New York State, Office of Cannabis Management

Cannabis Sampling Quality System Standard

May 2023

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I. Introduction and Scope

This standard ensures cannabis sampling firms are using consistent sampling procedures when sampling from a registered organization, cultivator, processor, cooperative, microbusiness, or any other person licensed pursuant to the Cannabis Law or authorized to cultivate medical cannabis or adult-use cannabis pursuant to the Cannabis Law.

This standard ensures sampling of cannabis is done securely pursuant to regulations (e.g., Part 130 of Title 9).

All items identified in this standard must be made available by the sampling firm during a regulatory audit, inspection, or upon request by the Office of Cannabis Management.

II. Definitions

Lot unique identifier means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of production, manufacturing, testing, holding, distribution, or recall of a lot of adult-use cannabis product can be determined.

Representative sample means a sample of cannabis product of the same size and composition that is required for cannabis product testing by a cannabis laboratory that represents a unique lot of cannabis product processed. The representative sample(s) must be stored on-site at the licensee facilities and can be used as a replacement laboratory testing sample in the event the first sample is compromised, or the results of the analysis require that the lot be re-tested.

III. General Quality System Standards

A sampling firm must establish a documented quality system that describes its policies and procedures.

Each administrative and technical standard operating procedure generated by the sampling firm must include the following information, where applicable (Note [1]). If the information is contained in another controlled document, it must be cross-referenced in the standard operating procedure (SOP).

1) Title or topic;
2) Document control number;
3) Revision number and date;
4) Approval signatory(ies) and date;
5) Page numbering;
6) Revision/change record section;
7) Table of contents;
8) Definitions;
9) Scope and application, including analytes to be analyzed and identification of the approved sampling method;
10) Summary of the method;
11) Interferences;

[1] Some sampling firms may wish to establish a single manual, which incorporates all administrative and technical procedures.

12) Security and safety;
13) Equipment, vehicles, and supplies;
14) Sample collection, preservation, shipment and storage;
15) Quality control;
16) Calibration and standardization of sampling methods;
17) Sampling Procedure;
18) Data analysis and calculations;
19) Sampling method performance;
20) Pollution prevention;
21) Data assessment and acceptance criteria for quality control measures;
22) Corrective actions for out-of-control or unacceptable samples;
23) Contingencies for handling out-of-control or unacceptable samples;
24) Waste management;
25) References; and
26) Any tables, bench or log sheets, diagrams, flowcharts and validation data or studies.

Pursuant to Part 130 of Title 9, a sampling firm must ensure each employee completes data integrity training (Note [2]) upon hire and annually thereafter, and such training shall be documented for each employee.

Furthermore, a sampling firm must demonstrate a technician's ability to perform sampling through:

1) a documented training checklist and
2) a documented attestation that the technician read and understands the current sampling SOP.

If the sampling SOP is significantly amended, a technician must be retrained on the procedure, and the training documented.

Additionally, a sampling firm must maintain a master of list of all controlled quality system documents and a signature log that includes the names, initials and signatures for all individuals who are responsible for signing or initialing any sampling and transportation record.

IV. Sampling Standards
General Cannabis Sampling.

For final product testing, a statistically significant number of samples from the adult-use licensee or registered organization containing the final cannabis product equivalent to the sealed cannabis product distributed to the public (e.g., liquid extract in a sealed bottle or intact sealed bottle of

[2] The data integrity (DI) training must address the following criteria: the sampling firms's organizational mission and its relationship to the critical need for honesty and full disclosure in all sample reporting, how and when to report data integrity issues, accurate record keeping, any infractions to sample data which will result in a detailed investigation that could lead to very serious consequences including immediate termination or civil or criminal prosecution, specific examples of breaches of ethical behavior, discussion regarding all DI procedures, DI training, in-depth data monitoring, and DI procedure documentation, and an emphasis on the importance of proper written narration on the technician's part with respect to those cases where analytical data may be useful, but are in some way partially deficient.

capsules) shall be collected and submitted for final product testing in a manner approved by the Office.

Sampling and testing of each lot of final cannabis product shall be conducted with a representative sample of a cannabis product batch by collecting a minimum number of sample increments relative to the batch size as set forth below.

Final Cannabis Product Batch and Pre-Roll Sampling.

a) The cannabis sampling technician (simply, technician) shall obtain a representative sample from each cannabis product batch or pre- roll batch.
b) The technician may collect a greater number of sample increments if necessary to perform the required testing or to ensure that the samples obtained are representative, and must document the change to the number of sample increments collected on the chain of custody and shipping manifest.
c) The cannabis product batch or pre-roll batch from which a representative sample is obtained shall contain no more than 150,000 units. Laboratory analyses of a sample collected from a cannabis product batch containing more than 150,000 units shall be deemed invalid and the cannabis product batch or pre-roll batch from which the representative sample was obtained shall not be released for retail sale.
d) The sampler shall obtain a representative sample of a cannabis product or pre-roll batch by collecting, at minimum, the number of sample increments relative to the batch size as listed in Table 1. Each sample increment consists of 1 packaged unit.

Table 1. Representative Sampling

Cannabis Product or Pre-roll Batch Size (units)	Number of Sample Increments (per sample)
≤ 50– 500	5
501 – 1,200	8
1,201 – 3,200	13
3,201 – 10,000	20
10,001 – 35,000	32
35,001 – 150,000	50

At the option of the licensee or registered organization, some forms of cannabis product samples may be collected and transported to the laboratory in the following manner:

- Bulk oil may be sent in a sanitary conical tube to the laboratory containing a volume of oil representative of the lot to perform all required compliance testing for final product. The only exception is metals testing.

- The producer of the product will also send a subset of samples in the apparatus the oil is intended for to be readily consumable (i.e., vape cartridge, vape pen, syringe, etc.) to perform metals testing.

Table 2 represents the volume of bulk oil and minimum number of oil in vaporization apparatus required for testing. Due to the low volume of some vaporization products, the lab may require additional oil in the apparatus to perform the test. Please work with the sampling firm and laboratory to ensure an appropriate amount of material is sent.

Table 2. Representative Sampling for Bulk Oil

Batch Size (units)	Bulk Oil Required (g)	Final Form Vapes Required (# of units)
50 – 500	3	1
501 – 1,200	4	2
1,201 – 3,200	6.5	3
3,201 – 10,000	10	4
10,001 – 35,000	16	7
35,001 – 150,000	25	10

V. References

9 NYCRR Section 130

9 NYCRR Section 113

Terms And Conditions And Guidance for Adult-Use Conditional Processor Licensing | Office of Cannabis Management (ny.gov)

VI. Change Record

August 2022 – Initial release

May 2023 – Added representative sampling process for bulk oil and oil in vaporization apparatus.