# SAINT REGIS MOHAWK TRIBE ADULT USE CANNABIS TESTING REGULATION

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# **SECTION 1.0 PURPOSE**

The Saint Regis Mohawk Tribe (The "Tribe") is responsible for the health, safety, education and welfare of all community members. With respect to the non-medical use of cannabis by persons 21 years of age and older ("adult use"), it has the authority, responsibility and jurisdiction to exercise sovereign rights in governing cannabis testing on the Saint Regis Mohawk Reservation (Reservation).

# **SECTION 2.0 AUTHORITY**

The authority of the Tribe to enact the Adult Use Cannabis Testing Regulation lies in the inherent sovereign authority of the Saint Regis Mohawk Tribe; the Tribal Procedures Act section IV (C) (1), (2), (10) and (13) (TCR 2013-32); and the Tribal Court and Judiciary Code Section V and VI (TCR 2008-22). The Tribe has adopted an Adult Use Cannabis Ordinance (the "Ordinance") authorizing the Cannabis Control Board ("CCB") and Cannabis Compliance Office ("CCO") to adopt regulations governing cannabis cultivation, processing, testing, sale and use by persons 21 years of age and older for non-medical purposes.

# **SECTION 3.0 TERMS AND DEFINITIONS**

This Regulation incorporates all definitions in Chapter One of the Saint Regis Tribe Adult Use Cannabis Ordinance.

"Action level" means a concentration of a particular contaminant that can reliably be measured by testing measures in use at a Testing Laboratory and that poses a risk to human health.

"Aspergillus" means a genus of fungus, including four species for which testing may be required.

"Cannabis waste" means any material containing cannabis, cannabis plants or cannabis products that is left over from the testing process or is not usable due to crop failure, spoilage, contamination or other reasons.

- "CBD potency" means the percentage by weight of cannabidiol (CBD) in the sample plus the percentage by weight of cannabidiolic acid (CBDA) multiplied by 0.877 (%CBD + [%CBDA  $\times$  0.877]).
- "Diversion" means transferring cannabis or cannabis products to anyone not authorized under the Ordinance to receive such a transfer.
- "Food Code" means the United States Food and Drug Administration's Food Code (2017), https://www.fda.gov/media/110822/download.
- "Inversion" means accepting a transfer of mature cannabis plants, cannabis or cannabis products from a source not authorized in the Ordinance.
- "ISO/IEC accreditation" means certification by an independent accrediting body that a Testing Laboratory meets one or more standards issued by the International Organization for Standardization and International Electrotechnical Commission.
- "Licensee" means a Cultivator, Processor, Retail Store, Testing Laboratory or other type of adult use cannabis business recognized by the CCB and CCO.
- "Mandatory testing" means a laboratory analysis required prior to sale or other transfer of cannabis or cannabis products.
- "Microbial contamination" means the presence of bacteria or fungi posing a risk to human health.
- "Registered entity" means a for-profit business or not-for-profit business registered pursuant to Chapter 7 of the Saint Regis Mohawk Tribe Medical Cannabis Ordinance, as amended.
- "Salmonella" means a genus of bacteria for which testing may be required.
- "Shiga toxin-producing E. Coli" or "STEC" means any strain of *Escherichia coli* bacteria capable of producing Shiga toxins.
- "Tamper-evident" means sealed using a method that provides clear, lasting evidence that a package has previously been opened.
- "THC potency" means the percentage by weight of tetrahydrocannabinol (THC) in the sample plus the percentage by weight of tetrahydrocannabinolic acid (THCA) multiplied by 0.877 (%THC + [%THCA  $\times$  0.877]).
- "Tier 1 Testing Laboratory" means a cannabis business licensed by the CCB to provide testing services for cannabis and cannabis products.
- "Tier 2 Testing Laboratory" means a cannabis business that is licensed by the CCB and meets additional requirements, including accreditation to ISO/IEC Standard 17025, *Testing and Calibration Laboratories*, and independence from any other licensee or Registered Entity.
- "Transport Manifest" means a triplicate document accompanying all transports of cannabis plants, cannabis or cannabis products by a licensee.

"Volatile hydrocarbon solvent" means a hydrocarbon solvent, other than alcohol, that is flammable or that readily evaporates at ambient temperatures and atmospheric pressure.

"Written report" means a document provided by a laboratory indicating one or more test results, including concentrations and whether a sample has passed or failed.

