

CHAPTER 1171. LABORATORIES—TEMPORARY REGULATIONS

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Authority

The temporary provisions of this Chapter 1171 issued and amended under the Medical Marijuana Act (35 P.S. §§ 10231.101—10231.2110), unless otherwise noted.

Source

The temporary provisions of this Chapter 1171 adopted December 23, 2016, effective December 24, 2016, expire on December 24, 2018, 46 Pa.B. 8036; amended May 11, 2018, effective May 17, 2018, expire on May 12, 2020, 48 Pa.B. 2801, unless otherwise noted. Immediately preceding text appears at serial pages (385039) to (385048) and (386743) to (386744).

§ 1171.21. Definitions.

The following words and terms, when used in this part, have the following meanings, unless the context clearly indicates otherwise:

Accreditation body—An organization which:

- (i) Certifies the competency, expertise and integrity of a laboratory and operates in conformance with the current version of International Organization Standard ISO/IEC 17011.
- (ii) Determines a laboratory's compliance with and conformance to the relevant standards established by the International Organization for Standardization, including ISO/IEC 17025.
- (iii) Is a signatory to the International Accreditation Cooperation Mutual Recognition Arrangement for Testing.
- (iv) Is not affiliated with a laboratory applicant for which it has or will issue a certificate of accreditation.

Approved laboratory—A laboratory that has applied for, and received, the approval of the Department to identify, collect, handle and conduct tests on samples from a grower/processor and test samples from the Department used in the growing and processing of medical marijuana or dispensing of medical marijuana products as required by the act and this part.

Certificate of accreditation—A document issued by an accreditation body evidencing that a laboratory is in compliance with International Organization for Standardization Standard ISO/IEC 17025 or other standards relevant to the operation of laboratories conducting tests on medical marijuana, medical marijuana products and other items used in the growing and processing of medical marijuana or dispensing of medical marijuana products.

Certificate of analysis—A document that confirms that the test performed by an approved laboratory on a harvest batch, harvest lot or process lot meets the testing requirements set forth by the Department.

Certified registered nurse practitioner—The term as defined in section 2 of The Professional Nursing Law (63 P.S. § 212).

Chain of custody—The written procedures used by employees of an approved laboratory to record the possession and transfer of samples and test samples from the time the samples and test samples are collected until the test of the sample or test sample is completed.

Harvest batch—A specifically identified quantity of medical marijuana plant that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location, and cured under uniform conditions.

Harvest lot—A specifically identified quantity of medical marijuana plant taken from a harvest batch.

Laboratory applicant—A laboratory that submits an application to the Department for approval to identify, collect, handle and test medical marijuana, medical marijuana products and other items used by a medical marijuana organization in the growing and processing of medical marijuana or dispensing of medical marijuana products as required under the act and this part for the Department or a grower/processor.

Medical marijuana extract—A substance obtained by separating cannabinoids from medical marijuana plants by a mechanical, chemical or other process.

Medical marijuana product—The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

Pharmacist—The term as defined in section 2 of the Pharmacy Act (63 P.S. § 390-2).

Physician—The term as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2) and section 2 of the Osteopathic Medical Practice Act (63 P.S. § 271.2).

Physician assistant—The term as defined in section 2 of the Medical Practice Act of 1985 and section 2 of the Osteopathic Medical Practice Act.

Process lot—Any amount of a medical marijuana product of the same type and processed using the same medical marijuana extract, standard operating procedures and the same or combination of different harvest lots.

Processing—The compounding or conversion of medical marijuana extract by a grower/processor into a medical marijuana product.

Sample—Medical marijuana or medical marijuana products collected by an employee of an approved laboratory from a grower/processor facility for testing by the laboratory.

Test sample—An amount of medical marijuana, medical marijuana products or an amount of soil, growing medium, water or solvents used to grow or process medical marijuana, dust or other particles obtained from the swab of a counter or equipment used in the growing or processing of medical marijuana, or other item used in the growing or processing of medical marijuana in a grower/processor facility taken by an employee of an approved laboratory or an agent of the Department at the request of the Department from a grower/processor facility and provided to an approved laboratory for testing.

§ 1171.22. 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 § 1171.23 (relating to approval of laboratories) and has entered into a written contract with the grower/processor under § 1171.29 (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 at least one 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, at least one 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 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.

§ 1171.23. 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 on a form and in a manner prescribed by the Department.

(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 manufacturer'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 § 1171.32 (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 § 1171.22 (relating to laboratories generally); and 28 Pa. Code § 1171.25 (relating to renewal of an approval issued to a laboratory).

§ 1171.24. 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.

