

Repeal of 55-2.2(a)(4) and 55-2.15 of Title 10 NYCRR and addition of Part 130 to Title 9 NYCRR. Pursuant to the authority vested in the Cannabis Control Board by Sections 13, 43, 89, 105 and 129 of the Cannabis Law, Chapter II of Subtitle B of Title 9 of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, and a new Part 130 is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 130

CANNABIS LABORATORIES

**Part 130 – Cannabis Laboratories**

**§ 130.1 Definitions.**

**§ 130.2 Cannabis Laboratory Permit Application.**

**§ 130.3 Cannabis Laboratory Fees.**

**§ 130.4 Cannabis Laboratory Permit Renewal Application.**

**§ 130.5 Cannabis Laboratory Permit Issuance.**

**§ 130.6 Cannabis Laboratory Permit Renewal Denial.**

**§ 130.7 General Cannabis Laboratory Requirements.**

**§ 130.8 Required Cannabis Proficiency Testing.**

**§ 130.9 Unsatisfactory Proficiency Test Performance.**

**§ 130.10 Laboratory Regulatory Audit.**

**§ 130.11 General Cannabis Personnel Qualifications.**

- § 130.12 Cannabis Technical Director Qualifications.**
- § 130.13 Cannabis Quality Assurance Officer Qualifications.**
- § 130.14 Cannabis Laboratory Technician Qualifications.**
- § 130.15 Approval of Laboratory-Developed Methods.**
- § 130.16 Laboratory Sampling Firm Approval.**
- § 130.17 Laboratory Sampling Firm Fee.**
- § 130.18 Laboratory Sampling Firm Reapproval.**
- § 130.19 Laboratory Sampling Firm Requirements.**
- § 130.20 Cannabis Sampling Technician Qualifications.**
- § 130.21 Sampling of Cannabis Product and Medical Cannabis.**
- § 130.22 Testing of Cannabis Product and Medical Cannabis.**
- § 130.23 Certificate of Analysis.**
- § 130.24 Cannabis Shipping Manifest.**
- § 130.25 Sample Chain of Custody.**
- § 130.26 Record Retention.**
- § 130.27 Security, Safety and Storage of Cannabis.**
- § 130.28 State Reference Lab.**
- § 130.29 Summary Suspension, Suspension, Cancellation and Revocation.**

## § 130.1 Definitions.

For purposes of this Part, the following terms shall have the following meanings:

- (a) *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.
- (b) *Analyte withdrawal* means a cannabis laboratory's request to remove approval for an analyte or group of analytes, in total or in part.
- (c) *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.
- (d) *Cannabis laboratory* means a laboratory testing facility as defined in the Cannabis Law.
- (e) *Cannabis laboratory permit* means a permit issued under this Part to a cannabis laboratory.
- (f) *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.
- (g) *Certificate of analysis* means a certified report from a cannabis laboratory meeting the requirements of this Part.
- (h) *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.

(i) *Gross Annual Receipts* means:

(1) for an independent cannabis laboratory or cannabis laboratory operated within a facility which can segregate its laboratory income from total facility income, gross annual receipts means the total income of a cannabis laboratory from all sources for all laboratory tests performed pursuant to its permit under this Part, less any amounts paid to reference laboratories for such tests which are referred;

(2) for a cannabis laboratory operated by a facility which is reimbursed by third-party payors for laboratory services as part of an all-inclusive facility per diem rate and which cannot segregate laboratory income from total facility income, gross annual receipts means (x) the total annual cost of a cannabis laboratory multiplied by a fraction, the numerator of which is the gross revenue of the facility and the denominator of which is the gross cost of the operating facility, less (y) any amounts paid to reference laboratories for such tests which are referred; or

(3) for any other cannabis laboratory unable to segregate its annual income from tests performed pursuant to its permit under this Part, gross annual receipts means the amount a cannabis laboratory would have received had it billed the prevailing rate for such services.

A cannabis laboratory must demonstrate to the Office its inability to segregate its annual income and obtain prior Office approval to use the approved method set forth in subdivision (c) of this section.

(j) *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.

(k) *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.

(l) *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.

(m) *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.

(n) *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.

(o) *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.

(p) *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.

- (q) *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.
- (r) *Proficiency test sample (PT sample)* means a sample that a PTP provides to a laboratory to conduct a proficiency test.
- (s) *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.
- (t) *Quality system* means a structured laboratory management system that meets the standards for a quality system as determined by the Office.
- (u) *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.
- (v) *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.

### **§ 130.2 Cannabis Laboratory Permit Application.**

(a) No person shall be a cannabis laboratory authorized to test medical cannabis and adult-use cannabis and issue laboratory test reports required by the Cannabis Law unless they have been granted a cannabis laboratory permit.

(b)(1) An application for a cannabis laboratory permit shall be submitted to the Office in a manner and format determined by the Board. The application shall be signed by technical directors of a cannabis laboratory, and the following individuals: (i) by the applicant (if an individual); (ii) by a managing member (if a limited liability company); (iii) by an officer (if a corporation), (iv) by all partners (if a partnership); or (v) by an officer, director or trustee if an institution, trust, estate, or any other legal entity.

(2) At the time of application for a cannabis laboratory permit, the Board may require information regarding a cannabis laboratory, including, but not limited to:

- (i) proof of ISO/IEC 17025 accreditation;
- (ii) ownership, true parties of interest, financiers, organization structure;
- (iii) quality control systems;
- (iv) proficiency testing program;
- (v) the premises;
- (vi) qualification of personnel;
- (vii) training programs;
- (viii) consumables including but not limited to reagents and standard reference materials;
- (ix) laboratory equipment;

(x) method of reporting results; and

(xi) any other information as requested by the Office.

(3) An application for a cannabis laboratory permit under this Part shall be accompanied by a non-refundable application fee in the amount of \$1,000.00. Prior to issuance or renewal of a permit, an application or renewal application fee of \$1,000, and permit fee shall be paid, unless otherwise expressly authorized by the Board pursuant to this Part.

(4) For an analyte or group of analytes which the Office requires testing, an application for a cannabis laboratory permit shall specify an analyte or group of analytes that a cannabis laboratory is seeking approval for, the cannabis product or medical cannabis and any other intermediates or forms to be analyzed, and the approved methods to be employed for an analyte or group of analytes in cannabis product or medical cannabis, and any other intermediates or forms.