# **SECTION 4.0 OPERATING REQUIREMENTS**

## SECTION 4.1 TIER 1 TESTING LABORATORIES

**Minimum Capability:** A Tier 1 Testing Laboratory must submit method validation studies indicating capability of performing all tests required by the CCB, including, at minimum, the following tests:

- THC potency
- CBD potency
- Presence/absence of Aspergillus (A. flavus, A. fumigatus, A. niger or A. terreus)
- Presence/absence of shiga toxin-producing E. coli
- Presence/absence of salmonella species

**Additional Capability:** Unless declared mandatory by the CCB, the following tests are optional and may be offered by a Tier 1 Testing Laboratory upon completion of a method validation study and its approval by the CCO:

- Concentration of other cannabinoids
- Concentration of terpenes
- Total yeast/mold count
- Bacterial counts
- Concentration of solvent residues
- Concentration of pesticide residues
- Water activity

**Waiver of Minimum Capability:** The CCO may, during a Tier 1 Testing Laboratory's first year of operation, waive any minimum capability requirement, except that the Tier 1 Testing Laboratory may not offer any test for which it has not performed a method validation study.

**Selection of Methods:** A Tier 1 Testing Laboratory may use methods for cannabis sample preparation and analysis approved by the Wadsworth Center of the New York State Department of Health: <a href="https://www.wadsworth.org/regulatory/elap/medical-marijuana">https://www.wadsworth.org/regulatory/elap/medical-marijuana</a> or any Standard Method Performance Requirement or Official Method of Analysis approved by the <a href="Cannabis Analytical Science Program">Cannabis Analytical Science Program</a> of AOAC International.

**Proficiency Testing:** A Tier 1 Testing Laboratory must conduct yearly proficiency testing for each field of testing it offers, administered by a provider that is accredited to ISO/IEC Standard 17043, *Conformity Assessment* — *General Requirements for Proficiency Testing*, using materials conforming to ISO/IEC 17043 requirements.

**Confirmation Testing:** The CCO may require a Tier 1 Testing Laboratory to split samples for concurrent testing by the Tier 1 Testing Laboratory and an independent testing laboratory for the purpose of confirming the validity of the Tier 1 Testing Laboratory's methods and the accuracy of results produced. The independent testing laboratory shall be accredited to ISO/IEC Standard 17025 or the standards of the New York Environmental Laboratory Approval Program. Based on the results of the testing, the CCO may temporarily suspend one or more fields of testing until the Tier 1 Testing Laboratory's successful completion of a plan of correction.

#### SECTION 4.2 TIER 2 TESTING LABORATORIES

**ISO/IEC 17025 Accreditation:** A Tier 2 Testing Laboratory must obtain from an independent accrediting body, and maintain in good standing, accreditation to ISO/IEC Standard 17025,. The Tier 2 Testing Facility must complete method validation studies and have within its scope of accreditation all mandatory tests, including, at minimum, the following tests:

- THC potency
- CBD potency
- Presence/absence of Aspergillus (A. flavus, A. fumigatus, A. niger or A. terreus)
- Presence/absence of shiga toxin-producing E. coli
- Presence/absence of salmonella species

**Proficiency Testing:** A Tier 2 Testing Laboratory must complete all proficiency testing required by the accrediting body.

**Additional Capability:** A Tier 2 Testing Laboratory may seek inclusion of additional tests in its scope of accreditation and may offer any test within its scope of accreditation.

**Independent Ownership:** No person with a direct or indirect management or ownership interest in an entity that cultivates, processes or sells cannabis may hold a direct or indirect management or ownership interest in a Tier 2 Testing Laboratory.

**Separate Premises:** No Tier 2 Testing Laboratory shall be located on the same lot or in the same building as any entity cultivating, processing or selling cannabis.

#### SECTION 4.3 CONTENTS OF APPLICATION

**Pre-clearance Required:** An applicant for a Testing Laboratory license must obtain pre-clearance pursuant to Section 4.01 of the Ordinance.

Complete Application, All Testing Laboratories: A complete application for a Testing Laboratory license includes an application on a form supplied by the CCO, copies of method validation studies for every analytical test, specifying the analyte and technology for each, the applicant intends to offer; an operating plan consistent with the Ordinance and this Regulation; and any required fees.

**Complete Application, Tier 1 Testing Laboratory:** For a Tier 1 Testing Laboratory, a complete application additionally requires a signed statement from all key participants

acknowledging that altering test results to benefit or impede any licensee or registered entity is grounds for revocation of a Testing Laboratory license.

**Complete Application, Tier 2 Testing Laboratory:** For a Tier 2 Testing Laboratory, a complete application additionally requires a copy of the Testing Laboratory's Scope of Accreditation and a signed statement from all key participants affirming that they have no direct or indirect management or financial interest in an entity cultivating, processing, or selling cannabis.

Contents of Operating Plan, All Testing Laboratories: In addition to all information required by the Ordinance, an operating plan shall include standard operating procedures for all preanalytical, analytical, and post-analytical processes performed by the laboratory; policies and procedures that ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results; and equipment to be used and its listing by UL (formerly Underwriters Laboratories) or another nationally recognized testing laboratory; a description of ventilation, fire suppression and other systems to ensure worker safety; a list of analytical tests, specifying the analyte and technology for each, the applicant intends to offer; procedures for cleaning and sterilizing utensils and equipment consistent with parts 4-6 and 4-7 (pp. 142–149) of the 2017 Food Code or the corresponding section of future revisions; storage and handling procedures for preventing contamination and spoilage of testing samples consistent with parts 3-3 through 3-7 (pp. 69–109) of the 2017 Food Code or the corresponding section of future revisions; the name of the person overseeing day-to-day operation of the laboratory; and chain of custody protocols and a sample chain of custody form.

