



# **RULES FOR THE TESTING OF ADULT USE CANNABIS**

18-691 C.M.R., Chapter 40

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

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## Chapter 40 – Sampling and Testing

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## Appendix

## Chapter 40 – Sampling and Testing

The terms used in this rule are defined in and governed by the *Rules for the Administration of the Adult Use Cannabis Program*, 18-691 CMR, ch. 10. The administration of this rule and the other rules governing the Adult Use Cannabis Program are also governed by 18-691 CMR, ch. 10. All applicants, licensees and individual identification cardholders that are authorized to conduct activities pursuant to licenses or individual identification cards issued pursuant to *Rules for the Licensure of Adult Use Cannabis Establishments*, 18-691 CMR, ch. 20 must also at all times comply with the requirements of that rule and of Title 28-B of the Maine Revised Statutes and the *Compliance Rules for Adult Use Cannabis Establishments*, 18-691 CMR, ch. 30, as well as the *Rules for the Certification of Cannabis Testing Facilities*, 18-691 CMR, ch. 5 and any other applicable local, state or federal laws or regulations. Collectively, 18-691 CMR, chapters 5, 10, 20, 30, and 40 are the “rules governing the adult use cannabis program”.

### § 1 - Sampling.

#### (1) Samples for Mandatory Testing or Research and Development.

(A) **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:

- (1) An employee of the testing facility;
- (2) A licensed sample collector; or
- (3) A self-sampling licensee, collecting samples of cannabis, or cannabis products cultivated, manufactured, or otherwise produced by that licensee in compliance with all requirements of the rules governing the adult use cannabis program.

(B) **Collection by Cannabis Testing Facilities or Sample Collectors.** An employee of a cannabis testing facility or a sample collector must collect samples of cannabis or cannabis products in compliance with:

- (1) 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; and
- (5) The rules governing the adult use cannabis program.

(C) **Collection by Self-Sampling Licensees.** A self-sampling licensee may collect samples of cannabis or cannabis 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:

- (1) 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) The rules governing the adult use cannabis program.

**(D) Required Documentation and Record Keeping.** A cannabis cultivation, manufacturing, or cannabis store licensee requesting testing by a cannabis testing facility must indicate in its request for testing, in writing, prior to the collection of the samples for testing, whether the requested testing is for mandatory testing purposes as required by the rules governing the adult use cannabis program, or for research and development purposes.

- (1) 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:
  - (a) A description of the cannabis, cannabis concentrate, or cannabis product submitted for mandatory testing;
  - (b) The identity of the testing facility conducting the mandatory testing; and
  - (c) The results of any and all mandatory testing conducted at the request of the licensee.

**§ 2 - Testing.** A licensee may not sell or transfer cannabis or a cannabis product to a cannabis store, or as applicable a tier 1, tier 2, or nursery cultivation facility, or a products manufacturing facility, licensee for sale to a consumer under 28-B MRS, ch. 1, and the rules governing the adult use cannabis program unless the cannabis or cannabis product has been tested pursuant to this rule and 18-691 CMR, ch. 5, and mandatory testing has demonstrated that the cannabis or cannabis 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. Unless permitted by the Department in writing to address a temporary instrument failure, a cannabis testing facility may not subcontract testing for any of the analyte categories required herein. A sample of cannabis or cannabis products submitted for mandatory testing may only be tested by the testing facility that received the sample for mandatory testing.

