

TITLE 28. HEALTH AND SAFETY
PART IX. MEDICAL MARIJUANA
CHAPTER 1171. LABORATORIES

- 1
- 2
- 3
- 4
- 5 § 1171.21. Laboratories generally.
- 6 § 1171.22. Approval of laboratories.
- 7 § 1171.23. Sampling procedures for testing.
- 8 § 1171.24. Selection protocols for samples.
- 9 § 1171.25. Testing requirements.
- 10 § 1171.26. Standards for testing.
- 11 § 1171.27. Test results and reporting.
- 12 § 1171.28. Quality assurance program.
- 13 § 1171.29. Transporting samples.
- 14 § 1171.30. Department request for testing.
- 15 § 1171.31. Laboratory reporting.
- 16 § 1171.32. Advertising.
- 17 § 1171.33. Ownership prohibition.
- 18 § 1171.34. Approval, suspension or revocation of a laboratory approval.
- 19 § 1171.35. Renewal of a laboratory approval.
- 20 § 1171.36. Stability testing and retention sampling.
- 21
- 22 § 1171.21. Laboratories generally.

- 1 (a) A laboratory may not identify, collect, or handle samples of medical marijuana from a
2 grower/processor unless the laboratory has been approved by the Department under § 1171.22
3 (relating to approval of laboratories).
- 4 (b) While at a facility operated by a grower/processor, a laboratory employee shall identify
5 and collect the following for testing:
- 6 (1) Samples of medical marijuana at the time of harvest according to § 1171.24
7 (relating to selection protocols for samples).
- 8 (2) Samples of medical marijuana at the time of final processing according to §
9 1171.24 (relating to selection protocols for samples).
- 10 (c) The Department will post on its website a list of laboratories that are approved by the
11 Department to test medical marijuana under this part.
- 12 (d) A laboratory shall employ at least one director to oversee and be responsible for the
13 testing operations of the proposed laboratory. A director must have earned, from a college or
14 university accredited by a national or regional certifying authority, at least one of the following:
- 15 (1) A doctorate of science degree or its equivalent in the basic sciences of
16 chemistry, biology or microbiology.
- 17 (2) A master's level degree in chemical or biological sciences and a minimum
18 of 2 years post-degree laboratory experience.
- 19 (3) A bachelor's degree in biological sciences and a minimum of 4 years post-
20 degree laboratory experience.
- 21 (e) An approval issued by the Department to a laboratory under this part is valid for 2 years
22 from the date of issuance and is valid only for the person named and the location specified in the
23 laboratory approval.

1 (f) A laboratory approval issued under this part is not transferable to any other person
2 or any other location unless the laboratory obtains the prior written consent of the
3 Department.

4
5 **§ 1171.22. Approval of laboratories.**

6 (a) Prior to identifying, collecting and handling samples as required by the act and under this
7 part, a laboratory shall submit an application for laboratory approval to the Department on a form
8 and in a manner prescribed by the Department.

9 (b) An application for laboratory approval shall include the following information:

- 10 (1) The name and address of the laboratory applicant.
- 11 (2) The name and address of the owner of the proposed laboratory, or its authorized
12 agent, and the medical or pharmacy licensure information regarding the owner.
- 13 (3) The name of the proposed laboratory director and other technical personnel who
14 are or will be employed at the proposed laboratory.
- 15 (4) A copy of the standard operating procedures of the proposed laboratory.
- 16 (5) A copy of the proposed laboratory's sampling procedures under § 1171.23
17 (relating to sampling procedures for testing).
- 18 (6) A list of the proposed specialized laboratory equipment to be utilized in the
19 testing of medical marijuana, including the manufacturer's name and model number, and
20 other specifications as may be required by the Department.
- 21 (7) A description of the tests to be performed at the proposed laboratory.
- 22 (8) The internal and external quality control systems to be employed by the
23 laboratory applicant at the proposed laboratory.

1 (9) The procedures to be followed to establish chain of custody when collecting
2 samples from a grower/processor.

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

4 (11) A copy of the evaluation process that the laboratory applicant uses to document
5 the competency of employees testing samples and overseeing quality assurance controls.

6 (12) Other information required by the Department.

7 (c) By submitting an application for laboratory approval to the Department, a laboratory
8 applicant consents to any investigation, to the extent deemed appropriate by the Department, of
9 the laboratory applicant's ability to meet the requirements under the act applicable to the
10 application.

