

**PROPOSED AMENDMENT OF REGULATIONS REGARDING
MEDICAL CANNABIS QUALITY CONTROL, INDEPENDENT
TESTING LABORATORIES, AND MEDICAL CANNABIS
CONCENTRATES AND MEDICAL CANNABIS-INFUSED
PRODUCTS; COMPLAINTS AND RECALL; INSPECTION**

10.62.15

10.62.16

10.62.17

10.62.23

10.62.33

10.62.15 Medical Cannabis Grower Quality Control

Authority: Health General Article, §§13-3301, 13-3302, 13-3306, and 13-3311, Annotated Code of Maryland

.01 Production and Process Controls.

A. A licensed grower shall cultivate each plant and produce each batch of medical cannabis in conformity with the standard operating procedures.

B. A licensed grower shall record the cultivation process of each batch in accordance to standard operating procedures to ensure:

- (1) Consistency of the batch with the variety; with the specification for the batch; and
- (2) Accuracy of the day-to-day production.

C. A licensed grower shall record in the log any deviation defined as a material change from the standard operating procedure which would impact the quality of the batch in the log.

D. A licensed grower may not release any batch of medical cannabis if there was any deviation in production of the batch from the standard operating procedure unless:

(1) After independent testing of the batch in accordance with the criteria set forth in Regulation .04 of this chapter the batch is tested by an independent testing laboratory and the licensee determines, as a result of such testing, that the batch meets the specification for the variety; and

(2) The determination is recorded. This subsection is unnecessary. The only criterion for release should be a satisfactory ITL report.

.02 In-Process Inspection by Grower.

During the process of cultivation, a licensed grower shall regularly inspect each plant to ensure proper growth and absence of pests and disease.

.03 Holding Procedure.

A licensed grower shall hold medical cannabis in secure, segregated storage until released for distribution.

.04 Independent Testing Laboratory Selection and Requirements.

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 Guidance 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.

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 Pharmacopoeia (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.

.05 Contents of Certificate of Analysis.

An independent testing laboratory shall issue a certificate of analysis to the licensed grower for each batch, with supporting data, to report:

A. Whether the chemical profile of the batch conforms to the variety for ~~The concentrations of~~ the following compounds:

(1) Δ^9 -Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinolic Acid (THCA);

(3) Cannabidiol (CBD);

(4) Cannabidiolic Acid (CBDA); ~~and~~

(5) The terpenes described in the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopoeia (AHP);

(6) Cannabigerol (CBG); ~~and~~

(7) Cannabinol (CBN); and

B. That the presence of the following contaminants does not exceed the levels ~~as required by the AHP monograph provided in the Commission's current version of Technical Guidance for Medical Cannabis Testing:~~

(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~~ Microbiological impurities such as:

(a) Total aerobic microbial count (TAMC);

(b) Total yeast ~~and~~ mold count (TYMC);

(c) ~~P. aeruginosa;~~ E. coli;

(d) ~~Aspergillus spp.;~~ Salmonella spp.;

(e) S. aureus;

~~(f) (f) Aflatoxin B1, B2, G1, and G2; and~~

~~(g) (g) Ochratoxin A.; and~~

~~(h) Pesticide residue; and~~

(4) Pesticide residue; and

C. Whether the batch is within specification for the characteristics of:

(a) Odor;

(b) Appearance;

(c) Fineness; and

(d) Moisture content; ~~and~~

(e) Water activity.

.06 Grower Determination That a Batch May be Released.

A. If a licensed grower, upon review of the certificate of analysis, determines that a batch meets the specifications 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:

(1) Rework ~~rework~~ or reprocess the batch according to their standard operating procedure. ~~procedure;~~

(2) Provide the ~~The~~ reworked or reprocessed batch shall to be resampled and ~~retested~~ reanalyzed by the independent testing laboratory ~~to ensure that all required specifications are met.~~ according to the licensed grower's standard operating procedures for reworked or reprocessed medical cannabis; and **Are we comfortable with this?**

(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:

(1) (a) Assign an expiration date to the batch;

(2) (b) Release the batch for distribution as reworked or reprocessed medical cannabis; and

- (3) (c) *Revise the status of the batch in the inventory control.*
- C. *A licensed grower shall retain every certificate of analysis.*
- D. *A batch meets specification if the certificate of analysis reveals that no criterion exceeds or is below specification by 15 percent.*
- E. *If any part of a batch that is offered for sale is found to exceed or is below specification by more than 15 percent, the grower shall order a recall of the entire batch.*

.07 Stability Testing and Retention Sampling.

