**GENERAL COMMENTS**

**COMMENT** (1): A commenter expressed concern that the New York Medical Cannabis Program either does not test for terpene levels or does not disclose terpene levels to patients. The commenter felt that consumers cannot make informed decisions, or avoid costly mistakes, without this. The commenter stated that terpene panels are available in all cannabis testing facilities and are disclosed in nearly every other state program.

**RESPONSE***:* Terpenoids will be tested and reported pursuant to Part 130.22 (c) of Title 9. Clarifications were made to the proposed regulation as a result of these comments.

**COMMENT** (2): A commenter asked the Office to consider the start-up of new labs to perform routine analysis on adult-use and medical cannabis. They were concerned that a small laboratory business would fail because it was not able to afford proper and accurate equipment to provide reliable data.

**RESPONSE***:* The Office acknowledges these comments, but this comment is outside the scope of the proposed regulations. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (5a, 10, 11a): Comments were received related to having Tribal Nations' cannabis products tested by independent cannabis laboratories permitted by the Office.

**RESPONSE***:* The Office acknowledges these comments and may consider them in future guidance and rulemaking when tribal-state compacts are established. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (6): A commenter requested the Office consider approval of methods certified by third party certification organizations such as Association of Official Agricultural Chemists (AOAC) International.

**RESPONSE***:* The Office acknowledges these comments, but this comment is outside the scope of the proposed regulations. No changes were made to the proposed regulations as a result of this comment.

**COMMENT** (9a): A commenter asked that the Office create a reasonable time limit for implementation of various portions of the sampling and testing process.

**RESPONSE***:* The Office has established guidance related to the timing of sampling and testing. No changes were made to the proposed regulations as a result of this comment.

**COMMENT** (9b): A commenter believes that it would be proactive for the Office to establish uniform guidelines and oversight when grievances arise and included a list of recommendations to handle them.

**RESPONSE***:* The Office acknowledges these comments and may consider them in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (9c): A commenter asked that the proposed regulation do not reference any federal law.

**RESPONSE**: The Office acknowledges these comments, but this comment is outside the scope of the proposed regulations. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (12): A commenter indicated that the testing regulations do not address the testing of homegrown products and they recommended that it be free or at low cost.

**RESPONSE***:* The Office acknowledges these comments, but this comment is outside the scope of the proposed regulations. No changes were made to the proposed regulations as a result of this comment.

**COMMENT** (15): A commenter recommended the Office approve third party training (such as course content/outline) to satisfy laboratory and sampling regulations, or recognize courses authorized by the New York State Education Department.

**RESPONSE***:* The Office acknowledges these comments, but this comment is outside the scope of the proposed regulations. No changes were made to the proposed regulations as a result of these comments.

**DEFINITIONS (130.1) COMMENTS**

**COMMENT**(3a): A commenter recommended removing reference to specific types of analytical instrumentation.

**RESPONSE**: The definition provides examples to give the public an idea of what the Office's expectations are; the list is not exhaustive. No changes were made to the proposed regulations as a result of this comment.

**COMMENT** (3b): A commenter recommended limiting the definition to phytocannabinoids to use the word "included" when referencing compounds.

**RESPONSE**: The Office acknowledges these comments and may consider them in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (3c, 3s): A commenter requested additional duties of the State Reference Laboratory to include the analysis of samples under investigation collected directly from inspections/investigations.

Another commenter indicated that the original definition for a state reference lab did not include 'investigation duties' nor does this subsection. They asked that method review (in special cases) and laboratory investigations (as needed) be included.

**RESPONSE**: The Office acknowledges these comments and will include as part of a memorandum of understanding or contract with a reference laboratory. Changes were made as a result of this comment.

**COMMENT** (4a): A commenter requested that the definition for "Proficiency Test Providers (PTP)" be amended to mean: "an entity with an ISO/IEC 17043 accreditation for cannabis proficiency testing and is independent of a cannabis testing laboratory for which it provides a proficiency test. A proficiency testing provider needs to be independent of a cannabis testing laboratory whether it provides proficiency testing to the laboratory or not."

**RESPONSE**: Changes were made to the proposed regulations as a result of these comments.

**CANNABIS LABORATORY PERMIT APPLICATION (130.2) COMMENTS**

**COMMENT** (13a): A commenter noted that the first-year permit application fee of $1,000 for a cannabis lab permit is twice the fee for clinical lab permits, which is $500 for an initial permit under the New York State Department of Health's Clinical Laboratory Evaluation Program ("CLEP") guidelines. For both initial and renewal application fees, the commenter asked that the fees be aligned such that the cannabis lab fee be set at $500.