Contents of Operating Plan, Tier 1 Testing Laboratory: For a Tier 1 Testing Laboratory, an operating plan shall additionally include a description of a program to assess and document, at least annually, the competency of all technical and scientific staff that perform preanalytical, analytical, and postanalytical processes; protocols for proficiency testing at least annually and documenting successful completion or corrective action; and instructions for submitting samples from each analyte and matrix type, including tools and equipment, prevention of contamination, sample amount, number of sample increments, packaging, labeling and storage conditions.

Contents of Operating Plan, Tier 2 Testing Laboratory: For a Tier 2 Testing Laboratory, an operating plan shall additionally include policies and procedures for collection of samples for mandatory or other testing, including: step-by-step procedures for collecting samples from each matrix type that are representative of the batch to be tested; method for collection, preparation, packaging, labeling, documentation and transport of samples from each matrix type; size of sample to be collected for each analytical test to be performed; safeguards against contamination, including protective garb, sanitizing of instruments, and care of sample collection containers; labeling of sample containers; and transport and storage conditions, including exposure to light, temperature, and humidity.

#### SECTION 4.4 TRACKING SYSTEM

**Adoption of Inventory Tracking System:** The Ordinance authorizes the CCO to adopt an inventory tracking system to monitor cannabis activities from the planting of cannabis to its sale in final form. The CCO will provide each licensee a reasonable timeframe in which it must implement the inventory tracking system that the CCO has selected. The timeframe for implementation by a Testing Laboratory shall be no more than 30 days after the tracking system is available to licensees.

Implementation of Inventory Tracking System: Within the timeframe specified by the CCO, each licensee shall establish an inventory tracking system account, install the necessary software, and identify an administrator. The administrator shall complete all necessary training requirements specified by the CCO within the timeframe specified by the CCO. The administrator shall then train each employee in proper use of the system before the employee is issued a system account or accesses the system. Both the administrator and all employees with accounts may be required to attend ongoing training in effective use of the system, if required by the CCO. The Testing Laboratory shall maintain training logs and shall produce them upon request of the CCO.

**Use of Inventory Tracking System:** Upon implementation, a Testing Laboratory shall enter in the testing system the amount, type and source of any samples received; any tests performed; the results of those tests; any samples transferred for further testing; and the destruction of samples.

**Fees:** A licensee is responsible for reasonable fees charged by the software vendor for system accounts, as well as expenses, if any, involved in linking the inventory tracking system to the licensee's other software.

**Prior to Implementation:** If the inventory tracking system is unavailable, including before it is adopted by the CCO and implemented by the Testing Laboratory or when the system is temporarily nonoperational, the Testing Laboratory shall maintain detailed inventory records of all cannabis samples received, tests performed, test results, and status of notifications to the licensee or Registered Entity. The Testing Laboratory shall make such records available to the CCO upon request. The Testing Laboratory shall provide the CCO with a written daily report of all test results communicated to licensees, using a standard format mutually agreed to by the Testing Laboratory and the CCO.

#### SECTION 4.6 EMPLOYEES, VISITORS AND CONTRACTORS

**Qualifications of Employees:** The licensee must ensure that any employee receives adequate training, based on industry standards, to perform all job duties. The Testing Laboratory shall document that an employee has received a minimum of 8 hours of training prior to assisting with or performing any laboratory analysis.

**Contents of Training:** Prior to allowing an employee to handle cannabis or cannabis products, a licensee shall provide adequate training, based on industry standards, specific to the employee's job duties, including as applicable, sanitation, sample collection, sample storage and transport,

prevention of sample contamination, safe operation of equipment, testing methods, recordkeeping requirements and reporting of results. Testing requirements shall be commensurate with job duties, and additional training shall be documented before an employee performs testing of a new analyte or testing using a new method.

**Documentation of Training:** The licensee shall document the training provided to each employee, including the date, number of hours and topic.

**Employee Identification Badges:** All employees of licensees must wear a tamper-proof photographic identification badge whenever the employee is on the premises of the licensee or is transporting cannabis. The badge shall contain the full name of the employee and the name and license number of the licensee. The licensee and key participants of a licensee are subject to this requirement. The CCO may require employees to wear CCO-issued badges if it determines that standardization of employee identification is necessary.

#### SECTION 4.7 RESTRICTED ACCESS

**Restricted Areas:** A Testing Laboratory's premises are restricted to employees of the licensee, employees and agents of the CCO, members of the CCB, law enforcement agents, and other Tribal officials designated by the CCO. No other person may be admitted except by following procedures for visitors.