**(1) Commencement of Mandatory Testing.** 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.

**(2) Mandatory Testing and Additional Analysis.**

**(A)** The following tests are mandatory for all cannabis or cannabis products, except seedlings, immature cannabis plants, and seeds, in final form prior to being sold to a cannabis store, or as applicable, a tier 1, tier 2, or nursery cultivation facility, or products manufacturing facility making sales to consumers by delivery, for sale to a consumer in accordance with this section. A licensee may choose whether to conduct some tests, as indicated below, before the cannabis or cannabis product is in its final form; however, the licensee that transfers cannabis or cannabis products to a licensee for sale to a consumer,

or as applicable, makes sales by direct delivery to consumers, shall ensure that every required test is conducted in accordance with this section prior to transfer to the licensee or as applicable, a consumer. The following tests are mandatory for all cannabis and cannabis products:

**(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, butane, ethanol, ethyl acetate, ethyl ether, heptane, 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 licensee is not required to analyze for residual solvents and processing chemicals in dried flower, kief, hashish, or cannabis products manufactured without chemical solvents. A licensee is not required to analyze an orally-consumed tincture containing alcohol for residual ethanol. A licensee is not required to test a cannabis product for residual solvents, poisons, and toxins if all cannabis concentrate used to make the cannabis product has previously passed mandatory testing for residual solvents.

**(3) Pesticides (e.g., insecticides, fungicides, herbicides, acaricides, plant growth regulators, disinfectants, etc.)** Pesticides listed in Table 6.8-A of the *Rules for Certification of Cannabis Testing Facilities*, 18-691 CMR, ch. 5. A licensee is not required to test a cannabis concentrate or a cannabis product for pesticides, fungicides, insecticides, and growth regulators if all cannabis flower and/or trim used to make the cannabis concentrate or cannabis product has previously passed mandatory testing for pesticides, fungicides, insecticides, and growth regulators. Cannabis products may not be manufactured using cannabis, including cannabis concentrate, that has not been tested for pesticides. A cannabis testing facility may not test fresh frozen cannabis flower, trim or kief for pesticides until the plant material has been dried and cured. A cannabis testing facility may not test cannabis products for pesticides.

**(4) Other harmful chemicals (Metals).** Other harmful chemicals (Metals) include, but are not limited to: Cadmium (Cd), lead (Pb), arsenic (As), and mercury (Hg). A licensee is not required to test a cannabis product for the other harmful chemicals listed herein if the cannabis concentrate used to make the cannabis product has previously passed mandatory testing for the other harmful chemicals listed herein.

**(5) Dangerous yeasts, molds, and mildew.** Any cannabis or cannabis product that fails an initial test for total yeast and mold, mycotoxins including aflatoxins (B1, B2, G1, and G2) and ochratoxin A are a danger to public health and safety. A sample that fails mandatory testing for dangerous molds and mildew shall be tested for mycotoxins upon retesting, regardless of remediation method, including methods that change the cannabis or cannabis product into a different form.

**(6) Harmful microbes.** Total viable aerobic bacteria, total coliforms, Enterobacteriaceae, Shiga toxin-producing *E. coli* (STEC) 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.** Testing for water activity is mandatory for solid and semi-solid edible cannabis products that do not require preservation by other means (e.g., refrigeration) and for cannabis plant material that is dried and prepared in its final form of intended use and that is to be sold or transferred by a cultivation facility or products manufacturing facility to a cannabis store.

**(B)** A licensed cultivation facility, licensed manufacturing facility, or licensed cannabis store may submit for additional analysis of cannabis for research and development purposes, but such testing shall not satisfy the mandatory testing requirements of the rules governing the adult use cannabis program.

**(C)** The Department shall publish a Best Practices Guide that includes a sampling plan and preservation instructions appropriate to each matrix type. All cannabis 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 the rules governing the adult use cannabis program and any instructions regarding sample collection, sample transport, and sample receipt provided to the licensee by the cannabis 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 licensee for sale to a consumer cannabis or a cannabis product without submitting it for testing if:

**(1)** The cannabis or cannabis product in its final form has previously undergone all required testing at the direction of another licensee or licensees as evidenced by a certificate of analysis, or in the case of cannabis concentrate or cannabis products that were tested for some analytes prior to final form, as evidenced by the certificates of analysis for testing done in accordance with the requirements of sub-§2 above;

**(2)** The previous testing demonstrated that the cannabis or cannabis 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 cannabis or cannabis 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 cannabis or cannabis product has been appropriately tracked in the inventory tracking system, and the cannabis or cannabis product has not been

altered in any way, including any further processing or manufacturing, other than packaging and labeling of the cannabis or cannabis product for retail sale, following the issuance of the certificate(s) of analysis indicated in sub-paragraph (1) above.

