CHAPTER 1171a. LABORATORIES

Sec.

Authority

The provisions of this Chapter 1171a added under section 301(a)(3) and (b) of the Medical Marijuana Act (35 P.S. § 301(a)(3) and (b)), unless otherwise noted.

Source

The provisions of this Chapter 1171a added March 3, 2023, effective March 4, 2023, 53 Pa.B. 1275, unless otherwise noted.

§ 1171a.22. Laboratories generally.

(a) A laboratory may not identify, collect, handle or conduct tests on samples from a grower/processor or conduct tests on test samples for the Department unless the laboratory has been approved by the Department under § 1171a.23 (relating to approval of laboratories) and has entered into a written contract with the grower/processor under § 1171a.29 (relating to testing requirements).

(b) The Department will post on its web site a current list of approved laboratories.

(c) An approved laboratory shall employ a director to oversee and be responsible for the identification, collection, handling and testing operations of the approved laboratory. A director shall have earned, from a college or university accredited by a National or regional accrediting authority, one or more of the following:

(1) A doctorate of science or an equivalent degree in chemistry, biology, or a subdiscipline of chemistry or biology.

(2) A master's level degree in a chemical or biological science and a minimum of 2 years post-degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.

(3) A bachelor's degree in a biological science and a minimum of 4 years post-degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.

(d) A principal or employee of a medical marijuana organization may not also own, be employed by or be affiliated with an approved laboratory that has a contract with that medical marijuana organization.

(e) An approval issued by the Department to a laboratory under this part is valid for 2 years from the date of issuance and is valid only for the laboratory named and the location specified in the approval.

(f) An approval issued by the Department to a laboratory under this part is not transferable to any other person or any other location unless the laboratory obtains the prior written consent of the Department.

(g) Notwithstanding the definitions of ''harvest batch,'' ''harvest lot,'' ''medical marijuana extract,'' ''process lot,'' ''processing,'' ''sample'' and ''test sample,'' this section and §§ 1171a.23—1171a.28 shall also apply to an approved laboratory's testing of harvested hemp.

§ 1171a.23. Approval of laboratories.

(a) A laboratory wishing to identify, collect, handle and conduct tests on samples and test samples and other items used by a grower/processor in the growing and processing of medical marijuana and medical marijuana products as required under the act and this part shall submit an application for approval to the Department. The application is available on the Department's public web site.

(b) An application submitted under this section must include the following information:

(1) The name and address of the laboratory applicant or its authorized agent.

(2) The name and address of the owner of the laboratory applicant, and if applicable, the medical or pharmacy licensure information regarding the owner.

(3) The name of the laboratory applicant's proposed director and technical personnel who are or will be employed by the laboratory at the location to be approved.

(4) A copy of the laboratory applicant's most recent certificate of accreditation.

(5) Copies of the standard operating procedures and sampling procedures adopted by the laboratory applicant and approved by the accreditation body that issued the certificate of accreditation to the laboratory applicant.

(6) A list of the specialized laboratory equipment utilized or to be utilized by the laboratory applicant in its testing operations, including the manufactur-

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er's name and the serial and model number of the equipment, and other specifications as may be required by the Department.

(7) A description of the tests which are capable of being conducted by the laboratory applicant at the location to be approved.

(8) A description of the laboratory applicant's quality assurance program, which must be in compliance with § 1171a.32 (relating to quality assurance program).

(9) The procedures to be followed to establish chain of custody when collecting samples or test samples.

(10) A copy of the evaluation process that the laboratory applicant uses or will use to monitor, evaluate and document the competency of employees when testing samples and test samples and overseeing quality assurance controls.

(11) Other information required by the Department.

(c) By submitting an application for approval to the Department, a laboratory applicant consents to an investigation of any person, information or physical location the Department or its authorized agents deem appropriate for the Department to make a determination of the laboratory applicant's ability to meet the requirements under the act and this part.