§ 1171.25. 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 § 1171.23 (relating to approval of laboratories) and update the information required to be submitted with the application as necessary.

§ 1171.26. Stability testing and retention of samples.

(a) A grower/processor shall request that a sample be identified and collected by an approved laboratory from each harvest batch sufficient to perform stability testing at 6-month intervals for a 1-year period.

(b) The stability test shall be performed to ensure product potency and purity and provide support for expiration dating.

(c) An approved laboratory shall retain a sample from each harvest batch sufficient to provide for stability testing and properly store the sample for 1 year.

§ 1171.27. 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, at a minimum, meet the following requirements:

(1) Be appropriate to the matrix being sampled.

(2) Be in accordance with guidance provided by the Department.

(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.

§ 1171.28. Selection protocols for samples.

(a) An employee of an approved laboratory may only enter a grower/processor facility for the purpose of identifying and collecting samples and shall 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.

§ 1171.29. 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) At a minimum, an approved laboratory shall perform tests as prescribed by the Department on the following items:

- (1) Samples from a harvest batch or harvest lot prior to being used to produce a medical marijuana product.
- (2) Samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.

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

- (1) Pesticides.
- (2) Solvents.
- (3) Water activity and moisture content.
- (4) THC and CBD concentration.
- (5) Microbiological contaminants.
- (6) Terpenes.

(e) Sampling and testing under this chapter shall be conducted with a statistically significant number and size of samples and with methodologies acceptable to the Department 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.

(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 factor sufficient to render the findings of questionable validity.

(g) An approved laboratory shall enter test results into the electronic tracking system and, under § 1151.40 (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 § 1171.22 (relating to laboratories generally); and 28 Pa. Code § 1171.31 (relating to test results and reporting).

§ 1171.30. Standards for testing.

An approved laboratory shall follow the methodologies, ranges and parameters acceptable to the Department that are contained in the scope of the certificate of accreditation issued to the laboratory.

§ 1171.31. 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 § 1171.29 (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 § 1171.29 and identified and collected by either an employee of a grower/processor or an employee of an approved laboratory.

(b) The test results for each sample 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 § 1171.29, 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).

(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.

(3) If the Department does not agree to accept the results from the approved laboratory, the sample shall be disposed of by the approved laboratory under § 1151.40 (relating to management and disposal of medical marijuana waste).

(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 process 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 chemical profile of the strain as determined by the Department for the following compounds:

- (i) THC.
- (ii) Tetrahydrocannabinolic acid.
- (iii) CBD.
- (iv) Cannabidiolic acid.
- (v) Cannabigerol.
- (vi) Cannabinol.

(2) That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the levels as determined by the Department 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) Any microbiological impurity, including:
 - (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.

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

- (A) Odor.
- (B) Appearance.
- (C) Fineness.
- (D) Moisture content.

Cross References

This section cited in 28 Pa. Code § 1171.35 (relating to laboratory reporting).

§ 1171.32. 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 routinely and properly calibrated.

(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 § 1171.23 (relating to approval of laboratories).

§ 1171.33. Transporting samples.

(a) An employee of an approved laboratory, grower/processor or third-party contractor shall follow the transportation requirements under §§ 1151.35 and 1151.36 (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 process lot 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 other environmental factors that may work to jeopardize the integrity of the sample.

§ 1171.34. 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 § 1171.35 (relating to laboratory reporting).

§ 1171.35. Laboratory reporting.

(a) An approved laboratory shall enter into the electronic tracking system the following information for each sample collected 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 § 1171.31 (relating to test results and reporting).
- (10) The date the testing results were provided to the grower/processor under § 1171.31 or the Department under § 1171.34 (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. 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.

§ 1171.36. 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 promo-

tional 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.

§ 1171.37. 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, medical marijuana or medical marijuana products.

§ 1171.38. Appeals.

Chapter 5, Subchapter A of 2 Pa.C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230 (relating to practice and procedure—temporary regulations), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

Source

The temporary provisions of this § 1171.38 adopted May 11, 2018, effective May 17, 2018, expire on May 12, 2020, 48 Pa.B. 2801.

§ 1171.39. Effective date and applicability.

(a) The amended temporary regulations in this chapter take effect on May 17, 2018.

(b) The amended temporary regulations in this chapter do not apply to the evaluation or scoring of a Medical Marijuana Organization Permit Application submitted to the Department from April 5, 2018, through May 17, 2018, as part of the implementation of Phase II of the Medical Marijuana Program.

Source

The temporary provisions of this § 1171.39 adopted May 11, 2018, effective May 17, 2018, expire on May 12, 2020, 48 Pa.B. 2801.

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