A. *A licensed grower shall ~~provide~~ enable an independent testing laboratory to obtain a methodologically valid number of samples from each batch a sample from each released batch to an independent testing laboratory sufficient to perform stability testing as provided in the Commission's current version of Technical Guidance for Medical Cannabis Testing.*

B. *The independent testing laboratory shall hold samples for stability testing and conduct analyses of the stability testing samples at the following intervals after harvest – 6 months, one year, and two years at 6 month intervals to:*

- (1) *Ensure product potency and purity; and*
- (2) *Provide support for expiration dating; and*
- (3) *Destroy the samples one year after the expiration date. What if the expiration date is less than two years?*

B. C. *A licensed grower shall retain a sufficient sample from each released batch to:*

- (1) *Sufficient to provide Provide for follow-up testing if necessary; and*
- (2) *Properly store Store the sample properly for one year past the date of expiration of the batch, after which it may be destroyed.*

.08 Report of Products Offered for Distribution.

A licensed grower shall submit to the Commission quarterly a list of the products and their specifications that the licensed grower offered for distribution in the previous quarter.

10.62.16 Independent Testing Laboratory Registration

Authority: Health General Article, §§13-3301, 13-3302, and 13-3311, Annotated Code of Maryland

.01 Definition.

A. *In this chapter, the following term have the meaning indicated.*

B. *Terms Defined.*

- (1) *"Accreditation body" means a nonprofit, an impartial organization that requires conformance to ISO/IEC 17025 requirements and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement for Testing.*
- (2) *"Certification of accreditation" means a certificate issued by an accrediting body for the independent testing laboratory facility, or entity, or site to be registered in Maryland.*
- (3) *"Independent testing laboratory" means any facility, or entity, or site in Maryland that offers or performs tests of medical cannabis or products containing medical cannabis and whose ownership and management is independent of any Maryland entity that grows, processes or dispenses cannabis. Current 10.62.16.05B. is to be deleted.*
- (4) *"Scope of accreditation" means a document issued by the an accreditation body which describes the methodologies, range, and parameters for testing medical cannabis or products containing medical cannabis for which the accreditation has been granted.*
 - (a) *"Laboratory Director" means a person who is the manager of the independent testing laboratory who:*
 - (i) *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.*

.02 Registration.

A. *In order to analyze medical cannabis or products containing medical cannabis in Maryland, an An independent testing laboratory shall register with be registered by the Commission.*

B. *To apply to register, an independent laboratory shall:*

- (1) *Submit a completed independent laboratory registration form;*
- (2) *Pay the registration fee specified in COMAR 10.62.35.01.*

(3) Submit a copy of the certification of accreditation *for the independent testing laboratory facility in Maryland* accompanied by the scope of accreditation; and

(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. 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.~~

~~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.~~

~~Laboratory director defined at top with minimum educational and managerial experience set forth.~~

~~C. The Commission may issue a~~

~~D. An independent testing laboratory may apply for a provisional registration to an if the independent testing laboratory ~~that~~ 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 applying to become accredited *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) Submits evidence the independent testing laboratory has been accredited by the accreditation body in another jurisdiction; and *This requirement should be dropped because it precludes the start-up of Maryland-based independent testing laboratories that have not previously operated in another jurisdiction.*~~

~~(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.~~

~~(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.~~

~~E. 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.~~

~~F. 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.~~

~~G. 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. *Can we direct the accrediting body to do anything? We have not registered them. They might not even do business in MD. Should the reference to them be dropped or modified?*~~

~~D. Once it has obtained a certification 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.~~

.03 Standards of Care.