(d) An application for approval submitted under this chapter must include a statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(e) The Department may issue an approval under this chapter if the Department determines that the laboratory applicant is financially and professionally suitable to conduct the testing required under the act and this part.

Cross References

This section cited in 28 Pa. Code § 1171a.22 (relating to laboratories generally); and 28 Pa. Code § 1171a.25 (relating to renewal of an approval issued to a laboratory).

§ 1171a.24. Suspension or revocation of an approval issued to a laboratory.

(a) An approval issued by the Department under this chapter may be suspended or revoked if the Department determines that the approved laboratory has engaged in unethical practices or has failed to do any of the following:

(1) Maintain proper standards of accuracy.

(2) Comply with the requirements of the act or this part applicable to the approved laboratory.

(b) An approval issued by the Department under this chapter may be revoked if the Department determines that the approved laboratory has engaged in any of the following conduct:

(1) Dishonest reporting.

(2) Repeated errors in conducting the required testing.

(3) Allowing unauthorized individuals to perform testing or to sign reports.

(4) Inclusion of false statements in the application for approval or renewal.

(5) Advertising of medical marijuana testing services to the general public.

(6) Knowingly accepting a sample from an individual other than a grower/processor or a test sample from an individual other than the Department or an authorized agent of the Department.

(7) Failure to maintain standard operating procedures approved by the accreditation body that issued the certificate of accreditation to the approved laboratory.

(8) Failure to properly enter test results into the electronic tracking system.

(9) Loss by the approved laboratory of its certificate of accreditation.

Cross References

This section cited in 28 Pa. Code § 1171a.22 (relating to laboratories generally).

§ 1171a.25. Renewal of an approval issued to a laboratory.

An approved laboratory wishing to renew its approval under this chapter shall, not more than 6 months nor less than 4 months prior to the expiration of the approval, submit an application under § 1171a.23 (relating to approval of laboratories) and update the information required to be submitted with the application as necessary.

Cross References

This section cited in 28 Pa. Code § 1171a.22 (relating to laboratories generally).

§ 1171a.26. Stability testing and retention of samples.

(a) A grower/processor shall retain a sample in an amount sufficient to perform stability testing from each process lot to ensure product potency and purity, and shall maintain documentation to support the expiration date.

(b) The stability test shall be performed at 6-month intervals for the duration of the expiration date period as listed on the medical marijuana product and once within 6 months of the expiration date if the medical marijuana product is still in inventory at a dispensary in this Commonwealth as determined by the seed-to-sale system.

(c) A grower/processor shall retain a sample from each process lot for subsequent stability testing, in an amount equivalent to the sample size initially identified and collected by an approved laboratory, for the duration of the expiration date period as listed on the medical marijuana product.

Cross References

This section cited in 28 Pa. Code § 1171a.22 (relating to laboratories generally).

§ 1171a.27. Sampling procedures for testing.

(a) An approved laboratory shall ensure that its employees prepare all samples in accordance with policies and procedures that include appropriate information necessary for identifying, collecting and transporting samples in a manner that does not endanger the integrity of the samples for any testing required by this part.

(b) The sampling policies must:

(1) Be appropriate to the matrix being sampled.

(2) Require samples to be representative of the harvest batch, harvest lot or process lot.

(3) Require the amount being removed to be based on applicable statistical criteria.

(c) The sampling procedures must include the following procedures:

(1) Surveying the conditions in which the sample is being stored.

(2) Using appropriate sampling equipment and consistent procedures.

(3) Selecting and removing equal portions for each sample.

(4) Random or systematic taking of samples throughout the harvest batch or harvest lot.

(5) Obtaining a minimum number of samples based on harvest batch or harvest lot size.

(6) Checking all parts of the harvest batch when harvest lots are created from that harvest batch.

(7) Recording on a form prescribed by the Department all observations and procedures used when collecting the sample.

(8) Creating a unique sample identification number that will be linked to the harvest batch or harvest lot number assigned by the grower/processor in the electronic tracking system.

(9) Entering all required information into the electronic tracking system.