(c) Upon receipt of such application, the Office shall review a cannabis laboratory's performance on proficiency tests and proficiency test samples, quality system documentation, technical director credentials, performance in laboratory regulatory audit, if applicable, and any additional materials and/or information requested by the Office. The Office shall make a preliminary determination whether the applicant qualifies for a cannabis laboratory permit, the analyte or group of analytes for which the applicant has applied, and the application and permit fee to be paid. The Board will issue the final determination on whether or not to approve or deny a cannabis laboratory permit.

(d) For purposes of the application and permit process, testing facilities housed in separate buildings shall be considered separate cannabis laboratories and require separate cannabis

laboratory permits, unless such facilities obtain a written waiver from the Office. The Office may provide a waiver if the Office determines that:

- (1) effective supervision of the operation of all such facilities can be exercised by the same technical director;
  - (2) the facilities can share the same quality manual, standard operating procedures and record and reporting templates; however, the analytical, record keeping, and reporting results are not duplicative between the facilities; and
  - (3) the facilities are owned by the same legal entity or same individual.
- (e) A cannabis laboratory applicant may withdraw an application at any time prior to the issuance or denial of a permit provided that:
- (1) a notice to withdraw an application is submitted to the Office in writing, dated, and signed by the applicant.
- (f) A cannabis laboratory applicant may reapply at any time following the withdrawal of an application and will be required to submit a new application and application fee prior to any deadline for such application.

**§ 130.3 Cannabis Laboratory Fees.**

- (a) Cannabis Laboratory Permit Fee. The fee for an annual permit under this Part shall be paid by an applicant. An applicant shall pay the appropriate cannabis laboratory permit fee based on its gross annual receipts determined by the Board.
- (1) A cannabis laboratory which has no gross annual receipts because it did not operate in New York State the previous permit year shall pay a first-year permit fee of \$1,000 regardless of

the number of months remaining in the permit year. When applying for renewal of that permit, a cannabis laboratory shall report its gross receipts for the calendar months in which it operated, and these receipts shall be projected to a twelve (12)-month basis for the purpose of computing gross annual receipts.

(2) A cannabis laboratory that had gross annual receipts in the previous permit year, and applies for a permit after commencement of the permit year shall pay a fee computed as an annual fee but prorated for the months remaining in the permit year, or \$1,000, whichever is greater.

(b) A cannabis laboratory that applies for additions to its current permit, adding an analyte or group of analytes for which approval is sought and any other changes, must pay an application change fee as determined by the Board.

(c) Any fee specified in this Part shall be paid to the New York State Office of Cannabis Management by the method approved by the Office at the time of submission of the application.

(d) Failure of a cannabis laboratory to pay the appropriate fee is grounds for denial, suspension, revocation pursuant to this Part.

#### **§ 130.4 Cannabis Laboratory Permit Renewal Application.**

(a) A cannabis laboratory shall submit a renewal application with the Office in a manner and format determined by the Office.

(b) An application to renew a permit issued under this Part shall be filed with the Office not more than six (6) months nor less than four (4) months prior to the expiration thereof. If a renewal application is not filed within four (4) months prior to the expiration thereof, the Board may determine that the permit shall have expired and become void on such expiration date.

(c) An application shall be accompanied by an application fee, which shall be non-refundable, and a permit fee as set forth in this Part. Only an application completed in accordance with this Part as determined by the Office and for which the application and permit fees have been submitted shall be considered if submitted in a timely manner. The permit fee shall be returned to the applicant if the applicant is not granted a renewal permit under this section.

(d) The Office shall consider applications for preliminary determination for renewal in accordance with the criteria set forth in this Part.

#### **§ 130.5 Cannabis Laboratory Permit Issuance.**

(a) An applicant for a cannabis laboratory permit may be granted a provisional permit for a period not to exceed twelve (12) months, provided it has:

(1) obtained ISO/IEC 17025 accreditation, or accreditation that is based on ISO/IEC 17025 accreditation by any other laboratory accreditation authority approved by the Office;

(2) satisfied the technical direction staff requirements as set forth in Section 130.11 – 130.14 hereof;

(3) satisfied proficiency test requirements;

(4) satisfied all fee requirements; and

(5) satisfied any other requirements for approval pursuant to this Part other than completion of a laboratory regulatory audit.

(b) A cannabis laboratory with a provisional permit shall be granted final approval for an analyte or group of analytes for which it seeks approval provided:

(1) the results of a laboratory regulatory audit confirm compliance with the staffing, methodological and other requirements of this Part; and

(2) the cannabis laboratory demonstrates effective implementation of its quality system for (i) planning and assessing the work it performs, and (ii) conducting required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test results.

(c) A cannabis laboratory permit shall set forth the nature of the permit (provisional or final); an analyte or group of analytes that a cannabis laboratory is authorized to examine and identify; the approved testing methods; the name of the laboratory's technical director(s), including lead technical director if there is more than one; and the expiration date of the permit, which shall be March 31 of the permit year.

(d) A cannabis laboratory may make additions to its permit, adding an analyte or group of analytes for which approval is sought and will be required to submit an application and pay a fee for such addition.

(e) A cannabis laboratory permit and any appendices shall be posted conspicuously in a cannabis laboratory and on its website, and a copy shall, upon request, be provided by a cannabis laboratory to any person requesting the services of a cannabis laboratory.

(f) A cannabis laboratory permit shall be effective only for a cannabis laboratory to which it was issued.

(g) A cannabis laboratory permit is not transferable or assignable, including, without limitation, to another cannabis laboratory.

(h) A cannabis laboratory meets the requirements of a testing laboratory as set forth in section 114.10 of Title 9 of the Official Compilation of Codes, Rules and Regulations of the State of New York.

### **§ 130.6 Cannabis Laboratory Permit Renewal Denial.**

(a) A cannabis laboratory's application for a permit, or an application for a renewal of a permit, may be denied for the following reasons, among others:

- (1) failure to submit a completed application;
- (2) failure to pay an application fee;
- (3) failure of laboratory staff to meet the personnel qualifications of education, training, and experience;
- (4) failure to successfully analyze and report proficiency test results;
- (5) failure to pass a required laboratory regulatory audit;
- (6) failure to respond to a laboratory audit report with a corrective action report;
- (7) failure to implement the corrective actions detailed in the corrective action report within the required timeframe;
- (8) failure to implement a quality system;
- (9) misrepresentation of any fact pertinent to receiving or maintaining a permit; and
- (10) denial of entry during normal business hours for a laboratory regulatory audit.

(b) A denial of a cannabis laboratory's application for a permit, or an application for a renewal of a permit, including any notices and challenges thereto, if any, shall be pursuant to Subchapter J of Title 9.