- A. The independent testing laboratory shall follow the methodologies, ranges, and parameters which are contained in the scope of the accreditation for testing medical cannabis or products containing medical cannabis.
- B. The independent testing laboratory shall require each independent testing laboratory employee to complete and execute an application for employment on a form provided by the Commission.
- C. The independent testing laboratory shall establish and follow written procedures for verifying the experience and education of laboratory employees.
- D. The independent testing laboratory shall submit the registration information for each independent testing laboratory employee within 15 days after the date the independent testing laboratory employee was hired.
- E. Upon termination of the association of the registered independent testing laboratory employee with the independent testing laboratory, the independent testing laboratory shall:
 - (1) Obtain any keys or other entry devices from the terminated independent testing laboratory employee;
 - (2) Ensure the terminated independent laboratory employee can no longer gain access to the laboratory premises; and
 - (3) Within 1 business day of the termination of independent laboratory employee, the independent testing laboratory shall notify the Commission of the termination.
- F. ~~The independent testing laboratory shall notify the Commission within 1 business day after the independent testing laboratory obtains notice of any kind that its accreditation has been denied, suspended or revoked.~~ Moved to 10.62.16.02G and expanded.

.04 Term and Renewal.

- A. The registration is valid for 2 years.
 - B. ~~The registration may be renewed by submitting to the Commission:~~ *The Commission may renew the registration of an independent testing laboratory after reviewing the application for renewal of registration by the independent testing laboratory including:*
 - (1) A copy of the independent testing laboratory registration *application renewal* form;
 - (2) Payment of the registration fee specified in COMAR 10.62.35; and
 - (3) Submission of copies of the most recent:
 - (a) Assessment from the accreditation body; and
 - (b) Periodic review of the proficiency testing of the results obtained by the independent testing laboratory.
- Given the expanded nature of the registration process, does renewal need more requirements?

.05 Independent Testing Laboratory Responsibilities.

- No independent testing laboratory may handle, test, or analyze cannabis or cannabis products unless the independent testing laboratory: ~~A. Has *has* been registered by the Commission; .~~
- ~~B. Is independent from all other persons and entities involved in the medical cannabis industry;~~
 - ~~C. Is accredited by an accreditation body or has a provisional registration from the Commission; and~~
 - ~~D. Has established standard operating procedures that provide for adequate chain of custody controls for samples transferred to the independent testing laboratory for testing.~~

10.62.17 Complaints, Adverse Events, and Recall

Authority: Health General Article, §§13-3301, 13-3302, 13-3304, 13-3305, 13-3306, 13-3307 13-3309, 13-3311, Annotated Code of Maryland

.01 Receipt and Documentation of Complaints and Adverse Events.

A licensed grower, licensed processor, licensed dispensary, certifying ~~physician~~ *provider*, *independent testing laboratory*, and the Commission shall establish a procedure to receive, organize, store and respond to all oral, written, electronic or other complaints regarding medical cannabis and adverse events.

.02 Report of Serious Adverse Event to Commission and Interested Parties.

- In the event a complaint associated with a serious adverse event is received, a licensee, *independent testing laboratory*, or certifying ~~physician~~ *provider*, shall promptly report the complaint to:
- A. The Commission;
 - B. Either the licensed grower from which the medical cannabis originated, or the licensed processor from which the medical cannabis concentrate originated; and
 - C. The certifying ~~physician~~ *provider* caring for the qualifying patient.

.03 Complaint Investigation by Grower or Dispensary.

- A. Whenever a complaint regarding the quality or safety of medical cannabis is received by a licensed grower, licensed processor or licensed dispensary, a licensee shall, within 24 hours, review the complaint to determine if it is substantive or reports a serious adverse event.
- B. If a licensee determines that the complaint is substantive or reports a serious adverse event, a licensee shall:

- (1) Promptly determine the batch number or lot number of the medical cannabis, the medical cannabis finished product, and medical cannabis concentrate that is the subject of the complaint; and
- (2) Investigate the record and circumstances of the production of the batch and lot to determine:
 - (a) If there was a deviation from the standard operating procedure in the production of the medical cannabis by reviewing production logs; and
 - (b) If the sample meets specification by submitting parts of the retention samples of the batch and lot to an independent testing laboratory.
- C. If sample analysis of the batch or lot reveals that the batch or lot fails to meet specification, the licensee shall:
 - (1) Order a recall of all products derived from or included in the batch or lot;
 - (2) Notify all patients, caregivers, and dispensaries who may have obtained medical cannabis products from such a batch or lot of the recall; and
 - (3) Offer and pay reimbursement for any returned medical cannabis.
- D. In a case of a report of a serious adverse event or a substantive complaint, if the investigation reveals a deviation from the standard operating procedure in the production of the batch or lot, the licensee may:
 - (1) Order a recall of all products derived from or included in the batch or lot;
 - (2) Notify all patients, caregivers, and dispensaries who may have obtained medical cannabis products from such a batch or lot of the recall; and
 - (3) Offer and pay reimbursement for any returned medical cannabis.

