

## **Some definitions from NYS Office of Cannabis Management:**

**Acceptable limit** – AL – These are the testing limits for contaminants as directed in Office of Cannabis Management’s Part 130 regulation of Title 9, and as provided in a guidance document by the Office.

**Analytical batch** consists of prepared samples which are analyzed together as a group. An analytical batch can include prepared samples originating from different matrices and can exceed twenty (20) samples.

**Batch** – Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents.

**Blank** – A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage, or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results.

**Bracketing** – A method using X-point standard calibration in order to suppress the indeterminate error caused by instrumental drift thus increasing the result precision.

**Certified reference material** – CRM – Reference material, accompanied by a certificate of conformance, having a value, measurement uncertainty, and stated metrological traceability chain to a national or international metrology institute.

**Continuing calibration verification** – CCV – One of the primary calibration standards, analyzed periodically to verify that the calibration is still valid.

**Data integrity training** – DI training – is defined in Part 130 of Title 9.

**Demonstration of capability** – DOC – A procedure to establish the ability of the analyst or technician or technician to generate acceptable accuracy and precision using the method.

**Electronic Laboratory Notebook** – ELN

**Laboratory control sample** – LCS – A portion of appropriate clean matrix that is spiked with known quantities of target analytes and carried through the entire sample preparation process, and treated exactly as a sample, including exposure to all glassware, equipment, solvents, and reagents that are used with other samples. The LCS measures the accuracy of the methodology. The LCS may be prepared from the same source as the calibration standards, or from a second source.

**Laboratory fortified blank** – LFB – A reagent-water sample (with associated preservatives) to which a known concentration of the analyte(s) of interest has been added. The LFB may be used as the LCS if the method requires a preliminary sample extraction or digestion.

**Laboratory information management system** – LIMS

**Laboratory reagent blank** – LRB – An aliquot of extraction and/or dilution solvent(s) that is treated exactly as if it were a sample including exposure to all glassware, equipment, solvents, internal standards, and reagents that are used with the samples. The LRB is used to determine whether method analytes or other interferences are present in the laboratory environment, reagents or apparatus.

**Limit of detection** – LOD – The statistically calculated minimum concentration of an analyte that can be measured with 99% confidence that the value is greater than zero. It is also referred to as method detection limit (MDL). Refer to the definition below.

**Limit of quantification** – LOQ – The concentration of an analyte that can be reported within the accuracy and precision limits defined by the method. The LOQ can be no lower than the lowest calibration standard used in the analysis. For reporting purposes, it is synonymous with the MRL.

**Linear dynamic range** – LDR – The concentration range over which the instrument response to an analyte has been demonstrated to be linear.

**Matrix** includes cannabis, and it may come in different forms such as oil, hemp, edible, pre-roll, and flower.

**Matrix-Assisted Laser Desorption/Ionization Time-of-Flight mass-spectrometer** – MALDI-TOF MS

**Matrix spike** – MS – A portion of an actual sample that is first spiked with a known quantity of target analytes, and then carried through the entire sample preparation and analysis process. The sample from which the portion to be spiked was taken must be analyzed separately to determine endogenous background analyte concentrations. The MS is corrected for background concentrations and used to determine whether or not the sample matrix affects the sample results. It is also referred to as a laboratory fortified matrix (LFM).

**Matrix spike duplicate** – MSD – A second portion of actual sample used to prepare the MS that is spiked and processed in the same manner as the MS. The MS and MSD are used together to measure the precision of the methodology. It is also referred to as a laboratory fortified matrix duplicate (LFMD).

**Method blank** – MB – An aliquot of appropriate pure matrix that is carried through the entire sample preparation process, and that is treated exactly as a sample including exposure to all glassware, equipment, solvents, and reagents that are used with other samples. The MB is used to determine whether contamination with method analytes or other interferences are present in the laboratory environment, reagents or apparatus.

