



MARYLAND
MMCC

Natalie M. LaPrade
Maryland Medical Cannabis Commission

**Maryland Medical Cannabis Commission
Policy Committee Meeting Minutes
September 7, 2017**

2:00 pm

Winchester Hall, 1st Floor Meeting Room
12 East Church Street,
Frederick, Maryland 21701

Commissioners Present:

J. Charles Smith (Chairman)
Rachel Rhodes
James Pyles
Brian Lopez (Chairman of Commission)

Commissioners Present by Telephone:

Charles LoDico

Commissioners Absent:

Barry Pope

Staff Present:

Patrick Jameson, Executive Director
Heather Nelson, Assistant Attorney General
Lori Dodson, Director of Compliance for Independent Testing Laboratories
Mary-jo Mather, Director of Administration
Myesha McQueen, Administrative Specialist
Kristen Shreves, Quality Assurance Specialist
Ideai Gray, Quality Assurance Specialist

Call to Order

Chairman Smith called the meeting to order at 2:07 pm and welcomed the attendees. Chairman Smith introduced the members of the Policy Committee. A quorum was achieved.

Approval of Minutes

Chairman Smith asked if Commissioners had time to review the draft minutes of the May 22, 2017 meeting and if there were any comments. He asked for a motion to approve the minutes. The motion was offered by Commissioner LoDico and seconded by Commissioner Pyles. The May 22, 2017 Minutes were approved unanimously.

Message from Executive Director

Executive Director Patrick Jameson began by welcoming the Commissioners to the Policy Committee Meeting. Mr. Jameson explained that at this Policy Committee meeting the Commissioners would not be addressing the definition of caregiver, caregiver's authority, and out of state patients. Mr. Jameson would like the Policy Committee to have time to review in detail the previous discussions on these matters. He suggested that at the next meeting these topics be the number one priority. He continued with what would be discussed at the meeting: Chapter 1: Definitions- Definition of Lot and Batch; Chapter 15: Grower Quality Control; Independent Laboratory selection and requirements; contents of Certificate of Analysis, reworking or reprocessing a batch. In Chapter 16: Independent Testing Laboratory Registration: Adding education/experience requirements for Laboratory Director or Technical Leads; registration requirements and background checks for Owners, Investors, and Lab Directors; and provisional registration requirements for applicants. In Chapter 23 – Medical Cannabis Concentrates and medical cannabis-infused products; Independent Testing Laboratory selection and requirements and contents of Certificate of Analysis and reworking or reprocessing a lot.

Quality Control and Independent Testing Laboratory Proposed Amendments

Chapter 1: Definitions

Definition of Batch 10.62.01.02 B (2)

Current:

Batch means all of the plants of the same variety of medical cannabis that have been:

- (i) Grown, harvested, and processed together
- (ii) Exposed to substantially similar conditions throughout cultivation and processing

New:

Batch means not more than 10 pounds of plants of the same variety of medical cannabis that have been:

- (i) Grown, harvested, and processed together; and
- (ii) Exposed to substantially similar conditions throughout cultivation and processing.

Definition of Lot 10.62.01.02 B (17)

Current:

Lot means all of a medical cannabis finished product that is uniform, that is intended to meet specification, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.

New:

Lot means all of a medical cannabis finished product that is uniform, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.

Throughout the regulations will also change the word “Physician” to “Provider”

Chairman Smith asked for a motion to adopt proposed draft revisions to Chapter 1 to include the new definition of batch and lot and to change “physician” to “provider”. This motion was offered by Commissioner LoDico and seconded by Commissioner Pyles. The Committee voted unanimously to adopt the proposed revisions to Chapter 1.

Chapter 15: Medical Cannabis Grower Quality Control

Independent Testing Laboratory Selection and Requirements 10.62.15.04

Current:

A licensed grower shall use an Independent Testing Laboratory:

- A. That has adopted a standard operating procedure to test medical cannabis and medical cannabis concentrate that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;
- B. To obtain samples of each batch according to a statistically valid sampling method by an agent of an Independent Testing Laboratory;
- C. To analyze the samples according to:
 1. The most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP); or
 2. A scientifically valid methodology that is equal or superior to that of the AHP monograph;
- D. In the event of a test result which falls out of specification, the laboratory shall follow their standard operating procedure to confirm or refute the original result;
- E. To issue a certificate of analysis; and
- F. To destroy the remains of the sample of medical cannabis after analysis is completed.

