NEW YORK STATE | Office of Cannabis Management

ENSURING ACCURATE & RELIABLE DATA from Cannabis Sampling Firms and Labs through Law, Regulations and Standards

Environmental Measurement Symposium
St. Louis, MO

AUGUST 1, 2025

Agenda

i. Introduction to Cannabis

ii. Required Analytes & Group of Analytes

iii. NYS Regulatory Framework

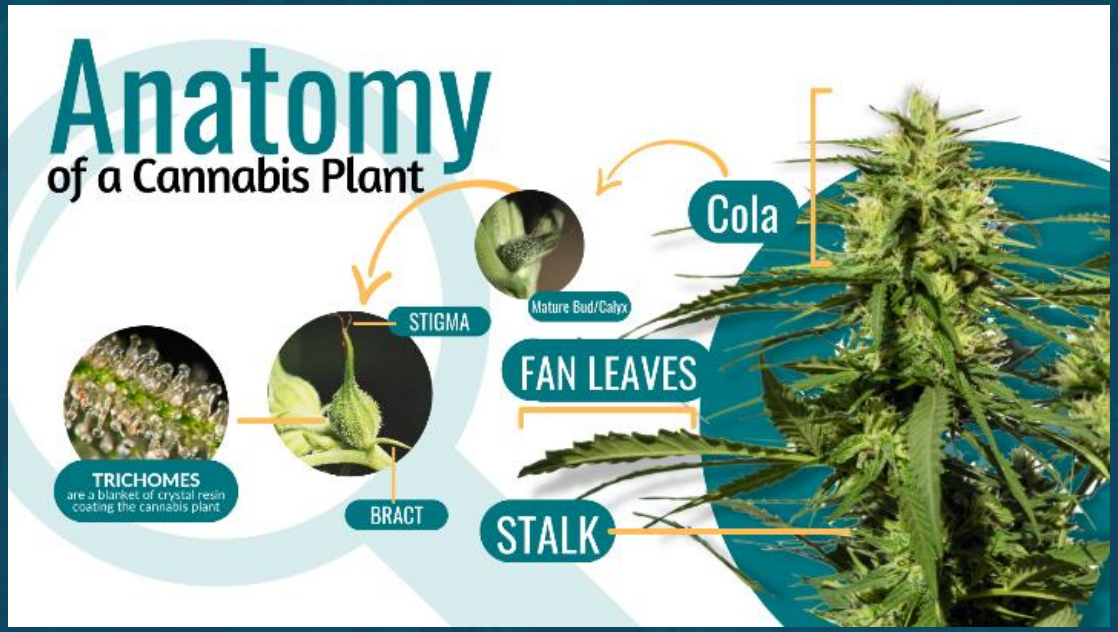
iv. Standards

v. State Reference Laboratory

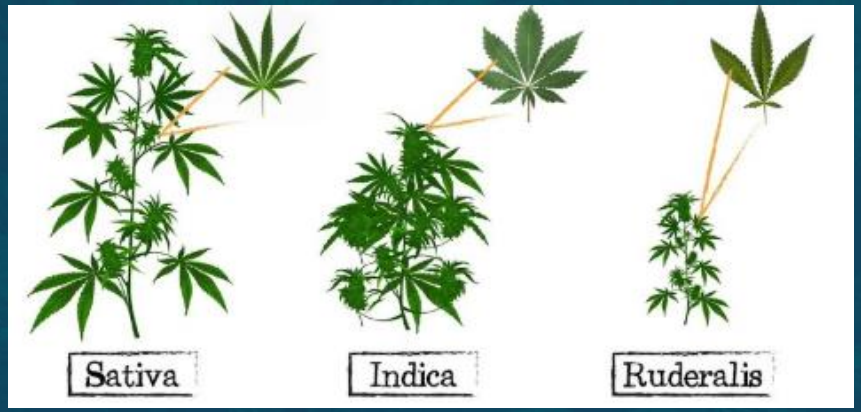
vi. Questions

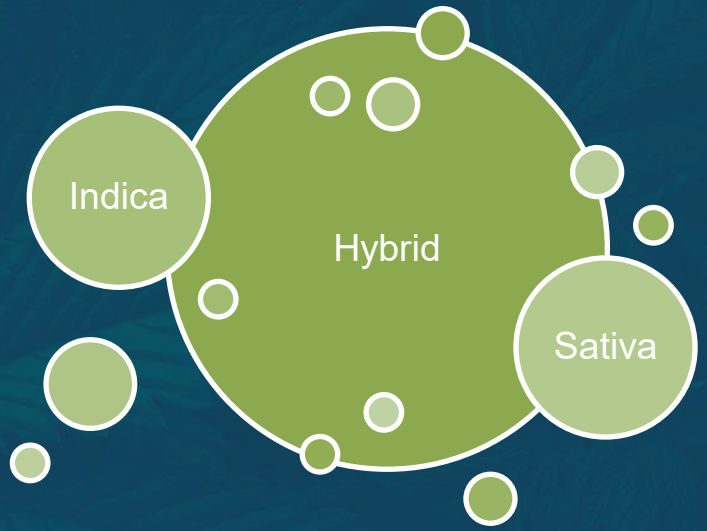
INTRODUCTION TO CANNABIS

Anatomy, Strains, and More



Cannabis, commonly known as marijuana, weed, pot, Ganja, dope, etc., is from the Cannabaceae plant family. The Cola (large, mature bud) of a female plant contains the highest concentration of psychoactive compounds. It has been used for medicinal, spiritual and recreational purposes.





All strains fall into three (3) main categories.
Each strain has its own profile related to potency, terpenes, and flavonoids.

Cannabinoids (also known as Phytocannabinoids) come from the trichomes. These chemical compounds vary in concentration from strain to strain.