**Method detection limit** – MDL – The minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results. For the purposes of this procedure, “spiked samples” are prepared from a clean reference matrix, such as reagent water, spiked with a known and consistent quantity of the

analyte. It is determined using the US EPA procedure federally codified under Title 40, Part 136, Appendix B. It is also referred to as the limit of detection (LOD).

**Minimum Reporting Limit** – MRL – See definition for LOQ.

**Polymerase chain reaction** – PCR

**Preparation batch** includes samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch consists of one to twenty samples (not including method blanks, lab control samples, matrix spikes and matrix duplicates) of the same matrix with a maximum processing time of twenty-four (24) hours between the first and last sample.

**Quality assurance** – QA

**Quality control** – QC

**Standard operating procedure** – SOP

**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.

**Analyte** means a contaminant, chemical and/or physical property, element, compound, organism, or group of any of the foregoing, the existence and amount of which a laboratory testing facility tests for or identifies in a sample.

**Analyte withdrawal** means a cannabis laboratory's request to remove approval for an analyte or group of analytes, in total or in part.

**Approved method** means an analytical method, including sample preparation, of proven reliability which has been approved or recognized by this Part, any New York State agency, or other regulatory program, for the specific purpose for which the method is to be used.

**Cannabis product batch** means a uniquely defined quantity of medical cannabis or cannabis product; including pre-roll, that is uniform in processing, manufacture, and packaging within a concurrent time frame.

**Certificate of analysis** means a certified report from a cannabis laboratory meeting the requirements of this Part.

**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.

**Laboratory regulatory audit** means an on-site or virtual assessment or audit conducted by the Office, or by a state regulatory program recognized by the Office pursuant to this Part.

**Lead technical director** means a technical director or manager (1) that a cannabis laboratory designates to be directly responsible for overall administration of the technical and scientific operation of a cannabis laboratory, including the supervision of other technical directors or managers, and (2) whose name appears on the permit issued under this Part and on the application, proficiency tests and any laboratory regulatory audit materials submitted by a laboratory to the Office in connection with an application for a permit under this Part.

**Laboratory technician** means a laboratory technician or analyst who is responsible for culturing, extracting or testing cannabis samples using analytical instrumentation including, but not limited to solid phase extraction, gas chromatography, liquid chromatography, inductively coupled plasma – mass spectrometry, and polymerase chain reaction.

**Permit year** shall mean the approval year which is a period during which a cannabis laboratory is authorized to operate, commencing on April 1 and ending on March 31, unless otherwise renewed or extended as set forth in this Part.

**Phytocannabinoid** refers to any of the chemical compounds, excluding terpenes or any other compounds set forth by the Office, that are the active principles of cannabis sativa, including but not limited to tetrahydrocannabinol (THC) and cannabidiol (CBD), and does not include synthetic cannabinoids as that term is defined in subdivision (g) of schedule I of section thirty-three hundred six of the public health law.

**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.

**Proficiency Test Provider (PTP)** means an entity with an ISO/IEC 17043 accreditation for cannabis testing and is independent of a laboratory for which it provides a proficiency test.

**Proficiency Test Provider Accreditor (PTPA)** means an entity independent of the laboratory and proficiency test provider (PTP) that accredits the PTP to ISO/IEC 17043 accreditation.

**Proficiency test sample (PT sample)** means a sample that a PTP provides to a laboratory to conduct a proficiency test.

**Quality assurance officer** means a quality assurance director, quality assurance manager or any other individual who is responsible for an integrated system of activities involving quality control, quality assurance, and quality improvements to ensure that a service meets defined standards of quality with a stated level of confidence.

**Quality system** means a structured laboratory management system that meets the standards for a quality system as determined by the Office.

**State reference laboratory** means a cannabis laboratory with which the Office contracts, or a laboratory operated by the NYS Department of Health, that reviews or retests samples submitted by other cannabis laboratories.

**Technical director** means an individual responsible for the technical and scientific operation of a cannabis laboratory, and who meets the minimum qualifications in this Part. If a cannabis laboratory employs more than one technical director, a cannabis laboratory shall designate one technical director as the lead technical director.