.04 Custody of Returned Recalled Material.

- A. The licensee shall develop a procedure to ensure medical cannabis that is recalled is stored and segregated until disposal of recalled material is authorized by the Commission.
- B. Within 24 hours of the receipt of notice from the Commission that the disposal of recalled medical cannabis is authorized, the licensee shall dispose of the recalled medical cannabis according to the standard operating procedure.

10.62.23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products

Authority: Health General Article, §§13-3301, 13-3302, 13-3309, and 13-3311, Annotated Code of Maryland

.01 Definitions.

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms Defined:
 - (1) "License" means a license issued by the Commission to operate as a processor.
 - (2) "Licensee" means a licensed processor.
 - (3) "Tincture" means a cannabis infused solution derived either directly from the cannabis plant or from a processed cannabis extract and typically combined with alcohol, glycerin, or vegetable oils.

None of these words need to be defined in this chapter. Tincture is not even used in this chapter!
Delete this regulation and renumber all others in the chapter.

.02.01 Controls for Processing of Medical cannabis Concentrates and Medical cannabis-Infused Products.

- A. A licensed processor of medical cannabis concentrates and medical cannabis-infused products shall:
 - (1) Develop standard operating procedures, good manufacturing practices, and a training plan before producing medical cannabis concentrates and medical cannabis-infused products;
 - (2) Require that any person involved in processing medical cannabis concentrates and medical cannabis-infused products is:
 - (a) Appropriately trained in accordance to their job description to safely operate and maintain the system used for processing and attendance records are retained;
 - (b) Has direct access to applicable material safety sheets and labels; and
 - (c) Follows **U.S. Occupational Safety And Health Administration** protocols for handling and storage of all chemicals;
 - (3) Assign a unique lot number to each lot of medical cannabis concentrate or medical cannabis-infused product; and
 - (4) Carry out a validation process on the first 10 lots of any new medical cannabis concentrate, medical cannabis-infused product, or process, to establish the validity of the production process.
- ~~B. A licensed processor shall establish a standard operating procedure for the methods, equipment, solvents, and gases when processing medical cannabis concentrates and medical cannabis-infused products. This is redundant to the language in A.(1) above.~~
- ~~C. If a licensee licensed processor uses a solvent based extraction method the solvents shall be at least 99 percent pure.~~
- ~~D. B. A standard operating procedure of a licensed processor shall require:~~

- (1) ~~Use Any of solvents used be at least 99 percent pure, and used~~ in a professional grade, closed-loop extraction system designed to recover the solvents;
- (2) ~~Work Processing to be done in --~~
- (i) ~~a spark-free environment;~~
 - (ii) ~~with With proper ventilation; and~~
- (3) ~~(ii) Following all applicable U.S. Occupational Safety And Health Administration regulations; and~~
- (iv) ~~Following all local and State fire, safety and building codes in the processing and storage of the solvents-~~
- and
- (v) ~~In the case of carbon dioxide gas extraction, use of vessels rated to a minimum of 900 pounds per square inch.~~

- ~~E. If a licensee uses carbon dioxide gas extraction the standard operating procedure shall require:-~~
- (1) ~~Every vessel be rated to a minimum of 900 pounds per square inch;~~
 - (2) ~~Use a professional grade, closed loop system;~~
 - (3) ~~Follow all applicable OSHA regulations, and local fire, safety and building codes in the processing and the storage of the solvents; and~~
 - (4) ~~Use carbon dioxide that is at least 99 percent pure.~~

~~F. C. A licensed processor may use heat, screens, presses, steam distillation, ice water, and other methods to produce medical cannabis concentrates.~~

