sampler, sample collector or employee of a marijuana testing facility must randomly select sample increments throughout the batch to ensure a representative sample.
- f. The self-sampler, sample collector or employee of a marijuana testing facility must obtain at least a minimum number of sample increments.
- g. The self-sampler, sample collector or employee of a marijuana testing facility must record all observations and procedures used while collecting the sample increments in the sample collection records kept in accordance with Section 3.11 of 18-691 CMR, ch.1.
- h. All samples collection containers must be sealed with tamper evident seals in front of a witness, who must be an individual identification cardholder employed by the requester. Both the self-sampler, sample collector, or employee of a marijuana testing facility and the witness must initial and record the time and date of sealing on the tamper evident seal(s) and must further sign and date an attestation in accordance with the sample collection recordkeeping requirements of Section 3.11 of 18-691 CMR, ch.1.

### **Random Sampling**

Sample increments should be randomly selected from different locations within the batch, which could be comprised of a container or set of containers, including prepackaged units of marijuana products. Random samples are determined by using the procedure below.

- a. Determine the size of the batch and how many containers make up the batch.
- b. Determine the number of samples needed based on the batch size.
- c. Count the number of containers in batch.
- d. Randomly select the containers to be sampled. The self-sampler, sample collector, or employee of a marijuana testing facility must have a random number generator or other means of randomly selecting sample increment units.

- e. Record the container numbers to be sampled in the sample collection records.
- f. Take the same approximate weight from each container that is sampled.

**Sampling a Batch of Marijuana Flower, Trim, or Pre-rolled Marijuana Cigarettes**

A harvest batch of marijuana flower, trim, or pre-rolled (uninfused) marijuana cigarettes must be sampled in accordance with the following table based upon the weight of the harvest batch after it has been “dried”, “cured” or is otherwise deemed ready for transfer by the requester.

<b>Harvest Batch Weight Range*</b>	<b>Composite Sample Amount*</b>
≤ 2.5 kg	6.5 g (13 increments of 0.5 grams each)
2.5 kg < w ≤ 5 kg	9.5 g (19 increments of 0.5 grams each)
5 kg < w ≤ 7.5 kg	16 g (16 increments of 1 gram each)
7.5 kg < w ≤ 10 kg	22 g (22 increments of 1 gram each)

\*For harvest batches in excess of 10 kg, the harvest batch must be divided and sampled in batches of 10 kg or less.

1. Weigh the empty sample container(s) and record the weight in the sample collection records.
2. Locate the batch to be sampled.
3. Review the container label information for harvest lot number, producer, and other pertinent information and match to the sampling request or transport information, as applicable.
4. Record the batch size and number of containers in the batch as reported by the requester.
5. Select the appropriate sampling tool to ensure that it reaches all portions of the container.
6. Visually inspect each test sample increment to assess uniformity, if non-uniformity is identified, record observation in the sample collection record. It is expected there will be variable sizes and appearance of flower material.
7. For harvest batches of marijuana flower, trim or pre-rolled marijuana cigarettes stored in storage containers such as plastic tubs, the harvest batch containers shall be sampled in a spatial pattern to ensure that each region of the container has been sampled.
8. When collecting sample increments, approximately equal amounts of product are to be taken with each increment and from each container. Care must be taken by the self-sampler, sample collector, or employee of a marijuana testing facility to not damage any portion of the product that is being sampled or any portion of the product that remains.
9. Collect sample increments (minimum of twelve) from random locations as determined above throughout the sample batch into a large sterile container. Sample increments for homogeneity testing must be placed in separate, sterile containers.
10. The sample increments should be collected, and each increment should be packaged in accordance with the requirements identified by the marijuana testing facility(ies) conducting the mandatory analyses.
11. Combine all sample increments to form the composite sample(s) as directed by the marijuana testing facility. Please note: sample increments to analyze homogeneity will require separate sample containers.
12. Weigh and record the weight of the sample(s) in the sample collection record.
13. Seal and label the composite sample(s). The self-sampler, sample collector or employee of a marijuana testing facility must seal each container holding sampled material using tamper evident seals bearing a unique tamper seal number in the presence of a witness who is an IIC-holder employed by the requester.



Both the self-sampler, sample collector or employee of a marijuana testing facility and the witness must initial and date the seal and sign the required attestation.