**RESPONSE**: The Office acknowledges this comment, however, the fee structure associated with the clinical laboratory permits is outside the scope of comparison to cannabis laboratory permits. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (14a): A commenter indicated that requiring laboratories to obtain ISO/IEC 17025 certification before issuing a provisional permit to test adult-use cannabis and cannabis products will inhibit the permitting of social equity laboratories and other less-capitalized applicants.

**RESPONSE**: This comment is outside the scope of the proposed regulations. Social and economic equity laws are in relation to adult-use licensees, not cannabis laboratories. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (3d): A commenter stated that the Office is using scientific resources to determine the validity of a laboratory's testing program. The commenter stated that the ability of the Board to overrule the Office's decision could introduce political influence into the process.

**RESPONSE**: The Office and the Board work collaboratively to ensure that the laboratories are using the best scientific resources necessary for the industry. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (13b): A commenter recommended that the second sentence of section 130.2(b)(3) be clarified to address: (1) the initial and annual application fee, and (2) the annual permit fee. They suggest either omitting the text referring to the annual permit fee, which is covered further in section 130.3(a), Cannabis Laboratory Permit Fee.

**RESPONSE**: The Office acknowledges these comments. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (14b): A commenter sought clarification as to whether proficiency testing applies to existing laboratories testing medical cannabis only. The commenter stated that new cannabis laboratory applicants will not have the capability nor the capacity to have an established proficiency testing program if they are completing or remediating on their ISO 17025 accreditation.

**RESPONSE**: A cannabis laboratory permitted by the Office can test adult-use and medical cannabis. The Office acknowledges this comment and established guidance related to the timing of proficiency testing. No changes were made to the proposed regulations as a result of these comments.

**CANNABIS LABORATORY FEES (130.3) COMMENTS**

**COMMENT** (3e): A commenter stated that the State Reference Laboratory be explicitly exempted from Cannabis Laboratory Fees in regulation.

**RESPONSE**: A State Reference Laboratory is defined differently than a Cannabis Laboratory, and it is not subject to the same fees as a cannabis laboratory. The Office acknowledges these comments. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (14c): A commenter sought clarification on the reasoning for permit fees to be based on gross annual receipts and if the permit applied to testing of adult-use and medical cannabis. They also noted that the proposed regulation sets the fee annually and adds to the high barrier to entry for third party cannabis testing laboratories.

**RESPONSE**: A cannabis laboratory permitted by the Office can test adult-use and medical cannabis. The annual permit fee will be based on a cannabis laboratory's gross annual receipts for any testing performed on adult-use and medical cannabis. No changes were made to the proposed regulations as a result of this comment.

**COMMENT** (9d): A commenter indicated that a portion of Section 130.3 of the regulations appears to be more applicable to subsection §130.4.

**RESPONSE**: Fees are addressed in 130.3, and therefore the renewal fee is also addressed in this section. No changes were made to the proposed regulations as a result of these comments.

**CANNABIS LABORATORY PERMIT RENEWAL APPLICATION (130.4) COMMENTS**

**COMMENT** (9e): A commenter offered the following amendments to § 130.4: "(c) 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."

**RESPONSE**: The Office acknowledges these comments. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (3f): A commenter indicated that renewal policies should specify maintaining the same requirements required to submit and retain an initial application.

**RESPONSE**: The Office acknowledges these comments. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (13c and 14d): Comments were received regarding the permit and renewal fee frequency. One commenter recommended adding the word 'annually' to clarify the frequency of renewal in section 130.4(a). Another commenter sought clarification related to the fee for renewal and annual permit fees.

**RESPONSE**: The Office acknowledges this comment and has made a clarifying change to the regulation.

**CANNABIS LABORATORY PERMIT ISSUANCE (130.5) COMMENTS**

**COMMENT** (8a): A commenter suggested removing reference to testing cannabinoid hemp in the regulation as Section 114.10 of Title 9 of the Official Compilation of Codes, Rules and Regulations of the State of New York is designated for testing hemp with analytes of interest, and their action limits.

**RESPONSE**: This provision clarifies that a laboratory that meets the requirements of this Part, also meet the standards to test cannabinoid hemp products as set out in Part 114 of Title 9 of the Official Compilation of Codes, Rules and Regulations of the State of New York. No changes were made to the proposed regulations as a result of the comment.

**GENERAL CANNABIS LABORATORY REQUIREMENTS (130.7) COMMENTS**

**COMMENT** (8b): A commenter indicated that the Office needs to provide a list of approved ISO/IEC 17025 laboratory accrediting bodies and accreditation types (i.e.: quality systems, sampling, and/or testing).

**RESPONSE**: The Office will post a list of ISO/IEC 17025 laboratory accreditation bodies on the Office's website in the near future. The accreditation type will be for quality systems only. A laboratory can choose to have additional accreditation types to help them meet sampling and testing activities. No changes to the proposed regulations were made as a result of these comments.