### (3) Reporting.

(A) If a sample's result exceeds an action level as required by 18-691 CMR, ch. 5, the cannabis 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 cannabis 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 cannabis testing facility determines that a sample has failed testing, the entity that submitted the sample may remediate the batch in accordance with sub-§4 before the batch is re-tested.

(2) The results of failed mandatory tests must be reported to both the Department and the entity that submitted the sample.

(3) The cannabis testing facility is not required to report to the Department the results of any tests if the requester notifies the cannabis 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 cannabis 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 distribution to a consumer.

**(4) Retesting and Remediation of Batches that Fail Mandatory Testing.** If a cannabis testing facility determines that a batch of cannabis or cannabis product fails mandatory testing, the cannabis testing facility must promptly report to the licensee and the Department that the sample failed mandatory testing. In accordance with this subsection, the licensee that submitted the sample may choose to have the batch retested without remediating the failed batch, or may remediate the failed batch and then submit samples for retesting.<sup>1</sup> Batches of cannabis and cannabis products that have failed mandatory testing for pesticides and heavy metals may not be remediated but may be retested in accordance with this subsection. Batches of cannabis and cannabis products that passed mandatory testing may not be retested in order to enhance the results indicating that the sample passed for all tested analyte categories.

(A) Batches of cannabis and cannabis products that have failed mandatory testing may be retested without remediation. A licensee seeking retesting of batch that failed mandatory testing without remediation shall submit two samples from the batch that failed

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<sup>1</sup>Office of Cannabis Policy, *Guidance Documents*, OCP Website: Resources, [https://www.maine.gov/dafs/ocp/sites/maine.gov.dafs.ocp/files/inline-files/OMP\\_Memorandum-AUMP\\_Retesting\\_of\\_Cannabis\\_Failed\\_Test.pdf](https://www.maine.gov/dafs/ocp/sites/maine.gov.dafs.ocp/files/inline-files/OMP_Memorandum-AUMP_Retesting_of_Cannabis_Failed_Test.pdf) (accessed April 29, 2022). On January 26, 2021, the Department issued a *Memorandum on Retesting and Remediation of Cannabis Items Subject to a Failed Test* which provides examples of the retesting and remediation requirements of this section.

mandatory testing to the same cannabis testing facility that issued the initial failed test result.

**(1)** Both samples submitted for retesting must pass all required testing required for any analyte that failed initial mandatory testing.

**(a)** Batches of cannabis or cannabis products that fail initial mandatory testing for yeast or mold must pass mandatory testing for total yeast and mold and mycotoxins upon retesting.

**(2)** If either sample submitted for retesting fails any required test for any analyte that failed initial mandatory testing, the batch of cannabis flower or trim may be transferred to another licensee for extraction following a failed retest and subsequently retested in accordance with sub-paragraph (B)(2) below.

**(3)** If either sample submitted for retesting fails any required test for any analyte that failed initial mandatory testing, the batch of cannabis concentrate or cannabis products may not be remediated or retested and must be destroyed.

**(B)** Batches of cannabis, cannabis concentrates, or cannabis products that have failed mandatory testing may be remediated and shall be retested following remediation. A licensee may attempt to remediate any batch that fails mandatory testing, except for batches that fail due to heavy metals or pesticide contamination. A licensee may attempt to remediate the batch at the licensee’s cannabis establishment or the licensee may transfer the failed batch to another licensee for remediation. Batches of cannabis, cannabis concentrate or cannabis products that have failed mandatory testing may not be remediated in a manner that involves the combination of the batch that failed mandatory testing with a batch, or batches, of cannabis, cannabis concentrate or cannabis product that has not been tested or that has passed mandatory testing.