**Visitors:** Visitors must be at least 21 years of age; must present photographic identification; must sign a visitor log collecting name, contact information and purpose of visit; and must be supervised by an employee of the licensee at all times.

**Use of Contractors:** Licensees may hire contractors to perform work onsite that does not involve handling cannabis, including but not limited to carpentry, plumbing, electrical or alarm work. However, such contractors are considered visitors and may not be left unattended in areas where cannabis or cannabis products are present.

#### SECTION 4.8 WASTE AND WASTEWATER

**Disposal of Excess Samples and Testing Samples:** A Testing Laboratory shall, unless directed by the CCO to retain materials for investigation, dispose of all excess cannabis or cannabis products not needed to complete the analysis, along with any cannabis-containing samples analyzed at the laboratory. The Testing Laboratory is not permitted to keep, transfer, or use cannabis or cannabis products obtained from a licensee, except that the Testing Laboratory may, with advance written notice to the CCO, run additional analyses on excess material for training or quality improvement purposes.

**Preparation of Cannabis Waste:** Prior to disposing cannabis waste, the licensee must render the waste unusable by grinding it and mixing it with an equal or greater volume of food waste, grass clippings, wood chips, yard waste or other material that renders it unusable and unrecoverable, consistent with the licensee's waste disposal plan.

**Classification:** Cannabis waste that has been rendered unusable shall not be considered hazardous waste unless it contains other components considered hazardous waste.

**Waste Collection:** After rendering cannabis waste unusable and unrecoverable, the licensee shall store the cannabis waste in an area inaccessible to the public until it is collected or disposed of in accordance with the Saint Regis Mohawk Tribe Solid Waste Management Code.

#### SECTION 4.9 STORAGE OF CANNABIS PRODUCTS

**Security.** Outside normal hours of operation, licensees must secure cannabis and cannabis products in a commercial quality safe or vault or a closet or refrigerator protected by a seismic sensor connected to the alarm system. During normal operation, licensees must secure cannabis and cannabis products in secure containers to the extent practicable.

**Environmental Conditions.** Licensees must store cannabis products under conditions that will protect products against physical, chemical and microbial contamination, as well as against deterioration of any container.

**Storage Prior to Testing.** Licensees must store, in sealed containers labeled with a batch number, any batch of cannabis products from which samples have been taken for laboratory testing until the laboratory returns a certificate of analysis to the licensee.

## **SECTION 4.10 SANITARY REQUIREMENTS**

**Employee Illness.** No person may perform work duties when suffering from an open or draining skin lesion, fever, respiratory infection, diarrhea or vomiting. Cuts must be covered with bandages and, if on the hand, disposable gloves.

**Hand Washing.** Each licensee must provide hand-washing facilities with warm running water, soap or detergent and paper towels or drying device. All persons must wash their hands before starting work; after eating, drinking or smoking; and when hands become soiled or contaminated.

**Litter Removal.** Each licensee must provide receptacles and regularly remove any litter or waste to avoid contamination of cannabis.

**Toilet Facilities.** Each licensee must provide employees with adequate and readily accessible toilet facilities in good repair and sanitary conditions.

**Surfaces and Equipment.** All counters, other surfaces, and equipment must be constructed of food grade materials that do not react with cannabis, cannabis products or any solvent, medium, or reagent used in testing. All surfaces and equipment must be cleaned and sanitized regularly to prevent cross-contamination between samples.

**Other Laws Remain in Effect.** Nothing in this section is intended to supersede or diminish any other food safety requirements applicable to an establishment preparing prepackaged food.

#### SECTION 4.11 TRANSPORTATION OF TESTING SAMPLES

**Transportation Limited to Employees of Licensees:** Any person transporting samples of cannabis or cannabis products for testing must be an employee of a licensee wearing an identification badge.

**Vehicle Requirements:** Licensees must provide, in advance, the make, model and license plate number of any vehicle used to transport cannabis or cannabis products. The vehicle must be insured, in good working order and equipped with an alarm and a locking compartment for securing cargo.

**Temperature Control:** Any vehicle used to transport samples of cannabis products must have adequate means to keep products within a temperature range that prevents melting, spoilage or other damage.

Transport Manifest: A licensee must create a transport manifest in advance each time the licensee transports cannabis or cannabis products. The transport manifest must include the name, address, phone number and license number of the licensee originating the shipment and the licensee receiving the shipment, description and quantities of each item in the shipment, date and time of shipment, vehicle make and model, license plate number, name and signature of the driver and any other employee in the vehicle and name and signature of the employee of the licensee receiving the shipment. A licensee shall use the tracking system to create the transport manifest, unless use of the tracking system is waived by the CCO. If the tracking system is temporarily unavailable, the licensee shall handwrite a transport manifest and enter the required information into the tracking system within one business day of the tracking system becoming operational.

