



ADULT USE MARIJUANA PROGRAM RULE

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

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

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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) CO₂;
 - (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.¹ 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:

¹ 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>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"> ● Pesticides ● Metals ● Water Activity and Moisture Content* <p>Additional Testing Required for Production Batches to be packaged and transferred for sale to consumers:</p> <ul style="list-style-type: none"> ● Residual solvents* ● Microbiological Impurities (Bacteria, Yeasts and Mold) ● Filth and Foreign Material ● Cannabinoid Profile*
<p>Marijuana Concentrate</p>	<p>All Production Batches:</p> <ul style="list-style-type: none"> ● Residual Solvents ● Pesticides ● Metals <p>Additional Testing Required for Production Batches to be packaged and transferred for sale to consumers:</p> <ul style="list-style-type: none"> ● Microbiological Impurities (Bacteria, Yeasts and Mold) ● Filth and Foreign Material ● Cannabinoid Profile ● Homogeneity
<p>Marijuana Product*</p>	<p>All Production Batches to be packaged and transferred for sale to consumers:</p> <ul style="list-style-type: none"> ● Microbiological Impurities (Bacteria, Yeasts and Mold) ● Filth and Foreign Material ● Cannabinoid Profile ● Water Activity ● Homogeneity ● Metals

*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.

Harvest Batch Weight Range*	Composite Sample Amount*
≤ 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.

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 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 pipette² 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

²Licenseses 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: _____

STATE OF MAINE**RULES FOR THE CERTIFICATION OF MARIJUANA TESTING
FACILITIES****CODE OF MAINE RULES****CHAPTER 5**

Department of Administrative and Financial Services

11 State House Station

Augusta, Maine 04333-0011

Effective date: September 18, 2020

SUMMARY STATEMENT

This rule is promulgated by the Maine Department of Administrative and Financial Services (DAFS) after consultation with the Department of Health and Human Services (DHHS), Center for Disease Control and Prevention (CDC), and the Department of Agriculture, Conservation and Forestry to establish the certification process for testing facilities analyzing marijuana and marijuana products. This rule is intended to protect public health by establishing standards for testing marijuana and providing assurance that results of testing for contaminants do not exceed the maximum level standards where testing is required.

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General

This rule is promulgated to establish the requirements for certification by the Maine Center for Disease Control and Prevention of marijuana testing facilities licensed under Maine's Adult Use Marijuana Program administered by the Office of Marijuana Policy, Department of Administrative and Financial Services, in order to mitigate potential threat to public health and safety by establishing minimum standards and procedures for the operation of marijuana testing facilities to provide information to consumers of adult use marijuana and marijuana for medical use.

The activities described in this rule may be considered a violation of federal law. Persons cultivating, manufacturing, testing, selling, purchasing or otherwise receiving adult use marijuana or marijuana for medical use, or marijuana products derived from the same, may be subject to federal sanctions for what may otherwise be considered authorized conduct in the State of Maine, and compliance with this rule does not exempt licensees, their employees or customers from possible federal prosecution. Neither the Department of Administrative and Financial Services nor the Department of Health and Human Services is responsible for the actions of licensed and/or certified marijuana testing facilities under this rule.

Section 1 – Marijuana Testing Facility Certification Program Established

Section 1.1 – Statutory Authority

The Department of Administrative and Financial Services (referred to heretofore as DAFS), acting through its Office of Marijuana Policy (referred to heretofore as OMP), has promulgated the following rule on an emergency basis in accordance with the statutory authority provided in 28-B MRS §104, in order to mitigate potential threat to public health and safety following emergency legislative action, for the purpose of implementing, administering and enforcing the provisions of 28-B MRS, chapter 1. The Department of Health and Human Services (referred to heretofore as DHHS), acting through its Center for Disease Control and Prevention (referred to heretofore as the CDC) shall implement the certification program described herein in accordance with the statutory authority provided in 22 MRS § 569.

Section 1.2 - Department Authority

DAFS and DHHS, through the CDC, may enforce this Rule and any relevant provisions of Titles 4, 5, 22 and 28-B, and any other general statutes, laws, executive orders or subsequently passed legislation. DAFS shall set licensing fees in accordance with 28-B MRS § 207, and CDC shall set certification and technology fees in accordance with 22 MRS § 569. DAFS, DHHS or an agent thereof shall have the authority to inspect, during operating hours, times of apparent activity or any other reasonable time, any marijuana testing facility and its business records. DAFS shall further have the authority to inspect, during operating hours, times of apparent activity or any other reasonable time, vehicles used to transport marijuana or marijuana products to a marijuana testing facility. Approval by the CDC of the plans, standard operating procedures, financial and business arrangements or other documents and information provided for certification by the CDC during the certification process does not constitute approval by DAFS for the purposes of licensure pursuant to the *Adult Use Marijuana Program Rule*, 18-691 CMR, ch. 1.

Section 1.3 - Communication with DAFS and/or DHHS

1.3.1 Written Communications. If an applicant or licensee is required to or elects to submit anything in writing to DAFS or DHHS, unless otherwise prescribed by DAFS or DHHS, the applicant or licensee may submit the writing to DAFS or DHHS 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 DAFS or DHHS, regardless of method used to submit the writing, by 5 p.m. Eastern Time.

Section 1.4 – Definitions

1. **A_w** means the water activity, which is the partial vapor pressure of water in a substance divided by the standard state partial vapor pressure of water. It is a measure of the quantity of water in a product that is available, and therefore capable of, supporting bacteria, yeasts and fungi.
2. **Acceptance criteria** means the specified limits placed on characteristics of an item, process or service that are used to determine data quality as defined in methods, rules or regulations.
3. **Accredited** means to be recognized as conforming to a standard by an accrediting organization, such as ISO/IEC 17025.
4. **Accredited college or university** is a college or university accredited by a regional or national accrediting agency recognized by the United States Department of Education.
5. **Accuracy** means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are a result of sampling and analytical operations; a data quality indicator.
6. **Action level** is the threshold value for determining whether a sample passes or fails an analytical test.
7. **Adult use marijuana** means marijuana cultivated, manufactured, distributed or sold by a marijuana establishment.
8. **Adult use marijuana product** means a marijuana product that is manufactured, distributed or sold by a marijuana establishment.
9. **Aliquot** is a portion of a sample that is used in an analysis performed by a testing facility.
10. **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.
11. **Analyte** is a chemical, compound, element, bacteria, yeast, fungus or toxin that is identified or measured.
12. **Analytical batch** means a group of samples that is prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents.
13. **Analytical method** is a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.
14. **AOAC International** means Association of Official Agricultural Chemists International, a non-profit scientific association that creates, validates and publishes reliable analytical test methods.
15. **Apparent activity** means any sight, sound, smell or other indication that persons are present at a marijuana establishment.
16. **Applicant** means a person who submits to certification by the Maine CDC as part of an application for a license to operate a marijuana testing facility issued by OMP.
17. **Approved proficiency testing provider** means a provider of proficiency testing samples whom the certification officer has deemed to meet the requirements of this Rule.

18. **Assessment** means the evaluation process used to measure or establish the performance effectiveness and conformance of a testing facility and/or its systems to defined criteria and standards and requirements of testing facility certification.
19. **Audit** means a systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management and reporting aspects of a system to determine whether quality assurance, quality control and technical activities are being conducted as planned. An audit is conducted to determine whether these activities will effectively achieve quality objectives.
20. **Batch** means:
 - a. A harvest batch; or
 - b. A production batch.
21. **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.
22. **Best Practices Guide** means the *Best Practices for the Sampling of Adult Use Marijuana*, published by the Department, incorporated by reference in 18-691 CMR, ch.1. 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.
23. **Bias** means the systematic or persistent distortion of a measurement process, which causes errors in one direction, resulting in the expected sample measurement being different from the sample's true value.
24. **Cannabinoid** is a chemical compound that is unique to, and derived from, marijuana.
25. **Calibration** means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system or values represented by a material measure or a reference material, and the corresponding values realized by standards.
 - a. In calibration of support equipment, the values realized by standards are established using reference standards that are traceable to the International System of Units (SI).
 - b. In calibration, per methods, the values realized by standards are typically established using reference materials that are either purchased by the testing facility with a certificate of analysis or purity or prepared by the testing facility using support equipment that has been calibrated or verified to meet specifications.
26. **Calibration curve** means the mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.
27. **Calibration standard** means a substance or reference material used for calibration.
28. **CAS number** is the unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service (CAS).
29. **CBD** is cannabidiol, CAS number 13956-29-1.
30. **CBDA** is cannabidiolic acid, CAS number 1244-58-2.
31. **Certificate of analysis** means the report prepared for the requester and OMP about the analytical testing performed and results obtained by the testing facility.

32. **Certification** means the process by which an agency or organization evaluates and recognizes a testing facility as meeting certain predetermined qualifications or standards, thereby certifying the testing facility. The Department of Health and Human Services is responsible for certification of all testing facilities.
33. **Certification officer** means the person designated by the Department of Health and Human Services to manage certification of testing facilities.
34. **Certified reference material** means reference material, accompanied by a certificate, having a value, measurement of uncertainty and stated metrological traceability chain to a national metrology institute.
35. **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.
36. **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.
37. **Colony forming unit (CFU)** means a unit of measurement of estimated number of bacteria or fungal cells in a sample.
38. **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.
39. **Corrective action** means an action taken by the marijuana testing facility to eliminate or correct the causes of an existing nonconformance to prevent the recurrence of the nonconformance.
40. **Corrective action plan** means a report, including specific corrective actions and a specific date of completion, generated in response to deficiencies or findings of non-compliance.
41. **Cultivar** means a specific variety of marijuana produced by selective breeding. Also commonly referred to as a “strain” of marijuana.
42. **Cultivation facility** means a facility licensed under Title 28-B and 18-691 CMR, ch. 1 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.
43. **Cultivator** means a cultivation facility licensed under 28-B MRS, Chapter 1, subchapters 2 and 3 or a person, qualifying patient, exempt caregiver, registered caregiver or registered dispensary that is authorized under 22 MRS, chapter 558-C to cultivate marijuana.
44. **Deficiency** means a failure of the testing facility to meet any one of the requirements in this rule.
45. **Demonstration of capability** means a procedure to establish the ability of the analyst to generate acceptably accurate and precise analytical results.

46. **Department of Administrative and Financial Services (DAFS)** means the Maine Department of Administrative and Financial Services. DAFS includes the Office of Marijuana Policy (OMP), which licenses adult use marijuana establishments, including marijuana testing facilities, and registers medical marijuana program participants including patients, registered caregivers, registered dispensaries, registered manufacturing facilities and registered inherently hazardous extraction facilities.
47. **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.
48. **Disciplinary action** means any action taken by the CDC to limit, suspend, revoke, or deny the certification of a marijuana testing facility as a result of the marijuana testing facility's violation or other nonconformance with this rule, 28-B MRS, chapter 1, or other rules promulgated by DHHS or DAFS.
49. **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.
50. **Exempt caregiver** means a medical marijuana caregiver who is exempt from the registration requirements of 22 MRS § 2425-A.
51. **Facility director** means the individual who is legally authorized to direct the activities of a testing facility and who commits the appropriate resources to comply with this rule.
52. **Field of testing** means those programs, matrices, methods or analyte combinations, for which certification is offered.
53. **Finished plant material** means marijuana that has been trimmed and dried. Trimming includes removing the leaves immediately subtending the buds and any dead leaves or stems.
54. **Foreign material** means any physical contaminant or filth, including without limitation hair, insects, feces, packaging contaminants and manufacturing waste and by-products.
55. **Full active license** means a license issued by the Department of Administrative and Financial Services, Office of Marijuana Policy to a marijuana testing facility that has received CDC full certification and ISO/IEC 17025:2017 or most recent version 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.
56. **Full certification** means certification granted by the CDC to a marijuana testing facility that has received ISO/IEC 17025:2017 or most recent version accreditation and meets all other requirements of this Rule and authorizing it to seek an active license from DAFS.
57. **Harvest batch** means a specific quantity of adult use marijuana harvested from adult use marijuana plants of the same cultivar, grown under the same conditions, and harvested during a specified period of time from a specified cultivation area within a cultivation facility.
58. **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.
59. **Increment or sample increment** means a smaller sample that, together with other increments, makes up the primary sample.

60. **ISO/IEC 17025:2017** or most recent version means the general requirements for the competence of testing and calibration laboratories issued in 2017 (or more recent) joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission.
61. **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.
62. **Limit of detection (LOD)** means an estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect.
63. **Limit of quantitation** means the minimum level, concentration or quantity of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.
64. **Manufacturer** means a manufacturing facility licensed under 28-B MRS, Chapter 1, subchapter 2 or a person, qualifying patient, registered caregiver or registered dispensary that is legally allowed to manufacture under 22 MRS, chapter 558-C.
65. **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.
66. **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 a 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.
67. **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.
68. **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.
69. **Marijuana product** means a product composed of marijuana or marijuana concentrate and other ingredients that is intended for use or consumption. “Marijuana product” includes without limitation an edible marijuana product, a marijuana ointment and a marijuana tincture. Marijuana product does not include marijuana concentrate.
70. **Marijuana store** means a facility licensed under Title 28-B and 18-691 CMR, ch. 1 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.
71. **Marijuana 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.
72. **Marijuana trim** means any part of a marijuana plant, whether processed or unprocessed, that is not marijuana flower or a marijuana seed.
73. **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.

74. **Matrix** means the component or substrate that contains the analyte of interest.
75. **Matrix spike** means a sample prepared by adding a known quantity of analyte and subjecting the sample to the entire analytical procedure to determine the ability to recover the known analyte or compound. The spiked concentration must be at a low to mid-range concentration of the calibration curve for the target analyte.
76. **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.
77. **Method blank** means an analyte-free matrix, to which all reagents are added in the same volumes or proportions as are used in sample preparation and is processed in exactly the same manner as the samples.
78. **Method detection limit** means the minimum measured concentration of a substance that can be reported with 99-percent confidence that the measured analyte is distinguishable from method blank results.
79. **Moisture content** means the percentage of water in a sample, by weight.
80. **Mycotoxin** means any toxic substance produced by a fungus and especially a mold.
81. **National Institute of Standards and Technology (NIST)** means a federal agency of the United States Department of Commerce's Technology Administration.
82. **Nonconformance or noncompliance** means a failure of a testing facility to meet any requirement in this rule.
83. **Non-target organism** means an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method.
84. **Percent recovery** means the percentage of a measured concentration relative to the added (i.e. spiked) concentration in a reference material, matrix spike sample or matrix spike duplicate. A testing facility shall calculate the percent recovery by dividing the sample result by the expected result then multiplying the quotient by 100.
85. **Pesticide** means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest; any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant; and any nitrogen stabilizer. It does not include multicellular biological controls such as mites, nematodes, parasitic wasps, snails or other biological agents not regulated as pesticides by the U.S. Environmental Protection Agency.
86. **Plant growth 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 growth regulator" does not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants or soil amendments.
87. **Practical experience** means hands-on post-secondary-education testing facility experience, using equipment, instruments, kits and materials routinely found in a testing facility.
88. **Precision** means the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision serves as a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.
89. **Preservation** means any conditions under which a sample must be kept to maintain chemical and/or biological integrity prior to analysis.

90. **Primary sample** means a portion of marijuana or marijuana products collected from a harvest or production batch for testing. Also called a “composite” sample.
91. **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.
92. **Products manufacturing facility** means a facility licensed under Title 28-B and 18-691 CMR, ch. 1 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
93. **Proficiency test** means an evaluation of a testing facility’s performance against pre-established criteria, by means of inter-testing facility comparisons of test measurements.
94. **Proficiency test sample** means a sample prepared by a party independent of the testing facility tasked with evaluating the sample, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing facility evaluating the sample and its personnel.
95. **Provisional certification** means the process by which CDC evaluates and recognizes a marijuana testing facility as meeting the requirements of this Rule with the exception ISO/IEC 17025 accreditation, for which an application must be pending.
96. **Provisional active license** means a license issued by DAFS to a marijuana testing facility that has received CDC provisional certification and has applied for, but not yet received, ISO/IEC 17025:2017 or most recent version 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.
97. **Proficiency testing** means a way to evaluate a testing facility’s performance under controlled conditions relative to a given set of criteria, through analysis of unknown samples provided by an external source.
98. **Proficiency testing program** means the aggregate of providing rigorously controlled and standardized samples to a testing facility for analysis, reporting of results, statistical evaluation of results and the collective demographics and results summary of all participating testing facilities.
99. **Proficiency test sample** means a sample, the composition of which is unknown to the testing facility, provided to test whether the testing facility can produce analytical results within the specified acceptance criteria.
100. **Protocol** means the detailed written procedure for field and/or testing facility operation (e.g., sampling, analysis) that must be strictly followed.
101. **Qualifying patient** means a person who possesses a valid certification for the medical use of marijuana pursuant to 22 MRS § 2423-B.
102. **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.
103. **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.

104. **Quality control sample** means a sample used to assess the performance of all, or a portion of, the measurement system. One of any number of samples, such as certified reference materials, a matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.
105. **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 marijuana testing facility, to ensure the quality of its product and the utility of its product to its users.
106. **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.
107. **Quantitate** means to undertake the arithmetic process of determining the amount of analyte in a sample.
108. **Raw data** means the documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, un-tabulated sample results, QC sample results, chromatograms, instrument outputs and handwritten records.
109. **Reagent** means a compound or mixture added to a system to cause a chemical reaction, or test if a reaction occurs. A reagent may be used to determine whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.
110. **Reference material** means a material or substance, one or more of which the property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
111. **Reference method** means a method by which the performance of an alternate method is measured or evaluated.
112. **Registered caregiver** means a caregiver who is registered by OMP pursuant to 22 MRS § 2425.
113. **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.
114. **Relative standard deviation** means the standard deviation expressed as a percentage of the mean recovery. It is the coefficient of variation multiplied by 100 and is calculated using the following equation:
RSD = (s / x) × 100%, where s = standard deviation and x = mean recovery. If any results are less than the limit of quantitation, the absolute value of the limit of quantitation is used.
115. **Reporting limit** means the lowest level of an analyte that can be accurately recovered from the matrix of interest (e.g., the level of quantitation).
116. **Requester** means a person who submits a request to a certified testing facility for state-mandated testing of marijuana or marijuana products.
117. **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 *Adult Use Marijuana Program Rule*, 18-691 CMR, ch. 1;
 - ii. By a sample collector, in accordance with 28-B MRS § 604 and 18-691 CMR, ch. 1; or
 - iii. By a self-sampler in accordance with 28-B MRS § 604-A and 18-691 CMR, ch.1;
- 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).