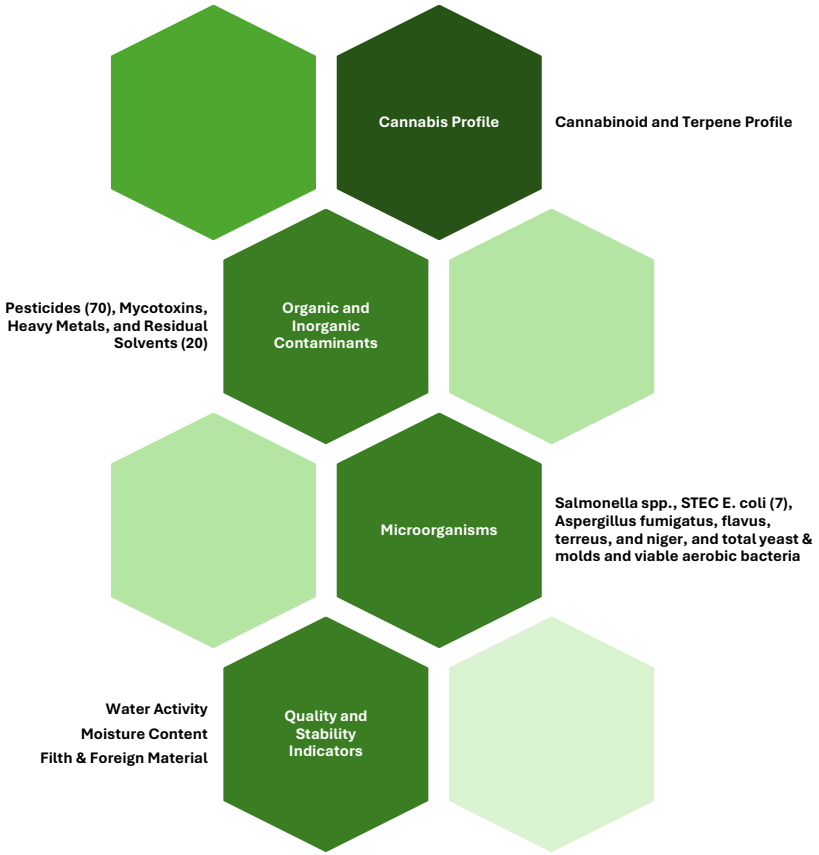
ANALYTES OR GROUP OF ANALYTES

Analyte contributions from soil, air, water, anthropogenic, rodent, fertilizers, etc.
Analytes are indicators of agricultural, manufacturing and laboratory (including sampling) practices. Goal is “Good” practices (i.e., GAP, GMP and GLP).

ocm-testing-limits-final-5-6-25.pdf

Mycotoxins
Total Aflatoxins (Sum of Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, and Aflatoxin G2, if determined individually)
Ochratoxin A

Trace / Heavy Metal Analyte (as a Total)
Antimony (Sb)
Arsenic (As)
Cadmium (Cd)
Chromium (Cr)
Copper (Cu)
Lead (Pb)
Mercury (Hg)
Nickel (Ni)



Phytocannabinoid Profile
Tetrahydrocannabinol (THC) as Total THC of:
Δ9-THC;
Δ8-THC;*
Δ10-THC (epimers); and*
the optical isomer of such substances
Tetrahydrocannabinolic acid (THCA)
Tetrahydrocannabivarin (THCV)
Total Cannabidiol (CBD)*
Cannabinadiolic acid (CBDA)*
Cannabidivarin (CBDV)
Cannabinol (CBN)
Cannabigerol (CBG)
Cannabichromene (CBC)
Any Other Marketed Phytocannabinoid

NEW YORK STATE REGULATORY FRAMEWORK

Then (2014 - 2020) and Now (2021 - Present)

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REGULATORY BACKGROUND

Compassionate Care Act

Signed in 2014 by Governor Cuomo

Public Health Law

Commissioner of Health

Department of Health

Part 1004 of Title 10 NYCRR

- **Office of Primary Care and Health Systems Management**
  - **Medical Marijuana Program (MMP)**

10 NYCRR Parts 55-2.2 (a)(5) and 55-2.15

- **Wadsworth Center**
  - **DLQC Environmental Laboratory Approval Program (ELAP)**
  - **DEHS Medical Marijuana Lab (MML)**

REGULATORY BACKGROUND

Marihuana Regulation & Taxation Act (MRTA)

Signed in 2021 by Governor Hochul	Cannabis Law	Office of Cannabis Management	Cannabis Control Board