### **§ 130.7 General Cannabis Laboratory Requirements.**

(a) A cannabis laboratory shall maintain ISO/IEC 17025 accreditation, or an accreditation that is based on ISO/IEC 17025 accreditation by any other laboratory accreditation authority approved by the Office.

(b) A cannabis laboratory shall participate in proficiency tests, 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.

(c) A cannabis laboratory shall undergo a periodic laboratory regulatory audit by the Office as specified under this Part and provide any or all records associated with its ISO/IEC 17025 accreditation, or an accreditation that is based on ISO/IEC 17025 accreditation by any other laboratory accreditation authority approved by the Office.

(d) A cannabis laboratory shall employ qualified staff as set forth in this Part.

(e) A cannabis laboratory and its true parties of interest shall have no interest in a registered organization, adult-use cultivator, processor, distributor, retail dispensary, cooperative, microbusiness, delivery, nursery, on-site consumption, registered organization cultivator processor distributor retail dispensary, registered organization cultivator processor distributor, cannabinoid hemp processor, or any other license pursuant to the Cannabis Law.

(f) A cannabis laboratory shall have a continuing duty to disclose material changes in the information provided as required in this Part. Any changes to among other things, ownership, major instrumentation, technical direction, and location shall be subject to the requirements as set forth in Subchapter J of Title 9.

(g) A cannabis laboratory shall dedicate a percentage, as determined by the Board, 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 this Title 9.

(h) A cannabis laboratory shall offer to businesses with limited resources as determined by the Office, terms and conditions for its services, including but not limited to pricing and priority of testing, that are at least as favorable as the terms and conditions granted by the cannabis laboratory to any other licensee or registered organization.

(i) A cannabis laboratory shall track and dispose of any quantity of cannabis product that is not consumed in samples used for testing. Disposal of cannabis shall mean that the cannabis has been rendered unrecoverable and beyond reclamation.

### **§ 130.8 Required Cannabis Proficiency Testing.**

(a) In connection with an application for a cannabis laboratory permit, a cannabis laboratory shall examine proficiency test samples supplied by a proficiency testing provider recognized by the Office, pursuant to this Part.

- (b) Once a cannabis laboratory completes a proficiency test, a cannabis laboratory shall prepare a report for an analyte or group of analytes for which a cannabis laboratory is seeking approval and for which samples have been supplied.
- (c) A cannabis laboratory shall submit the report directly to the proficiency testing provider.
- (d) Upon the proficiency testing provider's review of a cannabis laboratory's report related to a proficiency test sample that a cannabis laboratory examined, a cannabis laboratory shall cause the proficiency test provider to provide the results of the proficiency test directly to the Office and in a manner and format determined by the Office.
- (e) To obtain approval for a given analyte or group of analytes on its permit, a cannabis laboratory shall pass two (2) consecutive scheduled or unscheduled or supplemental proficiency tests. A cannabis laboratory may continue to attempt to obtain satisfactory performances beyond two (2) proficiency tests if the two (2) consecutive satisfactory performances are not obtained.
- (f) 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.
- (g) 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.
- (h) At least one (1) of the two (2) of three (3) consecutive scheduled or unscheduled proficiency test in which a cannabis laboratory has participated in an eighteen (18) month period must be less than six (6) months old.

(i) A proficiency test that a cannabis laboratory completes must be administered by a proficiency test provider that:

- (1) is accredited by a proficiency test provider accreditor to ISO/IEC 17043;
- (2) offers scheduled tests on at least a semi-annually basis, and unscheduled tests on at least a monthly basis;
- (3) agrees to supply the Office with proficiency test scores in a manner and format determined by the Office; and
- (4) agrees to submit any other information and documentation requested to resolve any issues concerning compliance with this Part.

**§ 130.9 Unsatisfactory Proficiency Test Performance.**

(a) A cannabis laboratory's analyte or group of analytes approval status shall be deemed automatically unapproved for an analyte or group of analytes in the event:

- (1) a cannabis laboratory fails two (2) out of three (3) most recent proficiency tests attempted for a particular analyte or group of analytes; or
- (2) a cannabis laboratory fails to provide a corrective action report to the Office within thirty (30) calendar days of a request for a corrective action report from the Office.

(b) The Office shall change the approval status from unapproved to approved of a cannabis laboratory whose analyte or group of analytes is automatically unapproved, as specified above, when a cannabis laboratory re-establishes a history of two (2) successful proficiency test results out of the three (3) most recent attempts for an analyte or group of analytes tested.

**§ 130.10 Laboratory Regulatory Audit.**

- (a) A cannabis laboratory shall maintain an ISO/IEC 17025 accreditation, or accreditation that is based on ISO/IEC 17025 accreditation by any other laboratory accreditation authority approved by the Office.
- (b) A cannabis laboratory shall have a laboratory regulatory audit every two (2) years during a cannabis laboratory's normal business hours.
- (c) The factors to be considered during a laboratory regulatory audit shall include, but not be limited to, the competence and qualifications of staff as specified in this Part, adequacy of facilities and equipment, appropriateness of sampling protocols, use of approved methods, and a cannabis laboratory's quality system, including, but not limited to, quality assurance and quality control procedures, and record keeping and reporting practices.
- (d) A cannabis laboratory shall demonstrate effective implementation of its quality system for planning and assessing work performed by a laboratory regulatory audit, and for conducting required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test results.
- (e) A cannabis laboratory, following a laboratory regulatory audit, shall obtain an audit report which shall set forth any recommendations of the audit and any findings to be corrected.
- (f) If findings are found during a laboratory regulatory audit, a cannabis laboratory may be granted a grace period not to exceed ninety (90) calendar days from the date of audit report to correct the findings, provided that, within thirty (30) calendar days of such audit report, a cannabis laboratory submits to the Office or another laboratory accreditation authority as

approved by the Office performing the audit a written plan of correction to be implemented within ninety (90) calendar days from the date of audit report to correct the findings. If at the end of the grace period any of the findings remain uncorrected, the affected analyte or group of analytes pursuant to this Part will be unapproved.

(g) If the findings do not have an effect or do not have an immediate effect on either the accuracy or reliability of results, and if a cannabis laboratory demonstrates in writing that corrections of findings have been delayed for reasons beyond its control, the grace period granted pursuant to this subsection may be extended further for a period not to exceed ninety (90) calendar days. Such extension may not be extended further.

#### **§ 130.11 General Cannabis Personnel Qualifications.**

(a) A cannabis laboratory shall:

- (1) only employ persons who are eighteen (18) years of age or older;
- (2) 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, which shall include, but not be limited to:
  - (i) health and safety training;
  - (ii) handling hazardous materials;
  - (iii) handling hazardous equipment; and
  - (iv) anything else as required by the Office.