118. **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 *Adult Use Marijuana Program Rule*, 18-691 CMR, ch. 1.

119. **Sample collector** means a person licensed pursuant to 18-691 CMR, ch. 1 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”).

120. **Sample increment** means a portion of a batch that, together with other increments, makes up the sample.

121. **Sampling date** means the date that a sample was collected in the field, in order to be reported as such, when reporting the sample results to testing facility clients or regulatory programs.

122. **Sanitize** means to sterilize, disinfect or make hygienic.

123. **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”).

124. **Solid** means a matrix that includes soils; sediments; solid waste; and sludges.

125. **Standard** means the certified reference materials produced by NIST or other equivalent organization and characterized for absolute content, independent of analytical method or the dilutions made from these certified reference materials for the purposes of calibration or determining accuracy of a test method.

126. **Standard operating procedure (SOP)** means a written document that details the method for an operation, analysis or action, with thoroughly prescribed techniques and steps. SOPs are officially approved by the testing facility’s senior management as the methods for performing certain routine or repetitive tasks.

127. **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.

128. **Target organism** is an organism that is being tested for in an analytical procedure or test method.

129. **Target or target analyte** means an analyte or list of analytes within a test method that may be analyzed and for which the testing facility has obtained certification from the certification officer to test as part of a field of testing.
130. **Technology** means a specific arrangement of analytical instruments, detection systems and/or preparation techniques.
131. **Technology Analyte Table (TAT)** means the table used to identify methods, analytes, programs and matrices available for certification.
132. **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 DAFS.
133. **THC** is tetrahydrocannabinol (delta-9 THC), CAS number 1972-08-3.
134. **THCA** is tetrahydrocannabinolic acid, CAS number 23978-85-0.
135. **Total CBD** means the sum of CBD and CBDA. Total CBD is calculated using the following equation:
Total CBD = CBD + (CBDA*0.877).
136. **Total THC** means the sum of THC and THCA. Total THC is calculated using the following equation:
Total THC = delta-9 THC + (THCA*0.877).
137. **Tincture** means a liquid edible marijuana product with a concentration of greater than 1 mg of THC per ounce of liquid.
138. **Total Yeast and Mold Count (TYMC)** means the total combined yeast and mold count in standardized plating methodologies and is usually expressed in number of colony forming units (CFU).
139. **Traceability** means the ability to trace the history, application or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.
140. **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.
141. **Validation** means the confirmation by examination and objective evidence that the requirements for a specific intended use are fulfilled.
142. **Verification** means the confirmation by examination of, and provision of, objective evidence that specified requirements have been fulfilled. Verification refers to the process of examining a result of a given activity to determine conformance with this rule.

Section 2 – General CDC Certification and ISO/IEC 17025: 2017 Accreditation Requirements Prior to Issuance of a Marijuana Testing Facility License

Section 2.1 – Certification of Marijuana Testing Facility Required Prior to Issuance of a Full Active or Provisional Active License

A marijuana testing facility must obtain certification by DHHS, CDC, as described in this Rule, before DAFS, OMP will issue to that marijuana testing facility a full active or provisional active license.

2.1.1. Marijuana Testing Facility General Requirements. The marijuana testing facility must:

- A. Be an entity that can be held legally responsible;
- B. Carry out its testing activities in such a way as to meet the requirements of this rule and to meet the needs of clients in accordance with the marijuana testing facility's quality assurance manual;
- C. Employ technical management and personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties and identify departures from the management system and initiate actions to prevent or minimize such departures;
- D. Use personnel employed by, or under contract to, the marijuana testing facility, and where contracted and additional technical and key support personnel are used, ensure that such personnel are supervised and competent and that they work in accordance with the marijuana testing facility's quality system;
- E. Have 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. Submission of this policy for the purposes of certification does not fulfill licensing requirements regarding undue influence evaluated by OMP, such information will be evaluated by OMP independent of any assessment made by the CDC;
- F. Have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
- G. Authorize specific personnel to perform particular types of sampling, if applicable, and environmental testing, issue test reports, give opinions and interpretations and operate particular types of equipment; and
- H. Authorize specific personnel to maintain document control policies, chain of custody forms for each sample tested and control access to certificate of analysis data.

2.1.2. Certification may be full or provisional. A marijuana testing facility must receive from the CDC full or provisional certification for at least one analyte and technology to be used for the testing of adult use marijuana and adult use marijuana products before that marijuana testing facility can seek a full active or provisional active license from OMP.

- A. Full certification will be granted by the CDC to a marijuana testing facility that can demonstrate that it has applied for and received ISO/IEC 17025:2017 or most recent version accreditation and that it meets all other requirements of this Rule.
- B. Provisional certification will be granted by the CDC to a marijuana testing facility that can demonstrate that it has had an application accepted for, but has not yet received nor been denied, ISO/IEC 17025:2017 or most recent version accreditation and that meets all other requirements of this rule.
- C. Certification may be denied when an applicant has deficiencies and the certification officer determines that the applicant cannot consistently produce valid data.

Section 2.2 - ISO/IEC 17025:2017 or most recent version Accreditation Requirements for CDC Marijuana Testing Facility Certification

2.2.1. The marijuana testing facility must demonstrate ISO/IEC 17025: 2017 accreditation before the CDC will issue a full testing facility certification. The marijuana testing facility may apply for full certification for only those fields of testing accredited by ISO/IEC 17025:2017 or most recent version. The marijuana testing facility may apply for an OMP-issued full active license for only those fields of testing for which it has received ISO/IEC

17025:2017 or most recent version accreditation and CDC certification. An on-site inspection by CDC will be required.

2.2.2. The marijuana testing facility must apply for ISO/IEC 17025:2017 or most recent version accreditation before the CDC will issue a provisional testing facility certification. A marijuana testing facility applicant meeting all general requirements for certification, except for ISO/IEC 17025:2017 or most recent version accreditation, may apply to the CDC for provisional certification by submitting a complete application and required fees. Following an on-site inspection of an applicant that has not received ISO/IEC 17025:2017 or most recent version accreditation, the CDC will perform a review of data validation studies and a review of all other proof that the marijuana testing facility has met certification requirements, and if the CDC determines the marijuana testing facility meets all requirements, the CDC may grant the applicant a provisional certification. The provisional certification, if granted, expires 12 months from the date of issuance.

- A. The marijuana testing facility may apply for an OMP-issued provisional active license for only those fields of testing included in the application for ISO/IEC 17025:2017 or most recent version accreditation.
- B. Upon receipt of ISO/IEC 17025:2017 or most recent version accreditation, the marijuana testing facility must demonstrate proof of accreditation to OMP and the CDC within 5 business days. Upon receipt of such notice and following confirmation of accreditation, the CDC will issue to the marijuana testing facility full certification for the accredited technologies and analytes which will expire on the same date as the originally issued provisional certification. A marijuana testing facility can request a change in licensure status from provisional active to full active licensure for the remainder of the term of the originally issued provisional active license. Nothing in this section shall be construed to extend the term of certification or licensure beyond the term of the originally issued provisional certification or provisional active licensure.
- C. Before the expiration of its provisional certification, the marijuana testing facility must obtain ISO/IEC 17025:2017 or most recent version accreditation for at least one field of testing included in its accreditation application; otherwise it must cease all operations until such accreditation is obtained for at least one field of testing.
- D. If ISO/IEC 17025:2017 or most recent version accreditation is denied to the marijuana testing facility holding provisional certification, the facility must notify the CDC of the denial within one business day of receipt of the denial. The CDC shall revoke the provisional certification, upon the marijuana testing facility's notification of denial of ISO/IEC 17025:2017 or most recent version accreditation. Upon revocation of a provisional certification by the CDC, OMP shall revoke immediately the marijuana testing facility's provisional active license.

Section 3 – Certification of Testing Facilities

Section 3.1 - Certification Required

A marijuana testing facility may test marijuana or marijuana products only if it holds a current certification from DHHS, CDC. Initial certification will be for a period of 1 year, and annual recertification is required.

3.1.1. Applications must meet all CDC requirements.

- A. At a minimum, the application for certification must include:
 - (1) The name of the facility director in charge of the marijuana testing facility and each employee's qualifications or job descriptions;
 - (2) Resumes that document appropriate experience and education, including college transcripts and evidence of a completed degree, for personnel specified in section 4;
 - (3) A quality assurance manual, meeting the specifications of subsection 3.2;
 - (4) Standard operating procedures, meeting the specifications of subsection 3.3; and
 - (5) The fields of testing for which the applicant seeks provisional certification or certification using the technology analyte table (TAT) maintained by the program and proof of ISO/IEC 17025:2017 or most recent version accreditation for such fields of testing or, if applying for a provisional certification, proof that the applicant has submitted an approved application for ISO/IEC 17025:2017 or most recent version accreditation for such fields of testing.
- B. Applications for certification will not be considered complete until payment of the non-refundable application fee.
- C. The marijuana testing facility must submit the following additional documentation to obtain provisional or full certification from the CDC:
 - (1) A description of the organization and management structure of the marijuana testing facility, its place in any parent organization and the relationships between quality management, technical operations and support services;
 - (2) 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;
 - (3) 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;
 - (4) Written policies and procedures for receipt of samples for mandatory or other testing; and
 - (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.

3.1.2. Certification is granted for specified matrices, technology and analytes.

- A. The CDC will only certify applicants for the matrices, technologies and analytes required for testing under this rule.
- B. The CDC may, at its discretion, allow applicants to submit an application to expand the scope of its certification for one or more of the fields of testing on an individual basis rather than requiring the applicant to meet all fields of testing for all available testing types.
- C. The CDC must conduct a comprehensive on-site inspection of each marijuana testing facility prior to granting certification. Following its inspection, the CDC must issue a written initial on-site assessment report which identifies any deficiencies noted during the CDC inspection. In order to receive certification, the marijuana testing facility must correct any deficiencies identified and provide documentation of the correction to CDC within 30 days of receipt of the initial on-site inspection report.

3.1.3. A marijuana testing facility must maintain its CDC certification at all times to remain licensed by DAFS.

- A. The CDC may, upon reasonable cause, complaint, or to assess continued compliance with this rule, conduct an onsite inspection or review written or electronic records to determine the marijuana testing facility's compliance with the certification requirements described in this section.
- B. Upon the finding of significant or intentional deviation from certification requirements or if the marijuana testing facility refuses to permit access to the site or records, the CDC may suspend or revoke the marijuana testing facility's certification.
 - (1) A marijuana testing facility may not conduct testing of marijuana or marijuana products while its certification is suspended or revoked.
 - (2) The CDC shall communicate any suspension or revocation in writing, along with a notice of the licensee's right to appeal, consistent with the Maine Administrative Procedures Act, 5 MRS, chapter 375.
 - (3) Simultaneously, the CDC shall inform OMP of its actions.
- C. Annual recertification is required.
 - (1) The recertification application shall include at minimum, the following:
 - (a) Any changes to assertions made during initial certification or most recent recertification;
 - (b) Any fines, enforcement or letters of warning by OMP;
 - (c) Copies of updated SOPs;
 - (d) Copy of current QA manual; and
 - (e) Updated copies, at the CDC's discretion, of any materials required for initial certification.
 - (2) The CDC may consider a marijuana testing facility's compliance with certification requirements, proficiency testing, accuracy of testing and reporting implicated in this rule when determining whether to renew the marijuana testing facility's certification.

Section 3.2 - Quality Assurance Program and Manual

3.2.1. The marijuana testing facility must develop and implement a quality assurance program. The program must be sufficient to ensure the reliability and validity of the analytical data produced by the marijuana testing facility. The marijuana testing facility operations must also meet the requirements of the ISO 17025:2017 accreditation.

3.2.2. The marijuana testing facility must develop and maintain a written quality assurance program manual.

- A. The manual must contain the following elements:
 - (1) Document title;
 - (2) Identification on each page to ensure that the page is recognized as part of the manual and clear identification of the end of the manual;
 - (3) The marijuana testing facility's name and address;
 - (4) Identification of the marijuana testing facility's approved signatories;
 - (5) A revision number;
 - (6) A date indicating when the revision became effective;
 - (7) A table of contents, applicable lists of references, glossaries and appendices;
 - (8) Listing of all certified testing methods;
 - (9) Relevant organizational charts showing the organization and management structure of the marijuana testing facility and, if applicable, its place within a larger business entity; and
 - (10) Job descriptions of key staff and reference to the job descriptions of other marijuana testing facility staff;
- B. The manual must address all aspects of the marijuana testing facility's quality assurance program, including without limitation the following:
 - (1) Quality control;
 - (2) Quality assurance objectives for measurement data;
 - (3) Traceability of all data, analytical results and certificates of analysis;
 - (4) Equipment preventative maintenance;
 - (5) Equipment calibration procedures and frequency;

- (6) Performance and system audits;
- (7) Corrective action;
- (8) Record retention, including retention of quality assurance records;
- (9) Document control;
- (10) Standardization of testing procedures;
- (11) Method validation;
- (12) Maintenance, calibration and verification procedures;
- (13) Major equipment, support equipment and reference measurement standards (e.g., NIST traceable thermometers and weights);
- (14) Verification practices, which may include proficiency testing programs, use of reference materials, internal quality control processes and inter-marijuana testing facility comparisons;
- (15) Reporting analytical results and generating the certificate of analysis;
- (16) Traceability of measurements;
- (17) Adoption of new testing methods;
- (18) Handling of samples, including subcontract testing;
- (19) Collection and transportation of samples, as applicable;
- (20) Receipt of samples for mandatory testing, or testing for research and development purposes;
- (21) Sample rejection;
- (22) Feedback and corrective action related to testing discrepancies or departures from documented policies and procedures;
- (23) Policy for permitting departures from documented policies and procedures or from standard specifications;
- (24) Handling of complaints;
- (25) Protection of confidentiality and proprietary rights;
- (26) Data review;
- (27) Chain of custody forms;
- (28) Annual internal audits;
- (29) Evaluation of employee credentials;
- (30) Employee training, including initial data integrity training for new personnel and annual data integrity training for all current employees with written documentation of attendance;
- (31) Electronic signatures, where applicable;
- (32) How data accuracy and precision are determined for each accredited method and analyte within each test category;
- (33) Disposal of marijuana waste; and
- (34) Review of all new work to ensure that the marijuana testing facility has appropriate facilities and resources before commencing such work; and
- (35) Meeting all applicable ISO 17025:2017 accreditation requirements.

C. The manual may include separate procedures or incorporate documents by reference.

3.2.3. The quality assurance program and manual must be reviewed and updated regularly to remain current.

- A. The facility director and quality assurance officer must review, amend if necessary and approve the quality assurance program and manual.
 - (1) Routine review is required at least annually.
 - (2) The facility director must also review and amend the quality assurance program and manual whenever there is a change in methods, marijuana testing facility equipment or facility director.
 - (3) Documentation of the review process must include the scope of the review, identification and signature of the reviewer and the date the review was completed.
- B. Method detection limits and reporting limits may be determined by methods used by the U.S. Environmental Protection Agency.
 - (1) The marijuana testing facility may use the procedure for determining the method detection limit described in 40 C.F.R. Part 136, Appendix B, revised as of July 1, 2017, as amended by Federal Register, Vol. 82, No. 165, p. 40836-40941, August 28, 2017; or

- (2) Other methods published by the federal U.S. Food and Drug Administration for the determination of limit of detection (LOD) and limit of quantitation including Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition, April 2015.

Section 3.3 - Standard Operating Procedures (SOPs).

3.3.1. Written SOPs are required. The marijuana testing facility must possess written SOPs used by marijuana testing facility personnel for the analysis of samples and must prepare written procedures for all marijuana testing facility activities, including, but not limited to, sample collection, sample acceptance, sample analysis, operation of instrumentation, generation of data and performance of corrective action.

- A. Only the facility director, quality assurance officer or designee may make changes to SOPs.
- B. Such changes are effective only when documented in writing and approved by the facility director or quality assurance officer.
- C. The SOPs must be formatted to include:
 - (1) A table of contents;
 - (2) A unique identification of the SOP, such as a serial number, an identification on each page to ensure that the page is recognized as a part of the manual and a clear identification of the end of the manual;
 - (3) Page numbers;
 - (4) The marijuana testing facility's name;
 - (5) A revision number; and
 - (6) A date indicating when the revision became effective.
- D. Each analytical method SOP must include or reference the following topics, where applicable:
 - (1) Identification of the method;
 - (2) Applicable matrix or matrices;
 - (3) Limits of detection and quantitation;
 - (4) Scope and application, including parameters to be analyzed;
 - (5) Summary of the method;
 - (6) Definitions;
 - (7) Interferences;
 - (8) Safety;
 - (9) Equipment and supplies;
 - (10) Reagents and standards;
 - (11) Sample collection, preservation, shipment and storage;
 - (12) Quality control (QC);
 - (13) Calibration and standardization;
 - (14) Procedure;
 - (15) Data analysis and calculations;
 - (16) Method performance;
 - (17) Pollution prevention;
 - (18) Data assessment and acceptance criteria for QC measures;
 - (19) Corrective actions for out-of-control data;
 - (20) Contingencies for handling out-of-control or unacceptable data;
 - (21) Waste management;
 - (22) References; and
 - (23) Any tables, diagrams, flowcharts and validation data.
- E. For pesticide analysis, the SOP must include established and documented detection limits for each matrix type.

3.3.2. Written SOPs are requirements of certification and licensing and must be followed.

- A. Actual practice must conform to the written procedures.

- (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. Standard operating procedure requirements may be considered confidential material, and OMP and the CDC may not disclose the information except in conjunction with agency actions.
- C. The marijuana testing facility must maintain a record of effective dates for all procedures and must review SOPs at least annually. A copy of the procedure and the record of effective dates must be maintained for the same period that records of the data generated by those procedures are required to be maintained.
- D. The marijuana testing facility must keep all standard operating procedures on the marijuana testing facility premises and in the field, as necessary, and must ensure that each standard operating procedure is accessible to marijuana testing facility personnel during operating hours. The marijuana testing facility must make the standard operating procedures available to the CDC upon request.
- E. All changes to the SOPs must be documented.
- (1) Changes to the SOPs must be incorporated at least annually.
 - (2) The marijuana testing facility's facility director must review, approve, sign and date each SOP and each revision to a SOP.
 - (3) The SOPs must include the dates of issue and dates of revision, if any.