Part 113 of Title 9 of NYCRR (Medical Cannabis)	Part 114 (Cannabinoid Hemp)	Part 115 (Home Cultivation)	Part 116 (Retail Dispensary)
Part 118-121, 124-125, and 131 (Adult Use Cannabis)	Part 128 & 129 (PLM)	**Part 130 (Cannabis Laboratories, including Sampling Firm)** • **Laboratories Unit under Licensing, Compliance and Laboratories**	Part 132 (Research)

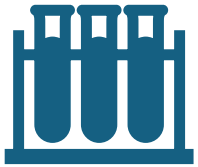
Part 133 (Enforcement)

PART 130

Similarities with the NELAC Institute (TNI) Standard include the following:

- Regulatory audits and inspections
- Minimum experience and education for technical director
  - Also applies to QA Officer and Technicians
- Proficiency testing (required starting April 1, 2025)
- Demonstration of capability
- Data integrity training

Records Audit



Unannounced

Desk Audit

Part 130 Laboratory Regulatory Audits

Permitted labs all initially inspected between 2023 and 2024

Labs inspected every two years following prior inspection; second round commenced in February 2025

Grace period of 90 days from notice to cure all findings, provided that within 30 days of notice submit a corrective action plan

Part 133 Inspections

Statement of findings linked to Violations (Category 1 – 5)

Correction action plan within 24 hours of notice (Category 1-3) or 15 calendar days (Category 4-5)

Announced

Virtual Audit

Onsite Audit

OCM takes the appropriate actions as prescribed within the law and regulations (i.e., Part 130 and/or 133) when findings of non-compliance are substantiated. In such cases, permittees are notified and required to implement a corrective action to cure the finding. If a permittee fails to take corrective action to cure the finding, OCM will proceed with disciplinary action. Examples include summary suspension, stop work orders, cancellation, revocation, debarment, or denial.