**Other Laws Remain in Effect.** Nothing in this section is intended to supersede or diminish state or federal laws and regulations applicable to transportation of cannabis or cannabis products off Tribal territory.

#### SECTION 4.12 DUTY TO REPORT INFORMATION TO CCO

Routine Reporting of Mandatory Testing Results: A Testing Laboratory shall report to the CCO the result of all tests performed on behalf of licensees, Registered Entities or the CCO, except those submitted exclusively for research and development purposes. Such reporting shall take place either through the inventory tracking system, if adopted, or through emails no less frequently than once per week.

Annual Report of All Test Results: A Testing Laboratory shall prepare an annual statistical summary of all testing results provided by the laboratory to licensees, Registered Entities and the CCO, including optional tests conducted for research and development purposes. The data shall be de-identified. For potency testing, the report shall provide an analysis of potency by category (flower, trim, vaporizer cartridges, inhalable concentrates, tinctures, oils, beverages, foods, and topical). For homogeneity and contaminant testing, the report shall break down pass/fail rates by testing field and by category. The report shall note any other statistical trends of interest to the CCO, including whether most failures in a field of testing resulted from a particular analyte.

Change in Management or Ownership: A licensee must report in writing to the CCO any change in management personnel or structure or ownership of the business. No person may assume a role meeting the definition of key participant in the Ordinance before the individual has obtained pre-clearance from the CCO and the CCO has determined that the change in management or ownership is consistent with limits on participation by non-Tribal Members.

**Theft or Other Loss of Cannabis or Cannabis Products:** A licensee must report by phone to the CCO and law enforcement, within 24 hours, the suspected theft of cannabis or cannabis products. A licensee must report any other loss of cannabis or cannabis products to the CCO within 24 hours.

**Other Unlawful Activity:** A licensee must report to the CCO within 48 hours any suspected diversion, inversion, attempt to obtain falsified testing results or other violations of the Ordinance or this Regulation.

**Failure of Security System:** A licensee must report to the CCO within 48 hours any failure of the licensee's security system, including video cameras, lasting more than 120 minutes.

**Traffic and Other Incidents:** A licensee must report to the CCO as soon as possible, and within 24 hours, any accident involving a motor vehicle transporting cannabis, any traffic citation involving a vehicle transporting cannabis or any stop or arrest by law enforcement while performing duties related to the operation of the licensee.

#### **SECTION 4.13 SECURITY**

**Building and Grounds:** A Testing Laboratory shall operate in a permanent building equipped with electricity, heat, running water and toilet facilities.

**Security Plan:** Each licensee shall maintain a security plan that includes a floor plan and indicates all doors, windows, alarm sensors, alarm panels, video cameras and video storage devices. The security plan shall explain how alarms and video are monitored and backed up in case of loss of power.

**Video Monitoring:** Cameras shall record, 24 hours per day and 7 days per week, the area around any exterior door, as well as any area where cannabis is tested, stored, destroyed, disposed or prepared for testing. The recordings shall be a minimum of 720 pixels, 15 frames per second, Internet Protocol compatible and accurately stamped with date and time. Cameras shall have a backup power source that allows uninterrupted operation for 120 minutes.

**Video Storage:** The licensee shall store video footage for 45 days, either in a locked cabinet or closet that prevents employee tampering or theft or on a secure third-party server. The licensee shall limit access to video footage and maintain a list of all individuals who have access to the footage. The licensee shall permit the CCO to access the video footage during normal operating hours.

**Windows and Doors:** All windows and doors shall be commercial grade and lockable to prevent theft. Each window or door shall have a monitored alarm sensor.

**Alarm Systems:** All licensees must have an alarm system that is remotely monitored by the licensee or an alarm company that can alert law enforcement of any breeches. The alarm system shall include perimeter sensors, motion sensors and vibration sensors.

# **SECTION 5.0 TESTING OF CANNABIS PRODUCTS**

#### SECTION 5.1 COLLECTION OF SAMPLES FOR TESTING

Collection for Testing by a Tier 1 Testing Laboratory: All samples for mandatory testing, inspection testing, or testing for the purposes of product labeling shall be collected by the CCO or its designee, following protocols described in the operating procedures of the Testing Laboratory to perform the testing.

Collection for Testing by a Tier 2 Testing Laboratory: All samples for mandatory testing or testing for the purposes of labeling shall be collected by an agent of a Tier 2 Testing Laboratory following protocols described in its operating procedures. All samples for inspection or confirmation testing shall be collected by the CCO or its designee following protocols described in the operating procedures of the Testing Laboratory to perform the testing.

**Authority of CCO Staff:** CCO staff are authorized to collect samples, transport samples to a Tier 1 or Tier 2 Testing Laboratory, and transport samples to other independent testing laboratories in New York to the extent authorized by other laws. The CCO staff shall follow chain of custody procedures specified by the laboratory.