**(1)** If a failed batch is remediated using a remediation method that does not change the cannabis or cannabis product into a different matrix of cannabis or cannabis product (e.g., remediation that does not change cannabis flower or trim into cannabis concentrate, or remediation that changes cannabis concentrate into a cannabis product), then the licensee must submit two samples from the remediated batch to the same cannabis testing facility that issued the initial failed test result.

**(a)** Both samples submitted for retesting must pass all required testing required for any analyte category that failed initial mandatory testing.

**(i)** Batches of cannabis or cannabis products that fail initial mandatory testing for yeast or mold must pass mandatory testing for total yeast and mold and mycotoxins upon retesting.

**(b)** If either sample submitted for retesting fails any required test for any analyte category that failed initial mandatory testing, the batch of cannabis or cannabis products may be remediated in accordance with this section or destroyed.

**(2)** If a failed batch is remediated using a remediation method that changes the cannabis or cannabis product into a different matrix of cannabis or cannabis



product, then the licensee must submit one sample from the remediated batch to the cannabis testing facility that issued the initial failed test result.

(a) The sample from the remediated batch must pass all mandatory testing required for the cannabis or cannabis product in the matrix it is in after remediation, including any tests previously passed, if applicable.

(i) Batches of cannabis or cannabis products that fail initial mandatory testing for yeast or mold must pass mandatory testing for total yeast and mold and mycotoxins upon retesting.

(b) If the remediated batch, that is in a new matrix, fails mandatory testing, the failed mandatory test is treated as an original failed mandatory test and the remediated batch may be retested or remediated in accordance with this section.

(C) A licensee that remediates any failed batch must appropriately record all remediation steps and processes in the Department’s inventory tracking system.

(D) A licensee must ensure at all times while submitting samples for testing or retesting, or transferring batches for remediation, that all cannabis and cannabis products are appropriately tracked in the Department’s inventory tracking system in accordance with the rules governing the adult use cannabis program.

(E) A licensee must take action to retest, remediate, or destroy a batch of cannabis or cannabis products within 30 days of receiving notice from the cannabis testing facility of the initial failed test result. If the licensee does not record an action on the failed batch within 30 days, the Department may issue an Order of Destruction.

**(5) Department Action Following Issuance of a Failed Mandatory Test Result by a Cannabis Testing Facility.** The Department may issue an Order of Destruction to a licensee that has not taken action to retest, remediate, or destroy a batch of cannabis or cannabis products that failed mandatory testing within 30 days of receiving notice from the cannabis testing facility of the initial failed test result. 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, ch. 375. The notice shall contain:

(A) The batch number of the cannabis or cannabis products to be destroyed;

(B) The method of destruction directed by the Department, if any;

(C) Any proof of destruction required by the Department; and

(D) The date by which destruction must occur and the Department must receive notice.

## Appendix A

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

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

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

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

Sample collection must be done in compliance with this standard operating procedure (SOP) and the rules governing the adult use cannabis program, 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 18-691 CMR, ch. 30.

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

This SOP applies to sample collection of cannabis, cannabis concentrate, and cannabis 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 Cannabis Program. All licensees collecting samples of cannabis, cannabis concentrate, and/or cannabis 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 Cannabis* published by the Department available at: <https://www.maine.gov/dafs/ocp/adult-use/applications-forms>. All licensees and any employee of a licensee collecting samples of cannabis, cannabis concentrate, or cannabis 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, Cannabis 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 cannabis testing facility, in accordance with chain of custody protocol prescribed by the cannabis 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 cannabis produced by selective breeding. Also commonly referred to as a “strain” of cannabis.
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 Cannabis Policy.
9. **Harvest Batch** means a specific quantity of cannabis harvested from cannabis 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 cannabis or cannabis 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, ch.1, subchapters 2 and 5 to operate a cannabis establishment.
13. **Primary Sample** means a portion of cannabis or cannabis 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 cannabis concentrate or a cannabis 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 cannabis product is based on chance, and every element of the batch has a probability of being selected. Random sampling helps produce representative cannabis samples by eliminating certain types of biases.
16. **Representative Sample** is a sample that accurately reflects the characteristics of the larger batch of cannabis product.
17. **Requester** means a person who submits a request to a licensed cannabis testing facility for State-mandated testing of cannabis or cannabis products.
18. **Sample** means, as applicable, an amount of:
  - a. Cannabis, cannabis concentrate, or cannabis product collected from a cannabis establishment for mandatory testing:
    - i. By an employee of a testing facility in accordance with 28-B MRS §604 and the rules governing the adult use cannabis program;
    - ii. By a sample collector, in accordance with 28-B MRS §604 and the rules governing the adult use cannabis program; or
    - iii. By a self-sampler in accordance with 28-B MRS §604-A and the rules governing the adult use cannabis program.