Minimum Education and Experience Requirements for Laboratory Technical Staff

Role	Comment	Technical Area	Education	Experience
Lead technical director (LTD)	Only 1	• Organic Chem. • Metals Chem. • Physical Chem. • Microbiology • Other (please specify)	B.S. or B.A. is min., and they must show 24 credit min. in chem or 16 credit min. in bio (with micro course) Or M.S. or Ph.D., and they must show 24 credit min. in chem or 16 credit min. in bio (with micro course)	If Bachelors only, they need at least 2 years of experience in testing samples in that technical area. If Masters or Doctorate, they need at least 1 year of experience in testing samples in that technical area.
Technical director(s) (TD)	Will be at least 2 more listed			
QA officer (QAO)	Only 1	QA/QC with science background	Min. of bachelor's degree in the natural sciences (bio, chem, physical, engr., environ. science, etc.)	Min. of 2 years of experience in implementing a quality system-QA/QC
Lab technician(s)	Will be at least 2 or more listed	ICP-MS GC LC or HPLC Culturing Chemical Extractions PCR Other (please specify)	Min. is an associate's degree or 2 years of college studies in natural sciences (bio, chem, physical, engr., environ. science, etc.)	Min. of 1 year of experience in testing of representative analyte or group of analyte

Adopted regulation was changed to at least 6 months. Emergency and proposed regulation had 1 year min.

EXPERIENCE SUBSTITUTION FOR EDUCATION

- - - Lead Technical Director (TD) or TD - - -

An individual who meets the experience requirements but not the educational and/or credential requirements of this Part, and is functioning in a technical director's capacity as subject to this section, and is functioning in a technical director's capacity on the date a cannabis laboratory becomes subject to these regulations, shall qualify as technical director of that cannabis laboratory, or any other cannabis laboratory permitted by the Office and performing similar testing, provided such individual has been technical director in that cannabis laboratory for the previous twelve (12) consecutive months, or more, will oversee only those areas of testing for which they were a technical director for at the least previous twelve (12) consecutive months, and can demonstrate the ability to comply with the proficiency test and quality system requirements of this Part. An individual who is admitted as a technical director under these conditions, and leaves a cannabis laboratory, will be eligible for hire as a technical director for the same area of testing in another permitted cannabis laboratory.

- - - QA Officer (QAO) - - -

An individual who meets the experience requirements but not the educational and/or credential requirements of this Part, and is functioning in a quality assurance officer's capacity as subject to this section, and is functioning in a quality assurance officer's capacity on the date a cannabis laboratory becomes subject to these regulations, shall qualify as quality assurance officer of that cannabis laboratory, or any other cannabis laboratory permitted by the Office and performing similar testing, provided such individual has been quality assurance officer in that cannabis laboratory for the previous twelve (12) consecutive months. An individual who is admitted as a quality assurance officer under these conditions, and leaves a cannabis laboratory, will be eligible for hire as a quality assurance officer in another permitted cannabis laboratory

PROFICIENCY TESTING

Proficiency test (PT) means a test that requires a laboratory to produce analytical results within acceptable limits on an analyte or group of analytes of which the concentration and identity is unknown to the laboratory or its employees but known to a proficiency test provider (§ 130.1 (o)).

- A cannabis laboratory shall participate in proficiency tests. If available and offered by an ISO/IEC 17043 approved proficiency test provider, at a frequency specified under this Part and have **successfully passed two (2) out of the most recent three (3) proficiency tests** as part of the permit requirements.