Section 3.4 - Proficiency Testing

The marijuana testing facility must participate in a proficiency-testing program provided by an ISO-17043-accredited proficiency test provider, at least annually by October 31 each year. The CDC may waive proficiency testing requirements if no proficiency tests are available.

3.4.1. Proficiency tests are required.

- A. Any marijuana testing facility seeking to obtain certification must successfully complete at least one proficiency test sample (unless a proficiency test is not available) for each requested field of testing.
- (1) The proficiency test must occur within six months prior to the date that the marijuana testing facility submits its application.
 - (2) When any marijuana testing facility is granted certification, it must continue to complete proficiency testing studies for each field of testing and maintain a history of at least one acceptable evaluation for each field of testing out of the most recent two proficiency test sample results submitted to the proficiency test provider.
 - (3) To maintain certification, the marijuana testing facility must complete the annual study, and any corrective action study required, by October 31 each year.
 - (4) Failure to participate in a proficiency test may result in disciplinary action against the marijuana testing facility, including suspension or revocation of certification.
- B. Proficiency testing must be conducted according to the following guidelines:
- (1) The marijuana testing facility must rotate the proficiency tests among marijuana testing facility staff, so that all methods and all staff performing the methods have participated in proficiency tests over a reasonable planned period, as defined in the marijuana testing facility quality assurance manual.
 - (2) The marijuana testing facility must analyze the proficiency test samples following the approved marijuana testing facility standard operating procedures and using the same equipment that are used for testing.
 - (3) Marijuana testing facility employees who participate in a proficiency test must sign corresponding analytical reports or attestation statements to certify that the proficiency test was conducted in the same manner as the marijuana testing facility ordinarily conducts testing.
 - (4) The facility director must review and approve all proficiency test samples analyzed and results reported.

- (5) The marijuana testing facility must authorize the proficiency test provider to release the results of the proficiency test to OMP and CDC at the same time that the results are submitted to the marijuana testing facility.
 - (6) Prior to the closing date of a study, marijuana testing facility personnel, including corporate personnel, may not:
 - (a) Communicate with any individual at another marijuana testing facility, concerning the analysis of the proficiency test sample prior to the closing date of the study;
 - (b) Subcontract the analysis of any proficiency test sample or a portion of a proficiency test sample to another marijuana testing facility for any analysis;
 - (c) Knowingly receive and analyze any proficiency test sample or portion of a proficiency test sample from another marijuana testing facility, for which the results of the proficiency test sample are intended for use for initial or continued certification; or
 - (d) Attempt to obtain the assigned value of any proficiency test sample.
 - (7) The marijuana testing facility must analyze proficiency test samples in the same manner used for routine samples, using the same staff, sample tracking, sample preparation and analysis methods, SOPs, calibration techniques, QC procedures and acceptance criteria.
 - (8) The marijuana testing facility must follow sample preparation steps for the proficiency test sample, as instructed by the approved proficiency test provider for which the proficiency test sample was obtained.
 - (9) Testing facilities under the same ownership may not participate in the same study by the same approved proficiency test provider for the same fields of testing, except when a study is not again available for that field of testing by any approved proficiency test provider within the calendar year.
- C. Errors in reporting the proper matrix, the method used or the tested analytes in the proficiency test study by the marijuana testing facility must be graded as “not acceptable.”

3.4.2. Marijuana testing facilities must provide proficiency test results.

- A. The marijuana testing facility must evaluate and report the analytical result for certification as follows:
 - (1) For instrument technology that employs a multi-point calibration, the working range of the calibration under which the proficiency test sample is analyzed must be the same range as used for routine samples.
 - (a) A result for any proficiency test at a concentration above or equal to the lowest calibration standard must be reported as the resultant value.
 - (b) A result for any proficiency test at a concentration less than the lowest calibration standard must be reported as less than the value of the lowest calibration standard.
 - (c) A result for any proficiency test greater than the highest calibration standard must be diluted to fall within the range of the calibration curve.
 - (2) For instrument technology (e.g., ICP-AES or ICP-MS) that employs standardization with a zero point and a single point calibration standard, the marijuana testing facility must evaluate the analytical result in the same range as used for routine samples.
 - (a) A result for any proficiency test at a concentration above or equal to the reporting limit must be reported as the resultant value.
 - (b) A result for any proficiency test at a concentration less than the reporting limit must be reported as less than the value of the reporting limit.
 - (c) A result for any proficiency test greater than the high calibration standard must be diluted to be within the working range.
- B. The marijuana testing facility must ensure that the proficiency test results include the correct physical address of the marijuana testing facility.
- C. The marijuana testing facility must report the analytical results to the proficiency test provider on or before the closing date of the study using the reporting format specified by the proficiency test provider.
- D. On or before the closing date of the study, the marijuana testing facility must authorize the proficiency test provider to release the marijuana testing facility’s final evaluation report directly to OMP and the CDC.

- E. The marijuana testing facility must supply results by authorizing the approved proficiency test provider to release all PT results and corrective action results to the certification officer by an electronic format specified by the certification officer. The CDC must evaluate only results received directly from the proficiency test provider.
- F. The marijuana testing facility may not request a revised report from the proficiency test provider, when the revisions to the report are due to any error on the part of the marijuana testing facility.

3.4.3. Successful performance is required.

- A. The marijuana testing facility must successfully participate in a proficiency test for each matrix, technology and analyte.
 - (1) Test results are considered “satisfactory” for an analyte tested in a specific technology, or if the results demonstrate a positive identification of an analyte tested in a specific technology, including quantitative results, when applicable.
 - (2) A marijuana testing facility must analyze only the analytes for which proficiency test results were considered “satisfactory.”
 - (3) The reporting of a false-positive result is an “unsatisfactory” score for the proficiency test.
- B. The marijuana testing facility must take corrective action and document corrective action, when the marijuana testing facility fails to score 100% on a proficiency test.
 - (1) Within 30 days of receiving an “unacceptable,” “questionable,” or “unsatisfactory” proficiency test result, a marijuana testing facility must submit the proficiency-test results and detailed corrective action responses to the CDC.
 - (a) This information must include root-cause analysis and remedial action plans.
 - (b) The marijuana testing facility must not accept samples or analyze the analytes for which proficiency test results were considered “unacceptable,” or “unsatisfactory,” until completing the corrective action and resolving the problem.
 - (c) The marijuana testing facility must enroll in the next available round of proficiency tests.
 - (d) Such enrollment should be documented in the corrective action plan initiated in response to a proficiency test failure.
 - (2) The marijuana testing facility may not continue to report results for analytes that were deemed “unacceptable,” “questionable” or “unsatisfactory” if the marijuana testing facility has two successive failed proficiency test studies for any analyte and technologies.
 - (3) Within 180 days of an unacceptable or unsatisfactory proficiency test result, the marijuana testing facility must submit a written report showing whether the marijuana testing facility successfully implemented the corrective action to the CDC.
 - (4) Within 30 days of receipt of a corrective action report, the marijuana testing facility must order a new proficiency test to demonstrate proficiency for reinstatement of certification.
- C. If the facility fails two successive proficiency test studies for any analyte and technology, certification for that analyte and technology is suspended immediately. Certification may be reinstated pending successful completion of two successive proficiency test studies.

3.4.4. Proficiency test sample study records must be maintained.

- A. The marijuana testing facility must maintain copies of all written, printed and electronic records pertaining to proficiency test sample analyses for 5 years.
- B. Proficiency test records must include, without limitation:
 - (1) Bench sheets;
 - (2) Instrument strip charts or printouts;
 - (3) Data calculations;
 - (4) Data reports; and
 - (5) Proficiency test study report forms used by the marijuana testing facility to record proficiency test results.

- C. The marijuana testing facility must make all retained records available to marijuana certification officers during on-site assessments of the marijuana testing facility.

Section 3.5 - Conducting Annual Internal Audit

- A. The marijuana testing facility must conduct an internal audit at least once per year, or per the ISO/IEC 17025:2017 or most recent version accrediting body's requirement, whichever is more frequent.
- B. The internal audit must cover everything required to be covered by this Rule and ISO/IEC 17025:2017 or most recent version internal-audit standards.
- C. The internal audit will be reviewed during the on-site assessment by the CDC, during an inspection by the CDC, or at the request of the CDC.
- D. Failure to conduct an internal audit or failure to submit the results of an internal audit to the CDC may subject the marijuana testing facility to suspension or revocation of certification.

Section 4 – Required Marijuana Testing Facility Personnel, Training and Supervision

Section 4.1 - Required Personnel

Certification requires a marijuana testing facility to employ a qualified facility director and sufficient marijuana testing facility analysts and staff to handle the anticipated volume of testing. The marijuana testing facility must either employ a qualified quality assurance officer (QAO) or designate the facility director to fulfill that role. The marijuana testing facility must ensure that a testing facility director or QAO meeting the requirements of this rule is onsite and available during the hours of operation indicated on the facility's operating plan.

4.1.1. General requirements.

- A. All management of the marijuana testing facility and performance of required testing and related activities must be performed by personnel who meet the required educational and experience requirements.
- B. Only degrees issued by, or courses completed at, an accredited college or university may fulfill the educational requirements of this section.
- C. To meet practical laboratory experience requirements, prior work experience must:
 - (1) Have involved full-time work of 30 or more hours per week;
 - (2) Not have been completed as part of any educational requirement, even if it did not lead to the conferring of a degree; and
 - (3) Have taken place in a laboratory or marijuana testing facility performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body.

4.1.2. Facility director.

- A. To be a facility director of a certified marijuana testing facility under this rule, a person must meet one of the following:
 - (1) A doctoral degree in a related science and 1 year of practical laboratory experience;
 - (2) A master's degree in a related science and 2 years of practical laboratory experience; or
 - (3) A bachelor of science or bachelor of art degree in a related science and 4 years of practical laboratory experience.
- B. The facility director must be capable of fulfilling all the following core responsibilities:
 - (1) Oversee and direct the scientific methods of the marijuana testing facility;
 - (2) Ensure that the marijuana testing facility achieves and maintains quality standards of practice;
 - (3) Supervise all personnel; and
 - (4) Be present in the marijuana testing facility an average of 60% of hours of operation.
- C. The facility director may not have been convicted of an offense punishable by 1 year or more in prison and related to conduct involving dishonesty, fraud, deceit or gross negligence with the intent to substantially benefit himself, herself or another or to substantially injure another.
- D. The testing facility must appoint a deputy when the testing facility director is absent from the testing facility for more than 15 consecutive calendar days.
 - (1) The deputy facility director must meet the qualifications for testing facility director or QAO.
 - (2) Testing facility management must notify OMP and CDC in writing when the absence of the testing facility director is expected to, or in fact exceeds, 60 consecutive calendar days.
- E. Any requests for a waiver of any provision under this paragraph must be submitted in writing to the CDC, which reserves the right to deny such a request.

4.1.3. Quality assurance officer (QAO).

- A. To be a QAO of a certified marijuana testing facility under this rule, a person must satisfy one of the following:
 - (1) Meet the qualification criteria required for a facility director; or

- (2) Hold a bachelor's degree in one of the related sciences; or
 - (3) Have completed at least 2 years of college coursework and at least 1 year of practical laboratory experience.
- B. The QAO must be capable of fulfilling all the following core responsibilities:
- (1) Ensure that the marijuana testing facility achieves and maintains quality standards of practice;
 - (2) Review marijuana testing facility quality control data, conduct annual internal audits, notify management of deficiencies found in the quality system, ensure the accuracy and integrity of certificates of analysis and be free from internal and external influences, when evaluating data and conducting audits;
 - (3) Provide documented training and/or experience in QA and QC procedures and demonstrate knowledge of the approved analytical methods and quality system requirements, as well as maintain the QA documents up to date;
 - (4) Have direct access to marijuana testing facility management; and
 - (5) Whenever possible, conduct functions that are independent from the marijuana testing facility operations for which they have quality assurance oversight.
- C. The QAO, regardless of other duties and responsibilities, must have defined responsibility and authority for ensuring that the management system related to quality and integrity of testing results is implemented and complied with at all times.
- D. The QAO duties and responsibilities may alternatively be carried out by the marijuana testing facility technical director.

4.1.4. Marijuana Testing Facility Analyst. Any person who performs analytical tasks must meet the experience and educational requirements of an analyst and must be able to demonstrate proper performance of all analytical tasks. To be an analyst employed by a certified marijuana testing facility pursuant to this Rule, a person must meet one of the following standards:

- A. Fulfill the qualification criteria required for the facility director; or
- B. Hold a bachelor's degree in one of the related sciences; or
- C. Demonstrate completion of at least 2 years of college coursework and at least 1 year of practical laboratory experience.

4.1.5 Marijuana Testing Facility Sample Collection. If the marijuana testing facility offers sample collection services, any person who performs sample collection for a marijuana testing facility must meet the experience and educational requirements of a sample collector contained in Section 5.1.5 of this Rule and be able to demonstrate appropriate sampling methods.

Section 4.2 - Verification and Maintenance of Personnel Documentation

The marijuana testing facility must verify and maintain documentation of qualifications of all employees and contracted workers. Required documentation includes the following:

- A. Documentation of the employee's education:
 - (1) The colleges and universities attended by the employee and the names and addresses of the colleges and universities, the major course of study, dates of attendance, degrees conferred and completion date;
 - (2) Official transcripts from the registrar of the colleges and universities attended by the employee showing all courses, course credits, degrees conferred, and dates degrees were conferred; and
 - (3) Records from credential evaluation services, including translations of transcripts from non-English-language colleges and universities. For an employee who attended a college or university not located in the United States (U.S.) or its territories, the requirement that the college or university be accredited is satisfied if the educational credentials of the employee are found, by the credential evaluation service, to be equivalent to those of a person who attended an accredited U.S. college or university.

- B. Documentation of each employee's experience:
 - (1) Name and address of the laboratory or marijuana testing facility where the employee received non-course related experience, dates of employment, number of hours per week employed and a description of the testing and analytic methods performed by the person; and
 - (2) Signed documentation of such experience from the director or equivalent of the laboratory or marijuana testing facility.
- C. Records of all individual identification cards including the identification number and the date of issuance and expiration for every principal office, board member and employee of the marijuana testing facility.
- D. Personnel plans reflecting sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions. marijuana testing facility management must:
 - (1) Specify and document the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests;
 - (2) Establish job descriptions to include the minimum level of qualifications, experience and basic marijuana testing facility skills necessary for all positions in the marijuana testing facility;
 - (3) Document authority of specific personnel to perform particular types of sampling and environmental testing, issue test reports, give opinions and interpretations and operate particular types of equipment; and
 - (4) Document authority of specific personnel to maintain document control policies, chain of custody forms for each sample tested and control access to certificate of analysis data.
- E. Records of the relevant authorization(s), demonstration(s) of capability, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information must be readily available and include the date on which authorization and/or competence is confirmed.
- F. Documentation of the initials and signatures of anyone analyzing or reviewing data so that the records can be traced back to the individual approving the data.

Section 4.3 - Personnel Training and Supervision

The marijuana testing facility management must:

- A. Provide adequate supervision of staff by persons familiar with methods and procedures;
- B. Formulate goals with respect to the education and training skills of the marijuana testing facility personnel, including:
 - (1) Policies and procedures for identifying training needs and providing training of personnel;
 - (2) Ensuring relevance of the training program to the present and anticipated tasks of the marijuana testing facility; and
 - (3) Making documentation available upon request from the CDC;
- C. Ensure all technical marijuana testing facility staff has demonstrated capability in the activities for which they are responsible; and
- D. Ensure that the training of the marijuana testing facility personnel is kept up to date (on-going) by providing the following:
 - (1) Documentation that each employee has read, understands and uses the latest version of the marijuana testing facility's quality documents and security plan;
 - (2) Training documentation on equipment, techniques and/or procedures;
 - (3) Training in ethical and legal responsibilities; and
 - (4) Documentation of each analyst's continued performance at least once per year.

Section 5 – Samples for Testing and Research

A marijuana testing facility may offer a service to collect samples for mandatory testing from a licensee. A marijuana testing facility may contract with or otherwise accept samples for mandatory testing from a sample collector licensed pursuant to Title 28-B and 18-691 CMR, ch. 1. A marijuana testing facility may accept samples for mandatory testing from a self-sampling licensee authorized to collect samples pursuant to Title 28-B and 18-691 CMR, ch. 1. All samples for mandatory testing must be collected in accordance with Title 28-B, 18-691 CMR, ch. 1 and this Rule.

Section 5.1 – Samples for Mandatory Testing or Research and Development

5.1.1. 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 18-691 CMR, ch. 1.

5.1.2. 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 recordkeeping requirements of 18-691 CMR, ch. 1;
- 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. The requirements and restrictions of 18-691 CMR, ch. 1.

5.1.3. 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 recordkeeping requirements of 18-691 CMR, ch.1;
- 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. The requirements and restrictions of 18-691 CMR, ch. 1.

5.1.4. 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 18-691 CMR, ch. 1, 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.

5.1.5. Qualifications. Employees of a marijuana testing facility or sample collectors who collect samples from licensees must have a current individual identification card issued by OMP and must:

- A. Be physically able to perform the duties, with or without reasonable accommodations;

- B. Pass initial and ongoing demonstrations of capability;
- C. When available, complete 8 hours of initial training on various sampling techniques; and
- D. When available, complete 8 hours of periodic refresher training annually.

5.1.6. Transportation of Samples. A sample collector or self-sampling licensee may transport a sample from a licensee to the marijuana testing facility for testing and analysis.

