Introduction

The New York State Office of Cannabis Management (Office or OCM) is issuing updated guidance to Adult-Use Conditional Cultivators (AUCC) and Adult-Use Conditional Processors (AUCP) clarifying cannabis product testing requirements. Specifically, this guidance details:

1. **Guidelines to address which cannabis products can be tested now by permitted laboratories and a timeline of testing availability for product forms where approved methods are still under development**
2. **A summary of all tests required under the Office's final product testing requirements**
3. **Updated guidance for the requirement of homogeneity for adult-use cannabis products**
4. **Cannabis Lot Testing Guidance**

The guidance did detail a temporary program, line testing, which ended July 1, 2023. It was designed to allow AUCC and AUCP licensees the opportunity to test multiple consistently processed lots of finished cannabis products that meet certain prerequisites to be tested at once, dramatically expanding the testing capacity available for AUCC and AUCP licensees seeking to advance their products through the supply chain, while still testing a statistically significant sample of every product.

Licensees should refer to this guidance, as well as any other regulations and guidance issued by the Office when preparing for final product testing of their adult-use cannabis products. If you have any questions about the guidance, please contact AUCommunications@ocm.ny.gov.

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Priority of Testing

Pursuant to Section 130.7 (g) of Part 130 laboratory regulations, laboratories are required to dedicate a percentage of its testing capacity to licensees that are businesses with limited resources as determined by the Office, and to Registered Organizations for medical cannabis product testing pursuant to the requirements set forth in Subchapter B of Title 9. As such, laboratories will reserve 60% of their daily capacity for individual lot testing for adult-use cannabis products from AUCC and AUCP licensees, 35% of their daily capacity for individual lot testing for medical cannabis products, and 5% for research and development. Should a laboratory's reserved capacity not be utilized for each of these categories, they may re-allocate testing slots to fill vacant testing slots.

Effective July 1, 2023, conditional adult-use licensees must begin utilizing approved cannabis sampling firms for the sampling and transportation of their final cannabis product samples for laboratory testing. Licensees should begin preparing to utilize approved cannabis sampling firms for the sampling of their cannabis products. A list of approved cannabis sampling firms can be found on the Office's website: Sampling Firms | Office of Cannabis Management (ny.gov).

Adult-Use Cannabis Product Testing Timeline

As required by Section 82 of Cannabis Law, every processor of cannabis products must contract with an independent cannabis laboratory, permitted pursuant to Section 129 of the Cannabis Law, to test the cannabis products it produces. Currently, permitted cannabis laboratories do not have valid testing methods developed for some types of adult-use cannabis product forms. Those forms will not be allowed until such time that the laboratory methods are established so the products can be tested by a permitted laboratory.

OCM anticipates valid testing methods for additional cannabis product types will be developed by the permitted laboratories over the next several months. If you have any questions about cannabis product testing and the roll out of approved testing methods, please reach out to labs@ocm.ny.gov.

Table 3. Laboratory Status of Various Cannabis Product Types or Forms

Taxed as	Type or Form	Description	Laboratory Status
Cannabis Flower Products ($0.005 per mg THC)	**Cannabis Flower Products**	All cannabis flower products, including whole flower, ground flower, or manufactured flower products (such as a pre-roll or tobacco-free blunt. This also includes pre-rolls dipped in kief).	Currently Testable and Allowed
Concentrated Cannabis ($0.008 per mg THC)	**Oil for Vaporization**	Oil to be used in a vaporizer.	Currently Testable and Allowed
	Topicals	All products intended for topical use containing >3% THC. Some examples are balms, lotions, and body oils.	Currently Testable and Allowed
	Wax or Shatter	Concentrated cannabis extracted using a solvent. Some examples are budder, crumble, sauce, shatter, crystals, and crumble.	Currently Testable and Allowed
	Resin	Concentrated cannabis extracted using a solventless method. Some examples are kief, hash, and rosin.	Currently Testable and Allowed
Cannabis Edible Products ($0.03 per mg THC)	**Gel-based foods**	Any cannabis edible product that is intended to be chewed and relies upon a gelling agent such as, but not limited to, gelatin, agar, or pectin to maintain its shape or texture. Some examples are fruit chews, gummies, and chewable gel capsules.	Currently Testable and Allowed
	Tablets, Capsules, and Lozenges	Includes all tablets, capsules, and lozenges.	Currently Testable and Allowed

Cannabis Edible Products ($0.03 per mg THC)	**Oral Liquids**	Homogeneous oral liquids including tinctures, oral solutions, syrups, and oral emulsions.	Currently Testable and Allowed
	Water-Soluble Edibles	Edible products which are intended to be dissolved in water before consumption. Some examples are dissolving powders and effervescent tablets.	Currently Testable and Allowed
	Solid Chocolates	Includes all solid chocolates.	Currently Testable and Allowed
	Other Foods	Any food that is not a gel-based food or a solid chocolate. Some examples are baked goods, ice cream, and coffee grounds.	Timeline TBD
	Beverages	All beverages and syrups.	Currently Testable and Allowed

Guidance for Required Laboratory Testing of Adult-Use Cannabis Products:

OCM released a timetable for implementation of required cannabis product testing. The timetable is located on the Office's website. Please note, that not all permitted laboratories may have a full scope of required testing. Check the OCM website for the scope of testing of permitted laboratories. The table below summarizes the type of testing that is currently required, as well as additional testing requirements that will be phased in at a future date.