- b. Cannabis, cannabis concentrate, or cannabis product provided to a testing facility by a cannabis establishment or other person for mandatory testing or testing for research and development purposes in accordance with 28-B MRS, ch. 1; or
  - c. Cannabis or cannabis product collected from a licensee by the Department for the purposes of testing the cannabis or cannabis 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 cannabis and cannabis 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 cannabis store licensee that collects samples of cannabis, cannabis concentrate, and cannabis products for mandatory testing or an employee of a cultivation facility, products manufacturing facility, or cannabis store licensee who collects samples of cannabis, cannabis concentrate, and cannabis 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 cannabis 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 cannabis 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 18-691 CMR, ch. 30.
- 2) The self-sampler or sample collector must contact the cannabis testing facility(ies) conducting analyses for mandatory testing prior to collecting any samples to ensure that the sampler is using sample containers appropriate for the matrix tested and analyses requested.
- 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 cannabis 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 cannabis testing facility conducting the mandatory analyses.

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

- 1) A cannabis testing facility collecting samples for mandatory testing from a 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 cannabis 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 cannabis testing facility's quality system.

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

The following equipment and supplies may 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).
- Balance (capable of 0.01g measurements, provided by licensee, and checked for calibration).
- Calibrated verification weights appropriate to verify accuracy of balance (provided by licensee).
- Amber jars, Whirl-Pak bags, PTFE Centrifuge Tubes or equivalent, sterile (for edible cannabis products).
- Borosilicate VOA vials, PTFE Centrifuge Tubes or equivalent, sterile (for cannabis concentrates or extracts)
- Amber Bottles/Whirl-Pak bags or equivalent, sterile (for cannabis plant material).
- 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 cannabis testing facility.
- Pens with indelible ink.
- Plastic cup or beaker to hold sample container upright while depositing sample.
- Security tamper evident tape.
- Sample labels (may write directly on sample container if appropriate).
- 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.
- Foil or other method of protecting sample containers from light (for mycotoxin testing).
- Clean lab wipes (Kimwipes or equivalent).
- Transport container for cannabis material that is stored at room temperature (cooler without ice pack is acceptable).
- Cannabis testing facility's sample collection/chain-of-custody form.

NOTE: For sample collectors or employees of cannabis 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 cannabis 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 cannabis 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 cannabis 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 cannabis testing facility shall look for differences in the usable cannabis 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 cannabis testing facility shall note these anomalies in the sample collection records kept by the licensee in accordance with 18-691 CMR, ch. 30.

General procedural guidelines that apply to all sample collection include:

- a. The self-sampler, sample collector, or employee of a cannabis testing facility must be given access to the entire batch.
- b. The self-sampler, sample collector, or employee of a cannabis testing facility must use of appropriate sampling equipment.
- c. The self-sampler, sample collector, or employee of a cannabis testing facility must consistently follow sample collection procedures based upon matrix type.