- A. The sample collector or self-sampling licensee shall ensure the samples are not visible to the public. Samples shall be locked in a fully enclosed box, container or cage that is secured to the inside of the vehicle or trailer. For the purposes of this section, the inside of the vehicle includes the trunk.
- B. The sample collector or self-sampling licensee shall ensure that packages or containers holding marijuana goods samples are neither tampered with nor opened during transport.
- C. An employee of a marijuana testing facility who is collecting samples of marijuana, marijuana concentrate or marijuana products for mandatory testing shall only travel between licensees for whom the marijuana testing facility is conducting mandatory testing and the marijuana testing facility’s premises when engaged in the transportation of samples; a sample collector not employed by a marijuana testing facility shall only travel between licensees for whom the sample collector is collecting samples and the marijuana testing facility(ies) conducting the mandatory testing. A sample collector shall not deviate from the travel requirements described in this section, except for necessary meals or rest required by law, or refueling.
- D. The sample collector may transport multiple samples obtained from multiple licensees at once. A self-sampling licensee may transport only those samples collected by the licensee and must deliver those samples to the marijuana testing facility directly.
- E. Only persons who are in possession of a valid individual identification card issued by OMP may be in a vehicle or trailer transporting samples.
- F. All samples being transported must have a label with the following statement: “For Testing Purposes Only.”

Section 5.2 – Protocols for Acceptance of Samples Collected by Licensees or Other Qualified Persons

The marijuana testing facility must develop and maintain a plan for receiving samples for mandatory and other testing.

5.2.1. SOPs. If the marijuana testing facility accepts samples from a sample collector or self-sampling licensee for mandatory or other testing, it must develop and maintain SOPs for receiving samples.

- A. A sample collector or self-sampling licensee must contact the marijuana testing facility(ies) and comply with the marijuana testing facility’s recommendations, based upon matrices sampled and analyses required, regarding, without limitation:
 - (1) Sample collection tools;
 - (2) Sample collection and transport containers;
 - (3) Whether any Field or Trip blanks are required to be collected, transported or otherwise used or delivered to the marijuana testing facility pursuant to the marijuana testing facility’s quality system; and
 - (4) Any limitations regarding sample delivery.
- B. The SOPs must have detailed chain of custody protocols for receiving samples.
- C. The SOPs must require sample collectors or self-samplers to address factors such as storage, environmental conditions, transportation of the batch or sample, tamper evident sealing and labeling samples for transport “For Testing Purposes Only.”
- D. The SOPs must address representativeness of the samples received from the sample collector or self-sampler; the sampling increments must be selected at random by the sample collector or self-sampler, and designed so that the samples collected reflect the total composition of the product.
- E. The SOPs must be designed to meet specified sample quality criteria, which is dependent upon whether the samples provided are for mandatory testing in compliance with the requirements of Title 28-B, ch. 1 or

additional analyses not required by law. For non-mandatory test samples, this requires a sampling plan that includes enough representative sample increments to meet the client-specified confidence intervals.

- F. The SOPs must address volume of sample to be collected by sample collector or self-sampler from each batch in compliance with the requirements of Section 6 of this rule for samples collected for mandatory testing, or client specifications for non-mandatory testing. This specification will ensure that adequate sample volume is collected for the analyses required, including all required quality control samples and any potential confirmation analysis.

Section 5.3 – Chain of Custody and Document Control Requirements

Testing facilities must develop and implement a chain of custody protocol to ensure accurate documentation of the handling, storage and destruction of marijuana samples. All samples for mandatory testing must also be accompanied by any documentation required by the testing facility.

5.3.1. Chain of custody forms. The chain of custody protocol must require the use of a chain of custody form that contains, at a minimum, the following:

- A. Marijuana testing facility name, physical address and certification number of the marijuana testing facility analyzing the sample;
- B. Requester name, physical address and license or registration number; or if a registered caregiver, the registration card identification number; or if an exempt caregiver, the caregiver's name and address; or if a qualifying patient, the patient's name and address;
- C. Information regarding each primary sample, as follows:
 - (1) Unique primary sample identifier, as indicated on the sample container;
 - (2) For sample increments from the same sampled batch that are separated for homogeneity testing, the unique sample increment identifier as indicated on the container holding the separate sample increment for homogeneity testing;
 - (3) The sample location, number and type of containers used to collect samples, and the sample collection technique(s) used to collect the samples;
 - (4) Date and time of the sample collection;
 - (5) The printed names and signatures of the sample collector(s);
 - (6) For marijuana products that need to be stored at specific temperatures: All conditions, including sample temperature at time of collection and temperature of the cooler used for transport;
 - (7) The printed name and signature of the person at the marijuana testing facility receiving the samples; and
 - (8) The location of the sample within the marijuana testing facility storage area.

5.3.2. Document control.

- A. Each time the sample changes custody, is transported, is removed from storage at the marijuana testing facility, or is destroyed, the date, time and the names and signatures of persons involved in these activities must be recorded on the chain of custody form.
- B. All documents must be controlled and retained in accordance with this rule.
 - (1) A complete chain of custody is required for each batch.
 - (2) If there is a quality assurance plan for the client, the sampling plan can be abbreviated to include the client and marijuana testing facility information and any variation or modification that occurred in the sampling event.

Section 5.4 - Sample Rejection

- A. When samples are received by the marijuana testing facility, the marijuana testing facility must check the integrity of the samples. The marijuana testing facility must deem a sample compromised if one or more of the following has occurred:

- (1) Broken shipping container;
 - (2) Evidence that the sample has been tampered with, manipulated, adulterated or contaminated;
 - (3) Evidence that the sample was not collected in the manner required by this rule or the DAFS-required sample collection SOP;
 - (4) Any missing or incomplete sample collection records required by testing facility in accordance with its quality system;
 - (5) The temperature of the sample is out of the required range to prevent microbial growth;
 - (6) The sample weight, as determined upon receipt by the marijuana testing facility, is greater than +/- 10% difference than the weight recorded on the transport manifest accompanying the samples; or
 - (7) Any other factor that may have negatively impacted the integrity of the sample since its collection.
- B. If the sample is rejected, the marijuana testing facility must document the sampling or handling errors, contact the requester and the sample collector (if the requester did not self-sample), schedule re-sampling and time for sample receipt, and document the conversation with all parties, including any additional specific instructions given to the sampling party to correct any sample deficiencies noted.

Section 5.5 - Sample Collection

5.5.1. Sample Collection by Marijuana Testing Facility Personnel.

- A. At minimum, the marijuana testing facility must use the *Maine Adult Use Marijuana Program Sample Collection Standard Operating Procedure for Mandatory Testing* included as Appendix A to the *Adult Use Marijuana Program Rule*, 18-691 CMR, ch.1, and must complete for every batch a sample collection record to ensure it is collecting samples that support accurate analyses of cannabinoids, residual solvents and processing chemicals, contaminants, pesticides, microbiological impurities, mycotoxins, water activity, filth and foreign material and heavy metals, in compliance with *Best Practice Guide for the Sample Collection of Adult Use Marijuana for Mandatory Testing* published by DAFS.
- B. The marijuana testing facility must collect adequate samples of the marijuana, marijuana concentrate or marijuana product in the form in which it will be conveyed to another licensee or consumer (finished or unfinished plant material; marijuana concentrate; or an unpackaged or pre-packaged marijuana product) in accordance with Table 5.5-A. The sample must comprise the number of sample increments, selected at random, indicated in Table 5.5-A. The marijuana testing facility will combine these increments to make one complete sample for testing.

Table 5.5-A. Required Sample Size Based Upon Matrix Type and Batch Size

Matrix Type	Harvest Batch Weight Range*	Production Batch Units*	Primary Sample Amount
Plant Material	≤ 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)
Concentrate	≤ 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)
Product **		≤ 50	2 units
		51 -150	3 units
		151 - 500	5 units
		501-1200	8 units
		1201 -3200	13 units
		3201-10000	20 units

*For harvest or production batches in excess of the sizes listed in this table (10 kg of plant material, 5 kg of concentrate or 10,000 production batch units), the batch must be divided and sampled in smaller batches in accordance with the batch size limits listed in this table, the requirements of this Rule, and the requirements of 18-691 CMR, ch. 1.

**For production batches of prepackaged marijuana products, one production unit is one sample increment. For production batches of unpackaged marijuana products, one serving size of the marijuana product is one sample increment.

5.5.2. Sample Collection by Sample Collectors and Self-Samplers.

- A. Sample collectors and self-samplers must collect samples of marijuana, marijuana concentrate and marijuana products in accordance with OMP’s *Maine Adult Use Marijuana Program Sample Collection*

Standard Operating Procedure for Mandatory Testing and must complete for every batch a sample collection record in accordance with 18-691 CMR, ch.1, §3.11, in addition to any additional forms, including chain of custody forms, required by the marijuana testing facility receiving the samples.

- B. Sample collectors and self-samplers must collect the required number of sample increments, based upon matrix type and batch size, in accordance with Table 5.5-A. The sample collector or self-sampler will specify in its sample collection records, after contacting the marijuana testing facility, the number and type of sample containers required to transport the primary sample and any separate sample increments to the testing facility for mandatory testing.
 - a. Sample increments for homogeneity testing must be stored in a separate sample collection container from the other combined primary sample to ensure accurate testing.
 - b. Sample increments for some analyses, depending on the instrumentation of the marijuana testing facility conducting the mandatory analyses, may require storage and transport in particular kinds of sample collection containers to ensure the integrity of the samples collected.

Section 5.6 - Sample Preparation and Testing

- A. The marijuana testing facility must designate an area for preparation of marijuana product samples for analysis.
- B. The preparation area must include:
 - (1) Disposable gloves to be worn, to avoid sample contamination;
 - (2) Decontaminated or single-use disposable tool(s), including stainless steel spatulas, knives and/or disposable pipettes;
 - (3) Decontaminated stainless-steel bowls and implements for homogenizing samples appropriately;
 - (4) Clean, decontaminated surfaces for sample processing;
 - (5) Decontaminated or single use, disposable sample containers appropriate for processing;
 - (6) Labels and pens with indelible ink; and
 - (7) Necessary supplies for thoroughly cleaning, decontaminating and drying sample preparation tools and equipment between samples.

Section 6 – Testing of Marijuana and Marijuana Products

Section 6.1 - Mandatory Testing Required

An adult use marijuana licensee may not sell or distribute adult use marijuana or an adult use marijuana product to a consumer or to another licensee unless the marijuana or marijuana product has been tested pursuant to this Rule and that 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, except that OMP may temporarily waive mandatory testing requirements under this section for any contaminant or factor for which OMP has determined that there exists no licensed marijuana testing facility in the state capable of and certified to perform such testing.

Section 6.2 - Mandatory Testing and Additional Analysis

Marijuana products must be tested in accordance with this Rule. OMP or a client may request additional analyses which will be specified by the marijuana testing facility in the written sampling plan.

- A. The following tests are mandatory for all marijuana or marijuana products prior to being sold or transferred to a consumer or another licensee:
- (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.
 - (3) **Pesticides (insecticides, fungicides, herbicides, acaricides, plant growth regulators, disinfectants, etc.).** Bifenthrin, cyfluthrin, daminozide, etoxazole, imazalil, myclobutanil, spiromesifen, trifloxystrobin, and any others reported by the cultivation facility licensee in its operating plan. Marijuana testing facilities must also report any pesticides that appear on testing and which are on the list of 195 pesticides federally prohibited for use on organic produce.
 - (4) **Other harmful chemicals.** Cadmium (Cd), lead (Pb), arsenic (As) and 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, Enterobacteriaceae, *E. coli* 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 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 registered or licensed cultivation facility, registered or licensed products manufacturing facility, registered inherently hazardous extraction facility, registered or exempt caregiver, or registered dispensary may submit for research and development purposes samples of marijuana, but such testing shall not be considered mandatory, and marijuana that is transferred to a licensee or consumer must then undergo mandatory testing.

- C. OMP or its designee will publish a best practices guidance document that includes examples of a sampling plan and preservation instructions appropriate to each matrix type.
- D. A marijuana testing facility must perform, and provide a certificate of analysis for, any test(s) requested by the CDC or OMP on any sample.

Section 6.3 - Testing Methodology

- A. Testing facilities must develop and implement scientifically valid testing methodologies for the chemical, physical and microbial analysis of marijuana and marijuana products. A method validated in accordance with this section is deemed a scientifically valid testing methodology. The marijuana testing facility must not perform testing using a method that has not been validated.
- B. To the extent practicable, the marijuana testing facility's testing methodologies must comport with the following guidelines:
 - (1) U.S. Food and Drug Administration's Bacterial Analytical Manual, 2016;
 - (2) AOAC International's Official Methods of Analysis for Contaminant Testing of AOAC International, 20th Edition, 2016;
 - (3) Methods of analysis for contaminant testing published in the 2016 United States Pharmacopeia and the National Formulary (USP-NF); or
 - (4) If the marijuana testing facility wants to use an alternative scientifically valid testing methodology, the marijuana testing facility must validate the methodology and submit the validation study and standard operating procedure for the new methodology to the CDC.

Section 6.4 - Validation of Non-Standard Test Methods or Technologies and Modified Standard Test Methods or Technologies

- A. The marijuana testing facility may use a nonstandard method, including the use of a technology or instrumentation that is not one of the suggested instrumentations indicated in this rule, and including the use of a marijuana testing facility-designed or -developed method, a standard method used outside its intended scope or an amplification or a modified standard method for the analysis of samples, so long as the marijuana testing facility receives CDC certification for the use of such a nonstandard method.
- B. The marijuana testing facility must validate a desired method to use for the analysis of samples for each matrix. The marijuana testing facility must use one of the following guidelines, or equivalent methodologies, for validating a method, depending on the type of method:
 - (1) U.S. Food and Drug Administration's Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition, 2015; or
 - (2) U.S. Food and Drug Administration's Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition, 2015.
- C. At a minimum, the marijuana testing facility must conduct a level-one (emergency-use) single-marijuana testing facility validation study for all methods for testing for microbiological impurities or chemicals.
- D. A marijuana testing facility must include and address the criteria listed in Table 6.4-A in the marijuana testing facility's level-one validation study.

Table 6.4-A. Microbiological-analysis method validation studies

Criteria	Requirement
Number of target organisms; inclusivity	5
Number of non-target organisms; exclusivity	5
Number of analyte levels per matrix: Qualitative methods	3 levels: high and low inoculum levels and 1 uninoculated level
Number of analyte levels per matrix: Quantitative methods	4 levels: low, medium and high inoculum levels and 1 uninoculated level
Replicates per food at each level tested	2 or more replicates per level
Reference method comparison	No

- E. For purposes of validating standards for microbiological analysis, the following definitions apply:
- (1) “Exclusivity” is the specificity of the test method. It evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms.
 - (2) “Inclusivity” is the sensitivity of the test method, meaning its capability to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. It evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness.
- F. For chemical analysis method validation studies:
- (1) When high-concentration reference standards are available, testing facilities must employ direct spiking of the sample matrix.
 - (2) When high-concentration standards for matrix spiking are unavailable, matrix spikes may be made through post-processing and dilution spiking of samples before analysis, rather than direct sample-matrix spike.
- G. Testing facilities must use reference materials validation studies when marijuana reference materials become available.

Section 6.5 - Certificate of Analysis

- A. For each primary sample of a batch tested, the marijuana testing facility must generate and provide a certificate of analysis to the requester and the CDC within two business days of the completion of the final data review.
- B. The certificate of analysis must, at a minimum, contain the following information:
- (1) Marijuana testing facility’s name, mailing address and physical address;
 - (2) Sample-identifying information, including matrix type and unique sample identifiers;
 - (3) Sample history, including date collected, date received by the marijuana testing facility, whether the sample was collected by the marijuana testing facility or received from a licensee and date or dates of sample preparations and analyses;
 - (4) The identity of the test methods used to analyze cannabinoids, residual solvents, pesticides, microbiological contaminants, mycotoxins, heavy metals and, if applicable, terpenes;

- (5) Test results for sample homogeneity, if applicable; cannabinoids; residual solvents; pesticides; microbiological contamination; and, if applicable, terpenes;
 - (6) Test results for water activity and visual inspection for filth and foreign material;
 - (7) The reporting limit for each analyte tested;
 - (8) The total primary sample weight in grams, reported to three significant figures;
 - (9) Whether the primary sample and batch “passed” or “failed” marijuana testing facility testing;
 - (10) The licensee for whom the testing was performed, including license number, name and production batch number; and
 - (11) A disclaimer that not all potential/existing hazards were tested.
- C. The marijuana testing facility must validate the accuracy of the information contained in the certificate of analysis, and the facility director or QAO must sign and date the certificate of analysis.
- D. In the event that an error is discovered following the issuance of the certificate of analysis, the marijuana testing facility must correct the error through the correction and reissuance of the certificate of analysis to correct the error. The corrected certificate of analysis must state that is a reissued version of a previous certificate of analysis and must include the original sample identifiers as well as the reason for reissuance.

Section 6.6 - Cannabinoids

- A. When testing cannabinoid profile, the minimum representative sample size of 0.5 grams is required for all marijuana and marijuana products.
- B. When testing cannabinoid profile, the marijuana testing facility must minimally test for and report measurements for the following cannabinoids using instrumentation stated in Table 6.6-A:

Table 6.6-A. Cannabinoid Potency

Cannabinoid Potency as % of weight	Suggested Instrumentation
Δ^9 -THC	LC-DAD, LC-MS, LC-MS/MS or GC-FID
THCA	LC-DAD, LC-MS, LC-MS/MS or GC-FID
CBD	LC-DAD, LC-MS, LC-MS/MS or GC-FID
CBDA	LC-DAD, LC-MS, LC-MS/MS or GC-FID
Total THC (as sum of THCA and delta-9 THC)	LC-DAD, LC-MS, LC-MS/MS or GC-FID
Total CBD (as sum of CBDA and CBD)	LC-DAD, LC-MS, LC-MS/MS or GC-FID

Note: Testing Facility calculation (only for instrumentation that does not employ heat for analysis) for Total THC = delta-9 THC + (THCA*0.877) and Total CBD = CBD + (CBDA*0.877) LC = Liquid Chromatography; DAD = Diode Array Detector; MS = Mass spectrometry; GC = Gas chromatography; FID = Flame ionization detector

- C. For samples of marijuana flower, non-edible marijuana products and marijuana concentrate, the marijuana testing facility must report, to three significant figures, the concentration in milligrams per gram (mg/g) of the cannabinoids listed in Table 6.6-A. For edible marijuana products, the marijuana testing facility must report, to three significant figures, the concentration in milligrams per serving (mg/serving) and milligrams per package (mg/package) of total THC in the product. The marijuana testing facility must report this information in the certificate of analysis. When determining whether a sample of marijuana product

exceeds the 10 mg/serving and 100 mg/package limits required by 28-B MRS § 703, the marijuana testing facility must account for laboratory uncertainty.