- **To maintain approval** for a given analyte or group of analytes on its permit, a cannabis laboratory shall attain satisfactory performance as determined by the Office, in **at least two (2) of three (3)** consecutive scheduled or unscheduled or supplemental **proficiency test** in which it has participated in **an eighteen (18) month period**.

- An **unscheduled or supplemental proficiency test** shall be **at minimum seven (7) days from the close date of the prior** scheduled or unscheduled **proficiency test**. An unscheduled proficiency test may also be a supplemental proficiency test that was unscheduled.

DEMONSTRATION OF CAPABILITY

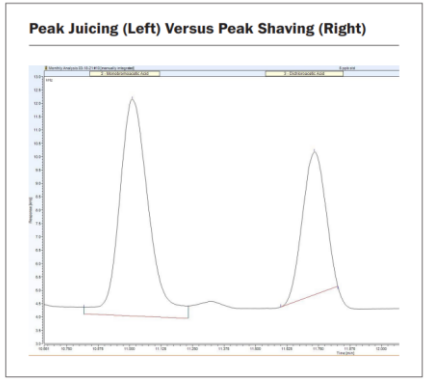
A cannabis laboratory shall develop and implement an **employee training program**, which shall include but not be limited to, a training checklist, and **an initial and continuing demonstration of capabilities**, to ensure competency of a laboratory employee for their assigned functions (§ 130.11 (a)(2)).

- An individual who performs any activity involved with preparation and/or analysis of samples must show a satisfactory initial DOC.
- An initial DOC must also be performed any time there is a change in instrument type, method, or any time that a method has not been performed by the technician in a twelve (12) month period.
- If the technician has successfully completed the DOC, the technician can begin testing samples.
- Annually thereafter, a continuing DOC is required.

DATA INTEGRITY TRAINING

- Data integrity training means training related to the following topics, among others: **organizational mission** and its relationship to the **critical need for honesty** and full disclosure in all sampling; transportation and analytical reporting; **how and when to report** data integrity issues; **record keeping**; and **breaches of ethical behavior**, including but not limited to, improper data manipulations, adjustments of instrument time-clocks, dry-labbing, and changes in: concentrations of standards, date and time of sampling, transport, and analysis (§ 130.1 (h)).
- A cannabis laboratory shall ensure an employee completes **data integrity training upon hire and annually thereafter**, and evidence that such training was performed for an employee shall be documented and available upon request (§ 130.11 (a)(2)).

Data Manipulation



Result Deception

Data Deletion

Data Fabrication

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NEW YORK STATE STANDARDS

Then (2014 - 2020) and Now (2021 - Present)

NEW YORK STATE | Office of Cannabis Management

Under DOH

Labs held to ISO/IEC 17025 testing standards plus the NELAC Institute (TNI) standards.

1004.14 (f) Testing of the cannabinoid profile shall include, at a minimum, those analytes specified in section 1004.11(c)(2) of this Part.

All labs required to test medical marijuana using NYS DOH validated test methods.

Under OCM

- Labs held to ISO/IEC 17025 testing standards plus OCM laboratory quality system standards (LQSS).
- 130.22 (b) Testing of the phytocannabinoid profile in cannabis product and or medical cannabis and any other intermediates or forms shall include, at a minimum, the analyte or groups of analytes specified under this Part.
- 130.22 (d) The Office shall make available a list of required analytes, their acceptable limits and approved testing methods on the Office's website and in any other manner as determined by the Board.
- THC as D-8, D-9, and D-10 (2 epimers)
- Approved method means any analytical method, including sample preparation, of proven reliability which has ben approved or recognized by this Part, any NYS agency, or other regulatory program, for the specific purpose for which the method is to be used.