- d. The self-sampler, sample collector, or employee of a cannabis testing facility must take equal portions for each sample increment.
- e. The self-sampler, sample collector, or employee of a cannabis 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 cannabis testing facility must obtain at least a minimum number of sample increments.
- g. The self-sampler, sample collector, or employee of a cannabis testing facility must record all observations and procedures used while collecting the sample increments in the sample collection records kept in accordance with 18-691 CMR, ch. 30.
- 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 cannabis 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 18-691 CMR, ch. 30.

**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 cannabis 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 cannabis 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 Cannabis Flower, Trim, or Pre-rolled Cannabis Cigarettes**

A harvest batch of cannabis flower, trim, or pre-rolled (uninfused) cannabis cigarettes must be sampled in accordance with the following table based upon the weight of the harvest batch after it has been “dried” or “cured”.

| 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 cannabis flower, trim, or pre-rolled cannabis cigarettes stored in storage containers (I.e., 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 cannabis 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 cannabis testing facility(ies) conducting the mandatory analyses.
11. Combine all sample increments to form the composite sample(s) as directed by the cannabis 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 cannabis testing facility must seal each container holding sampled material using tamper evident seals 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 cannabis 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 Cannabis Concentrate and Cannabis Products**



For unpackaged or pre-packaged 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 pre-packaged unit (i.e., one unpackaged serving or one pre-packaged unit containing multiple servings is one sample increment).

| # of Unpackaged servings or Pre-packaged retail 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 pre-packaged samples, more than the listed number of increments may need to be taken as directed by the cannabis 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 pre-packaged sample increments from the beginning third, middle third, and end third of the container(s) holding the unpackaged servings or pre-packaged 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 cannabis testing facility must seal each container holding sampled material using tamper evident seals 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 cannabis 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 cannabis concentrate, based on batch weight, the required number of sample increments is listed in the following chart.

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

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

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

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

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

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

Note: The container holding the oil or tincture shall be inverted a minimum of three (3) 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 cannabis testing facility may allow viscous substances to come to room temperature to promote inversion.

- Weigh the empty sample container(s) and record the weight in the sample collection record.
- Locate the batch to be sampled.
- Review the container label information for production batch number, producer, and other pertinent information and match to the sampling request or transport information.
- Record the batch size and number of containers in the batch as reported by the requester.
- Invert oil as described above.
- Weigh and record the weight and of the production batch in the sample collection record. Using a 0.5 mL, 1.0 mL, 10.0 mL or other appropriate sterile disposable pipette<sup>1</sup> or syringe, remove the sample amount for each sample to be collected into sterile vial or other appropriate container as directed by the cannabis 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 cannabis testing facility must seal each container holding sampled material using tamper evident

seal 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 cannabis testing facility and the witness must initial and date the seal and sign the required attestation.

9. 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 Cannabis 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 cannabis testing facility(ies) conducting the analyses, except that a cannabis testing facility may offer a service to retrieve samples collected from a self-sampler at the cannabis 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 18-691 CMR, ch. 30, §2.

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 cannabis, cannabis concentrate, or cannabis product is stored to prevent microbial growth. The self-sampler, sample collector, or employee of a cannabis testing facility must provide appropriate refrigeration during transport for samples requiring refrigeration.

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

Cannabis 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 cannabis 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 cannabis 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.

At all times, licensees, including cannabis 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 cannabis testing facility collecting samples for mandatory testing.

**Section 16: Waste Management**

All waste must be disposed of in accordance with the requirements of 18-691 CMR, ch. 30.

**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 cannabis testing facility | Office of Cannabis Policy                         | 2 copies per <i>Adult Use Cannabis Program Rule</i> |
| Chain-of-Custody Form, per cannabis testing facility SOP  | Cannabis Testing Facility Licensees               | Per cannabis testing facility SOP as applicable     |

**Section 18: Sample Collector Signatures**

By signing below the self-sampler, sample collector, or employee of a cannabis 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 18-691 CMR, ch. 30, §2, 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: \_\_\_\_\_

Fiscal impact note, included pursuant to 5 MRS §8063: The Department estimates that the changes implemented by this rulemaking will have a de minimus fiscal impact on municipalities and counties.