Cross References

This section cited in 28 Pa. Code § 1171a.22 (relating to laboratories generally).

§ 1171a.28. Selection protocols for samples.

(a) An employee of an approved laboratory may enter a grower/processor facility for the purpose of identifying and collecting samples and shall only have access to limited access areas in the facility for these purposes.

(b) An employee identifying and collecting samples under subsection (a) shall follow the chain of custody procedures included in the approved laboratory's application and approved by the Department.

(c) While at a grower/processor facility, an employee of an approved laboratory shall identify and collect the following for testing:

(1) Samples at the time of harvest.

(2) Samples of medical marijuana product before being sold or provided to a dispensary.

(3) Test samples at other times when requested by the Department.

(4) Samples for stability testing.

Cross References

This section cited in 28 Pa. Code § 1171a.22 (relating to laboratories generally); 28 Pa. Code § 1171a.29 (relating to testing requirements); 28 Pa. Code § 1171a.3 (relating to test results and reporting); and 28 Pa. Code § 1171a.35 (relating to laboratory reporting).

§ 1171a.29. Testing requirements.

(a) Prior to conducting any testing of a sample at the request of a grower/processor, an approved laboratory shall enter into a written contract with the grower/processor for testing services. The approved laboratory shall provide a copy of the contract to the Department within 2 days following the Department's request.

(b) A grower/processor shall submit through the electronic tracking system a request to the approved laboratory with which it has a written contract under subsection (a) for each test to be conducted.

(c) Testing shall be performed as follows:

(1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product.

(2) An approved laboratory other than the one that tested the harvest batch or harvest lot shall test samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.

(3) An approved laboratory may test other samples and test samples at the request of a grower/processor or the Department.

(d) The samples identified in subsection (c) shall be tested for the following:

(1) Pesticides.

(2) Solvents.

(3) Water activity and moisture content.

(4) THC and CBD concentration.

(5) Microbiological contaminants.

(6) Terpenes.

(7) Heavy metals.

(8) Mycotoxins.

(e) Sampling and testing under this chapter shall be conducted with a statistically significant number and size of samples and with approved methodologies to ensure that all harvest batches, harvest lots and medical marijuana products are adequately tested for contaminants and that the cannabinoid profile is consistent throughout the harvest batch, harvest lot or medical marijuana products. Testing

methods must be fully validated to address the accuracy, precision, specificity, linearity, range and sensitivity of the testing method.

(e.1) PCR testing is not an approved methodology.

(f) An approved laboratory may not test any samples when there is evidence of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection of the sample and testing, or any other obvious circumstance that compromises the sample.

(g) An approved laboratory shall enter test results for samples collected under § 1171a.28(c)(1) and (2) (relating to selection protocols for samples) into the electronic tracking system and, under § 1151a.40 (relating to management and disposal of medical marijuana waste), properly dispose of all tested and untested samples and test samples.

Cross References

This section cited in 28 Pa. Code § 1171a.22 (relating to laboratories generally); 28 Pa. Code § 1171a.31 (relating to test results and reporting); 28 Pa. Code § 1171a.35 (relating to laboratory reporting); and 28 Pa. Code § 1171a.39 (relating to clarification of the requirements of §§ 1171a.29(c) and 1171a.31(c)—statement of policy).

§ 1171a.30. Standards for testing.

(a) An approved laboratory shall follow the methodologies, ranges and parameters that are consistent with the scope of the certificate of accreditation issued to the laboratory and in accordance with this chapter.

(b) Testing methods used by an approved laboratory shall meet or exceed the minimum standards under the American Herbal Pharmacopeia's "Cannabis Inflorescence Standards of Identity, Analysis and Quality Control," 2014 Revision Edition.

Cross References

This section cited in 28 Pa. Code § 1151a.27 (relating to requirements for growing and processing medical marijuana).

§ 1171a.31. Test results and reporting.