- (3) ensure and document that a laboratory employee meets the employee qualifications;
- (4) 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; and
- (5) ensure an employee does not have a direct or indirect interest in a cannabis sampling firm, a registered organization or a cannabis permit, registration or license.

**§ 130.12 Cannabis Technical Director Qualifications.**

- (a) (1) A cannabis laboratory shall appoint one or more technical directors, who shall be full-time members of the laboratory's staff, and who shall exercise actual supervision of laboratory operations, including the reporting of results from testing samples, during normal business hours. The designation of a lead technical director shall be documented; and
- (2) a technical director shall have the requisite credentials and experience for an area of analysis, such as microbiology, analytical chemistry, organic chemistry, metals, inorganic chemistry, and physical analysis, and shall supervise only the areas of testing for which they meet the qualifications required by this section.
- (b) A technical director's responsibilities shall include, but not be limited to, development and implementation of a quality system as defined in this Part, including: monitoring standards of performance in quality control and quality assurance; monitoring the validity of analyses performed and data generated to ensure reliable data; ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and providing educational direction to laboratory staff.

(c) A technical director may not serve as a technical director for more than one cannabis laboratory without written authorization from the Office. Circumstances to be considered in the Office's decision to grant such authorization may include, but not be limited to, the extent to which the operating hours of the laboratories to be directed overlap, adequacy of supervision in a cannabis laboratory, and availability of cannabis laboratory services in the area served.

(d) A technical director who is absent from a cannabis laboratory for a period of time exceeding fifteen (15) consecutive calendar days shall designate another full-time technical director, or where none is available, another staff member who meets the qualifications of this Part, to assume the responsibilities of technical director temporarily. Whenever the term of such temporary designation exceeds thirty-five (35) consecutive calendar days, the Office shall be notified in writing.

(e) A technical director of a cannabis laboratory engaged in organic chemical analysis shall be an individual with:

(1) an earned doctoral or master's degree in the chemical, environmental, physical or biological sciences, or engineering, with twenty-four (24) college semester credit hours in chemistry, or more, and one (1) or more years of experience in analysis of representative organic analytes for which the laboratory is permitted or seeking a permit; or

(2) a bachelor's degree in the chemical, environmental, physical or biological sciences, or engineering, with twenty-four (24) college semester credit hours, or more, in chemistry and two (2) or more years of experience in analysis of representative organic analytes for which the laboratory is permitted or seeking a permit.

(f) A technical director of a cannabis laboratory engaged in metals analysis shall be and individual with:

(1) an earned doctoral or master's degree in the chemical, environmental, physical or biological sciences, or engineering, with twenty-four (24) college semester credit hours, or more, in chemistry, and one (1) or more years of experience in analysis of representative metals analytes for which the laboratory is permitted or seeking a permit; or

(2) a bachelor's degree in the chemical, environmental, physical or biological sciences, or engineering, with twenty-four (24) college semester credit hours, or more, in chemistry and two (2) or more years of experience in analysis of representative metals analytes for which the laboratory is permitted or seeking a permit.

(g) A technical director of a cannabis laboratory engaged in inorganic chemistry analysis, other than metals analysis, and physical chemistry analysis, among other analysis, shall be a person with an associate's degree in the chemical, physical, biological or environmental sciences, or two (2) years of equivalent and successful college education, with sixteen (16) college semester credit hours, or more, in chemistry. In addition, such a person shall have two (2) or more years of experience performing such representative inorganic and physical chemistry analysis.

(h) A technical director of a cannabis laboratory engaged in microbiological and/or biological testing shall be an individual with:

(1) an earned doctoral degree or master's degree in the chemical, environmental, physical or biological sciences, or engineering, with sixteen (16) college semester credit hours, or more, in the biological sciences, including, for microbiological testing, at least once course having

microbiology as a major component, and one (1) or more years of experience in analysis of representative microbiological analytes for which the laboratory is permitted or seeking a permit;  
or

(2) a bachelor's degree in the chemical, environmental, physical, or biological sciences, or engineering, with at least sixteen (16) college semester credit hours, or more, in the biological sciences, including, for microbiological testing, at least one course having microbiology as a major component, and two (2) or more years of experience in analysis of representative microbiological analytes for which the laboratory is permitted or seeking a permit.

(i) 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, including those individuals who are functioning in a technical director's capacity for those laboratories that were authorized to test medical cannabis products in New York State that existed prior to the effective date of these regulations, shall qualify as a 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.

**§ 130.13 Cannabis Quality Assurance Officer Qualifications.**

- (a) A cannabis laboratory shall appoint a quality assurance officer, who shall exercise oversight of a cannabis laboratory's quality system during normal business hours. The individual so appointed shall have documented training, and/or experience in quality assurance and quality control procedures; be knowledgeable in the required quality system; possess a general knowledge of analytical methods for which they perform data review; and have a bachelor's degree in the chemical, environmental, physical or biological sciences, or engineering, and two (2) or more years of experience in implementing a laboratory quality system.
- (b) The quality assurance officer shall, at a minimum:
- (1) serve as the focal point for a cannabis laboratory's quality assurance and quality control, and be responsible for monitoring and/or review of quality control data;
  - (2) evaluate data objectively and perform independent managerial reviews without outside influence;
  - (3) arrange for or conduct annual internal audits of a cannabis laboratory's entire quality system and testing operation; and
  - (4) notify cannabis laboratory management of any deficiencies in the quality system as part of an internal audit and monitor required corrective actions.
- (c) The quality assurance officer shall have direct access to the highest level of management at which decisions are made on cannabis laboratory policy or resources, as well as to a technical director.

(d) The quality assurance officer shall fulfill their functions independently from cannabis laboratory operations for which they maintain quality assurance oversight.

(e) For cannabis laboratories with limited staffing, the quality assurance officer may also be a lead technical director or technical director; and an individual meeting the requirements of this section may not be the quality assurance officer of more than one cannabis laboratory without written authorization from the Office.

(f) 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.

#### **§ 130.14 Cannabis Laboratory Technician Qualifications.**

(a) A cannabis laboratory shall employ laboratory technicians. A laboratory technician shall have documented training or experience in laboratory procedures; possess a strong working knowledge of all methods for which they perform; and perform routine and non-routine sample preparations, tests, and analyses using the appropriate equipment, instrumentation, reagents, standards, and methods.

(b) A laboratory technician engaged in microbiology, analytical chemistry, organic chemistry, metals, inorganic chemistry, or physical chemistry testing shall have an associate's degree or two years of equivalent college or university studies in the chemical, environmental, physical or biological sciences, or engineering, and at least one (1) year of experience in testing of representative analyte or group of analytes for which the laboratory is permitted or seeking a permit.