- D. The marijuana testing facility may test for, and provide test results for, additional cannabinoids, if requested to do so by the client of the marijuana testing facility; however, these additional tests will not be certified by the CDC.
- E. If synthetic cannabinoids are detected during analysis, the COA must report that the batch failed analysis.
- F. When testing for homogeneity of cannabinoids in marijuana products:
 - (1) The marijuana testing facility must perform a homogeneity test for Total THC or Total CBD, whichever is purported by the manufacturer to be the largest ingredient content, for each production batch. If the amounts of Total THC and Total CBD are very similar (near 1:1), the marijuana testing facility must test for homogeneity of Total THC.
 - (2) A homogeneity test requires at least two increments, collected separately from those collected for the field primary sample, from different regions of the production batch, and analyzed as separate samples. Sample collection must be in accordance with procedures in the OMP's best practices guidance document for sampling marijuana for mandatory testing purposes and the marijuana testing facility's standard operating procedure for sampling.
 - (3) The marijuana testing facility must determine the relative standard deviation of Total THC or Total CBD content using test results of the two separately collected increments and the field primary sample collected for potency analysis. If the relative standard deviation is greater than 15%, then the batch "fails" the homogeneity test.
 - (4) If a homogeneity test is not performed or if a batch fails homogeneity testing, the batch fails and must be destroyed or, at the discretion of OMP, remediated and retested.
 - (5) If the product batch passes homogeneity testing, the marijuana testing facility may perform all other analyses required under this rule.
- G. When testing for homogeneity of edible marijuana products, a minimum size sample of 0.5 grams per increment is required.
 - (1) The number of samples required for analysis is specified in Table 5.5-A. Each increment constitutes one packaged unit.
 - (2) Total THC and, if applicable, Total CBD values between samples must not vary by more than 15% or the product fails testing.

Section 6.7 - Residual Solvents and Processing Chemicals

- A. The minimum sample size of 0.5 grams of representative sample is required for residual solvent analysis.
- B. The marijuana testing facility must analyze samples in each production batch for residual solvents and processing chemicals, including but not limited to inherently hazardous substances, in accordance with Table 6.7-A.
 - (1) The marijuana testing facility is not required to analyze for residual solvents and processing chemicals in dried flower, kief and hashish or marijuana products manufactured without chemical solvents.
 - (2) The marijuana testing facility is not required to analyze an orally-consumed tincture marijuana product containing alcohol for residual ethanol.
- C. For the purposes of residual solvent testing, the marijuana testing facility must report that the sample "passed" residual-solvent testing, if the concentrations of residual solvents are reported at or below the residual solvents and processing chemicals action levels in Table 6.7-A below. However, the marijuana testing facility must report a sample failed if the marijuana testing facility detects any level of a potentially or inherently hazardous substance which the licensee does not have listed on their operating plan.
- D. The marijuana testing facility must report the solvents and processing chemicals listed in this section, in parts per million (ppm) to three significant figures. The marijuana testing facility must report this information in the certificate of analysis.

- E. The marijuana testing facility must test both the concentrations of solvents and processing chemicals in the sample within the certificate of analysis, as well as document clearly whether the sample “passed” or “failed” residual solvent and processing-chemicals testing.
- F. If the sample fails residual solvent testing, the batch may be remediated in accordance with all applicable rules from OMP.
- G. A remediated batch that previously failed a test due to exceeding the action levels for residual solvents must be retested for solvents.
- H. The batch must be destroyed when it is either not remediated, or a sample from the remediated batch fails testing.

Table 6.7-A. Concentration Limits for Residual Solvents, (mg/kg)

Chemical Name	CAS No.	Marijuana Product
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Butanes ^a	106-97-8	5000
Ethanol ^b	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethyl ether	60-29-7	5000
Heptanes	142-82-5	5000
Hexane**	110-54-3	290
Isopropyl alcohol ^b	67-63-0	5000
Methanol	67-56-1	3000
Pentane	109-66-0	5000
Propane ^a	74-98-6	5000
Toluene**	108-88-3	890
Total Xylenes (m, p, o-xylenes) **	1330-20-7	2170
1,2-Dichloroethane	107-06-2	1
Benzene**	71-43-2	1
Chloroform	67-66-3	1
Ethylene oxide	75-21-8	1

Methylene chloride	75-09-2	1
Trichloroethylene	79-01-6	1
Any other solvent detected not permitted for use		None Detected

** Due to the possible presence in the solvents approved for use, limits have been listed accordingly

Note:

- a) USP does not provide residual solvent limits for this solvent, the default USP Class 3 limits for acceptable use solvents was assigned as a limit.
- b) Products that are orally consumed and/or topically applied are exempt from ethanol limits.

Section 6.8 - Residual Pesticides and Growth Regulators

- A. The minimum sample size is 0.5 grams of representative samples for all marijuana and marijuana products.
- B. The marijuana testing facility must test all finished plant material samples for residual pesticides, including plant regulators, to ensure pesticide use and use of plant regulators are in compliance with applicable rules related to pesticides. Once a batch has passed this testing, the marijuana product resulting from this batch does not need to be tested again for pesticides and growth regulators.
- C. The results of pesticide analyses must be less than the marijuana testing facility's established detection limit for each matrix. The marijuana testing facility may not adjust the established detection limit for any matrix without approval from OMP and the CDC. The marijuana testing facility will need to provide documentation of detection limit studies prior to approval of newly adjusted testing limits.
- D. The marijuana testing facility must report the levels detected in micrograms per kilogram ($\mu\text{g}/\text{kg}$) to three significant figures in the certificate of analysis. If a sample is found to contain pesticides above the marijuana testing facility's detection limit, the sample "fails" pesticide testing.
- E. The marijuana testing facility must analyze pesticides, in addition to those in listed in Table 6.8-A, based on the approach used by USDA in its *2010-2011 Pilot Study: Pesticide Residue Testing of Organic Produce*, November 2012, to analyze 195 prohibited pesticides the USDA has prohibited in organic food. The marijuana testing facility must utilize analytic procedures in accordance with 7 CFR, Part 205 and the *Official Methods of Analysis of the AOAC International* or other current applicable validated methodologies for determining the presence of contaminants in agricultural products.
 - (1) Although no single analytical method currently exists to analyze all 195 prohibited pesticides, testing facilities must analyze as many compounds on the USDA target analyte list for organic food as required by OMP. A marijuana establishment licensee may not use any of the prohibited substances listed in Table 6.8-A, nor may it use any of the 195 prohibited pesticides on the USDA's prohibited pesticides list. A complete list of the USDA National Organic Program prohibited pesticides is included in Appendix A of this rule.
 - (2) If result(s) of pesticide analysis indicates the presence of any of the prohibited pesticides, or, if, as an approved pesticide, test result is in excess of the tolerances or maximum residue limits (MRLs) determined unsafe or potentially harmful by the US Environmental Protection Agency (US EPA) for that pesticide, the batch fails.
- F. The list of pesticides and growth regulators in Table 6.8-A and Appendix A is not comprehensive, however, the vast majority of available pesticide products are prohibited from use on marijuana. Using a pesticide or growth regulator on a site for which it is not labeled or applying a pesticide or growth regulator in a manner inconsistent with label instructions is a violation of State and Federal law.

Table 6.8-A. Instrumentation Requirements for Pesticides and Growth Regulators

Pesticide	CAS #	Chemical Class	Suggested Instrumentation
Bifenthrin	82657-04-3	Insecticide	GC-ECD; GC-MS/MS OR LC-MS/MS
Cyfluthrin	6859-37-5	Acaricide	LC/UV; LC-MS/MS
Daminozide	1596-84-5	Growth Regulator	LC/UV; LC-MS/MS
Etoxazole	153233-91-1	Insecticide	GC-MS (/MS); LC-MS/MS
Imazalil	35554-44-0	Fungicide	GC-ECD; LC-MS/MS
Myclobutanil	88671-89-0	Fungicide	GC-ECD; GC-NPD; GC-MS/MS; LC-MS/MS
Spiromesifen	283594-90-1	Insecticide	GC-MS; LC-MS/MS
Trifloxystrobin	141517-21-7	Fungicide	GC-NPD; GC-MS/MS

GC = Gas Chromatography; FLD = Fluorescence; LC = Liquid Chromatography; Detector; MS = Mass spectrometry; ECD = Electron Capture Detector; UV = Ultra Violet Detector; NPD = Nitrogen-Phosphorus Detector

Section 6.9 - Heavy Metals

- A. The minimum representative sample size is 0.5 grams of all marijuana and marijuana products.
- B. When testing for heavy metals, the marijuana testing facility must analyze all samples for concentrations of the heavy metals listed in Table 6.9-A below.
- C. The marijuana testing facility must report the concentration of each heavy metal in micrograms per kilogram ($\mu\text{g}/\text{kg}$) in the certificate of analysis.
- D. The marijuana testing facility must report that the sample “passed” heavy-metal testing, if the concentrations of heavy metals listed in the table below are below the following heavy metal action levels.
- E. The marijuana testing facility may test for and report test results for additional metals, if the instrumentation detects additional metals in the samples, or if requested by the State or the client of the marijuana testing facility testing.

Table 6.9-A. Concentration Limits for Metals, (µg/kg)

Heavy Metal	Inhalation	Ingestion or Suppository	Topical Application	Suggested Instrumentation
Cadmium (Cd)	200	500	5000	AA, ICP-OES or ICP-MS
Lead (Pb)	500	500	10,000	AA, ICP-OES or ICP-MS
Arsenic (As)	200	1500	1000	AA, ICP-OES or ICP-MS
Mercury (Hg)	100	3000	1000	CVAA or ICP-MS

AA – Atomic Adsorption; ICP = Inductively Coupled Plasma; OES – Optical Emission Spectrometry;

MS = Mass Spectrometry; CVAA = Cold Vapor Atomic Absorption Review USP 2232

*These limits apply to marijuana and marijuana concentrate intended for ingestion, inhalation or dermal application. These limits are based on inhalation limits described in USP<232> Elemental Impurities-Limits.

Section 6.10 - Microbiological Impurities

- A. The minimum, representative sample size of 1.2 grams of finished plant material is required for analysis. The minimum representative sample size of 1.0 g of edible products is required for analysis.
- B. The marijuana testing facility must also test all marijuana concentrates for microbiological impurities. For the purposes of microbiological testing, the marijuana testing facility must report that the sample “passed” microbiological-impurity testing if the contaminants listed in Table 6.10-A below do not exceed the limits. If the marijuana product is found to have a contaminant in levels exceeding those established as permissible under this rule, then it failed contaminant testing.
- C. If a processing method can effectively sterilize the batch, then the batch may be:
 - (1) Used to make a concentrate or extract (if unprocessed); or
 - (2) Further processed (if processed); or
 - (3) Destroyed.
- D. If the licensee chooses the option to remediate following a failed fungus or mold test, the batch will need to be retested by the same marijuana testing facility and will need to include mycotoxin analysis. This will include Aflatoxins (B1, B2, G1 and G2) and Ochratoxin A. The total combined result of the five required mycotoxins must be less than 20 µg/kg to be considered a passing result.

Table 6.10-A. Limits for Microbiological Contaminants in CFU/g

Marijuana Material	Total Viable Aerobic Bacteria	Total Yeast and Mold	Total Coliform Bacteria	Enterobacteriaceae	E. coli and Salmonella (spp.)
Unprocessed and Processed Plant Material	10 ⁵	10 ⁴	10 ³	10 ³	<1/g sample
CO ₂ and Solvent-Based Extracts	10 ⁴	10 ³	10 ²	10 ²	<1/g sample

Based on analytical limits based on American Herbal Pharmacopoeia, Revision 2014.

- E. The marijuana testing facility must report the concentration of each mycotoxin in micrograms per kilogram ($\mu\text{g}/\text{kg}$) to three significant figures in the certificate of analysis.
- F. The marijuana testing facility must report whether the strains listed in Table 6.10-A are detected, or are not detected, in 1.0 gram. The marijuana testing facility must report this information in the certificate of analysis. If any strains are detected above limits set in Table 6.10-A above, the batch fails testing and may not be released for sale.
- G. The marijuana testing facility may test for and provide test results for additional microorganisms if requested.

Section 6.11 - Water Activity and Moisture Content

- A. The minimum representative sample size of 0.5 grams of dried flower and 1.0 g of edible products is required for analysis.
- B. If the water activity in a dried flower production batch sample is at or below, $0.65 A_w$, the sample “passes” water-activity testing.
- C. If the water activity in solid and semi-solid edible marijuana products that do not require additional preservation (e.g. refrigeration) is at, or below, $0.85 A_w$, the sample “passes” water-activity testing.
- D. The marijuana testing facility must report the moisture content of dried flower, trim and other plant material that has been dried, cured or otherwise prepared in a manner to reduce or eliminate moisture from the plant material.
- E. The marijuana testing facility must report the water-activity level of the sample in A_w and the moisture content of the sample in percent to two significant figures.
- F. The marijuana testing facility must report this information in the certificate of analysis.
- G. The marijuana testing facility may provide additional information on moisture content and water activity results, if the marijuana testing facility determines that it is important, or if it is requested.

Section 6.12 - Visual Inspection for Filth and Foreign Material

- A. The minimum sample size is 0.5 grams of representative samples.
- B. The marijuana testing facility must visually inspect all samples for signs of filth and foreign material present in the sample. “Filth and foreign material” includes, but is not limited to, hair, insects, feces, packaging contaminants and manufacturing waste and by-products.
 - (1) The samples shall not pass if any living or dead insect, at any life cycle stage; one hair; or one count of mammalian excreta is found.
 - (2) The sample shall not pass if more than one fourth of the total area is covered by mold, sand, soil, cinders, dirt or imbedded foreign material.
- C. The marijuana testing facility must report in the certificate of analysis whether the sample “passed” or “failed” visual inspection for filth and foreign material.
 - (1) If it fails visual inspection for filth and foreign-material, the batch fails testing.
 - (2) A production batch that fails must be destroyed unless it can be remediated pursuant to any rules of OMP.
 - (3) Failed batches not successfully remediated must be destroyed.

Section 6.13 - Terpenes

- A. The marijuana testing facility may also report individual terpene results, as requested.
- B. If the product labeling reports that the sample contains discrete terpenes, the marijuana testing facility must test for those terpenes. The marijuana testing facility must report to one-hundredth of a percent the concentration in percentage in the certificate of analysis.

Section 6.14 - Quality Control

- A. The marijuana testing facility must use quality control samples in the performance of each assay for chemical and microbiological analyses.
- (1) The marijuana testing facility must analyze the quality control samples in the exact same manner as the test samples, to validate the testing results.
- B. The marijuana testing facility must run quality control samples with every analytical batch of samples. For chemical analyses, the marijuana testing facility must prepare and analyze samples in batches of up to 20 samples, to include a method blank, a laboratory control sample, a sample duplicate, a matrix spike sample, and a certified reference material when available.
- (1) A method blank means an analyte-free matrix, to which all reagents are added in the same volumes or proportions as are used in sample preparation.
 - (a) Method blanks are analyzed under the same conditions, including sample preparation steps, as the other samples in the analytical batch to demonstrate the analytical process does not introduce contamination.
 - (b) If the method blank contains analyte(s) of interest greater than half of the reporting limit or limit of quantitation, the data needs to be flagged with a “B” and an explanation noted in the certificate of analysis.
 - (c) If the method blank contains analyte(s) of interest above the limit of quantitation, it should be reanalyzed once. If the method blank is still above the limit of quantification, the marijuana testing facility should seek to locate and reduce the source of the contamination, and then the entire batch should be re-prepared and reanalyzed. If the method blank results still do not meet the acceptance criteria, and reanalysis is not practical, then the marijuana testing facility must halt performing the analysis until resolution of this issue. Resolution of the issue requires the reduction of method blank measurements below the limit of quantification.
 - (2) A laboratory control sample means a simplified sample matrix, free from analytes of interest, spiked with known amounts of analytes, using a second source standard (a standard obtained from a different supplier than the calibration standards), where available, and taken through all sample preparation and analytical steps of the procedure, unless otherwise noted in a reference method (also known as a laboratory fortified blank, spiked blank or quality control check sample).
 - (a) When reference standards are commercially available in usable concentrations, and are applicable to the method being run, the marijuana testing facility must prepare and run one or more matrix samples spiked with the standard at a known concentration for each analytical batch up to 20 samples.
 - (b) The marijuana testing facility must calculate the percent recovery for quantitative chemical analysis, for the laboratory control sample spiked with a known amount of reference standard. The acceptable percent recovery is $\pm 20\%$.
 - (c) If the percent recovery is outside of the acceptable range, the marijuana testing facility must investigate the cause, correct the problem and re-run the batch of samples. If the problem persists, the marijuana testing facility must re-prepare the samples and run the analysis again, if possible. If a laboratory control sample is performed and fails, it must be flagged with “*” and an explanation noted in the certificate of analysis.
 - (3) A sample duplicate means a separate aliquot of the sample carried through the complete preparation and analytical procedure.
 - (a) The acceptance criteria between the primary sample and the duplicate sample must be less than 20% relative percent difference. Relative percent difference is calculated using the following equation: $RPD = \frac{|(\text{primary sample measurement} - \text{duplicate sample measurement})|}{([\text{primary sample measurement} + \text{duplicate sample measurement}] / 2)} \times 100\%$.
 - (b) Limits must be set at $<20\%$ until enough data points are established to create lab defined limits. At no point can lab calculated limits be greater than the 20% listed in this rule.