(a) Only the results of the following tests are in compliance with the testing requirements of this chapter:

(1) Tests conducted on harvest batch samples or harvest lot samples requested by a grower/processor under § 1171a.29 (relating to testing requirements) and identified and collected by an employee of an approved laboratory.

(2) Tests conducted on process lot samples requested by a grower/processor under § 1171a.29 and identified and collected by an employee of an approved laboratory.

(b) The test results for each sample collected under § 1171a.28(c)(1) and (2) (relating to selection protocols for samples) shall be entered into the electronic tracking system and shall only be accessible to the grower/processor submitting the sample and to the Department.

(c) If a sample fails any test required under § 1171a.29, the following apply to the sample:

(1) The approved laboratory that performed the initial test may re-test the sample upon a request from the grower/processor in accordance with subsection (d).

(1.1) If the re-tested sample fails, the lot shall be disposed of under § 1151a.40 (relating to management and disposal of medical marijuana waste) unless the lot failed only for yeast or mold and the grower/processor chooses to process the lot into a topical form under section 702(a)(3) of the act (35 P.S. § 10231.702(a)(3)).

(2) If the sample passes the re-test, another approved laboratory shall sample the same harvest batch, harvest lot or process lot to confirm the passing test result.

(2.1) Following the confirming test, and to determine whether to accept the confirming result, the Department may require any or all of the following:

(i) The grower/processor to provide a root cause analysis for the initially failed result.

(ii) Documentation from the grower/processor and the confirming laboratory that required testing procedures were followed and detailing chain of custody.

(iii) An affirmation by the grower/processor that the sample was not modified in any manner and was not subjected to any form of decontamination or remediation between the initially failed and confirming passing results.

(iv) An additional confirming test by an approved laboratory other than the two who conducted the first and second tests.

(3) If the Department does not agree to accept the confirming results from the approved laboratory, the sample shall be disposed of by the approved laboratory under § 1151a.40.

(d) A grower/processor shall notify the Department and the approved laboratory through the electronic tracking system of its intent to re-test the sample or test another sample from the same harvest batch, harvest lot or process lot that failed a test.

(e) An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot or pro-

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cess lot sample that was tested at the request of the grower/processor. The certificate of analysis must include the following information:

(1) Whether the chemical profile of the harvest batch, harvest lot or process lot conforms to the approved chemical profile of the strain for the following compounds:

(i) THC.
(ii) THCA.
(iii) CBD.
(iv) CBDA.
(v) CBC.
(vi) CBN.
(vii) THCV.
(viii) CBDV.
(ix) CBG.
(x) D8.

(2) That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the approved maximum levels for the following:

(i) Heavy metals, mercury, lead, cadmium or arsenic.

(ii) Foreign material such as hair, insects, or any similar or related adulterant.

(iii) Microbiological impurity, including any of the following:

(A) Total aerobic microbial count.
(B) Total yeast mold count.
(C) *P. aeruginosa.*
(D) *Aspergillus spp.*
(E) *S. aureus.*
(F) Aflatoxin B1, B2, G1 and G2.
(G) Ochratoxin A.
(H) Pesticide residue.
(I) *E. coli.*
(J) *Salmonella.*

(iv) Whether the harvest batch, harvest lot or process lot is within the specification for the strain for the following characteristics:

(A) Odor.
(B) Appearance.
(C) Fineness.
(D) Moisture content, when applicable for process lot.

(f) If an approved laboratory detects an amount of a pesticide that exceeds normal or acceptable limits, the approved laboratory shall notify the Department immediately. If an approved laboratory detects a prohibited pesticide or a pesticide within the National Institute of Standards and Technology library during the testing process, the approved laboratory shall notify the Department immediately.

An approved laboratory shall report whether any residual pesticides are detected above the limit of detection and shall report the results to the Department immediately. The Department may obtain test samples from a grower/processor to conduct pesticide residue testing.

(1) An approved laboratory shall establish a limit of quantification of 0.1 ug/g or lower for all pesticides.

(2) An approved laboratory shall analyze at minimum 0.5 grams of the representative sample of medical marijuana to determine whether residual pesticides are present.