**§ 130.15 Approval of Laboratory-Developed Methods.**

(a) A cannabis laboratory shall obtain approval from the Office prior to performing a laboratory-developed method, or other method not otherwise approved or given similar recognition as described in this Part. The Office may approve such a method, provided a cannabis laboratory submits data and other information as required supporting the technical merit of the method, and demonstrating that method's precision and accuracy are equivalent or superior to that of an approved method. Such data and information shall include, but not be limited to:

- (1) a description of the method, including analyte or group of analytes, sample type, working range, reagents and their preparation, equipment specifications, analytical procedures, precision, accuracy, related calculations, intended purpose and pertinent literature citations;
- (2) the anticipated date of method implementation;
- (3) comparative data, if of the same technology, including: sample types, dates and times collected, and product or form, whether the sample was spiked, and, if so, the spiking procedure,

and spiking samples at different concentrations; the approved method used; and analytical results for both the approved method and the method submitted for approval;

(4) data from two (2) or more proficiency tests;

(5) demonstration of capability data;

(6) limit of detection data, if applicable; and

(7) any other information pertinent to the Office's determination of the method's technical merit.

(b) Provided all other requirements of subdivision (a) above are met, the Office may approve a method for which reproducibility has not been demonstrated by inter-laboratory comparisons if a cannabis laboratory demonstrates that its performance of the method is technically acceptable for the intended sample types and analytical purpose. Such approval shall be limited to a cannabis laboratory which applied for such approval.

(c) In addition to the requirements of subdivisions (a) and (b) above, the Office may conduct a laboratory regulatory audit.

(d) The Office shall respond to a cannabis laboratory's request for method approval, notifying a cannabis laboratory of method approval, proposed denial of the request by the Office, or the need for further information.

(e) The Office may propose to deny a request for method approval if a method does not meet the established requirements. A cannabis laboratory shall be advised of a proposed denial and the reasons for the denial. A proposed denial shall become final thirty (30) calendar days from the date of notice of proposed denial, unless a cannabis laboratory submits, prior to the date that is

thirty (30) calendar days after the date of such notice, a written request for reconsideration, including all documentation and rationale in support of such request. The Office shall consider a request for reconsideration and shall issue a final determination concerning the request for reconsideration.

(f) Notwithstanding the provisions of this Part, the Office may conduct an independent review of any approved method to substantiate or refute its technical merit. If the method's technical merit is found to be unacceptable, the Office shall notify a cannabis laboratory of its proposed determination that the method may not be performed under a New York State cannabis laboratory's permit, giving the reasons for such determination. Such proposed determination shall become final thirty (30) calendar days from the date of the notice of proposed determination, unless a cannabis laboratory offering such method submits, within thirty (30) calendar days of the date of the notice, a written request for reconsideration, including all documentation and rationale in support of such request. The Office shall consider a request for reconsideration and shall issue a final determination concerning the request for reconsideration.

(g) All information and data pertinent to method approval shall be documented and be made available for Office review at the time of a laboratory regulatory audit or upon request for a minimum of five (5) years after the date of the method's discontinuation.

#### **§ 130.16 Laboratory Sampling Firm Approval.**

(a) No person may conduct sampling and transportation of cannabis product or medical cannabis and any other intermediates or forms for purposes of testing such cannabis product

or medical cannabis by a cannabis laboratory unless they have been granted approval as a laboratory sampling firm.

(b) Prior to approval, a laboratory sampling firm shall submit a description of the sampling and transportation process describing how cannabis product or medical cannabis and any other intermediates or forms will be sampled and transported in the field or on premises, or a copy of the standard operating procedure addressing sampling and transportation.

(c) Approval of a laboratory sampling firm and its employees shall be conducted in a manner and format determined by the Office.

(d) Approval shall be effective for a period not to exceed two (2) years and shall expire on March 31.

(e) Approval of a laboratory sampling firm is not transferable or assignable, including, without limitation, to another laboratory sampling firm.

(f) A cannabis laboratory may receive conditional approval as a laboratory sampling firm with a written waiver from the Office. The Office may provide a waiver if the Office determines that a cannabis laboratory has met the conditions specified in sections 130.16 - 130.21 of this Part.

### **§ 130.17 Laboratory Sampling Firm Fee.**

(a) Laboratory Sampling Firm Application Fee and Approval Fee. A non-refundable application fee for a laboratory sampling firm is \$500. The approval fee for the two (2) year approval period shall be \$1000. The approval fee shall be returned to the applicant if the applicant is not granted approval under this Part.

(b) Any fee specified in this Part shall be paid to the New York State Office of Cannabis Management by the method approved by the Office at the time of submission of the application.

(c) Failure of a laboratory sampling firm to pay the appropriate fee is grounds for non-reapproval pursuant to this Part.

### **§ 130.18 Laboratory Sampling Firm Reapproval.**

(a) A laboratory sampling firm and its employees shall submit a reapproval application to the Office in a manner and format determined by the Office.

(b) An application to reapprove shall be filed with the Office not more than six (6) months nor less than four (4) months prior to the expiration thereof. If a reapproval application is not filed within four (4) months prior to the expiration thereof, the Office may determine that the firm's approval shall have expired and become void on such expiration date.

(c) An application shall be accompanied by a non-refundable application fee and approval fee as set forth in this Part. Only an application completed in accordance with this Part as determined by the Office and for which the application and approval license fees have been submitted shall be considered if submitted in a timely manner.

(d) The Office shall consider applications for reapproval in accordance with the criteria set forth in this Part.

(e) A denial of a cannabis laboratory sampling firm's application for a permit, or an application for a reapproval of a permit, including any notices and challenges thereto, if any, shall be pursuant to Subchapter J of Title 9.