New:

- A. A licensed grower shall use an Independent Testing Laboratory that is registered with the Commission.
- B. An Independent Testing Laboratory shall comply with the Commission's current version of Technical Authority for Medical Cannabis Testing and:
 - 1. Provide trained staff to obtain samples of each batch according to a statistically valid sampling method;
 - 2. Analyze the samples according to a scientifically valid methodology;
 - 3. Provide a certificate of analysis for each batch; and
 - 4. Destroy the remains of the samples of medical cannabis after analysis is completed according to the Commission's current version of Technical Authority for Medical Cannabis Testing.

Contents of Certificate of Analysis 10.62.15.05

Current:

An Independent Testing Laboratory shall issue a certificate of analysis for each batch, with supporting data, to report:

- A. Whether the chemical profile of the batch conforms to the variety for the following compounds:
 - 1. THC
 - 2. THCA
 - 3. CBD
 - 4. CBDA; and
 - 5. The terpenes described in the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP);
 - 6. CBG; and
 - 7. CBN; and
- B. That the presence of the following contaminants does not exceed the levels as required by the AHP monograph:
 - 1. Heavy metals, mercury, lead, cadmium, or arsenic;
 - 2. Foreign material such as hair, insects, or any similar or related adulterant;
 - 3. Any microbiological impurity, including:
 - a. TAMC;
 - b. TYMC;
 - c. P.aeruginosa
 - d. Aspergillus spp;
 - e. S. aureus;
 - f. Aflatoxin B1, B2,G1, and G2; and
 - g. Ochratoxin A; and
 - h. Pesticide residue; and

4. Whether the batch is within specification for the characteristics of:
 - a. Odor;
 - b. Appearance;
 - c. Fineness; and
 - d. Moisture Content.

New:

An Independent Testing Laboratory shall issue a certificate of analysis to the licensed grower for each batch, with supporting data, to report:

- A. The concentrations of the following compounds:
 1. Δ 9-Tetrahydrocannabinol (THC);
 2. Tetrahydrocannabinolic Acid (THCA);
 3. Cannabidiol (CBD);
 4. Cannabidiolic Acid (CBDA);
 5. The terpenes described in the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP);
 6. Cannabigerol (CBG);
 7. Cannabinol (CBN);
- B. That the presence of the following contaminants does not exceed the levels provided in the Commission's current version of Technical Authority for Medical Cannabis Testing:
 1. Heavy metals
 2. Foreign material such as hair, insects, or any similar or related adulterant;
 3. Microbiological impurities such as:
 - a. Total aerobic microbial count (TAMC);
 - b. Total yeast and mold count (TYMC);
 - c. E. coli;
 - d. Salmonella spp;
 - e. Aflatoxin B1, B2, G1, and G2; and
 - f. Ochratoxin A.; and
 4. Pesticide residue; and
- C. Whether the batch is within specification for the characteristics of:
 1. Odor;
 2. Appearance;
 3. Fineness;
 4. Moisture content; and
 5. Water activity.

Reworking or Reprocessing a batch 10.62.15.06

Current:

- A. If a licensed grower, upon review of the certificate of analysis, determines that a batch meets the specification for the variety, the licensed grower may:
 1. Assign an expiration date to the batch;
 2. Release the batch for distribution; and

3. Revise the status of the batch in the inventory control.
- B. If a licensed grower receives test results that do not meet specifications, the licensed grower may rework or reprocess the batch according to their standard operating procedure. They reworked or reprocessed batch shall be resampled and retested by the Independent Testing Laboratory to ensure that all required specifications are met.
 - C. A licensed grower shall retain every certificate of analysis.

New:

- A. If a licensed grower, upon review of the certificate of analysis, determines that a batch meets the specifications, the licensed grower may release the batch for distribution; and shall:
 1. Assign an expiration date to the batch; and
 2. Revise the status of the batch in the inventory control.
- B. If a licensed grower receives test results that do not meet specifications, the licensed grower may:
 1. Rework or reprocess the batch according to their standard operating procedure;
 2. Provide the reworked or reprocessed batch to be resampled and reanalyzed by the independent testing according to the licensed grower's standard operating procedures for reworked or reprocessed medical cannabis; and
 3. If upon review of the certificate of analysis, determines that the batch meets the specification for reworked and reprocessed medical cannabis the grower may:
 - a. Assign an expiration date to the batch;
 - b. Release the batch for distribution as reworked or reprocessed medical cannabis; and
 - c. Revise the status of the batch in the inventory control.
 4. A licensed grower shall retain every certificate of analysis.