14. Complete the sample collection record while at the sampling location and generate an appropriate transport manifest and test sample labels in the inventory tracking system. Make sure all notes, containers sampled, and all field information is appropriately recorded.

**Sampling Unpackaged Servings or Prepackaged Retail Units of Marijuana Concentrate and Marijuana Products**

For unpackaged or prepackaged samples, based on batch size, the required number of increments collected from each batch is listed in the following chart. Each sample increment is one serving of an unpackaged retail unit or one prepackaged unit for retail sale (i.e. one unpackaged serving or one pre-packaged retail unit containing multiple servings is one sample increment).

# of Unpackaged servings or Pre-packaged Units in Production Batch*	Number of Sample increments**	Where to take samples:
≤ 50	2 units	One from beginning and one from end
51 -150	3 units	Beginning(1), Middle(1), End(1)
151 - 500	5 units	Beginning(2), Middle (2), End(1)
501-1200	8 units	Beginning (3), Middle (2), End (3)
1201 -3200	13 units	Beginning (4), Middle (5), End (4)
3201-10000	20 units	Beginning (6), Middle (7), End (7)

\*For production batches in excess of 10,000 units, the production batch must be divided and sampled in batches of 10,000 units or less.

\*\*Depending on the weight of the prepackaged samples, more than the listed number of increments may need to be taken as directed by the marijuana testing facility.

The increments sampled should cover the range of the batch. See table above.

1. Weigh the empty sample container(s) and record the weight in the sample collection record.
2. Locate the batch to be sampled.
3. Review the container label information for production batch number, producer, and other pertinent information and match to the sampling request or transport information.
4. Record the batch size and number of containers in the batch as reported by the requester.
5. For unpackaged sample increments, select the appropriate sampling tool to ensure that it reaches all portions of the container.
6. Visually inspect each test sample increment to assess uniformity, if non-uniformity is identified, record observation in the sample collection record
7. Randomly select unpackaged or prepackaged sample increments from the beginning third, middle third, and end third of the container(s) holding the unpackaged servings or prepackaged retail units. For unpackaged sample increments, sample increments for homogeneity testing must be placed in separate, sterile containers.
8. Weigh and record the weight of the sample(s) in the sample collection record.

9. Seal and label the composite sample(s). The self-sampler, sample collector or employee of a marijuana testing facility must seal each container holding sampled material using tamper evident seals bearing a unique tamper seal number in the presence of a witness who is an IIC-holder employed by the requester. Both the self-sampler, sample collector or employee of a marijuana testing facility and the witness must initial and date the seal and sign the required attestation.
10. Complete the sample collection record while at the sampling location and generate an appropriate transport manifest and test sample labels in the inventory tracking system. Make sure all notes, containers sampled, and all field information is appropriately recorded.

**Sampling Shatter/Wax/Slab Concentrates**

For marijuana concentrate, based on batch weight, the required number of sample increments is listed in the following chart.

<b>Production Batch Weight*</b>	<b>Composite sample amount</b>
≤ 0.5 kg	6 g (12 increments of 0.5 grams each)
0.5 kg < w ≤ 1 kg	8 g (16 increments of 0.5 grams each)
1 kg < w ≤ 1.5 kg	10 g (20 increments of 0.5 grams each)
1.5 kg < w ≤ 2 kg	12 g (24 increments of 0.5 grams each)
2 kg < w ≤ 5 kg	14 g (28 increments of 0.5 grams each)

\*For production batches in excess of 5 kg, the production batch must be divided and sampled in batches of 5 kg or less.

Note: The shatter, wax, or other concentrate slab may have varying degrees of thickness; thus, the amounts of cannabinoids or potential residual solvent(s) may vary with the thickness of the concentrate. It is important that the samples taken are equivalent from each region of thickness to provide a representative sampling of the overall product. The thinner portions of the concentrate slab will have more surface area exposed allowing for a higher rate of diffusion of residual solvents from the wax or shatter than the thicker portions.