**§ 130.19 Laboratory Sampling Firm Requirements.**

- (a) A laboratory sampling firm may only employ persons who are twenty-one (21) years of age or older.
- (b) A laboratory sampling firm shall train all sampling and transportation employees on appropriate sampling and transportation procedures, and such training shall be documented.
- (c) A laboratory sampling firm shall require all sampling and transportation employees to complete data integrity training upon hire and annually thereafter, and evidence that such training was performed for a sampling and transportation employee shall be documented and available upon request.
- (d) An employee of a laboratory sampling firm shall carry a copy of the firm's approval and the copy shall, upon request, be provided to any person requesting the services of a laboratory sampling firm.
- (e) A laboratory sampling firm shall conduct all sampling as set forth in this Part.
- (f) A shipping manifest shall accompany every transport of cannabis product or medical cannabis and any other intermediates or forms from a registered organization, cultivator, processor, cooperative, microbusiness, or any other person licensed pursuant to the Cannabis Law or authorized to cultivate or process medical cannabis or adult-use cannabis pursuant to the Cannabis Law.
- (g) While transporting cannabis product or medical cannabis and any other intermediates or forms, a laboratory sampling firm shall ensure the cannabis product or medical cannabis and any other intermediates or forms are not visible to and secure from the public:

- (1) The cannabis product or medical cannabis and any other intermediates or forms shall be locked in a fully enclosed box, container, or cage that is secured to the inside of the vehicle or trailer. No portion of the enclosed box, container, or cage shall be comprised of any part of the body of the vehicle or trailer. For the purposes of this section, the inside of the vehicle includes the trunk.
- (2) A vehicle and trailer transporting cannabis product or medical cannabis and any other intermediates or forms shall while left unattended be locked and secured.
- (3) A vehicle or trailer containing cannabis product or medical cannabis and any other intermediates or forms shall not be left unattended in a residential area or parked overnight in a residential area.
- (4) An employee of a laboratory sampling firm shall ensure that any vehicle or trailer used by the firm for transporting cannabis product or medical cannabis and any other intermediates or forms has a functioning alarm system.
- (5) An employee of a laboratory sampling firm shall ensure that packages or containers holding cannabis product or medical cannabis and any other intermediates or forms are neither tampered with, nor opened during transport.
- (6) An employee of a laboratory sampling firm, who is transporting cannabis product or medical cannabis and any other intermediates or forms shall only travel between the licensed premises and a cannabis laboratory, conducting testing.
- (7) An employee of a laboratory sampling firm shall not deviate from the travel requirements described in this section, except for necessary rest, fuel, or vehicle repair stops.
- (8) An employee of a laboratory sampling firm may transport multiple cannabis product or medical cannabis and any other intermediates or forms obtained from multiple licensees at once.

- (9) An employee of a laboratory sampling firm shall preserve the integrity of the cannabis product or medical cannabis and any other intermediates or forms during transport by maintaining environmental conditions that would not impact the cannabis product or medical cannabis, and any other intermediates or forms, including but not limited to, avoiding temperature and humidity extremes.
- (10) Vehicles or trailers transporting cannabis product or medical cannabis and any other intermediates or forms are subject to inspection by the Office at any licensed premises or during transport at any time.
- (11) No person under the age of twenty-one (21) years old shall be in a vehicle or trailer transporting cannabis product or medical cannabis and any other intermediates or forms.
- (12) Only employees of a laboratory sampling firm shall be in any vehicle containing cannabis product or medical cannabis and any other intermediates or forms while being transported.
- (h) Upon request, a laboratory sampling firm shall provide, at a minimum, the following transport vehicle information to the Office:
- (1) A certificate of ownership or registration card issued by New York State Department of Motor Vehicles for a vehicle used to transport cannabis product or medical cannabis and any other intermediates or forms;
  - (2) The year, make, model, license plate number, and numerical Vehicle Identification Number (VIN) for a vehicle or trailer used to transport cannabis product or medical cannabis and any other intermediates or forms; and
  - (3) Proof of insurance for a vehicle used to transport cannabis product or medical cannabis and any other intermediates or forms.

(i) A laboratory sampling firm shall provide the Office with the information required by this section in writing for any new vehicle or trailer that will be used to transport cannabis product or medical cannabis and any other intermediates or forms prior to using the vehicle or trailer.

(j) A laboratory sampling firm's approval to conduct sampling and transportation shall be deemed retracted immediately upon a significant change in the sampling process or procedure, change in employees who perform sampling and transportation and change in vehicles used in transportation. However, provided a re-application has been made in writing to the Office within thirty (30) calendar days of the change, the Office may reinstate the firm's approval for a period not to exceed ninety (90) calendar days after any change in the sampling and transportation process or procedure.

#### **§ 130.20 Cannabis Sampling Technician Qualifications.**

(a) A laboratory sampling firm shall employ sampling and transportation technicians. A sampling and transportation technician shall have documented training, and/or experience in sampling and transportation procedures; possess a strong working knowledge of all sampling and transportation methods for which they perform; and perform routine and non-routine sampling and transportation of cannabis product or medical cannabis and any other intermediates or forms using appropriate equipment, instrumentation, and methods.

(b) A technician of a laboratory sampling firm shall be an individual with, at minimum, a high school diploma or high school equivalency diploma.

(c) A technician of a laboratory sampling firm must be twenty-one (21) years of age.

**§ 130.21 Sampling of Cannabis Product and Medical Cannabis.**

- (a) A laboratory sampling firm shall obtain a representative sample of medical cannabis or adult-use cannabis as determined by the Office for testing by a cannabis laboratory.
- (b) A laboratory sampling firm shall meet the standards for sampling cannabis product batch and harvest batch as approved by the Office.
- (c) An employee of a registered organization, cultivator, processor, cooperative, microbusiness, or any other person licensed pursuant to the Cannabis Law or authorized to cultivate or process medical cannabis or adult-use cannabis pursuant to the Cannabis Law that has requested the sampling and testing of medical cannabis or adult-use cannabis shall be physically present to observe an employee of a laboratory sampling firm obtain the sample of cannabis product or medical cannabis and any other intermediates or forms for testing and shall ensure that the increments are taken from throughout the batch.
- (d) The sampling shall be video-recorded with the batch number stated verbally or in writing on the video at the beginning of the video and a visible time and date indication on the video recording footage. The video recordings shall be maintained for at least ninety (90) calendar days by the licensee.
- (e) After the sample has been selected by a laboratory sampling firm employee, both (1) the licensee requesting the sampling and testing, and (2) the laboratory sampling firm employee shall sign and date the chain of custody form as set forth in this Part, attesting to the sample selection having occurred according to the sampling process or procedure a laboratory sampling firm submitted to the Office pursuant to this Part and the requirements set forth in Subchapters B and E of Title 9.

(f) 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 shall not assist a laboratory sampling firm employee nor touch the cannabis product or medical cannabis and any other intermediates or forms or the sampling equipment while a laboratory sampling employee is obtaining the sample.

**§ 130.22 Testing of Cannabis Product and Medical Cannabis.**

(a) All testing of samples provided by a laboratory sampling firm to a cannabis laboratory shall be conducted by a cannabis laboratory employing methods approved by the Office and shall:

(1) be within the scope listed on the laboratory's current permit or on any appendices thereto; and

(2) require the prior completion of a demonstration of capability conducted at the same site where samples were prepared or analyzed using an approved method.