Table 4. Scheduled Rollout of Required Testing

Type of Testing	Currently Required	Additional Requirement after 1/1/2023	Additional Requirement after 03/01/2023
Cannabinoid Profile	X		
Pesticides	X, indole-3-butyric acid (IBA), pyrethrins (as Cinerin I, Cinerin II, Jasmolin I, Jasmolin II, Pyrethrin I, Pyrethrin II), azadiractin, and myclobutanil OR any declared pesticide used by an AUCC used during the cultivation of cannabis. +		X, expanded list
Metals	X		
Mycotoxins	X		
Microbiology	X	++	
Moisture Content		X	
Filth/Foreign Material		X	
Water Activity		X	
Residual Solvents			X
Terpenes			X

+ At this time only the pesticides listed in the table require testing and any pesticide declared by a Conditional Cultivator that was used during the cultivation of cannabis.

++ Total Viable Aerobic Bacteria Count and Total Yeast and Mold Count is not required until January 1, 2023. Other Microbiology testing such as Salmonella species, Shiga toxin-producing Escherichia coli and required Aspergillus species must be tested on lots now.

Please note that while Total Viable Aerobic Bacteria Count and Total Yeast and Mold Count tests are required beginning on January 1, 2023, there will not be a defined limit for unextracted products (e.g. cannabis flower products) in the adult-use program. Total Yeast and Mold should be used as a general quality indicator. Yeast and Mold growth is a common occurrence in our environment and more prevalent on outdoor grown cannabis. Total yeast and mold tests do not necessarily correlate with the presence or absence of a harmful mold. Molds can potentially be a cause of allergic hypersensitivity reactions in consumers, can be harmful to consumers who are immunocompromised, and affect a cannabis product's shelf stability. It is the responsibility of the licensee to consider these test results and any impact to stability and expiration dating of the product, as well as any risks to the health of consumers. OCM will monitor these laboratory testing results and licensees may be required to conduct further testing where results indicate concerns with product quality or safety.

Homogeneity Testing for Adult-Use Cannabis Products

Except for cannabis flower products, a final cannabis product must be homogenous, with phytocannabinoid content evenly distributed throughout the cannabis product. Unless otherwise approved by OCM, cannabis product shall not be considered homogenous if the concentration of total THC and CBD in milligrams per single serving for five (5) samples of a cannabis product lot/batch submitted for testing is greater than +/- one (1) standard deviation of the mean concentration for total THC and CBD in milligrams per serving for that submitted lot/batch.

Laboratories must test five (5) samples of cannabis product for homogeneity when products submitted for testing are new offerings from a conditional adult-use licensee. Once initial homogeneity testing is completed on three (3) consecutive lot/batches and the results demonstrate the product is homogeneous, all subsequent lots/batches may forego homogeneity unless:

- There is a significant change to the standard operating procedures affecting the manufacturing of a previously produced cannabis product including but not limited to batch/lot size or volume, mixing or handling methods, change in ingredients, change in equipment; or
- Any other instance that may significantly affect homogeneity.

It is the licensee's responsibility to retain homogeneity records for five (5) years and make such records readily available to the OCM upon request, to justify foregoing homogeneity testing. Homogeneity testing is not required for cannabis flower products.

Cannabis Lot Testing Guidance

Each batch/lot of cannabis product must be tested by an OCM permitted laboratory. A representative sample must be used to conduct this testing.

A representative sample is defined in the OCM Sampling Quality System Standard as 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 that is processed. Licensees are required to retain representative sample(s), and they must be stored on-site at the licensee's facilities to allow for testing in the future if requested by OCM.

Full lot processing completion, in ready-to-consume final product form, is mandatory prior to submitting samples for final product testing. This ensures that random sampling is performed and that the samples are representative of the lot produced.

Ready-to-consume final product form is a cannabis product that requires no further processing and ready for final packaging. Examples of final product form include but are not limited to: flower ready to jar, tablets, capsules, and chewable gels ready to be bottled, concentrates or oils ready to be placed in a device or cartridge, tinctures or other oral liquids ready to be bottled, beverages ready to be bottled/canned.

The samples collected from a lot must be placed in the final packaging before they can be sent to the laboratory for testing. This can be done at the time of sample collection.