1. Weigh the empty sample container(s) and record the weight in the sample collection record.
2. Locate the batch to be sampled.
3. Review the container label information for production batch number, producer, and other pertinent information and match to the sampling request or transport information.
4. Record the batch size and number of containers in the batch as reported by the requester.
5. Identify three (3) thicknesses or regions to the product.
6. Using spatula or forceps, collect the determined number of sample increments needed from each region of the overall production batch to meet the minimum number of increments required above.
7. Collect sample increments (minimum of twelve) from random locations throughout the sample batch into a container. Sample increments for homogeneity testing must be placed in separate, sterile containers.
8. Weigh and record the weight of the sample(s) in the sample collection record..
9. Seal and label the sample containers. The self-sampler, sample collector or employee of a marijuana testing facility must seal each container holding sampled material using tamper evident seals bearing a unique tamper seal number in the presence of a witness who is an IIC-holder employed by the requester. Both the self-sampler, sample collector or employee of a marijuana testing facility and the witness must initial and date the seal and sign the required attestation.

- Complete the sample collection record while at the sampling location and generate an appropriate transport manifest and test sample labels in the inventory tracking system. Make sure all notes, containers sampled, and all field information is appropriately recorded.

### Sampling Oils, Tinctures, and Other Liquids

Unless already prepackaged into individual retail units (see above), sample increments of oils or tinctures will be collected from container(s) holding the production batch of the oil or tincture in accordance with the following chart.

Production Batch Weight*	Composite Sample Amount
≤ 0.5 kg	6 g (12 increments of 0.5 grams each)
0.5 kg < w ≤ 1 kg	8 g (16 increments of 0.5 grams each)
1 kg < w ≤ 1.5 kg	10 g (20 increments of 0.5 grams each)
1.5 kg < w ≤ 2 kg	12 g (24 increments of 0.5 grams each)
2 kg < w ≤ 5 kg	14 g (28 increments of 0.5 grams each)

\*For production batches in excess of 5 kg, the production batch must be divided and sampled in batches of 5 kg or less.

Note: The container holding the oil or tincture shall be inverted a minimum of three times to ensure that the oil or tincture is homogenous. Each inversion shall be complete, i.e., the oil shall flow to the cap of the container and back to the base three times. Viscous substances such as oil may need to be allowed to come to room temperature before inversion occurs. A self-sampler, sample collector or employee of a marijuana testing facility may allow viscous substances to come to room temperature to promote inversion only if doing so will not promote microbial growth during the sample collection process. The requester will inform the self-sampler, sample collector, or employee of a marijuana testing facility whether allowing the viscous substance to come to room temperature would be expected to promote microbial growth in the substance.

- Weigh the empty sample container(s) and record the weight in the sample collection record.
- Locate the batch to be sampled.
- Review the container label information for production batch number, producer, and other pertinent information and match to the sampling request or transport information.
- Record the batch size and number of containers in the batch as reported by the requester.
- Invert oil as described above.
- Weigh and record the weight and of the production batch in the sample collection record.
- Using a 0.5 mL, 1.0 mL, 10.0 mL or other appropriate sterile disposable pipette<sup>2</sup> or syringe, remove the sample amount for each sample to be collected into sterile vial or other appropriate container as directed by the marijuana testing facility. The sample increments (minimum of twelve) shall be taken at different depths of the oil or tincture to ensure that the oil or tincture is sampled representatively. The top third of the container, middle third of the container, and bottom third of the container must be sampled. Sample increments for homogeneity testing must be placed in separate, sterile containers.
- Weigh and record the weight of the sample(s) in the sample collection record.
- Seal and label the sample containers. The self-sampler, sample collector or employee of a marijuana testing facility must seal each container holding sampled material using tamper evident seal bearing a unique tamper seal number in the presence of a witness who is an IIC-holder employed by the requester. Both the self-sampler, sample

<sup>2</sup>Licenseses must ensure that samples of liquid or other viscous materials are measured by weight and not volume.

collector or employee of a marijuana testing facility and the witness must initial and date the seal and sign the required attestation.

10. Complete the sample collection record while at the sampling location and generate an appropriate transport manifest and test sample labels in the inventory tracking system. Make sure all notes, containers sampled, and all field information are appropriately record.

Note: Sample amounts collected will be no less than the minimum sample size required by Table 5.5-A in *Rules for the Certification of Marijuana Testing Facilities*, 18-691 CMR, ch.5. That table is reproduced in sections above. If there is a discrepancy between the tables above and Table 5.5-A, the table in the rule controls. A testing facility may require that additional sample material be taken for quality control samples.