(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.

(c) Testing for contaminants in cannabis product or medical cannabis, and any other intermediates or forms shall include, but not be limited to, microorganisms, foreign material, metals, moisture content and water activity, mycotoxins, pesticides, residual solvents,

terpenoids, and any other analyte or group of analytes determined by the Office, consistent with the acceptable limits determined by the Office for each of the foregoing.

(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.

### **§ 130.23 Certificate of Analysis.**

(a) Once a cannabis laboratory completes testing a sample, a cannabis laboratory shall prepare a certificate of analysis which shall include a summary of analytical results of the testing.

(b) A cannabis laboratory shall issue confidentially the certificate of analysis to 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 on whose behalf a cannabis laboratory performed the testing.

(c) A certificate of analysis, that is issued by cannabis laboratory, shall be reported in a manner and format determined by the Office.

(d) A cannabis laboratory must report all results of tests that a cannabis laboratory performs directly to the Office in a manner and format determined by the Office. The results shall be reported to the Office within forty-eight (48) hours of release of the certificate of analysis to 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 on whose behalf a cannabis laboratory performed the testing.

- (e) A certificate of analysis shall include, but not be limited to, the following:
  - (1) a title;
  - (2) cannabis laboratory name, contact person, phone number, and address;
  - (3) office laboratory permit identifier;
  - (4) permit identifier issued by ISO/IEC 17025 accreditation, or accreditation that is based on ISO/IEC 17025 accreditation by any other laboratory accreditation authority approved by the Office;
  - (5) client name, contact person, phone number, and address;
  - (6) description or unique identification of sample(s) tested;
  - (7) methods used;
  - (8) analyte or group of analytes tested, analyte results and units of measurements;
  - (9) sample collection site, date and time;
  - (10) analysis date and time;
  - (11) any deviations from approved sampling, transportation and testing methods;
  - (12) reference to approved sampling and transportation operating procedures;
  - (13) name, signature and date of individual approving the release of the reported results;
  - (14) regulatory limits established by the Office;
  - (15) laboratory reporting limits;
  - (16) any non-approved methods or analyte or group of analytes reported;

(17) any methods used and analyte or group of analyte results reported by another OCM permitted cannabis laboratory;

(18) pagination of the report if greater than one (1) page in length; and

(19) any other information requested by the Office.

(f) An incomplete, verbal or informal certificate of analysis shall not be released by a cannabis laboratory without the written approval by the Office.

(g) Any amendments to a certificate of analysis after issuance shall be reported in a revised or amended certificate of analysis, and the amendments clearly noted and statement on the certificate to which report was superseded.

#### **§ 130.24 Cannabis Shipping Manifest.**

(a) A laboratory sampling firm shall ensure and verify that the samples being taken into possession for transport at the originating licensed premises are as described and accurately reflected in the shipping manifest.

(b) A laboratory sampling firm is responsible for any discrepancies between the shipping manifest and the samples in its possession during transport, and may be subject to any enforcement or disciplinary action related to such discrepancy, including cancelation, suspension or revocation of its approval.

(c) A laboratory sampling firm shall not void or change a shipping manifest for samples after departing from the originating licensed premises with such samples.

**§ 130.25 Sample Chain of Custody.**

(a) A cannabis laboratory shall develop and implement a chain of custody (COC) procedure to ensure accurate documentation is recorded for the sampling, transport, receipt, handling, storage, and destruction of samples.

(b) A COC procedure shall require the use of a COC form. A laboratory sampling firm employee shall use the COC to record, at a minimum, the following information for a sampled batch:

(1) permitted cannabis laboratory's name, permitted premises address, and permit number;

(2) date and time sampling started and ended;

(3) name of the licensee requesting the sampling, licensed premises address, and license number;

(4) batch number of the batch from which the representative sample was obtained and assigned unique sample identifier;

(5) sample type from cannabinoid hemp, cannabis product, or medical cannabis and any other intermediates or forms;

(6) total batch size, by weight, or unit count;

(7) total weight, or unit count of the representative sample;

(8) sampling and transportation conditions or problems encountered during the sampling and transportation process, if any;

(9) printed name and signature of the licensee requesting the sampling; and

(10) printed name and signature of the laboratory sampling firm employee and name of laboratory sampling firm.

(c) At each point a sample changes custody, is transported, or is destroyed, the date, time, and the names and signatures of persons involved in these activities shall be recorded on the COC form.

(d) Once the custody of the sample changes, the COC form for that change of custody may not be altered.

### **§ 130.26 Record Retention.**

(a) A cannabis laboratory shall retain the following records for no less than five (5) years and shall identify accurately and reliably:

(1) the samples transported, collected, accepted, prepped, examined, and disposed of;

(2) procedures used and personnel involved; and personnel training records;

(3) document test conditions, observations, and results of analyses; and

(4) all quality system related records including, but not limited to:

(i) quality manual;

(ii) standard operating procedures;

(iii) internal audits;

(iv) management reviews;

(v) corrective action reports;

(vi) analytical logbooks;

(vii) equipment logs;

(viii) consumable logs; and

- (ix) purchasing records.
- (b) In the event a cannabis laboratory goes out of business or ownership is transferred to another permitted cannabis laboratory, a cannabis laboratory must have a plan or procedure in place to ensure all associated records are maintained for not fewer than five (5) years.
- (c) A laboratory sampling firm shall maintain sampling and transportation records, including but not limited to, all employee training records, and standard operating procedures related to sampling and transport, for no less than five (5) years and shall identify accurately and reliably the samples collected and transported.
- (d) In the event a laboratory sampling firm goes out of business or ownership is transferred to another approved laboratory sampling firm, a laboratory sampling firm must have a plan or procedure in place to ensure all associated records are maintained for not fewer than five (5) years.

**§ 130.27 Security, Safety and Storage of Cannabis.**

- (a) A facility operated by a cannabis laboratory shall have a security system to prevent and detect diversion, theft or loss of cannabinoid hemp, cannabis product, or medical cannabis and any other intermediates or forms, utilizing commercial grade equipment.
- (b) A cannabis laboratory shall keep security equipment in full operating order and shall test such equipment no less than semi-annually. Records of security tests must be maintained for five (5) years and made available to the Office upon request.
- (c) A cannabis laboratory must be securely locked and protected from unauthorized entry at all times.

(d) All cannabinoid hemp, cannabis product, or medical cannabis and any other intermediates or forms must be stored in a secure area or location within a cannabis laboratory that is accessible to a minimum number of employees essential for efficient operation, to prevent diversion, theft or loss.