However, the entire lot does not have to be packaged in final packaging prior to sample collection provided that the licensee has the following information:

- Certificates of analysis on ingredients/excipients indicating:
  - For all products except vaporization products: ingredients/excipients are appropriate for the cannabis product type manufactured and are, at a minimum, food grade or considered generally recognized as safe;
  - For vaporization products: except for cannabis or botanically derived terpenes, excipients and ingredients must be pharmaceutical grade and appropriate for an inhaled cannabis product; and
- Documentation that indicates that the containers are food-grade, or of a similar standard as approved by the Office, for the storage of cannabis and cannabis products. Containers shall be clean, in good repair, suitable for the established use, and must be compliant with Part 128 Packaging and Labeling regulations.
- Quarantined product awaiting testing and packaging must be segregated in a designated area for storage and must be clearly labeled as to include but not limited to product name, product type, total quantity, lot/batch number, date of production, and date of expiration.

- Quarantined product that has passed all compliance testing must be packaged in a timely manner to ensure quality of the product in accordance with individual standard operating procedures using good manufacturing practice for each product type.

Once the licensee receives passing compliance testing results from the permitted laboratory, the licensee must package the entire lot prior to releasing for retail sale.

Acceptable final packaging, for testing purposes, is the layer of packaging in which the product comes in contact. Examples:

- Sealed Vaporization Cartridge /disposable pen
- Gummies in mylar bags
- Whole Flower in jars
- Pre-rolls in tubes
- Bottles of tincture

Final packaging, for testing purposes, does not require complete regulatory labeling, but at minimum must include the product name and form, specific unique lot number, net contents and target potencies.

Table 5:

Product Type	Description	Lot and Sample
Cannabis Flower	Loose cannabis flower whole or ground.	Samples must be in packaging/containers as it would be sold to the consumer. (Jar, bag, etc.) Remainder of the lot can be packed after receiving passing compliance testing results.
Pre-Rolled Cannabis Flower	Cannabis flower loaded, rolled and ready for consumption.	Samples must be packed in final packaging (Bag, doob tube, other compliant containers). Pre-roll lots in their entirety must be rolled prior to testing and can be stored in a manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after receiving passing compliance testing results.
Oil for Vaporization	Pre-filled vape cartridges and prefilled disposable pens.	Samples must be in the layer of packaging in which the product comes in contact (Prefilled cartridge or disposable pen).

		Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.
Topicals	All products intended for topical use containing >3% THC. Some examples are balms, lotions, and body oils.	Samples must be in packaging/containers as it would be sold to the consumer. Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.
Wax, Shatter, Resin	Concentrated cannabis extracted using a solvent. Some examples are budder, crumble, sauce, shatter, crystals, and crumble.	Samples must be in packaging/containers as it would be sold to the consumer. Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.
Gel-based foods, Water-Soluble Edibles, Tablets, Capsules, Solid Chocolates, a nd Lozenges	Includes: • Any cannabis edible product that is intended to be chewed and relies upon a gelling agent such as, but not limited to, gelatin, agar, or pectin to maintain its shape or texture. Some examples are fruit chews, gummies, and chewable gel capsules. • Tablets, capsules, and lozenges. • Edible products which are intended to be dissolved in water before consumption. Some examples are dissolving powders and effervescent tablets.	Samples must be in packaging/containers as it would be sold to the consumer (bottles, mylar bags, jars, vials, etc). Remainder of the lot must be stored in a manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after receiving compliance testing results.

	• Edible products which are intended to be dissolved in water before consumption. Some examples are dissolving powders and effervescent tablets.	
Oral Liquids	Homogeneous oral liquids including tinctures, oral solutions, syrups, and oral emulsions.	Samples must be in the layer of packaging in which the product comes in contact (bottle, vial, dropper, etc). Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.
Beverages	All beverages and syrups.	Samples must be sent in the bottled/canned form ready for consumption. Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.

A random statistically significant sample of products from each lot of cannabis products produced must be tested. "How much" or the representative sample of products depends on the lot size. Page 4 of OCM's Sampling Quality System Standard includes a table with the number of random sample increments for different batch or lot size ranges.

Table 6:

Cannabis Final Product (units)	Number of Sample Increments
≤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

Table 7:

Example	How Samples Must Be Packaged
Licensee is processing whole flower that will be offered to consumers in the amount of 3.5g packaged in a regulatory compliant jar. It is determined that 20 samples must be sent for testing to statistically represent the lot.	Each of the 20 samples must contain 3.5g of whole flower individually sealed in regulatory compliant jars the product will be sold to consumers at retail. One sample = One 3.5g jar of flower
Licensee is processing gummies that will be offered to consumers in a regulatory compliant mylar bag containing 20 gummies. It is determined that 32 samples must be sent for testing to statistically represent the lot.	Each of the 32 samples must contain 20 gummies sealed in the regulatory compliant mylar bags the product will be sold to consumers at retail. One sample = One mylar bag of 20 gummies

All cannabis products must include a lot-unique identifier. The OCM Sampling Quality System Standard for final product testing defines a lot-unique identifier as 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.

A cannabis product batch, or lot, is defined in Part 130 laboratory regulations as a uniquely defined quantity of cannabis product; including pre-rolls, that is uniform in processing, manufacture, and packaging within a concurrent time frame. The time frame may extend to more than one shift over a few workdays, provided that the prior criteria is met.