**COMMENT** (8e): A commenter indicated that the Office needs to provide a determination as to the percentage of testing capacity laboratories are to hold open for the businesses with limited resources and how they will designate these businesses. The commenter stated that without knowing the percentage of the laboratory capacity to be dedicated, and how businesses are going to be designated, laboratories cannot to demonstrate compliance with this requirement.

**RESPONSE**: The percentage will be determined by the Board as stated in Section 130.7(g) of This Part. No changes were made to the proposed regulations as a result of these comments.

**REQUIRED CANNABIS PROFICIENCY TESTING (130.8) COMMENTS**

**COMMENT** (3g): A commenter asked for the Office to clarify or define the term, "unscheduled" to mean or indicate "supplemental."

**RESPONSE**: An unscheduled Proficiency Test is also considered a supplemental Proficiency Test. Clarifying changes were made as a result of these comments.

**COMMENT** (3h): A commenter was concerned with the availability of Proficiency Test samples from an ISO 17073 PT provider and frequency at which Proficiency Test samples are to be tested.

**RESPONSE**: The industry standard for proficiency test providers is to have studies scheduled, at a minimum, on a monthly basis. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (8d): A commenter requested that the Office define the requirements for proficiency testing based on matrix/analyte/technology or matrix/analyte/method. Also, they asked that the Office post or provide a list of approved proficiency testing providers.

**RESPONSE**: The Office acknowledges this comment and will release a guidance document on the Office's website, including the analyte or group of analytes to be proficiency tested and a list of approved proficiency testing providers. No changes were made to the proposed regulation as a result of these comments.

**COMMENT** (9f): A commenter stated that the existing verbiage is cumbersome to follow given the similarity and repetition of the words “provide,” “proficient,” and their various conjugations. They asked that this subdivision be revised for comprehension by the reader.

**RESPONSE**: The Office acknowledges these comments. No changes were made to the proposed regulations as a result of these comments.

**LABORATORY REGULATORY AUDIT (130.10) COMMENTS**

**COMMENT** (3i, 8c, 8f, 9g): Commenters asked for clarification on the audit process and time frame for responding to an audit report.

**RESPONSE**: A laboratory must have an ISO/IEC 17025 audit as part of the permit application process and renewal of a permit. The Office will audit the cannabis laboratory on a routine basis (i.e., initially and every two years thereafter) and as needed. A technical change has been made to clarify the frequency at which a correction action report is to be received.

**GENERAL CANNABIS PERSONNEL REQUIREMENTS (130.11) COMMENTS**

**COMMENT** (3j): A commenter requested adding the initial demonstration of capability and ongoing demonstration of capability to this subsection and changing ‘training checklist’ to ‘documented training program.’

**RESPONSE**: The Office acknowledges these comments. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (9h): A commenter requested amending the title of this subsection to specify “Laboratory” personnel.

**RESPONSE**: The Office acknowledges these comments. A technical change has been made to the subdivision title to include “Laboratory,” and the Office has made changes to the table of contents, too.

**CANNABIS TECHNICAL DIRECTOR QUALIFICATIONS (130.12) COMMENTS**

**COMMENT** (8g): A commenter indicated that the requirement of college course work does not guarantee proficiency or is a sufficient knowledge base for working in a cannabis quality control

laboratory. They also indicated that training received and experience in a laboratory are equally important to the basic education of an accredited degree program.

**RESPONSE**: This requirement aligns with other laboratory programs in New York State. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (13d): A commenter had concerns with Section 130.12(c), which states '[a] technical director may not serve as a technical director for more than one cannabis laboratory without written authorization from the Office.' They understood that this requirement follows the current New York State Environmental Laboratory Approval Program certification policy and noted that it is more restrictive than Clinical Laboratory Evaluation Program, which allows the director to serve at two sites.

**RESPONSE**: The Office acknowledges these comments and may consider them in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (13e): A commenter was concerned with the absentee period for a technical director. They noted that the time frame is much shorter than what is required under the Environmental Laboratory Approval Program (ELAP). Under ELAP it is 65 days while the proposed regulation indicates 35 days.

**RESPONSE**: The Office acknowledges these comments related to another agency's requirement. No changes were made to the proposed regulations as a result of these comments.

**CANNABIS LABORATORY TECHNICIAN QUALIFICATIONS (130.14) COMMENTS**

**COMMENT** (3k, 8h): Commenters expressed concern with experience requirement for laboratory technician.

**RESPONSE**: Changes were made as a result of this comment.

**APPROVAL OF LABORATORY DEVELOPED METHODS (130.15) COMMENTS**

**COMMENT** (3l): A commenter indicated that method comparison data should be allowed by splitting samples with outside laboratories that run an alternate method. They also indicated that requiring in-house comparison means the laboratory has to generate two (2) methods and be proficient to compare them.