(e) All cannabinoid hemp, cannabis product, or medical cannabis and any other intermediates or forms must be stored in such a manner as to protect against physical, chemical and microbial contamination and deterioration until extraction and analyses of the cannabinoid hemp, cannabis product, or medical cannabis and any other intermediates or forms begins.

(f) A cannabis laboratory shall ensure the safe and secure transport of cannabis product or medical cannabis and any other intermediates or forms as specified in this Part when subcontracting the analyses of any of the cannabis to another permitted cannabis laboratory.

#### **§ 130.28 State Reference Lab.**

(a) If the Office suspects fraudulent, inaccurate or compromised testing of cannabinoid hemp, cannabis product, or medical cannabis, and any other intermediates or forms by a permitted cannabis laboratory, the Office may obtain the cannabinoid hemp, cannabis product, or medical cannabis, and any other intermediates or forms and request the state reference lab to perform testing on the cannabinoid hemp, cannabis product, or medical cannabis, and any other intermediates or forms in question.

(b) At the discretion of the Office, the Office may randomly pull samples of cannabinoid hemp, cannabis product, or medical cannabis, and any other intermediates or form directly 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. The Office may pull such samples during hours of operation. The cannabinoid hemp, cannabis product, or medical cannabis, and any other intermediates or forms pulled will be tested by the state reference lab.

(c) The state reference lab may assist the Office in method development.

### **§ 130.29 Summary Suspension, Suspension, Cancellation and Revocation.**

(a) A cannabis laboratory's permit shall be deemed summarily suspended for the following reasons:

(1) failure to submit an application for a change in laboratory ownership, major instrumentation, technical direction, or location, and;

(2) failure to remit the annual permit fee.

(b) A cannabis laboratory's permit may be suspended in part or in full for the following reasons:

(1) a pattern of deficiencies on a laboratory regulatory audit or other demonstration that a cannabis laboratory lacks an effective quality system for planning and assessing work performed by the laboratory, and for conducting required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test results;

(2) except as provided in this Part, failure to undergo a laboratory regulatory audit or failure to demonstrate, during a laboratory regulatory audit so conducted: compliance with the staffing, methodological and other requirements of this Part; and effective implementation of a quality system for planning and assessing work performed by a cannabis laboratory and for conducting

required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test results;

(3) failure of a cannabis laboratory technical director to meet the required qualifications of this Part;

(4) misrepresentation of any material fact pertinent to obtaining or retaining approval for any cannabis laboratory owned or directed by an owner or technical director listed on the application including, but not limited to, inclusion of false reports on or related to a laboratory analysis or submission of proficiency test results which were, in fact, generated by a laboratory other than the laboratory to which the samples were distributed;

(5) failure to remit the required application and permit fees;

(6) failure to respond to a laboratory regulatory audit report with a corrective action plan within the required thirty (30) calendar days after receipt of the audit report;

(7) failure to respond to a laboratory regulatory audit report with an acceptable corrective action plan within the specified timeframe; and

(8) failure to maintain ISO/IEC 17025 accreditation, or accreditation that is based on ISO/IEC 17025 accreditation by any other laboratory accreditation authority approved by the Office.

(c)(1) A cannabis laboratory's permit may be revoked in an affected analyte or group of analytes for reasons including:

(i) failure to respond to a laboratory regulatory audit report with an acceptable corrective action plan within the specified timeframe;

(ii) a pattern of deficiencies on a laboratory regulatory audit, or other demonstration that a cannabis laboratory lacks an effective quality system for planning and assessing work performed by the laboratory, and for conducting required quality assurance and quality control procedures to promote and maintain the accuracy and reliability of test results;

(iii) failure to implement the responsive actions detailed in the corrective action plan within the specified timeframe;

(iv) failure to correct the deficiencies meriting suspension within six (6) months of the effective date of the suspension; or

(v) for a cannabis laboratory suspended pursuant to this Section, unsatisfactory performance in the next proficiency test, resulting in three (3) consecutive failed proficiency tests.

(2) A cannabis laboratory whose permit is revoked pursuant to paragraph (1) above shall retain approval for an analyte or group of analytes for which it continues to meet Office requirements, and a cannabis laboratory may reapply for a permit once the deficiencies meriting revocation have been corrected.

(3) A cannabis laboratory's permit may be revoked, in total, for reasons including:

(i) failure to respond to a laboratory regulatory audit report which includes findings or deficiencies with a corrective action plan within the required thirty (30) calendar days after receipt of the audit report;

(ii) falsification of any report on or related to a laboratory test or analysis, including, but not limited to, submission of proficiency test results which were, in fact, generated by a laboratory other than the laboratory to which the samples were distributed;

- (iii) misrepresentation of any material fact pertinent to obtaining or maintaining approval;
  - (iv) denial of laboratory entry to perform a laboratory regulatory audit during normal business hours;
  - (v) sustained charges of administrative violations of state or federal laws, rules and regulations related to the provision of cannabis laboratory services, or reimbursement for such services, against the owner or technical director, individually or jointly, or against any cannabis laboratory owned or directed by such individuals;
  - (vi) conviction of any crime, including, but not limited to, any offense related to furnishing of, or billing for, cannabis laboratory services, which is considered an offense involving theft or fraud;
  - (vii) failure to remit the annual approval fee, or, for partial fee payments, failure to remit such payments within the timeframes established by the Office;
  - (viii) aiding and/or abetting in the violation of any of the provisions of this Part; and/or
  - (ix) a finding by a municipality that a cannabis laboratory has violated a local ordinance related either to sampling, transportation and analysis of cannabis product or medical cannabis and any other intermediates or forms, or to reporting of results for analysis of such samples.
- (4) If cannabis laboratory's permit has been revoked pursuant to paragraph (3) above and the Office finds that the violation was willful, or due to recklessness or gross negligence, no application shall be accepted, for a period of time to be determined by the Office from any person who was an owner or technical director of such cannabis laboratory on the date of notification of proposed revocation.

(d) A summary suspension, suspension, cancelation, or revocation of a cannabis laboratory permit, including any notices and challenges thereto, if any, shall be pursuant to Subchapter J of Title 9.

(e) In addition to summary suspension, suspension, cancelation, or revocation of a cannabis laboratory permit, a cannabis laboratory that fails to comply with this Part may be subject to any fines, fees or any other penalties pursuant to Cannabis Law.

(f) A person who does not hold a valid permit pursuant to this Part or who otherwise does not comply with this Part shall be subject to any fines, fees, or any other penalties pursuant to Cannabis Law.