# SECTION 5.2 RECEIPT OF SAMPLES FOR OPTIONAL TESTING

A Tier 1 or Tier 2 Testing Laboratory may receive samples submitted by any licensee, registered entity, or Tribal Member 21 years of age or older for the purposes of conducting any optional test, including samples submitted to conduct an otherwise mandatory test for research and development purposes. Prior to accepting such samples, the Tier 1 or Tier 2 Testing Laboratory shall publish its sample collection procedures and make available suitable containers for storing and transporting samples.

# SECTION 5.3 DE-IDENTIFICATION OF SAMPLES SUBMITTED TO A TIER 1 TESTING FACILITY

A Tier 1 Testing Facility shall not make any attempts to identify the source of any sample submitted for mandatory testing. Prior to submission, the CCO shall assign a random batch identifier to the sample to ensure that a Tier 1 Testing Laboratory is unable to prioritize or favor samples submitted by an entity associated with the Tier 1 Testing Laboratory. The CCO shall maintain secure records outside of the inventory tracking system to protect against the identification of samples.

#### **SECTION 5.4 WRITTEN REPORTS**

A Tier 1 or Tier 2 Testing Laboratory shall provide a written report for all mandatory tests performed for a licensee, Registered Entity, or CCO. When applicable, the written report shall plainly indicate whether the sample has passed or failed. For any sample collected by the person or entity requesting the test (Section 5.2) or when the sample was submitted for the purpose of research and development testing, the written report shall clearly state in minimum 12-point type, all capital letters, the disclaimer, "UNOFFICIAL TEST RESULTS. NOT VALID FOR TRANSFER OR SALE."

#### **SECTION 5.5 FEES**

**Setting of Fees:** A Tier 1 or Tier 2 Testing Laboratory may charge reasonable fees for its services. Prior to setting or changing testing fees, the Testing Laboratory shall submit the proposed fees to the CCO for approval. The CCO shall consider fees charged by laboratories in New York and neighboring states, along with information provided by the Testing Laboratory about its operating costs, in evaluating the reasonableness of the proposed fees.

**Discount to CCO:** A Tier 1 or Tier 2 Testing Laboratory shall charge the CCO no more than eighty (80) percent of approved testing fees, reflecting the CCO's role in sample collection.

**Responsibility for Testing Fees:** The Cultivator, Producer, Retail Store, or Registered Entity from which the sample was collected shall be responsible for paying the approved testing fees under all circumstances. In the case of testing in which the CCO collects the sample, the Cultivator, Producer, Retail Store, or Registered Entity shall make payment of the full posted rate directly to the CCO, and the CCO shall pay the discounted rate to the Testing Laboratory.

#### SECTION 5.6 CONCENTRATION OF CANNABINOIDS AND TERPENES

**Potency Testing Required:** Prior to transfer to another licensee or final packaging to retail sale, a Cultivator, Processor or Registered Entity shall segregate each batch of cannabis, cannabis extract, or cannabis product for the purposes of potency testing. The batch shall not be transferred or sold until a written report is obtained from a Testing Laboratory. Potency shall be expressed in the written report as a percentage by weight.

**THC Potency:** All batches must be tested for THC potency, which shall be reported as the percentage by weight of THC in the sample plus the percentage by weight of tetrahydrocannabinolic acid (THCA) multiplied by 0.877.

**CBD Potency:** Any batch to be labeled with CBD content must be tested for CBD potency, which shall be reported as the percentage by weight of CBD in the sample plus the percentage by weight of cannabidiolic acid (CBDA) multiplied by 0.877.

Concentration of Other Cannabinoids and Terpenes: Testing for other cannabinoid or terpene concentrations is mandatory only if the Cultivator, Processor or Registered Entity includes representation as to their content on a product label.

**Homogeneity:** Prior to retail sale, all cannabis products must be tested for homogeneity of the batch. A product will be deemed to have passed this test if the relative standard deviation of THC concentration of three sample increments in the same batch is no more than 15%. For solid or semi-solid edible cannabis products, a single package or its equivalent weight must also be tested for homogeneity as packaged or as intended to be packaged prior to retail sale. A product will be deemed to have passed this test if the relative standard deviation of THC concentration of three sample increments in the same package (or its equivalent weight) is no more than 15%. The written report shall indicate pass or fail as the result of homogeneity testing.

# **SECTION 5.7 MICROBIAL CONTAMINATION**

Microbial Testing Required: Prior to transfer to another licensee or final packaging to retail sale, a Cultivator, Processor or Registered Entity shall segregate each batch of cannabis, cannabis extract, or cannabis product for the purposes of testing for the presence of Aspergillus (A. flavus, A. fumigatus, A. niger or A. terreus); shiga toxin-producing E. coli; and salmonella species. The batch shall not be transferred or sold until a written report is obtained from a Testing Laboratory. A batch shall pass microbial testing if none of the target analytes is present in a one gram sample. The written report shall indicate whether each test has passed or failed and shall report any target microbes detected in colony forming units (CFU) per gram of sample.