- (c) If the RPD exceeds the acceptance limits for a sample duplicate, it must be flagged with a “*” and an explanation noted in the certificate of analysis.
 - (4) A matrix spike means a sample prepared by adding a known quantity of analyte and subjecting the sample to the entire analytical procedure to determine the ability to recover the known analyte or compound.
 - (a) When reference standards are commercially available in usable concentrations and are applicable to the method being run, the marijuana testing facility must prepare and run one or more matrix samples spiked with the standard at a known concentration for each analytical batch up to 20 samples.
 - (b) The marijuana testing facility must calculate the percent recovery for quantitative chemical analysis by analyzing an aliquot of sample spiked with a known amount of reference standard. An aliquot of the sample is analyzed without the spike, and the result is subtracted from the spiked value. The sample result, after subtraction, is divided by the expected result and multiplied by 100. If interferences are present in the sample, results may be significantly higher or lower than the actual concentration contained in the sample. The acceptable percent recovery is 70% to 130%.
 - (c) If the percent recovery is outside of the range, the marijuana testing facility must investigate the cause, correct the problem and re-run the batch of samples. If the problem persists, the marijuana testing facility must re-prepare the samples and run the analysis again, if possible. If a matrix spike is performed and fails, it must be flagged with an “*” and an explanation noted in the certificate of analysis.
 - (5) A certified reference material (CRM) means a reference material, accompanied by a certificate, having a value, measurement of uncertainty and stated metrological traceability chain to a national metrology institute. The CRM must be in a matrix comparable to the samples being analyzed.
 - (a) When available, certified reference material must be obtained from an outside source.
 - (b) If an in-matrix CRM is not available from an outside source, the marijuana testing facility may make its own in-house reference material. In-house reference material must contain verified amounts of analytes determined by analyzing a batch of thoroughly homogenized sample material a minimum of ten times and using the average result of those ten replicate analyses as the accepted verified value.
 - (c) The CRM must fall within the quality control acceptance criteria given in its certificate, criteria given in a referenced test method, or be within +/- 20% of the given value, whichever is most stringent. If an in-house reference material is used, the result must fall within +/-20% of the verified value as determined in (b) above. If the result does not meet these criteria, the marijuana testing facility must investigate the cause, correct the problem and re-run the batch of samples. If the problem persists, the marijuana testing facility must re-prepare the samples and run the analysis again, if possible. If a CRM or in-house reference material is performed and fails, it must be flagged with an “*” and an explanation must be noted in the certificate of analysis.
- C. For microbiological analysis, the marijuana testing facility must prepare and analyze a negative control sample and a positive control sample for each new lot of testing media or reagent.
 - (1) A negative control sample means a QC sample for microbiological testing that is expected to produce a reaction which indicates the absence of the target organism.
 - (2) A positive control sample means a QC sample for microbiological testing that is expected to produce a reaction which indicates the presence of the target organism.
 - (3) Positive and negative control samples are analyzed under the same conditions as samples in an analytical batch to demonstrate the analytical process does not adversely affect test results.
 - (4) If the positive or negative control sample results do not meet acceptance criteria, the marijuana testing facility must investigate the cause, correct the problem, and rerun the positive and negative control samples. If the problem persists, the marijuana testing facility must reject the lot of testing media or reagent and use a new lot that passes QC testing.
- D. The marijuana testing facility must prepare calibration standards by diluting a standard solution to produce working standards used for calibration of the instrument and quantitation of analyses in samples.

- E. Marijuana testing facility must perform initial calibration of instruments and calibration verification.
- (1) Initial Calibration
- a. Sufficient records must be retained to permit reconstruction of the instrument calibration such as calibration date, approved method identification, instrument, analysis date, each analyte name, the manual or electronic identification of the analyst performing the test, concentration and response, calibration curve or response factor or unique equation or coefficient used to reduce instrument responses to concentration.
 - b. Sample results must be quantitated from the most recent instrument calibration and may not be quantitated from any earlier instrument calibration verification.
 - c. All instrument calibrations must be verified with a standard obtained from a second source such as a different manufacturer, when available. Traceability must be to a national standard, when available.
 - d. Criteria for the acceptance of an instrument calibration must be established, such as correlation coefficient or relative standard deviation. The criteria used must be appropriate to the calibration technique employed and must be documented in the laboratory's SOP.
 - e. The following must occur for methods employing standardization with a zero point and a single point calibration standard:
 - (i) Before the analysis of samples, the linear range of the instrument must be established by analyzing a series of standards, one of which must encompass the single point quantitation level;
 - (ii) A zero point and a single point calibration standard must be analyzed with each analytical batch;
 - (iii) A standard corresponding to the RL must be analyzed with each analytical batch and must meet established acceptance criteria;
 - (iv) The linearity must be verified at a frequency established by the method or the manufacturer; and
 - (v) If allowed in the rule, a sample result within an analytical batch, higher than its associated single point standard, can be reported if the following conditions are met:
 - (1) A standard with a concentration at or above the analyte concentration in a sample must be analyzed and must meet established acceptance criteria for validating the linearity;
 - (2) The sample must be diluted such that the result falls below the single point calibration concentration; or
 - (3) The data must be reported with an appropriate data qualifier or an explanation in the narrative of the test report.
 - f. If the instrument calibration results are outside established acceptance criteria, corrective actions must be performed, and all associated samples reanalyzed. If reanalysis of the samples is not possible, data associated with an unacceptable instrument calibration must be appropriately qualified on the test report.
 - g. Calibration standards must include concentrations at or below the limit specified in the rule.
 - h. The minimum number of calibration standards shall be three, one of which must be at the RL, not including blanks or a zero standard, with the exception of instrument technology for which it has been established by methodologies and procedures that a zero and a single point standard are appropriate for calibrations. The marijuana testing facility must have an SOP that documents the protocol for determining the number of points required for the instrument calibration employed and the acceptance criteria for calibration.
 - i. It is prohibited to remove data points from within a calibration range while still retaining the extreme ends of the calibration range.
- (2) Calibration verification
- a. When an instrument calibration is not performed on the day of analysis, the instrument calibration must be verified before analysis of samples by analyzing a calibration standard with each batch.
 - b. Calibration verification must be repeated at the beginning of each batch, after every tenth sample, excluding QC samples, and at the end of each batch.
 - c. Sufficient raw data records must be retained to permit reconstruction of the calibration verification, such as: instrument; analysis date; each analyte name, concentration and response;

calibration curve or response factor; or unique equations or coefficients used to convert instrument responses into concentrations. Calibration verification records must explicitly connect the verification data to the instrument calibration.

- d. Criteria for the acceptance of calibration verifications must be established and evaluated using the same technique used to evaluate the instrument calibration.
 - e. If the calibration verification results obtained are outside established acceptance criteria, corrective actions must be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then the marijuana testing facility must either demonstrate performance after corrective action by performing one successful calibration verification or perform a new instrument calibration. If the marijuana testing facility has not demonstrated acceptable performance after the corrective action, sample analyses must not occur until a new instrument calibration is established and verified. Sample data associated with unacceptable calibration verification may be reported as qualified data under the following special conditions if allowed in rule:
 - (i) When the acceptance criteria for the calibration verification are exceeded high (high bias) and all associated samples contain analytes below the RL, those sample results may be reported.
 - (ii) When the acceptance criteria for the calibration verification are exceeded low (low bias), the sample results may be reported if the concentration exceeds a maximum regulatory limit as defined by the rule.
 - f. When allowed by rule, verification procedures may result in a set of correction factors. If correction factors are employed, the marijuana testing facility must have procedures to ensure that copies of all data records, such as in computer software, are correctly updated.
 - g. Test equipment, including both hardware and software, must be safeguarded from adjustments that would invalidate the test results.
- F. The marijuana testing facility must store stock standards and reagents per manufacturer's recommendations and use or discard by manufacturer's expiration dates. All prepared standards and reagents must be traceable to stocks, and the date of preparations and expiration date must be traceable in facility documentation.
- G. All quality control measures must be assessed and evaluated on an ongoing basis. QC acceptance criteria in the marijuana testing facility's QA manual must be used to determine the validity of data.
- H. If the marijuana testing facility finds evidence that a sample is contaminated due to contamination in the sample collection process, the marijuana testing facility will contact the individual or entity responsible for sample collection to validate the sample collector or self-sampling licensee's decontamination procedure.
- I. Upon request by the CDC, the marijuana testing facility must in a timely manner generate and submit to CDC a quality control sample report that includes QC parameters and measurements, analysis date and matrix.
- J. CDC may require in writing reasonable additional quality control measures for any testing methodology as found in previously established Federal or State guidelines such as:
- (1) AOAC International's Official Methods of Analysis for Contaminant Testing of AOAC International, 20th Ed., 2016;
 - (2) U.S. Food and Drug Administration's NCIMS 2400 Forms, Rev. 04/2019; or
 - (3) State of Maine Comprehensive and Limited Environmental Laboratory Accreditation Rule, 10-144 CMR Ch. 263 (2018).

Section 7 – Recordkeeping Requirements

Section 7.1 - Recordkeeping Requirements

- A. The marijuana testing facility must maintain analytical records to demonstrate to 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 recordkeeping may be on paper or on electronic, magnetic or optical media and must be stored in such a way that the data are readily retrieved when requested by the OMP or the CDC.
 - (2) If the marijuana testing facility recordkeeping is not on paper, the marijuana testing facility must be able to produce them in hard copy for OMP or the CDC, upon request.
 - (3) All marijuana testing facility records must be kept for a minimum of five years.
 - (4) OMP 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 listed below.
- B. The marijuana testing facility must maintain all documents, forms, records and standard operating procedures associated with the marijuana testing facility's methods, including without limitation the following:
- (1) Current personnel qualification, training and competency documentation, including, but not limited to, resumes, training records, continuing education records, analytical proficiency testing records and demonstration of capability records or attestations for marijuana testing facility work;
 - (2) Method verification and validation records, including records relating to method modification; method detection limit and reporting limit determination; ongoing verification, such as proficiency testing; and reference material analysis;
 - (3) Quality control and quality assurance records, including the marijuana testing facility's quality assurance manual and control charts with control limits;
 - (4) Any sample collection records the testing facility requires licensees to submit with every sample collected and submitted for mandatory testing, if applicable in accordance with the testing facility's quality system;
 - (5) Chain of custody records, including chain of custody forms, applicable field sample logs, and record relating to sample receipt, sample descriptions, sample rejections, laboratory information management system (LIMS), sample storage, sample retention and disposal;
 - (6) Records relating to purchasing and supply, purchase requisitions, packing slips, and supplier records;
 - (7) Certificates of analysis;
 - (8) Records of equipment installation, maintenance and calibration, including date; name of person performing the installation, calibration or maintenance; and description of the work performed; internal maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records and daily verification-of-calibration records;
 - (9) Customer service records, including include contracts with customers, customer request records, transaction records and customer feedback;
 - (10) Records related to the handling of complaints, nonconformities, and corrective action, including records of internal investigations, customer notifications and implementation of corrective action plans;
 - (11) Internal and external audit records, including audit checklists, standard operating procedures and audit observation and findings reports, including the date and name of the person or persons performing the audit;
 - (12) Management review records, including technical data review reports and final management review reports, with review date and the identity of the reviewer;
 - (13) Marijuana testing facility data reports, data review and data approval records, which must include the analysis date and the name of the analysts, including instrument and equipment identification records, records with unique sample identifiers, analysts' marijuana testing facility notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data and test-method raw data;
 - (14) Proficiency testing records, including the proficiency test schedule, proficiency test reports, and records of data review, data reporting, nonconforming work, corrective action, quality control and quality assurance;

- (15) Electronic data, backed-up data, records regarding the protection of data and marijuana testing facility security records, including raw unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, authorized personnel records and marijuana testing facility access records and surveillance- and security-equipment records;
 - (16) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' marijuana testing facility notebooks and logbooks, supplier records and all other data-related records; and
 - (17) Marijuana testing facility contamination and cleaning records, including autoclave records, acid wash logs and records and general marijuana testing facility safety and chemical-hygiene protocols.
- C. If the records are missing or incomplete, or if the marijuana testing facility does not produce the records for OMP or the CDC upon request, OMP or the CDC may take disciplinary action against the marijuana testing facility. The marijuana testing facility shall have 7 calendar days from issuance of request to respond.

Section 7.2 - Data Package Requests

- A. The marijuana testing facility must retain the entire data package for each sample the marijuana testing facility analyzes for a minimum of five years and make available to OMP or the CDC upon request. The data package must contain, at a minimum, the following information:
- (1) The name and address of the marijuana testing facility that performed the analytical procedures;
 - (2) Any sample collection records required by the testing facility's quality system, if applicable, for each batch of marijuana, marijuana concentrate or marijuana product submitted for mandatory testing;
 - (3) The names, functions and signatures of the marijuana testing facility personnel that performed sample preparation and analyses and reviewed and approved the data;
 - (4) All sample and batch quality control sample results;
 - (5) Raw data for each sample;
 - (6) Instrument raw data, if any;
 - (7) Instrument test method with parameters;
 - (8) Instrument tune report;
 - (9) All instrument calibration data;
 - (10) Test method worksheets or forms used for sample identification, characterization and calculations, including chromatograms, sample preparation worksheets and final datasheets;
 - (11) Quality control report with worksheets, forms or copies of marijuana testing facility notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials and standards used for analysis;
 - (12) Analytical batch sample sequences;
 - (13) The field sample log and the chain of custody form; and
 - (14) The certificate of analysis created, as required under this rule.
- B. The marijuana testing facility must make the data package for a sample available.
- C. After the data package has been compiled, the facility director or QAO must:
- (1) Review the analytical results for technical correctness and completeness;
 - (2) Verify that the results of each analysis carried out by the marijuana testing facility are reported accurately, clearly, unambiguously and objectively and that the measurements are traceable; and
 - (3) Approve the measurement results by signing and dating the data package prior to release of the data by the marijuana testing facility.
- D. The testing facility must submit requested sample results to the CDC in an electronic format acceptable to the Maine Marijuana Certification Program (MMCP). This includes the reporting of all required laboratory quality control information and associated acceptance limits.

Section 7.3 - Electronic Data

- A. Testing facilities 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.
- B. Testing facilities must install, manage and maintain password-protection for electronically stored data, including any certificate of analysis.

Section 8 – Waste Disposal Plan

Section 8.1 – Waste Disposal SOP required

In addition to the SOPs required in Section 3 of this rule, a marijuana testing facility must possess and follow written SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products. All waste must be managed according to the following requirements:

- A. Solid waste, as defined in the *Maine Hazardous Waste, Septage and Solid Waste Management Act*, 38 MRS § 1303-C(29), must be managed in accordance with the *Solid Waste Management Rules*, 06-096 CMR, Ch. 400-425.
- B. The marijuana testing facility must destroy nonhazardous used or unused marijuana test samples in accordance with the facility's standard operating procedure and this rule.
- C. To render marijuana goods into marijuana waste, the marijuana testing facility must add the marijuana to other material not suitable for human consumption (e.g. agricultural manure suitable for composting, other compostable material) and mix it thoroughly. The resulting mixture must be at least 50% non-marijuana material. Licensees must render goods into marijuana waste one batch at a time and track that batch through its disposal in the statewide inventory tracking system.
- D. It is unlawful for any marijuana testing facility to dispose of marijuana goods or waste in a trashcan, dumpster or other similar receptacle, unless the nonhazardous goods or waste is composted and made unusable as described in this section. Testing facilities are required to quarantine marijuana goods on the premises for at least 3 business days to permit OMP time to investigate or witness the destruction process.
- E. The marijuana testing facility must document the quarantine, rendering into marijuana waste, and disposal or deposition of the marijuana waste. A marijuana testing facility may retain and utilize marijuana and marijuana products for use as standards or for method development.
- F. Hazardous wastes, as defined by 38 MRS § 1303-C(15), with the exception of infectious and pathogenic wastes, and in 06-096 CMR, Ch. 850, must be managed in accordance with Maine's Standards for Hazardous Waste Facilities Rules, Interim Licenses for Waste Facilities for Hazardous Wastes Rules, Licensing of Hazardous Waste Facilities Rules and Hazardous Waste Manifest Requirements (See 06-096 CMR, Chs. 850-857).
- G. If there is a conflict between another applicable rule or regulation and this rule, the more restrictive requirement applies.

Section 9 – Changes to Marijuana Testing Facility Operations

Section 9.1 - Post-Certification Change Notification

- A. The marijuana testing facility must provide OMP and the CDC with a written notice of any change described below at least thirty calendar days prior to the proposed effective date of the change:
 - (1) Change in ownership of the marijuana testing facility as defined in Section 2 of this rule;
 - (2) Change in the marijuana testing facility's facility director or QAO;
 - (3) Changes in the approved location for an analysis;
 - (4) Major changes in analytical equipment;
 - (5) Change to approved premises floor plan submitted to OMP in the marijuana testing facility's license application, including without limitation proposed premises expansion;
 - (6) Discontinuation of, or failure to launch, marijuana testing facility activities.
- B. When there is a change in location or change in technology of analysis, the marijuana testing facility must provide results of proficiency testing samples or a demonstration of capability, analyzed in the new marijuana testing facility location or analyzed under a change in instrumentation.

Section 9.2 - Post-Certification Change Notification

Unless the marijuana testing facility provides timely notification of the above changes and receives prior approval or waiver of the requirement of prior notice and approval by OMP and the CDC, the certification of the field of testing is void and must be returned to the CDC.

Section 10 – Denial, Suspension, Limitation or Revocation of Certification by the CDC

Section 10.1 - Denial, Suspension or Revocation of Provisional Certification

- A. The CDC may suspend a provisional certification if the provisional licensee fails to obtain ISO/IEC 17025:2017 or most recent version accreditation within the period of the original provisional certification.
- B. The CDC shall revoke a provisional certification if the provisional licensee is denied ISO/IEC 17025:2017 or most recent version accreditation.

Section 10.2 - Denial, Suspension or Revocation of Certification

- A. The CDC may deny, revoke, suspend, or not renew the certification of any marijuana testing facility for engaging in conduct that includes, but is not limited to, the following:
 - (1) Failure to observe any term of certification;
 - (2) Failure to observe any order, request or other directive made under the statutory authority vested in OMP or the CDC;
 - (3) Engaging in, aiding, abetting, causing or permitting any action prohibited under 22 MRS, chapter 558-C or 28-B MRS, chapter 1;
 - (4) Failure to comply with any regulatory requirement of these rules and any other applicable state regulation or statute;
 - (5) Making false or deceptive representation on any application for certification or renewal thereof;
 - (6) Failure to maintain professional, competent and ethical standards of practice;
 - (7) Making false or deceptive representation of any testing results and reports thereof;
 - (8) Failure to provide timely and accurate data reporting;
 - (9) Engaging in false or deceptive advertising; or
 - (10) Providing services associated with product labeling for a licensed establishment, registered dispensary, or an exempt or registered caregiver; a principal officer, board member of a registered dispensary; or an employee or assistant of a registered dispensary or an exempt or registered caregiver who has a financial or other interest in the marijuana testing facility.
- B. The CDC may deny, revoke or suspend the certification of any marijuana testing facility if the municipality wherein the marijuana testing facility is located has informed OMP that it has revoked, suspended or not renewed local authorization of the marijuana testing facility.
- C. The CDC shall communicate any denial, suspension or revocation in writing, along with a notice of the licensee's right to appeal, consistent with the Maine Administrative Procedures Act, 5 MRS, chapter 375.