11 (d) An application for laboratory approval submitted under this part must contain the
12 following statement signed by the laboratory applicant:

13 A false statement made in this application is punishable under the applicable provisions
14 of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

15
16 **§ 1171.23. Sampling procedures for testing.**

17 (a) A laboratory must prepare all samples in accordance with sampling policies and
18 procedures that contain all of the information necessary for identifying, collecting and
19 transporting samples in a manner that does not endanger the integrity of the sample for any
20 testing required by this part.

21 (b) The sampling policies shall at a minimum:

22 (1) Be appropriate to the matrix being sampled.

23 (2) Be approved by an accrediting body that is posted on the Department's website.

- 1 (3) Be in accordance with guidance provided by the Department.
- 2 (c) The sampling procedures shall include the following:
- 3 (1) A survey of the conditions in which the medical marijuana is being stored.
- 4 (2) The use of appropriate sampling equipment and consistent procedures.
- 5 (3) The choosing and removing of equal portions for each sample.
- 6 (4) The random or systematic taking of samples throughout the batch or lot.
- 7 (5) Obtaining a minimum number of samples based on batch or lot size.
- 8 (6) Checking all parts of the harvest batch when lots are created from that batch.
- 9 (7) Recording on a form prescribed by the Department all observations and
- 10 procedures used when collecting the sample.
- 11 (8) Creating a unique sample identification number that will be linked to the batch or
- 12 lot number assigned by the grower/processor in the electronic tracking system.
- 13 (9) Entering all required information into the electronic tracking system.

14

15 **§ 1171.24. Selection protocols for samples.**

16 (a) An employee of a laboratory may only enter a facility operated by a grower/processor for

17 the purpose of identifying and collecting samples and shall have access to any limited access

18 areas to identify and collect samples for testing purposes.

19 (b) An employee of a laboratory identifying and collecting samples under this section shall

20 follow the chain of custody procedures established by the laboratory and approved by the

21 Department.

22

23 **§ 1171.25. Testing requirements.**

- 1 (a) Prior to conducting any testing of a sample of medical marijuana for a grower/processor,
2 a laboratory shall enter into a written contract with the grower/processor for medical marijuana
3 testing services.
- 4 (b) A laboratory shall provide a copy of the written contract under subsection (a) within 2
5 days of a request by the Department.
- 6 (c) Prior to a laboratory identifying and collecting samples, a grower/processor shall submit
7 a written request, on a form prescribed by the Department, to the laboratory for each test the
8 grower/processor is requesting the laboratory to conduct.
- 9 (d) A grower/processor shall perform, at a minimum, testing:
- 10 (1) On samples from a harvest batch or lot prior to being processed into medical
11 marijuana extract.
- 12 (2) On samples from each process lot before the medical marijuana is sold to a
13 medical marijuana organization.
- 14 (e) The samples identified and collected under subsection (d) shall be tested for the
15 following:
- 16 (1) Pesticides.
- 17 (2) Solvents.
- 18 (3) Water activity and moisture content.
- 19 (4) THC and CBD concentration.
- 20 (5) Microbiological contaminants.
- 21 (f) Sampling and testing under this part shall be conducted with a statistically significant
22 number of samples and with acceptable methodologies as prescribed by the Department to assure

1 that all batches or lots of medical marijuana at harvest or after final processing are adequately
2 assessed for contaminants and that the cannabinoid profile is consistent throughout.

3 (g) A laboratory shall not test any samples because of improper collection, improper
4 preservation, apparent spoilage, excessive time lapse between collection of the sample and
5 testing and, when applicable, any other reason sufficient to render the findings of questionable
6 validity.

7 (h) A laboratory shall track in the electronic tracking system and properly dispose of any
8 samples that are not tested under § 1151.40 (relating to disposal of medical marijuana).

9
10 **§ 1171.26. Standards for testing.**

11 A laboratory shall follow the methodologies, ranges, and parameters which are contained in the
12 scope of the accreditation for testing medical marijuana at the time of harvest and after final
13 processing.

14
15 **§ 1171.27. Test results and reporting.**

16 (a) Tests results that are acceptable to the Department are limited to:

17 (1) Harvest batch samples or harvest lot samples requested by a grower/processor
18 under § 1171.25 (relating to testing requirements) for testing and identified and collected
19 by an employee of a laboratory.

20 (2) Process lot samples requested by a grower/processor under § 1171.25 (relating to
21 testing requirements) for testing and identified and collected by either an employee of a
22 grower/processor or an employee of a laboratory.