**Exception for Volatile Hydrocarbon or Alcohol Extraction:** A Cultivator or Registered Entity is not required to have tested for microbial contamination flower or trim prior to transferring it to a Processor for the purpose of extraction using volatile hydrocarbon solvents or an approved alcohol. A Processor or Registered Entity is not required to test for microbial contamination a cannabis product that is or contains only cannabis extract produced using volatile hydrocarbon solvents or an approved alcohol.

#### **SECTION 5.8 HEAVY METAL CONTAMINATION**

Heavy Metal Testing Required: A Cultivator or Registered Entity shall provide one sample of cannabis flower or trim per harvest cycle (a minimum of four samples per year) for the purposes of testing for arsenic, cadmium, lead and mercury contamination. A Processor or Registered Entity shall provide one sample of each cannabis product it manufactures at least once every 90 days for the purposes of testing for arsenic, cadmium, lead and mercury. A sample shall pass heavy metal testing if none of the analytes exceed the action levels for cannabis samples in Table 1 below. The written report shall indicate whether each test has passed or failed and shall report the concentration of heavy metals in  $\mu g/g$  (ppm).

Soil Testing for Outdoor Cultivation: A Cultivator or Registered Entity cultivating any cannabis outdoors shall submit at least annually representative soil samples to a cannabis testing laboratory or another independent testing laboratory performing soil analysis and submit to the CCO a certificate indicating soil concentrations below the action levels for soil in Table 1 below. If a soil or cannabis product sample exceeds the relevant actions levels, then the cannabis establishment shall submit samples from each batch of cannabis harvested outdoors until the CCO determines that the source of the contamination has been identified and controlled.

**Additional Testing:** The CCO may order random heavy metal testing of cannabis, cannabis products or soil or may order testing in response to complaints from consumers or patients.

Table 1. Heavy Metal Testing Action Levels					
Analyte	CAS	Action Level*: Soil	Action Level*: Cannabis		
Arsenic	7440-38-2	13.0	2.0		
Cadmium	7440-43-9	2.5	0.8		
Lead	7439-92-1	63.0	1.2		
Mercury	7439-97-6	0.4	0.4		
*µg/g (ppm)					

#### **SECTION 5.9 RESIDUAL PESTICIDES**

The CCO may order testing of cannabis flower, trim, extract or products for pesticide residue on a random basis, upon suspicion of the use of a non-approved pesticide, or in response to complaints from consumers or patients. A Cultivator, Processor or Registered Entity shall segregate each affected batch, and the batch shall not be transferred or sold until a written report is obtained from a Testing Laboratory. A batch shall fail residual pesticide testing if any pesticide not approved for use in cannabis cultivation is detected at concentrations greater than  $0.1 \mu g/g$  (ppm) or if any approved pesticide is detected at concentrations greater than the lowest tolerance expressed for that pesticide in 40 C.F.R. Part 180, Tolerances and Exemptions for Pesticide Chemical Residues in Food. The written report shall indicate whether each test has passed or failed and shall report the concentration of pesticide residues in  $\mu g/g$  (ppm).

#### **SECTION 5.10 RESIDUAL SOLVENTS**

The CCO may order testing of cannabis extract manufactured using alcohol or a volatile hydrocarbon solvent, or a cannabis product manufactured using such extract, for residual solvents on a random basis, upon suspicion of the use of a non-approved extraction method, or in response to complaints from consumers or patients. A Processor or Registered Entity shall segregate each affected batch, and the batch shall not be transferred or sold until a written report is obtained from a Testing Laboratory. A batch shall fail residual solvent testing if any solvent is detected at concentrations greater than the action level in Table 2 below. An edible product shall not fail residual solvent for the presence of ethanol. The written report shall indicate whether each test has passed or failed and shall report the concentration of solvent residues in  $\mu g/g$  (ppm).

Table 2. Action Levels for Residual Solvents				
Class	Solvent	CAS	Action level	
Propane	propane	74-98-6	5000	
Butanes	<i>n</i> -butane	106-97-8	5000	

	isobutane	75-28-5	5000
Pentane	<i>n</i> -pentane	109-66-0	5000
Hexane	<i>n</i> -hexane	110-54-3	290
Benzene	benzene	71-43-2	2.0
Toluene	toluene	108-88-3	890
Heptane	<i>n</i> -heptane	142-82-5	5000
Ethylbenzene and Xylenes	ethylbenzene	100-41-4	2170
	ortho-xylene	95-47-6	
	<i>meta</i> -xylene	108-38-3	Total
	para-xylene	106-42-3	1 3 3 3 3 3
	ethanol	64-17-5	5000
Alcohols	methanol	67-56-1	3000
	isopropanol	67-63-0	5000
Acetone	acetone	67-64-1	5000

#### **SECTION 5.11 WATER ACTIVITY**

The CCO may order testing of cannabis flower, trim, extract produced without the use of alcohol or a volatile hydrocarbon solvent or products containing such extracts for water activity on a random basis, upon suspicion of microbial contamination, or in response to complaints from consumers or patients. A sample may be deemed to have passed the water activity test if it has a water activity of 0.85 or less for solid and semi-solid edible cannabis products or 0.65 for any other item for which the CCO requires testing.