Section 11 – Certification Fees for Testing Facilities

Section 11.1 - CDC Certification Fees

The following fees are required for marijuana testing facility certification. However, these fees are subject to an annual maximum of \$2,500 per marijuana testing facility.

- A. Provisional Certification: A marijuana testing facility that has applied for but has not yet obtained ISO/IEC 17025:2017 or most recent version accreditation is required to pay a base fee of \$1,250 plus appropriate technology fees to apply for a provisional certification.
- B. Full Certification: The CDC shall issue full certification to a marijuana testing facility holding provisional certification in good standing once the marijuana testing facility provides proof of ISO/IEC 17025:2017 or most recent version accreditation and pays an application fee of \$500.
- C. Full Certification without Provisional Certification: An applicant that has received ISO/IEC 17025:2017 or most recent version accreditation but does not have provisional certification may apply for full certification directly. The marijuana testing facility is required to pay an application fee of \$1,000 for initial certification, plus applicable technology fees.
- D. Renewal: The marijuana testing facility is required to pay an annual application fee of \$1,000 plus appropriate technology fees to apply for annual recertification.
- E. Technology fees: An applicant must pay the fees listed in Table 11.1-A for each technology certified.

Table 11.1-A. Technology Fees

Analyte Category	Technology Fee
Microbiological Contaminants Visual Inspection Water Activity Moisture Content	\$50 per technology
Metals	\$125 per technology
Solvents Pesticides Cannabinoids	\$150 per technology

Section 11.2 - Payment of Certification Fees Required Prior to Full Active or Provisional Active Licensure

- A. OMP may not issue a provisional active license or active license until the applicant meets all requirements and pays all applicable fees.

- B. All applications or requests to change the scope of activities to be conducted under a marijuana testing facility license must be accompanied by the applicable fees specified in this section.
 - C. Application fees apply to the addition of technologies for reinstatement after revocation or denial of licenses.
 - D. Payment of fees must be in the form of a check or money order, made payable to the “Treasurer, State of Maine.”
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STATUTORY AUTHORITY:

28-B MRS ch. 1; 22 MRS §569

EMERGENCY ADOPTION:

September 4, 2019 – filing 2019-161

ADOPTION:

December 16, 2019 – filing 2019-224

Appendix A

List of 195 pesticides prohibited from use on organic produce by the USDA National Organic Program (NOP), adapted from NOP and USDA Science and Technology Programs' *2010-2011 Pilot Study: Pesticide Residue Testing of Organic Produce*, November 2012.

Pesticide	Type of Pesticide
1-Naphthol	Insecticide
2,4 Dimethylphenyl formamide (DMPF)	Insecticide
3-Hydroxycarbofuran	Insecticide
4,4-Dibromobenzophenone	Acaricide
5-Hydroxythiabendazole	Fungicide
Acephate	Insecticide
Acetamiprid	Insecticide
Acetochlor	Herbicide
Aldicarb	Insecticide
Aldicarb sulfone	Insecticide
Aldicarb sulfoxide	Insecticide
Aldrin	Insecticide
Allethrin	Insecticide
Atrazine	Herbicide
Azinphos methyl	Insecticide
Azoxystrobin	Fungicide
Bendiocarb	Insecticide
BHC alpha	Insecticide
Bifenazate	Acaricide
Bifenthrin	Insecticide
Biteranol	Fungicide
Boscalid	Fungicide
Bromacil	Herbicide
Buprofezin	Insecticide
Captan	Fungicide
Carbaryl	Insecticide
Carbendazim (MBC)	Fungicide
Carbofuran	Insecticide
Carfentrazone ethyl	Herbicide
Chlorantraniprole	Insecticide
Chlordane cis	Insecticide
Chlordane trans	Insecticide

Chlorfenapyr	Insecticide
Chlorothalonil	Fungicide
Chlorpropham (CIPC)	Herbicide / Growth Regulator
Chlorpyrifos	Insecticide
Chlorpyrifos methyl	Insecticide
Chlorthal (DCPA)	Herbicide
Clofentezine	Acaricide
Clothianidin	Insecticide
Coumaphos	Insecticide
Cyazofamid	Fungicide
Cycloate	Herbicide
Cyfluthrin	Insecticide
Cyhalothrin lambda	Insecticide
Cypermethrin	Insecticide
Cyprodinil	Fungicide
Cyromazine	Insect Growth Regulator
DDD o,p'	Insecticide
DDD p,p'	Insecticide
DDE o,p'	Insecticide
DDE p,p'	Insecticide
DDT p,p'	Insecticide
Deltamethrin	Insecticide
Diazinon	Insecticide
Diazinon oxygen analog	Insecticide
Dichlorvos (DDVP)	Insecticide
Dicloran	Fungicide
Dicofol o,p'	Insecticide
Dicofol p,p'	Insecticide
Dieldrin	Insecticide
Difenoconazole	Fungicide
Diiflubenzuron	Insecticide
Dimethoate	Insecticide
Dimethomorph	Fungicide
Dinotefuran	Insecticide
Diphenamid	Herbicide
Diphenylamine	Fungicide
Disulfoton sulfone	Insecticide

Diuron	Herbicide
Endosulfan I	Insecticide
Endosulfan II	Insecticide
Endosulfan sulfate	Insecticide
Endrin	Insecticide
Epoxiconazole	Fungicide
Esfenvalerate	Insecticide
Ethion	Insecticide
Ethoprop	Insecticide
Ethoxyquin	Fungicide / Growth Regulator
Etoxazole	Acaricide
Etridiazole	Fungicide
Famoxadone	Fungicide
Fenamidone	Fungicide
Fenamiphos	Insecticide
Fenamiphos sulfone	Insecticide
Fenamiphos sulfoxide	Insecticide
Fenarimol	Fungicide
Fenbuconazole	Fungicide
Fenhexamid	Fungicide
Fenoxaprop ethyl	Herbicide
Fenpropathrin	Insecticide
Fenpyroximate	Acaricide
Fenthion	Insecticide
Fipronil	Insecticide
Flonicamid	Insecticide
Fludioxonil	Fungicide
Fluoxastrobin	Fungicide
Fluridone	Herbicide
Flutolanil	Fungicide
Fluvalinate total	Insecticide
Folpet	Fungicide
Fonofos	Insecticide
Heptachlor	Insecticide
Heptachlor epoxide	Insecticide
Hexachlorobenzene	Fungicide
Hexaconazole	Fungicide

Hexythiazox	Insecticide
Hydroprene	Insect Growth Regulator / Acaricide
Imazalil	Fungicide
Imidacloprid	Insecticide
Indoxacarb	Insecticide
Iprodione	Fungicide
Lindane	Insecticide
Linuron	Herbicide
Malathion	Insecticide
Malathion oxygen analog	Insecticide
Metalaxyl	Fungicide
Methamidophos	Insecticide
Methidathion	Insecticide
Methiocarb	Insecticide
Methomyl	Insecticide
Methoxychlor	Insecticide
Methoxyfenozide	Insecticide
Metolachlor	Herbicide
Metribuzin	Herbicide
Mevinphos total	Insecticide
MGK-264	Insecticide
Myclobutanil	Fungicide
Naled	Insecticide
Napropamide	Herbicide
Nonachlor cis	Insecticide
Nonachlor trans	Insecticide
Norflurazon	Herbicide
Norflurazon desmethyl	Herbicide
Omethoate	Insecticide
o-Phenylphenol	Fungicide
Oxadixyl	Fungicide
Oxamyl	Insecticide
Oxamyl oxime	Insecticide
Oxydemeton methyl sulfone	Insecticide
Oxyfluorfen	Herbicide
Parathion methyl	Insecticide
Pendimethalin	Herbicide

Pentachlorobenzene	Fungicide
Permethrin total	Insecticide
Phenmedipham	Herbicide
Phorate sulfone	Insecticide
Phorate sulfoxide	Insecticide
Phosalone	Insecticide
Phosmet	Insecticide
Piperonyl butoxide	Insecticide
Pirimicarb	Insecticide
Prallethrin	Insecticide
Prochloraz	Fungicide
Procymidone	Fungicide
Profenofos	Insecticide
Prometryn	Herbicide
Pronamide	Herbicide
Propanil	Herbicide
Propargite	Insecticide
Propetamphos	Insecticide
Propham	Herbicide
Propiconazole	Fungicide
Pymetrozine	Insecticide
Pyraclostrobin	Fungicide
Pyridaben	Insecticide / Acaricide
Pyrimethanil	Fungicide
Pyriproxyfen	Insecticide / Growth Regulator
Quinoxifen	Fungicide
Quintozene	Fungicide
Resmethrin total	Insecticide
Simazine	Herbicide
Spinetoram	Insecticide
Spirodiclofen	Acaricide
Spiromesifen	Insecticide
Sulfentrazone	Herbicide
Tebuconazole	Fungicide
Tebufenozide	Insecticide
Tefluthrin	Insecticide
Tetrachlorvinphos	Insecticide

Tetraconazole	Fungicide
Tetradifon	Insecticide
Tetrahydrophthalimide (THPI)	Fungicide
Tetramethrin	Insecticide
Thiabendazole	Fungicide
Thiacloprid	Insecticide
Thiamethoxam	Insecticide
Thiodicarb	Insecticide
Triadimefon	Fungicide
Triadimenol	Fungicide
Tribufos	Herbicide
Trifloxystrobin	Fungicide
Triflumizole	Fungicide
Trifluralin	Herbicide
Vinclozolin	Fungicide



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
 AND POLLUTION PREVENTION

October 15, 2020

Dear AAPCO and SFIREG Colleagues:

Leo Reed (AAPCO President; Office of the Indiana State Chemist)
 Rose Kachadoorian (AAPCO Immediate Past President; OR Dept. of Agriculture)
 Gary Bahr (SFIREG Chair; WA State Dept. of Agriculture)
 Liza Fleeson-Trossbach (AAPCO Director; VA Dept. of Agriculture & Consumer Services)
 Jeff Rogers (SFIREG POM Working Committee Chair; VA Dept. of Agriculture & Consumer Services)
 Carrie Leach (SFIREG EQI Working Committee Chair; Purdue University, Laboratory)
 Amy Sullivan (AAPCO Executive Secretary)

RE: EPA Response to 10/16/2018 SFIREG Issue Paper - Pesticide Impurities in EPA Registered Products

Thank you for submission of the SFIREG Issue Paper "Pesticide Impurities in EPA Registered Products." This letter presents EPA's response and planned next steps for addressing related issues associated with organic products, market barriers, and herbicide products.

SFIREG's issue paper discussed various states' experiences regarding pesticide products that were contaminated with other pesticidal active ingredients not listed on the Confidential Statement of Formula (CSF) or in the discussion of impurities. The issue paper pointed to the definition of "toxicologically significant levels" as identified in EPA Pesticide Registration Notice (PRN) 96-8 "Toxicologically Significant Levels of Pesticide Active Ingredients" and raised several concerns. The issue paper also proposed certain remedies that EPA could take to improve the status quo or provide resolution, and SFIREG requested that EPA investigate those options.

EPA has explored the concerns raised by the issue paper, and our next steps are described below. In the near term, EPA proposes to support the states and better understand the scope of the issue by providing laboratory support for testing of pesticide products with suspected high levels of impurities through the Office of Pesticide Programs' (OPP) Biological and Economic Analysis Division's (BEAD) Analytical Chemistry Branch Laboratory in Fort Meade, MD. Additional work may also be explored over a longer period, as new information comes to light. EPA responses to specific topics raised in the issue paper are provided in the following sections.

Products Labeled with "Organic" Claims

One of the main areas of concern discussed in this issue paper is the topic of pesticide products with label claims accepted by EPA pursuant to EPA's policy implementing the USDA's National Organic Program (NOP) set forth in Pesticide Registration Notice 2003-1 "Labeling of Pesticide Products under the National Organic Program," and subsequently-issued Clarification. Such claims may include "For organic production," "For organic gardening," "OMRI listed," and EPA's three leaf logo.

The issue paper described challenges to taking enforcement action against pesticides with NOP-related claims that are found to be contaminated with synthetic pesticides not permitted by the NOP for use on commodities labeled “organic.” One of those challenges is confusion about whether the Agency’s position in PRN 96-8, which sets forth the minimum levels of certain impurities that EPA considers “toxicologically significant,” would prevent enforcement where levels of synthetic contaminants are found in “organic”-labeled products in amounts below the thresholds set therein.

EPA’s Office of Enforcement and Compliance Assurance (OECA) and Office of Chemical Safety and Pollution Prevention (OCSPP) have been monitoring this issue and the confusion about the impact of PRN 96-8. It is the opinion of those Offices, with input from the Office of General Counsel (OGC), as was communicated to EPA Regions and their state partners in March 2020, when registered pesticides with EPA-accepted organic labeling claims are found to be contaminated with NOP-prohibited synthetic pesticides in an amount that would not be considered “toxicologically significant” as set forth by PRN 96-8, those products may nevertheless be “misbranded” as defined by FIFRA section 2(q)(1)(A) and “adulterated” as defined by FIFRA section 2(c)(1). When a registered product is labeled with any EPA-accepted “organic” claim and there are any levels of any NOP-prohibited substance in it, then the claims related to the product’s qualifications as acceptable for use in “organic” production are false. Also, whether a product is “adulterated” per 2(c)(1) does not depend on whether the impurity found is “toxicologically significant,” but is instead determined by what level of strength or purity the label promises it to be. EPA-accepted “organic” claims represent that the product is entirely free of NOP-prohibited substances. Sale or distribution of such “organic”-labeled pesticides that are “misbranded” and “adulterated” is prohibited by FIFRA section 12(a)(1)(E).

While this position is based on an analysis of FIFRA and not any particular state law, we believe the states may still find it useful to know that EPA does not believe PRN 96-8 poses vulnerabilities to its own enforcement in this area.

Market Barriers

A second concern relayed in SFIREG’s issue paper was related to “market barriers” for treated agricultural goods and potential for tolerance exceedances in those foods if the labeling information is not truthful. The issue paper suggests that the thresholds of “toxicologically significant levels of contaminants” from PRN 96-8 are too permissive and could lead to foods in the channels of trade that may be adulterated because residues are not covered by an appropriate tolerance or tolerance exemption. Current sources of data such as the USDA’s Pesticide Data Program (PDP)¹, however, suggest that adulterated foods are not a common or system-wide ongoing concern. The standard for whether a food item is considered adulterated under FFDC, the food safety law, relates to whether any residues of a pesticide chemical for which a tolerance or tolerance exemption has not been established are detected in the food. PRN 96-8 does not weaken this protective standard. At the federal level, EPA, FDA and USDA work together to ensure food safety requirements for pesticides are met.

¹ From <https://www.ams.usda.gov/datasets/pdp>. “The Pesticide Data Program (PDP) is a national pesticide residue monitoring program and produces the most comprehensive pesticide residue database in the U.S. The Monitoring Programs Division administers PDP activities, including the sampling, testing, and reporting of pesticide residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities highly consumed by infants and children.” Accessed 4/13/2020.

Herbicide Products

A third area discussed in the issue paper is related to herbicide products labeled for over-the-top use, and SFIREG included a request that this group of products be exempted from PRN 96-8 and the “toxicologically significant level of contaminants” defined therein. The issue paper stated, “ODA (*Oregon Department of Agriculture*) is not aware of any verified instances of damage or illegal residues, but many people are aware of allegations that have been made regarding this topic.” No additional supporting evidence was provided, and at this time, EPA is not aware of herbicide products approved for use on herbicide-tolerant crops that have been proven to be contaminated with other pesticide active ingredients. EPA would need to evaluate additional information on verified occurrences to pursue further action on these herbicide products as related to PRN 96-8. We are willing to continue to engage on this issue moving forward.

Conclusions

As discussed at the beginning of this letter, as a result of receiving this issue paper and subsequent conversations within OPP and with SFIREG, EPA would like to provide laboratory capacity for testing product samples in cases where contamination is suspected. This will require continued collaboration with SFIREG and within EPA to determine the logistics and volume of samples expected and to ensure the requested testing is within EPA’s capacity. This is a concrete way in which EPA can assist states in the short term and inform the concern for products contaminated with other pesticide active ingredients. EPA hopes to gain more insight as to the depth and national scope of this product contamination issue to inform future actions. If SFIREG and the states are interested in pursuing this option, please contact Sandra O’Neill (ONeill.Sandra@epa.gov; 703-347-0141), and we will coordinate a meeting between BEAD laboratory management and the interested parties.

EPA acknowledges that almost 25 years have passed since PRN 96-8 was issued and recognizes that scientific advancement, methods assessment, and product integrity have continued to improve in the intervening years. With the intermediate steps outlined above, EPA and SFIREG can work together to determine the best long-term course of action. EPA would like to continue to work with your departments, our federal partners, and the public on other appropriate methods and collaborations for ensuring food safety and pesticide label accuracy. Therefore, please keep the lines of communication open with us on these topics and relay your enforcement findings and data so that we can continue to work together to ensure pesticide safety.

EPA would like to thank SFIREG for raising these issues to our attention and for the additional EPA and SFIREG brainstorming that occurred at the December 2019 Full SFIREG meeting and during subsequent conference calls with SFIREG members and leadership. We look forward to continuing our work with SFIREG, AAPCO, state, and EPA Regional partners on these and other important pesticide issues.

Sincerely,

Ed Messina, Esq., Acting Director, Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention

State of Maine

Best Management Practices for Pest Prevention and Management in Maine Medical Marijuana Cultivation



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WALTER WHITCOMB
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October 2015

Re: Best Management Practices in Maine Medical Marijuana Cultivation

The purpose of this document is to provide guidance for preventing, minimizing and managing pests in the production of medical marijuana. The ultimate aim is to reduce the risk of product contamination, ensure a safe workplace, and minimize negative impacts on the environment.

This document was developed in accordance with 22 MRSA Section 2423 and Section 2428, which prohibit a registered dispensary or primary caregiver from using a pesticide on marijuana unless it is used "consistent with best management practices approved by the Commissioner of Agriculture, Conservation and Forestry." This document describes Best Management Practices (BMPs) for pest control in the cultivation of marijuana by Maine dispensaries and primary caregivers.