Chairman Smith asked for a motion to adopt proposed draft revisions to Chapter 15 to include the revisions to Independent Testing Laboratory Selection and Requirements, Contents of Certificate of Analysis, and Reworking or Reprocessing a batch. This motion was offered by Commissioner LoDico and seconded by Commissioner Pyles. The Committee voted unanimously to adopt the proposed revisions to Chapter 15.

Chapter 16 Independent Testing Laboratory Registration

Definitions 10.62.16.01 (B) 5-7

Current: Current COMAR does not include education and experience requirements

- (5) "Laboratory Director" means a person who is the manager of the Independent Testing Laboratory who:
- a) Has been awarded an earned masters or doctoral degree from an accredited academic institution in:
 - i) A natural science such as chemistry, physics, or biology; or

- ii) A subspecialty of a natural science such as organic chemistry, biochemistry, or molecular biology; and
- b) Has at least:
 - i) 3 years of documented laboratory experience; and
 - ii) 2 years of documented managerial or supervisory experience; and
 - iii) Is, other than as employed by a registered Independent Testing Laboratory, is independent from any other person and entity licensed or registered by the Commission or otherwise involved in the medical cannabis industry in Maryland.
- (6) "Technical Lead" means an individual who is the technical lead of the Independent Testing Laboratory who has been awarded an earned Bachelor of Science degree or an earned advanced degree from an accredited academic institution in:
 - a) A natural science such as chemistry, physics, or biology; or
 - b) A subspecialty of a natural science such as organic chemistry, biochemistry, or molecular biology.
- (7) "Quality Assurance Manager" means an individual who is the quality assurance manager of the Independent Testing Laboratory who has been awarded an earned Bachelor of Science degree or an earned advanced degree from an accredited academic institution in:
 - a) A natural science such as chemistry, physics, or biology; or
 - b) A subspecialty of a natural science such as organic chemistry, biochemistry, or molecular biology.

Registration 10.62.16.02 B (4)

Current:

- (4) Submit the name, address, date of birth and Social Security Number of each Independent Testing Laboratory employee and a copy of the application form completed by each Independent Testing Laboratory employee.

New:

- 4) For laboratory director and each of the officers, directors and investors who own five percent or more of the investment in the Independent Testing Laboratory entity
 - a) Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository and the Director of the FBI;
 - b) Pay the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland for access to State criminal history records; and
 - c) Request that for these persons their state and national criminal history record information be forwarded to the Commission; and
 - d) For the managers and laboratory director submits a detailed statement of their qualifications.

Registration 10.62.16.02 (C)

Current:

- C) The Commission may issue a provisional registration to an Independent Testing Laboratory that has not yet been issued a certificate of accreditation in Maryland if the Independent Testing Laboratory:
- 1) Submits a completed independent laboratory registration form;
 - 2) Pays the registration fee specified in COMAR 10.62.35.01;
 - 3) Submits a copy of the contract with the accreditation body applying to become accredited accompanied by a copy of the proposed scope of accreditation;
 - 4) Submits evidence the Independent Testing Laboratory has been accredited by the accreditation body in another jurisdiction; and
 - 5) Submits the name, address, and date of birth and Social Security Number of each Independent Testing Laboratory employee and a copy of the application form completed by each Independent Testing Laboratory employee.

New:

- C) The Commission may register or provisionally register an Independent Testing Laboratory to operate in Maryland for a period of two years, after reviewing:
- 1) The application;
 - 2) All pertinent criminal history record information and other evidence regarding good moral character;
 - 3) The established standard operating procedures, including procedures for adequate chain of custody controls for samples for analysis transferred from licensees to the Independent Testing Laboratory; and
 - 4) The qualifications of the laboratory director as having sufficient scientific and managerial expertise.