STANDARDS FOR LAB-DEVELOPED METHODS

Before Office approval of a test method, the following must have been evaluated (LQSS, section VII):

- Validation study
  - Organic and Metals Chemistry (evaluate precision, bias and selectivity and LOQ verification)
  - Microbiology (Culture/MPN and PCR – specificity, sensitivity, inter and intra-assay reproducibility, and accuracy)
- Standard operating procedure(s), describing prep of different cannabis matrices, extraction solvent, sample volume, calibration curve, etc.
- Initial demonstration of capability for primary technician(s) who prep samples and run instrument
- Test report (COA) template
- Limit of detection (method detection limit) (LOD, MDL) study (using 40 CFR 136, Appendix B)
- Limit of quantification (LOQ) study
- Proficiency test (PT) study
- Technical director that meets experience and education to oversee testing area
- Technician(s) that meets experience and education to perform extractions and instrument analysis

Organic and Metal Chemistry

- LOD Determination
- LOQ or MRL determination
- Initial Calibration
- Initial Calibration Verification
- Continuing Calibration Verification
- Precision and Bias
- Negative Control (LRB or MB)
- Positive Control (LCS)
- Matrix Spikes and Matrix Spike Duplicates
- Surrogate Spikes (organic only and if method was validated using them)
- Linear Dynamic Range (metals only)
- Internal Standards (if method was validated using them)
- Isotope Dilution (if method was validated using them)
- Data reduction
- Retention Times

Physical Chemistry

Water activity

- Sample duplicates
- Calibration and calibration verification
- Monitor temp & humidity daily

Moisture content

- 1-gram sample required
- Use wither moisture analyzer or drying oven (with analytical balance and desiccator)
- Temp must be within 90-105 degrees C

Filth & foreign matter

- Use not less than 30% of total representative sample collected by weight
- Separate into no less than 10 increments (subsamples)
- Use microscope with both low and high power and photographic capabilities

MICROBIOLOGY STANDARDS

Culture and Most Probable Number (MPN) Methods

Quality Control	Specific Control	Frequency
Positive Control (Qualitative Culturing)	Analyze a Matrix Spike	Per batch or on a regular basis
Positive Control (Quantitative Culturing using Tempo, 3M, Hardy Compact Dry, etc.)	Analyze a Matrix Spike (true organism) for TAMC and TYAM or Sample Duplicates (for samples with expected values >25 cfu/g) Analyze a CRM (in actual matrix)	Per batch or on a regular basis Per batch
Method Blank = Negative Control (Qualitative Culturing)	Analyze a Method Blank	Per batch
Method Blank =Negative Control (Quantitative Culturing)	Incubate and analyze a dilution buffer for TAMC and TYAM	Per batch
Analyst or technician Quantitative Performance	Plate count comparisons • 2 or more analyst or technicians within 10% • 1 analyst or technician within 5%	Monthly

Molecular Methods (i.e., polymerase chain reaction (PCR) assay)

Quality Control	Specific Control	Frequency
Positive Controls	1) PCR Positive Control 2) PCR Inhibition Positive Controls (Internal Sample Control) 3) Matrix Spike	Per each PCR assay run In every extracted sample With each batch or on a regular basis
Negative Controls	1) PCR Negative Control 2) No Template Control 3) Method Blank	With each PCR assay run With each PCR assay run Once per extraction batch
QC for Confirmation Procedures	1) Probe-based Quantitative PCR and Melting Curve Analysis	See section below.

STATE REFERENCE LAB

A cannabis laboratory with which the office contracts, or a laboratory operated by the NYS department of health, whose duties include, but are not limited to, reviews or retests of samples and investigational support as requested by the office.

STATE REFERENCE LAB

- Memorandum of understanding was executed between OCM and DOH in April 2023.
- The Wadsworth Center has conducted testing to support OCM's enforcement and research efforts.
- The Wadsworth Center is being leveraged to perform product quality testing related to potency profile, contaminant testing (microbiology and heavy metals), and stability indicators (moisture content and water activity).
- They are in the process of validating methods for pesticides/mycotoxins, terpenes, residual solvents, and filth & foreign material.

QUESTIONS

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