~~.03.02 Independent Testing Laboratory Selection and Requirements.~~

- A. ~~A licensed processor shall use an independent testing laboratory that is registered with the Commission.~~
- B. ~~An independent testing laboratory shall:~~
- (1) ~~Provide trained staff to obtain samples of each lot --~~
 - (a) ~~According to a statistically valid sampling method; and~~
 - (b) ~~Such samples in total may not be less than 0.5% of the mass of the lot;~~
 - (2) ~~Analyze the samples according to a scientifically valid methodology that complies with the Commission's current version of Technical Guidance for Medical Cannabis Testing;~~
 - (3) ~~Provide a certificate of analysis for each lot;~~
 - (4) ~~Destroy the remains of the samples after analysis is completed.~~

~~Upon successful completion of a validation process, the licensee shall use an independent testing laboratory that:~~

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;~~

~~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 destroy the remains of the sample of medical cannabis after analysis is completed.;~~ and

~~F. To destroy the remains of the sample of medical cannabis after analysis is completed.~~

~~.04.03 Contents of Certificate of Analysis.~~

A. ~~An independent testing laboratory shall issue to the licensed processor 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 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 as required by the AHP monograph provided in the Commission's current version of Technical Guidance for Medical Cannabis Product Testing:~~

- (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~~ **Microbiological impurities such as:**
 - (i) Total aerobic microbial count (TAMC);
 - (ii) Total yeast **and** mold count (TYMC);
 - (iii) ~~P. aeruginosa~~ **E. Coli;**
 - (iv) ~~Aspergillus spp.~~ **Salmonella spp.;**
 - (v) ~~S. aureus;~~
 - (vi) ~~(v) Aflatoxin B1, B2, G1, and G2; and~~
 - (vii) ~~(vi) Ochratoxin A.; and~~
- (d) (3) Whether the ~~batch~~ **lot** is within specification for:
 - (i) Odor; and
 - (ii) 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 Guidance for Medical Cannabis Product Testing*

.05.04 Licensed Processor Determination That a Lot May be Released.

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~~ **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. ~~The reworked or reprocessed lot shall be resampled and retested by the independent testing laboratory to meet all required specifications.~~

D. A ~~licensee~~ **licensed processor** shall retain every certificate of analysis.

.06.05 Stability Testing and Retention Sampling.

A. A ~~licensee~~ **licensed processor** shall ~~enable an independent testing laboratory to obtain methodologically valid samples from each lot~~ **provide a sample from each released lot to an independent testing laboratory** sufficient to perform stability testing ~~at 6 month intervals to~~ **as provided in the Commission's current version of Technical Guidance for Medical Cannabis Product Testing:**

- (1) Ensure product potency and purity; and
- (2) Provide support for expiration dating.

B. A ~~licensee~~ **licensed processor** shall retain a **sufficient** sample from each released lot **to:**

- (1) ~~Sufficient to provide~~ **Provide** for follow-up testing if necessary; and
- (2) ~~Properly store~~ **Store** the sample **properly** for 1 year past the date of expiration of the lot.

.07.06 Report of Products Offered for Distribution.

A ~~licensee~~ **licensed processor** shall submit to the Commission within 30 days following the end of a quarter a list of the products and the products' specifications that the ~~licensee~~ **licensed processor** offered for distribution in the quarter.

Chapter 33 Inspection

10.6233.08 Report of Inspection.

A. An inspector shall:

- (1) Prepare a report of:
 - (a) The observations and findings of the inspection; and
 - (b) Any suggestions or demands for corrective action;
- (2) Deliver a copy of the report to the inspected entity and obtain a receipt for the delivery; and
- (3) If possible, discuss the inspection and inspection report with the licensee **or registrant.**

B. If an inspection report contains a suggestion or demand for corrective action, within 10 business days from the delivery of the report, the inspected entity shall:

- (1) Respond in writing to every suggestion or demand for corrective action; and

(2) Set forth the plan for corrective action to be taken and the timetable for correction.

C. If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, or the risk to public health, an inspector may direct that the licensed *or registered* premises may not distribute or participate in the *production, analysis or* distribution of any medical cannabis *or medical cannabis-infused product* until the violation has been corrected and the premises pass re-inspection.

###

THIS DOCUMENT HAS BEEN ARCHIVED