Registration 10.62.16.02 D-G

Current:

- D) Once it has obtained a certificate of accreditation, a provisionally registered Independent Testing Laboratory shall apply to be registered, but:
- 1) The term of the registration may not exceed the term of the provisional registration; and
 - 2) No additional registration fee need be paid for that term.

New:

- D) An Independent Testing Laboratory may apply for a provisional registration if the Independent Testing Laboratory has not yet been issued a certification of accreditation in Maryland if the Independent Testing Laboratory:
- 1) Submits a completed independent laboratory provisional registration form;
 - 2) Pays the registration fee specified in COMAR 10.62.35.01;
 - 3) Submits a copy of the contract with the accreditation body proposed to accredit the Independent Testing Laboratory in Maryland accompanied by a copy of the proposed scope of the accreditation and the proposed timeline from the accreditation body for issuing a certificate of accreditation to the Independent

Testing Laboratory;

- 4) For the laboratory director and each of the officers and directors, and investors who own five percent or more of the investment in the Independent Testing Laboratory entity –
 - a) Submits to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository and the Director of the FBI;
 - b) Pays the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland for access to State criminal history records; and
 - c) Requests that for these persons their state and national criminal history record information be forwarded to the Commission; and
- 5) For the managers and laboratory director submits a detailed statement of their qualifications.
- 6) A provisional registration shall expire two years after the date it was issued and may not be renewed, although it may be supplanted when the Commission issues a registration under COMAR 10.62.16.02C.
- 7) The Commission shall inspect any provisionally registered Independent Testing Laboratory no less frequently than every six months and batch testing records no less frequently than every three months.
- 8) If an accreditation body denies, restricts, suspends, revokes or fails to renew the accreditation of an Independent Testing Laboratory, the accreditation body and the Independent Testing Laboratory shall notify, within 1 business day of the determination, the Commission and all licensees for which it has been providing analyses, the registration of the Independent Testing Laboratory shall be suspended, and no licensee shall provide medical cannabis or products containing medical cannabis to such Independent Testing Laboratory.

Chairman Smith asked for a motion to adopt proposed draft revisions to Chapter 16 to include the revisions to the Definitions of Laboratory Director, Technical Lead, and Quality Assurance Manager, adding registration requirements, and provisional registration requirements. This motion was offered by Commissioner LoDico and seconded by Commissioner Pyles. The Committee voted unanimously to adopt the proposed revisions to Chapter 16.

Chapter 23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products

Independent Testing Laboratory Selection and Requirements 10.62.23.03

Current:

Upon successful completion of a validation process, the licensee shall use an Independent Testing Laboratory:

- A) That has adopted a standard operating procedure to test medical cannabis and medical cannabis concentrate that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;
- B) To have an agent of the Independent Testing Laboratory obtain samples according to a statistically valid sampling method for each lot;
- C) To analyze the samples according to
 - 1) The most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP); or
 - 2) A scientifically valid methodology that is equal or superior to that of the AHP monograph;
 - 3) In the event of a test result which falls out of specification, the laboratory shall follow their standard operating procedure to confirm or refute the original result;
 - 4) To destroy the remains of the sample of medical cannabis after analysis is completed; and
 - 5) To destroy the remains of the sample of medical cannabis after analysis is completed.

New:

Section has been renumbered to .02

- A) A licensed processor shall use an Independent Testing Laboratory that is registered with the Commission.
- B) An Independent Testing Laboratory shall comply with the Commission's current version of Technical Authority for Medical Cannabis Testing and:
 - 1) Provide trained staff to obtain samples of each lot according to a statistically valid sampling method; --
 - 2) Analyze the samples according to a scientifically valid methodology
 - 3) Provide a certificate of analysis for each lot;
 - 4) Destroy the remains of the samples after analysis is completed according to the Commission's current version of Technical Authority for Medical Cannabis Testing.
 - 5)

Contents of Certificate of Analysis 10.62.23.04

Current:

- A) An Independent Testing Laboratory shall issue a certificate of analysis for each lot, with supporting data, to report:
 - 1) Whether the chemical profile of the lot conforms to the specifications for the lot for the following compounds:
 - a) THC;
 - b) THCA;
 - c) CBD;
 - d) CBDA;
 - e) Terpenes described in the AHP;
 - f) CBG; and
 - g) CBN; and

- 2) That the presence of the following contaminants do not exceed the levels as required by the AHP monograph:
 - a) Any residual solvent or processing chemicals;
 - b) Foreign material such as hair, insects, or any similar or related adulterant;
 - c) Any microbiological impurity; including:
 - (1) TAMC
 - (2) TYMC
 - (3) *P. aeruginosa*;
 - (4) *Aspergillus* spp.;
 - (5) *S. Aureus*;
 - (6) Aflatoxin B1, B2, G1, and G2; and
 - (7) Ochratoxin A; and
 - d) Whether the batch is within specification for:
 - (1) Odor; and
 - (2) Appearance.