(g) The Department will maintain oversight of testing methods and sampling standards under this chapter. The Department may conduct onsite visits and review certificates of analysis submitted by an approved laboratory.

Cross References

This section cited in 28 Pa. Code § 1171a.35 (relating to laboratory reporting); and 28 Pa. Code § 1171a.39 (relating to clarification of the requirements of §§ 1171a.29(c) and 1171a.31(c)—statement of policy).

§ 1171a.32. Quality assurance program.

(a) An approved laboratory shall establish and implement a quality assurance program to ensure that measurements are accurate, errors are controlled, and devices used for testing are properly calibrated annually or more frequently if recommended by the manufacturer.

(b) The quality assurance program required under subsection (a) must include the following components:

(1) An organizational chart that includes the testing responsibilities of each employee of the approved laboratory named in the chart.

(2) A description of sampling procedures to be utilized.

(3) Appropriate chain of custody protocols.

(4) Analytical procedures.

(5) Data reduction and validation procedures.

(6) A plan for implementing corrective action, when necessary.

(7) A requirement for the provision of quality assurance reports to management.

(8) A description of the internal and external quality control systems.

Cross References

This section cited in 28 Pa. Code § 1171a.23 (relating to approval of laboratories).

§ 1171a.33. Transporting samples.

(a) An employee of an approved laboratory, grower/processor or third-party contractor shall follow the transportation requirements under §§ 1151a.35 and 1151a.36 (relating to transportation of medical marijuana; and transport manifest) when transporting a sample or test sample under this part.

(b) An employee of an approved laboratory, grower/processor or third-party contractor who transports samples from a grower/processor to an approved laboratory shall:

(1) Protect the physical integrity of the sample.

(2) Keep the composition of the sample intact.

(3) Protect the sample against factors that interfere with the validity of testing results, including the factors of time, temperature and any other circumstance that appears to have compromised the sample.

§ 1171a.34. Department request for testing.

(a) The Department, in its sole discretion, may identify and collect a test sample from a grower/processor at any time and request an approved laboratory to conduct proficiency testing, conduct quality assurance measures and perform tests under this chapter.

(b) The approved laboratory shall provide the Department with a written report of the test results from a test sample tested under subsection (a) within 7 days of the collection of the test sample, or sooner if requested by the Department.

Cross References

This section cited in 28 Pa. Code § 1171a.35 (relating to laboratory reporting).

§ 1171a.35. Laboratory reporting.

(a) An approved laboratory shall enter into the electronic tracking system the following information for each sample collected under § 1171a.28(c)(1) and (2) (relating to selection protocols for samples) and each test conducted:

(1) The unique sample identification number the approved laboratory assigns to the sample.

(2) The name of the grower/processor that supplied the sample.

(3) The employee identification number of the employee of the approved laboratory who identified and collected the sample at the request of the grower/processor.

(4) The date and time the sample was collected from the grower/processor.

(5) The date and time the sample was received by the approved laboratory.

(6) The date the test was completed.

(7) The condition of the sample when it was received by the approved laboratory.

(8) A description of each test performed.

(9) The results from the certificate of analysis issued under § 1171a.31 (relating to test results and reporting).

(10) The date the testing results were provided to the grower/processor under § 1171a.31 or the Department under § 1171a.34 (relating to Department request for testing).

(b) An approved laboratory shall keep for 4 years a paper or electronic copy of the certificate of analysis performed on samples submitted by a grower/processor or test samples submitted by the Department including test results not required to be entered into the electronic tracking system under § 1171a.29 (relating to testing requirements). The following apply:

(1) Regarding tests results not entered into the electronic tracking system, the approved laboratory shall immediately provide to the Department by e-mail an electronic copy of the certificate of analysis.

(2) Regarding test results entered into the electronic tracking system, the approved laboratory shall provide a copy of a certificate of analysis to the Department within 2 days of a request made by the Department.