Dr. Kathy Murray, Integrated Pest Management specialist, Maine Department of Agriculture, Conservation and Forestry is the lead author. Helpful reviews and comments on earlier drafts were contributed by a number of Maine growers and outside reviewers.

A handwritten signature in cursive script that reads "Walter E. Whitcomb".

Walter E. Whitcomb, Commissioner
Maine Department of Agriculture, Conservation and Forestry

Best Management Practices for Pest Prevention and Management in Maine Medical Marijuana Cultivation

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Best Management Practices for Pest Prevention and Management in Maine Medical Marijuana Cultivation

Introduction

This document was developed in accordance with 22 MRSA Section 2423 and Section 2428, which prohibit a registered dispensary or primary caregiver from using a pesticide on marijuana unless it is used “consistent with best management practices approved by the Commissioner of Agriculture, Conservation and Forestry.” This document describes Best Management Practices (BMPs) for pest control in the cultivation of marijuana by Maine dispensaries and primary caregivers.

For prevention and management of pests, BMPs can best be described as the widely accepted principles and practices of integrated pest management (IPM). It is State of Maine policy to promote adoption of IPM to minimize reliance on pesticides according to 22 MRSA Section 1471-X. IPM is described in Chapter 413 7 MRSA as ‘the selection, integration and implementation of pest damage prevention and control based on predicted socioeconomic and ecological consequences, including a) understanding the system in which the pest exists, b) establishing dynamic economic or aesthetic injury thresholds and determining whether the organism or organism complex warrants control, c) monitoring pests and natural enemies, d) when needed, selecting the appropriate system of cultural, mechanical, genetic, including resistant cultivars, biological or chemical prevention techniques or controls for desired suppression, and e) systematically evaluating the pest management approaches utilized.’

The purpose of this document is to provide guidance for preventing, minimizing and managing pests in the production of medical marijuana. The ultimate aim is to reduce the risk of product contamination, ensure a safe workplace, and minimize negative impacts on the environment.

Integrated Pest Management

The basic components of IPM are 1) accurate identification of pests and pest-caused damage, 2) systematic pest monitoring, 3) reliance on combinations of biological, mechanical, cultural, or other pest prevention and mitigation methods to keep pests at or below acceptable levels, and 4) documentation and periodic review. Each of the pest prevention and pest management tactics listed in this document have been shown to be effective under certain conditions, however the specific set of tactics selected by a grower may vary depending on the pests encountered, cultivation systems used, economic factors and other conditions.

A pest is any living organism causing health, economic, aesthetic or environmental harm. Pests can include weeds, insects, mites, plant pathogens, and other living organisms. Any organism can be harmful under some conditions and not harmful or even beneficial in other situations. The aim is not to eliminate all potential pests, but to optimize plant health and avoid unacceptable levels of pest-associated risk.

Best Management Practices for Pest Prevention and Control

The following BMPs are intended to prevent and manage pest-associated losses while minimizing risks of product contamination. *Note: Throughout this document the term 'pest' refers to any living organism posing unacceptable levels of risk and includes but is not limited to insects, mites, birds, and other animals, plant pathogens, mold and mildew, and weeds. Furthermore, under Maine law, a pesticide is any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest and includes disinfectants, insecticides, herbicides, fungicides, plant regulators, defoliants and plant desiccants.*

BMP 1. Design and operate facilities to prevent introduction and spread of pests.

- Cultivation and processing facilities must be operated in a manner that promotes good plant health while discouraging pest organisms. Indoor operations must be sufficiently equipped to provide adequate ventilation, drainage, lighting and temperature controls to promote plant health while discouraging pests, plant disease and mold.
- Facilities and operations must be designed to permit isolation and sanitation processes necessary to minimize the risks of introduction, establishment and spread of pest organisms and permit their management while promoting good plant health and worker safety.
- Post-harvest handling facilities must be designed and operated to prevent contamination of product by insects and rodents, mold, bacteria, viruses, chemicals or other contaminants.
- Adequate hand-washing facilities must be provided for workers.

BMP 2. Use, store and dispose of pesticides only in accordance with state and federal regulations including the following:

- Pesticides may only be used in strict accordance with the product label requirements including, but not limited to directions pertaining to application, storage and disposal of the pesticide product.
- State pesticide regulations can be found at <http://www.maine.gov/dacf/php/pesticides/laws.shtml>.
- Pesticide products must be registered with, and not prohibited for the intended usage by, the Maine Department of Agriculture, Conservation and Forestry Board of Pesticides Control pursuant to Title 7, section 607, and must be used in a manner consistent with these BMPs approved by the Commissioner of Agriculture, Conservation and Forestry.
- Application of nutrients or pesticides through an irrigation system (chemigation) must be performed in accordance with federal, state and local agricultural regulations.
- Disposal of waste water or growing media containing pesticides or nutrients must be performed in accordance with federal, state and local agricultural regulations.
- Home-made pest control substances (including food-based solutions) are not allowed.
- When using a pesticide, ensure that the primary caregiver or the registered primary caregiver's employee is licensed as an Agricultural Basic Pesticide Applicator by the Maine Board of Pesticides Control, pursuant to section 1471-D.
- Ensure that any employee who has direct contact with pesticide-treated plants has completed safety training pursuant to the U.S. Environmental Protection Agency (USEPA) Worker Protection Standards, 40 Code of Federal Regulations, Section 170.130.
- Ensure that any employee who is not licensed pursuant to section 1471-D and who is involved in the application of the pesticide or handling of the pesticide or equipment first

completes the Pesticide Handler safety training described in 40 Code of Federal Regulations, Section 170.230.

- Pesticide storage, mixing and use must be in compliance with the USEPA Worker Protection Standards and must meet product label requirements for fire and chemical safety. Ensure all necessary personal protective equipment is available, clean, and properly stored.
- Ensure pesticide application equipment is properly calibrated.
- Detailed records of all pesticides used in the cultivation and processing of the crop, including any added to the growing media, or applied to the space or surfaces of the facility before or during cultivation, processing or storage must be kept according to Chapter 50 of Maine Board of Pesticides Control regulations. These regulations can be found at <http://www.maine.gov/dacf/php/pesticides/laws.shtml>.
- All pesticide use records must be provided to the appropriate Maine state regulatory bodies upon request.

BMP 3. Establish and utilize sanitation protocols to prevent the spread of pests and contaminants within the facility by workers.

- Develop site-specific pest-preventive protocols for each section of every facility.
- Place emphasis on starting with pest-free plant material.
- Do not allow smoking, eating or drinking within the cultivation and processing areas of the facility.
- Ensure all workers utilize appropriate sanitation protocols before entering the plant cultivation and processes areas, including thoroughly washing hands after eating, drinking, smoking or using the bathroom.
- Ensure all workers receive adequate training.

BMP 4. Provide optimal growing conditions to promote healthy plant growth, encourage natural enemies, and minimize pest-conducive conditions.

- Supply proper plant nutrition, moisture, and pH to support optimal plant growth while discouraging pests.
- In indoor cultivation and processing facilities, operate ventilation, lighting and heating systems to optimize humidity, temperatures and patterns of air movement that support plant growth and natural enemies while discouraging establishment, growth and spread of pests.
- Provide optimal plant spacing to prevent pest movement among plants and to allow adequate air circulation.
- Keep facilities free of weeds, plant debris, pest harborage, mold, mildew and algae.
- On late flowering plants, avoid application of liquids on leaves and flowers and encourage rapid drying to avoid mold and mildew contamination of product.

BMP 5. Implement effective procedures to regularly and systematically monitor for pests.

- Develop site-specific pest monitoring protocols for each section of every facility.
- Train employees in all pest prevention, detection, identification, monitoring and record-keeping protocols.
- Identify unknown insect and disease problems.

- Keep records of where, when and how many of each pest that is encountered and all actions taken to manage them. Record observations and/or releases of beneficial organisms.

BMP 6. Develop and utilize an integrated pest management plan that includes least-risk protocols for preventing and managing common pests.

- Develop and utilize site-specific comprehensive integrated pest management protocols for each section of each facility. Update protocols as needed and as new research-based information becomes available.
- Use pesticides only in strict accordance of all applicable regulations including those specified on the product label. Avoid the use of pesticides on flowering plants.



SFIREG Issue Paper: Pesticide Impurities in EPA Registered Pesticides

Background

On January 24, 1996, EPA published in the Federal Register (FR) a "Statement of Policy Regarding Toxicologically Significant Levels of Pesticide Active Ingredients; Notice of Availability and Request for Comments", 61 FR 1928, Docket OPP-00424. Comments were accepted until March 25, 1996. Prior to the FR notice, EPA had released a draft "Pesticide Regulation (PR) Notice 96-?" titled "Toxicologically Significant Levels of Pesticide Active Ingredients", December 8, 1995, 730 0 96 001. The draft PR Notice addressed cross-contamination of active ingredients in pesticide products by contaminants that are also pesticide active ingredients.

According to the 1996 FR Notice regarding the draft PR Notice, "EPA's current policy is that any level of an impurity that is also an active ingredient in another pesticide is considered "toxicologically significant" and must be reported to EPA." There was language in the draft PR Notice which would change EPA's definition of "toxicologically significant" levels of active ingredients to a risk-based standard. The draft PR notice was eventually finalized and became Pesticide Regulation (PR) Notice 96-8.

Many years later, on August 14, 2007, EPA posted a FR Notice requesting comments on PR Notice 96-8, EPA-HQ-OPP-2007-0814-0001. The docket appears to be still open, and there is no evidence that any comments were received. PR Notice 96-8 provided further interpretation of 40 CFR 158.167 [currently §158.340], "Discussion of formation of impurities"; and also 40 CFR 158.175 [currently §158.350], "Certified limits".

PR Notice 96-8 states, "EPA requires all impurities of toxicological significance to be reported and accepted as part of product registration (40 CFR 158.167). EPA also requires that registrants propose upper certified limits for toxicologically significant impurities in technical grade active ingredients or products produced by an integrated system (40 CFR 158.175), and may require upper certified limits for other impurities. At the time EPA promulgated these regulations [i.e., 40 CFR 158.167 and 40 CFR 158.175] it did not set quantitative criteria for determining whether an impurity is toxicologically significant."

A contaminant is defined as an active ingredient that is not on the product's confidential statement of formula or listed in the discussion of impurities. A toxicologically significant level is the concentration at or above which EPA would consider the contaminant to be toxicologically significant. The toxicologically significant levels apply to all registered products that are sold or distributed, regardless of whether the container is nonrefillable (i.e., "packaged product") or refillable (i.e., "bulk product.")

Issues identification

The Oregon Department of Agriculture (ODA) was notified by another Oregon state agency that a pesticide (permethrin) was detected in an agricultural crop, see results in Table 1- "Ag. Crop Tested". However, there were no pesticide labels which would allow for use on that particular crop, which is a food crop. Also the grower was adamant that he did not apply any product containing permethrin to the crop. Independently, the grower had a commercial laboratory analyze the EPA-registered product he had been using, and permethrin was detected.

As part of the investigative process, ODA pesticide investigators collected samples from four locations where unopened containers of the pesticide product (referred to as Pesticide AZ) were available for sale; the ODA regulatory laboratory analyzed the contents of the containers. The results are indicated in Table 1 below (NUF 1-4). The results were shared with other SLAs, and in some instances, they found up to five additional pesticide active ingredients at various levels. Some of the contaminant pesticides found in Pesticide AZ are active ingredients in products that are classified by EPA as restricted use.

The levels of the contaminant active ingredients detected in Pesticide AZ appeared to be related to the lot number of the product. All of the contaminant pesticides detected in Pesticide AZ by the ODA laboratory were manufactured or somehow processed at the same plant as Pesticide AZ. This suggests that contamination took place at the EPA Producer Establishment Facility. EPA did recognize in PR 96-8 that "cross contamination is a reality..."

Table 1. Levels of various pesticides found in unopened containers of Pesticide AZ; contaminant levels found in ag. crop tissue; and examples of EPA established tolerance levels (ppm).						
Formulated Product Sample #	Pesticides (ppm)					
	permethrin	bifenthrin	cypermethrin	cyfluthrin	chlorpyrifos	malathion
NUF -1	2.8	1.1	not tested	0.42	0.15	< 0.040
NUF - 2	200	0.37	not tested	0.088	0.51	< 0.040
NUF - 3	25	1.1	12 ppm	< 0.10	2.0	< 0.040
NUF - 4	1.0	0.27	< 0.040	< 0.10	< 0.040	< 0.040
Ag. Crop Tested	0.2 - 0.60	0.21 - 0.48				
Example Tolerances						
Pome Type	0.05 pome	0.5 pear	2.0 pome	0.5 pome	0.01 apple	8 apple
Sweet Cherry	4.0	N/A	1.0	0.3	1.0	8
Radish	N/A	0.10	0.1	1.0	2.0	8
Grape	N/A	0.2	2.0	1.0	0.01 (Regional)	8
Pepper, bell	0.50	0.5	0.2	0.50	1.0	8

Pesticide products from additional registrants containing the same stated active ingredient that is in Pesticide AZ, were also tested by the ODA laboratory. These products also contained various levels of the contaminant pesticides.

Market Barriers

All of the levels of the contaminant pesticides were well below the EPA definition of toxicologically significant levels provided in PR Notice 96-8. However, the contaminant pesticide levels detected in the agricultural crop tested in the ODA investigation suggests that there could be possible exceedance in the established tolerances on certain crops, such as apples or bell peppers.

EPA acknowledged in PR Notice 96-8 that, "theoretically a contaminant could cause residues in food or feed for which no tolerance has been established or that are in excess of an established tolerance", and further added that it would be "a highly unlikely occurrence". However, based on the levels of contaminants found in the agricultural crop tested, this topic should be reexamined to determine whether EPA's original assertion, that it would be "a highly unlikely occurrence", is still valid.

Consumer Confidence and Truth in Labeling

Pesticide AZ is a product bearing the OMRI label, and is a product that can be used under the National Organic Program. Registrants can obtain EPA approval of label language indicating that all ingredients (active and inert) in a pesticide product and all uses of that pesticide meet the criteria defined in the United States Department of Agriculture's (USDA) National Organic Program (NOP) Rule.

It is highly likely that consumers, organic growers, and entities that review products to be used in the NOP are unaware that pesticide products being used in organic production, in fact may also contain undeclared conventional pesticides such as, permethrin, bifenthrin, chlorpyrifos, etc.

Herbicide-Resistant Crops

The number of crops bred to be resistant to over-the-top herbicide use have proliferated since 1996. The levels of herbicide contaminants allowable in herbicide products may no longer meet EPA's risk based standard.

ODA is not aware of any verified instances of damage or illegal residues, but many people are aware of allegations that have been made regarding this topic.

Proposed Resolutions or Remedies

Exclusions

EPA currently excludes three contamination scenarios from PR Notice 96-8. These scenarios include: rodenticides; microbial and biochemical pesticides that are manufactured in fermenters; and plant incorporated protectants (PIPS). In these scenarios, any level of contaminant is considered potentially toxicologically significant.

SFIREG requests that products labeled or approved for use in organic production also be added to the exclusions in PR Notice 96-8. See Pesticide Registration (PR) Notice 2003-1 regarding labeling of pesticide products under the National Organic Program (NOP), and EPA's clarification of PR Notice 2003-1.

SFIREG also requests that herbicide products labeled for use on crops which have over-the-top use directions also be added to the exclusions. When PR Notice 96-8 was developed, herbicide-resistant crops were not as widely grown.

- It is SFIREG's opinion that the “resolvability” of this particular issue is very high. It will resolve inconsistencies and conflicts with PR 2003-1, and with the USDA National Organic Program. Ideally this issue could be resolved within one year.

Review

(1) EPA stated in PR Notice 96-8 that they considered unreasonable adverse effects and reviewed the risks for several endpoints, including: (1) human health effects; (2) adulterated food; (3) ground water; and (4) ecological effects, including phytotoxicity. EPA determined that when addressing cross contamination, phytotoxicity to target plants was the most sensitive endpoint. However, this determination is not truly risk-based, as explained in the following paragraph. SFIREG recommends that EPA re-review the endpoints, particularly the potential adverse effects if food should become adulterated or non-target species adversely affected.

EPA should consider applying the requirement stated for Category 2 (column 3 in Toxicologically Significant Levels of Contaminants table in PR Notice 96-8) to all nine categories of contaminants, not just “Herbicide, plant growth regulator, defoliant, or desiccant”. The existing requirement essentially states that the “Herbicide...” contaminant needs to be accepted for use on all sites for which the product is labeled. Applying this requirement to all nine categories of contaminants is important because “toxicological significance” depends not only on the active ingredient and its target species but also on the site. For example,

if you have an aquatic herbicide such as Polaris (a.i. imazapyr) and it is contaminated with glyphosate at 10,000 ppm, it is likely lower risk than if it was contaminated with a pyrethroid such as bifenthrin at 100 ppm. In the former case, both the legitimate active ingredient and the contaminant have the same target species (plants), but the latter with the insecticide contaminant in an EPA registered herbicide would likely result in non-target mortality of fish and aquatic invertebrates. Therefore, the assertion that phytotoxicity is always the most sensitive endpoint is not appropriate. This simple change to require that a contaminant in a pesticide product be accepted for use on all sites for which the product is labeled may go a long way to addressing the non-target toxicity aspect of "toxicologically significant" because if the active ingredient is labeled for use on the site, even if it is a contaminant, then it would likely be relatively low risk.

- It is SFIREG's opinion that the "resolvability" of this particular issue is high. It will resolve potential inconsistencies and conflicts with the Federal Food Drug and Cosmetic Act (FFDCA) and FIFRA. Ideally this issue could be resolved within two years.

(2) SFIREG requests that EPA conduct a comprehensive review of its interpretation of the term "toxicologically significant", and incorporate further refinements based on current analytical methods (levels of quantification), current pesticide residue tolerance levels, and agricultural trade practices.

EPA should require additional studies from registrants with products that have short preharvest intervals on any crops. A contaminant with a long half-life may result in a tolerance exceedance.

As part of the review, EPA should evaluate if it has considered each contaminant individually (as indicated in PR Notice 96-8), and also review how registrants are implementing PR Notice 96-8.

- It is SFIREG's opinion that the "resolvability" of this particular issue is moderate and a SFIREG workgroup should be formed. Ideally this issue could be resolved within four to six years.

Respectfully submitted,

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November 2017