New:

Section has been renumbered to .03

- A. An Independent Testing Laboratory shall issue to the licensed processor a certificate of analysis for each lot, with supporting data, to report:
 - (1) The concentrations of the following compounds:
 - (a) Δ 9-Tetrahydrocannabinol (THC);
 - (b) Tetrahydrocannabinolic Acid (THCA);
 - (c) Cannabidiol (CBD);
 - (d) Cannabidiolic Acid (CBDA);
 - (e) The terpenes described in the most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP);
 - (f) Cannabigerol (CBG); and
 - (g) Cannabinol (CBN); and
 - (2) That the presence of the following contaminants do not exceed the levels provided in the Commission's current version of Technical Authority for Medical Cannabis-Testing:
 - (a) Any residual solvent or processing chemicals;
 - (b) Foreign material such as hair, insects, or any similar or related adulterant;
 - (c) Microbiological impurities such as:
 - (i) Total aerobic microbial count (TAMC);
 - (ii) Total yeast and mold count (TYMC);
 - (iii) *E. Coli*;
 - (iv) *Salmonella* spp.;
 - (v) Aflatoxin B1, B2, G1, and G2; and
 - (vi) Ochratoxin A.;
 - (d) Pesticide residue; and
 - (3) Whether the lot is within specification for:
 - (a) Odor; and
 - (b) Appearance and

- (4) That residual levels of volatile organic compounds (VOCs) shall be below the levels provided in the Commission's current version of Technical Authority for Medical Cannabis Testing

Reworking or Reprocessing a Lot 10.62.23.05

Current:

- A. If a licensed processor, upon review of the certificate of analysis, determines that a lot meets the specification for the product, the licensed processor may:
 - (1) Assign an expiration date to the lot;
 - (2) Release the lot for distribution; and
 - (3) Revise the status of the lot in the inventory control.
- B. If a licensed processor receives test results that the lot does not meet specifications, the licensed processor may rework or reprocess the lot according to their standard operating procedure.
- C. The reworked or reprocessed lot shall be resampled and retested by the Independent Testing Laboratory to meet all required specifications.
- D. A licensee shall retain every certificate of analysis.

New:

Section has been Renumbered to .04

- A. If a licensed processor, upon review of the certificate of analysis, determines that a lot meets the specification for the product, the licensed processor may:
 - (1) Assign an expiration date to the lot;
 - (2) Release the lot for distribution; and
 - (3) Revise the status of the lot in the inventory control.
- B. If a licensed processor receives test results that the lot does not meet specifications, the licensed processor may:
 - (1) Rework or reprocess the lot according to their standard operating procedure;
 - (2) Provide the reworked or reprocessed lot to the Independent Testing Laboratory to be resampled and reanalyzed; and
 - (3) If upon review of the subsequent certificate of analysis, determines that the lot meets the specifications for reworked and reprocessed medical cannabis products,
 - (a) Assign an expiration date to the lot;
 - (b) Release the lot for distribution as reworked or reprocessed medical cannabis product; and
 - (c) Revise the status of the lot in the inventory control.
- C. A licensed processor shall retain every certificate of analysis.

Chairman Smith asked for a motion to adopt proposed draft revisions to Chapter 23 to include Independent Testing Laboratory Selection and Requirements, Contents of Certificate of Analysis, and Reworking or Reprocessing a Lot. This motion was offered by Commissioner LoDico and seconded by Commissioner Pyles. The Committee voted unanimously to adopt the proposed revisions to Chapter 23.

Adjournment

After querying Commissioners as to any New Business and receiving no response, Chairman Smith asked for a Motion to Adjourn which was offered by Commissioner LoDico, and appropriately seconded by Commissioner Pyles. The meeting adjourned at 2:42 pm.