#### **SECTION 5.12 ADDITIONAL TESTING**

A Tier 1 Testing Laboratory or Tier 2 Testing Laboratory may offer additional testing, and the CCO may require additional testing at the discretion of the CCB.

#### SECTION 5.13 CONSEQUENCES OF A FAILED TEST

**Notification:** A Testing Laboratory shall notify the CCO whenever a sample is deemed to have failed a test.

**Failure of Routine Testing:** A Cultivator, Processor or Registered Entity may elect to voluntarily destroy the batch that failed testing. If the failed test is for homogeneity, microbial contamination, residual solvents, or water activity, the Cultivator, Processor, or Registered Entity may elect to remediate the batch according to the requirements of Section 5.14 and submit a sample for additional testing. If the Cultivator, Processor or Registered Entity is unable or unwilling to remediate the batch and the failing result was reported by a Tier 1 Testing Laboratory, the CCO may order the Cultivator, Processor or Registered Entity to hold the batch until the result is confirmed by additional laboratory testing. If the failing result is confirmed, or

if the initial result was reported by a Tier 2 Testing Laboratory, the CCO may order the Cultivator, Processor or Registered Entity to destroy the batch. A Cultivator, Processor or Registered Entity may appeal the CCO's decision to the CCB.

**Failure of Periodic Heavy Metal Testing:** A Cultivator, Processor or Registered Entity failing heavy metal testing of any sample shall segregate each batch of cannabis or cannabis products for heavy metal testing prior to transfer to another licensee or final packaging for retail sale. The batch from which the sample was drawn shall be subject to confirmation testing and an order of destruction as described above. When the CCO is satisfied that the licensee has corrected the source of contamination, the licensee will be allowed to discontinue testing every batch.

#### SECTION 5.14 REMEDIATION OF FAILED BATCHES

**Failed Homogeneity Test:** A batch that fails homogeneity testing may be remediated by chopping, melting, mixing, extracting, or otherwise combining the batch to ensure more even distribution of cannabinoids among the batch. The resulting cannabis or cannabis product must pass homogeneity testing before it is distributed or sold.

**Failed Microbial Test:** A batch of flower or trim that fails microbial testing may be extracted using alcohol or volatile hydrocarbon solvent extraction. The resulting extract must pass microbial testing before it is distributed or sold.

**Failed Residual Solvent Test:** A batch of cannabis product that fails residual solvent testing for a prohibited solvent may not be remediated. A batch of cannabis product that fails residual solvent testing for a permitted solvent may be remediated through evaporation under heat and/or vacuum. The cannabis product must pass repeat residual solvent testing before it is distributed or sold.

**Failed Water Activity Test:** A batch of cannabis flower, cannabis trim, or cannabis product that fails a water activity test may be remediated through heating or drying. The batch must pass both repeat water activity testing and repeat water activity testing before it is distributed or sold.

# **SECTION 6.0 PENALTIES**

# SECTION 6.1 MAJOR LICENSE VIOLATIONS

Monetary Penalties in Addition to Revocation or Suspension: The CCO may impose monetary penalties in addition to revoking or suspending the licenses of any Testing Laboratory committing violations of the Ordinance affecting public health and safety.

**Diversion of Cannabis:** The CCO may impose monetary penalties for any transfers of cannabis or cannabis products not permissible under the Ordinance, including a minimum penalty of \$500 and a maximum penalty of \$500 per pound of cannabis or \$5,000 per pound of concentrate.

**Falsification of Test Results:** The CCO may impose monetary penalties of up to \$5,000 per written report for intentionally falsifying test results, including elevating potency or underreporting contaminants.

**False Statements to CCB, CCO or Law Enforcement:** The CCO may impose monetary penalties up to \$10,000 for knowingly making false statements to the CCB, the CCO or Law Enforcement in an effort to conceal violations of this Regulation or the Ordinance.

Other Violations Affecting Public Health or Safety: The CCO may impose monetary penalties up to \$5,000 for any other violation affecting public health or safety.

#### SECTION 6.2 MINOR LICENSE VIOLATIONS

**Failure to Provide Required Notifications:** The CCO may impose monetary penalties up to \$250 per instance on Testing Laboratories who fail to provide required notifications to the CCO or CCB.

Other Violations Not Affecting Public Health or Safety: The CCO may impose monetary penalties up to \$500 for any other violation not affecting public health or safety.