#### **Section 12: Sample Transportation and Receipt**

The licensee collecting samples for mandatory testing must transport those samples to the marijuana testing facility(ies) conducting the analyses, except that a marijuana testing facility may offer a service to retrieve samples collected from a self-sampler at the marijuana establishment where the samples were collected. All samples must be accompanied by a transport manifest generated by the METRC inventory tracking system in accordance with the requirements of Section 4 of the *Adult Use Marijuana Program Rule* 18-691 CMR, ch.1.

Except as noted in *Sampling Oils, Tinctures and Other Liquids*, samples must be maintained at all times during collection and transport at the temperature at which the marijuana, marijuana concentrate or marijuana product is stored to prevent microbial growth. The self-sampler, sample collector or employee of a marijuana testing facility must provide appropriate refrigeration during transport for samples requiring refrigeration.

Self-samplers and sample collectors must deliver samples to a marijuana testing facility in accordance with any instructions or restrictions indicated by the marijuana testing facility during its pre-sampling discussion with the self-sampler or sample collector.

Marijuana testing facilities must receive and account for all samples for mandatory testing in accordance with the testing facility's SOP regarding sample receipt. A testing facility must inspect all samples upon receipt and promptly notify the requester, and if applicable, the sample collector, if samples are rejected and the reason for such rejection and record the same in the sample collection record and in the inventory tracking system.

#### **Section 13: Recording Sampling Events in METRC Inventory Tracking System**

Self-samplers, sample collectors, and employees of a marijuana testing facility must track all inventory, including sample collection events, in accordance with the user guide provided by the Department's required inventory tracking system.

#### **Section 14: Quality Control**

A marijuana testing facility may require any licensee to collect and remit additional sample increments or analytic blanks (e.g. equipment, trip, field blanks) as required by the testing facility's quality system.

A marijuana testing facility must ensure that all samples for organic chemical analysis (i.e. residual solvent analysis) are accompanied by a trip blank. Unless the marijuana testing facility is conducting sample collection, the marijuana testing facility will provide trip blanks to the self-sampler or sample collector and advise the self-sampler or sample collector on the handling and return of the trip blank for quality control purposes. Trip blanks analyzed must be less than the reporting level of the associated test(s). A marijuana testing facility must analyze the trip blanks in the event that a sample fails mandatory testing for organic chemical analyses.

At all times, licensees, including marijuana testing facilities, must comply with their Department-approved standard

operating procedures, including this SOP and the licensee’s quality control system.

**Section 15: Calibration and Standardization**

The field balance must be initially verified as within the standards listed in the National Institute of Standards and Technology (NIST) Handbook by a scale dealer or repairman registered pursuant to 10 MRS §2651, and calibrated on a yearly basis.

The field verification weights must be calibrated on a yearly basis.

The field balance must be verified each day it is use with weights that bracket the range of use. These verifications will be documented and recorded in the equipment log maintained by the self-sampler, sample collector or employee of a marijuana testing facility collecting samples for mandatory testing.

**Section 16: Waste Management**

All waste must be disposed of in accordance with the *Adult Use Marijuana Program Rule*, 18-691 CMR, ch.1.

**Section 17: Documentation**

The following Quality Records shall be generated and managed for every sample collected:

Required Record	Form Steward	Copies to be Retained By
Sample collection record, to be completed by licensee collecting samples	Licensee collecting samples for mandatory testing	Licensee collecting samples for mandatory testing
Transport Manifest, generated by METRC, to accompany every sample from sampling site to marijuana testing facility	Office of Marijuana Policy	3 copies per <i>Adult Use Marijuana Program Rule</i>
Chain-of-Custody Form, per marijuana testing facility SOP	Marijuana Testing Facility Licensees	Per marijuana testing facility SOP as applicable

**Section 18: Sample Collector Signatures**

By signing below the self-sampler, sample collector, or employee of a marijuana testing facility collecting samples for mandatory testing affirms that they have read, understand and agree to follow this current version of the SOP. They also agree that they have read and understood the *Adult Use Marijuana Program Rule*, 18-691 CMR, ch. 1, *Rules for the Certification of Marijuana Testing Facilities*, 18-691 CMR, ch. 5, this SOP and the Best Practices Guide.

Name \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_