(c) The Department may conduct an investigation based on the results shown on any certificate of analysis.

§ 1171a.36. Advertising.

(a) An approved laboratory may not advertise, market or otherwise promote its medical marijuana testing services to the general public.

(b) An approved laboratory may only promote its medical marijuana testing services to a grower/processor. An approved laboratory may use advertising, marketing and promotional materials directed at a grower/processor to promote its medical marijuana testing services. The advertising, marketing and promotional materials proposed to be used by an approved laboratory under this section shall be reviewed and approved by the Department prior to circulation or other use.

(c) Personal solicitation by an employee, representative or agent of an approved laboratory to a grower/processor is considered advertising, marketing or otherwise promoting its medical marijuana testing services for the purposes of this section.

(d) An approved laboratory may only advertise, market or otherwise promote its medical marijuana testing services that are performed onsite at the location designated in the laboratory's application.

(e) A sign installed at the location of an approved laboratory that is designed to identify the laboratory or access to the laboratory is permissible as long as the sign meets local zoning requirements and does not violate the provisions of this section.

§ 1171a.37. Ownership prohibition.

The following individuals may not have a management, a direct or indirect financial, or other ownership interest in an approved laboratory:

(1) A principal, owner, financial backer or employee of a medical marijuana organization.

(2) A practitioner.

(3) A physician, pharmacist, physician assistant or certified registered nurse practitioner who is currently employed by a medical marijuana organization.

(4) Any other person, other than a patient, who may receive a direct or indirect financial benefit from the growing, processing, transporting, dispensing or selling of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products.

§ 1171a.38. Appeals.

Sections 501—508 of 2 Pa.C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

§ 1171a.39. Clarification of the requirements of §§ 1171a.29(c) and 1171a.31(c)—statement of policy.

(a) This section clarifies §§ 1171a.29(c) (relating to testing requirements) and 1171a.31(c) (relating to test results and reporting). The Department interprets ''an approved laboratory other than the one that tested the harvest batch or lot'' in § 1171a.29(c)(2) to be a separate and distinct approved laboratory that meets all financial and professional suitability requirements under this chapter independently from the approved laboratory that conducted the harvest batch or harvest lot test. The Department will consider the following factors to determine whether an approved laboratory is a separate and distinct laboratory:

(1) Separate, independent location from the other approved laboratory, such as no interest in the land or the building in which the other approved laboratory is located or part interest in any mortgage, deed, trust, note or the long-term liability secured in whole or in part by the land or building in which the other approved laboratory conducts testing. For clarification, this statement of policy does not impact the Department's ability to approve laboratories with multiple locations, including those with shared finances, staffing or operations.

(2) Separate legal entity from the other approved laboratory.

(3) No shared financial ownership with the other approved laboratory, such as filing joint tax returns, shared Federal or Tax Identification Numbers, having direct or indirect ownership interest in another laboratory, commingling of funds or shared bank accounts.

(4) Separate ownership and management in terms of members of a board of directors, shareholders or partners that represent a controlling interest, or management, compliance staff or employees in common with the other approved laboratory.

(5) Separate accreditation from the other approved laboratory.

(6) Separate operations from the other approved laboratory, such as no shared policies or standard operating procedures, reliance on input or oversight of the other approved laboratory or reliance on the other approved laboratory to financially support the approved laboratory's operations.

(7) No shared equipment or interest in any mortgage, deed, trust, note or other long-term liability secured in whole or in part by equipment used by the other approved laboratory.

(b) The Department will consider the factors in subsection (a)(1)—(7) with respect to determining approved laboratories to conduct confirming tests for re-testing of previously failed samples in § 1171a.31(c).

Authority

The provisions of this § 1171a.39 added under sections 102(3)(ii), 301(a)(4) and 704(a) of the act (35 P.S. §§ 10231.102(3)(ii), 10231.103(a)(4) and 10231.704(a)).

Source

The provisions of this § 1171a.39 added March 3, 2023, effective March 4, 2023, 53 Pa.B. 1179.

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