**RESPONSE**: There are no prohibitions regarding the activities described in the above comment. No changes were made to the proposed regulations as a result of these comments.

**LABORATORY SAMPLING FIRM COMMENTS**

**COMMENT** (7a): A commenter indicated that they strongly support the requirements for independent sample pickers found in § 130.16 Laboratory Sampling Firm Approval.

**RESPONSE**: The Office acknowledges these comments in support of the proposed regulations. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (3m): A commenter wanted to know what deems a significant change in the sampling process or procedure for section 130.19(j).

***RESPONSE**: The Office acknowledges this comment and will include in future guidance. No changes were made to the proposed regulations as a result of these comments.*

**COMMENT** (4b, 4c): A commenter suggested that a cannabis laboratory sampling firm maintain ISO/IEC 17025 accreditation for the sampling of cannabis, by a non-profit accreditation body that is in conformance with ISO/IEC 17011 and is a signatory to mutual recognition arrangements such as the Asia Pacific Accreditation Cooperation (APAC).

**RESPONSE**: The Office acknowledges these comments. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (5b, 5c, 5d, 11b, 11c, 11d): Commenters requested language be changed in 130.19 and 130.21 to include reference to NYS Indian nation or tribe, as defined by section two of the Indian Law.

**RESPONSE**: The Office acknowledges these comments and may consider them in future guidance and rulemaking when tribal-state compacts are established. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (3n): A commenter recommended utilizing a GPS system to track/identify the location of the samples. They also indicated that samples could be taken from a separate location/building/field to misrepresent the batch which would not be captured by a video system.

**RESPONSE**: There is no prohibition on GPS systems to track/identify the location of samples. No changes were made to the proposed regulations as a result of these comments.

**TESTING OF CANNABIS PRODUCT AND MEDICAL CANNABIS (130.22) COMMENTS**

**COMMENT** (3o): A commenter requested including a requirement for method verification of equipment installed on-site, not just an on-site demonstration of capability.

**RESPONSE**: The Office acknowledges these comments. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (7b): A commenter indicated that they strongly support the required testing for microorganisms found in § 130.22 Testing of Cannabis Product and Medical Cannabis and encourage the Board to maintain this in the final regulations.

**RESPONSE**: The Office acknowledges this comment in support of the required testing. No changes were made to the proposed regulations as a result of this comment.

**COMMENT** (13f): A commenter suggested for sections 130.22 (b), (c), and (d) that the Office include the more direct, specific language found in Section 1004.14 of Title 10 NYCRR - Laboratory testing requirements for medical marihuana which provides a list of the minimum analytes for which laboratories are required to test.

**RESPONSE**: The testing limits for required analytes are readily available on the Office's website. No changes were made to the proposed regulations as a result of this comment.

**CERTIFICATE OF ANALYSIS (130.23) COMMENTS**

**COMMENT** (3p): A commenter requested adding CAS numbers to the certificate of analysis to unequivocally identify analytes. For example, they indicated that the pyrethrins currently analyzed have 6 different CAS numbers, however, they are named very similarly.

**RESPONSE**: The Office acknowledges these comments. No changes were made to the proposed regulations as a result of these comments.

**COMMENT** (3q): A commenter asked to clarify a 'client' as the grower or sampler. Also, they indicated that sampler and their license number should be included.

**RESPONSE**: The client is the adult-use licensee or registered organization that requested testing. No changes were made to the regulations as a result of this comment.

**RECORD RETENTION (130.26) COMMENTS**

**COMMENT** (3r): A commenter asked that 'previous/archive versions of documents' also be encompassed within record retention requirements.

**RESPONSE**: Changes were made as a result of this comment.

**COMMENT** (4d): A commenter asked that this section be revised to state: "(i) quality manual or equivalent quality management documents." They indicated that ISO/IEC 17025 does not include a requirement for a "quality manual" because laboratories routinely maintain electronic files that may not be structured as one complete manual but several individual electronic documents.

**RESPONSE**: Changes were made as a result of this comment.

**SUMMARY SUSPENSION, SUSPENSION, CANCELLATION AND REVOCATION (130.29) COMMENTS**

**COMMENT** (3t): A commenter had concerns with revoking a laboratory as a result of a finding by a municipality that a cannabis laboratory has violated a local ordinance related to 'reporting of results for analysis of such samples.' They indicated that the municipality does not have the expertise to investigate the 'reporting of results for analysis of such samples' and could issue new ordinances to drive out a testing laboratory.

**RESPONSE**: Changes were made as a result of this comment.