1 (b) The test results for each sample shall be entered into the electronic tracking system and
2 shall only be accessible to the grower/processor submitting the sample and requesting the
3 analysis and the Department.

4 (c) A grower/processor shall notify the Department and the laboratory, in writing, prior to re-
5 sampling or re-testing a harvest batch, harvest lot or process lot that failed a test.

6 (d) If a sample fails any test required under § 1171.26 (relating to standards for testing), the
7 laboratory that performed the testing may reanalyze the sample upon a request from the
8 grower/processor and the prior written approval of the Department.

9 (e) If the sample taken in subsection (d) is reanalyzed and passes any test required under
10 §1171.26 (relating to standards for testing), another independent laboratory must sample the
11 same harvest batch, harvest lot or process lot to confirm the passing test result.

12 (f) A sample that fails a test required under § 1171.26 (relating to standards for testing), and
13 is not approved by the Department for reanalysis, must be disposed of by the laboratory under §
14 1151.40 (relating to disposal of medical marijuana).

15 (g) A laboratory shall issue to a grower/processor a certificate of analysis, including the
16 supporting data, for each batch or lot sample that a grower/processor requests to be tested. The
17 certificate of analysis shall include:

18 (1) Whether the chemical profile of the batch or lot conforms to the chemical profile
19 of the strain for the following compounds:

20 (i) Δ 9-Tetrahydrocannabinol (THC).

21 (ii) Tetrahydrocannabinolic Acid (THCA).

22 (iii) Cannabidiol (CBD).

23 (iv) Cannabidiolic Acid (CBDA).

1 (v) Cannabigerol (CBG).

2 (vi) Cannabinol (CBN).

3 (2) That the presence of the following contaminants within the batch or lot does not
4 exceed the levels as determined by the Department:

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

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

7 (iii) Any microbiological impurity, including:

8 (A) Total aerobic microbial count (TAMC).

9 (B) Total yeast mold count (TYMC).

10 (C) *P. aeruginosa*.

11 (D) *Aspergillus* spp.

12 (E) *S. aureus*.

13 (F) Aflatoxin B1, B2, G1 and G2.

14 (G) Ochratoxin A.

15 (H) Pesticide residue.

16 (iv) Whether the batch or lot is within the specification for the strain for the
17 characteristics of:

18 (A) Odor.

19 (B) Appearance.

20 (C) Fineness.

21 (D) Moisture content.

22

23 **§ 1171.28. Quality assurance program.**

1 (a) A laboratory shall establish and implement a quality assurance program to assure that
2 measurements are accurate, errors are controlled and devices used to test medical marijuana are
3 routinely and properly calibrated.

4 (b) The quality assurance program under subsection (a) shall include the following
5 components:

6 (1) An organizational chart that includes the testing responsibilities of each individual
7 named in the chart.

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

9 (3) Appropriate chain of custody protocols.

10 (4) Analytical procedures.

11 (5) Data reduction and validation procedures.

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

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

14

15 **§ 1171.29. Transporting samples.**

16 (a) An employee of a laboratory, grower/processor or third-party contractor must follow the
17 transportation requirements under § 1151.35 (relating to transportation of medical marijuana)
18 and § 1151.36 (relating to transport manifest) when transporting a sample under this part.

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

21 (1) Protect the physical integrity of the sample.

22 (2) Keep the composition of the sample intact.

1 (3) Protect the sample against factors that will interfere with the validity of testing
2 results, including the factors of time, temperature and other environmental factors that are
3 critical to the preservation of the sample.

4 (c) An employee of a laboratory, grower/processor or third-party contractor who transports
5 process lot samples to a laboratory shall comply with the requirements of this section.

6
7 **§ 1171.30. Department request for testing.**

8 (a) The Department, in its sole discretion, may identify and collect a sample from a
9 grower/processor at any time and request a laboratory to conduct tests.

10 (b) The laboratory shall provide the Department with a written report of the test results from
11 a sample taken under subsection (a) within 7 days of the collection of the sample.

12
13 **§ 1171.31. Laboratory reporting.**

14 (a) A laboratory shall report and enter into the electronic tracking system the following
15 information for each sample collected and test conducted:

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

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

18 (3) The name of the individual who identified and collected the sample at the request
19 of the grower/processor.

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

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

22 (6) The date the tests were completed.

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

- 1 (8) A description of each test performed.
- 2 (9) The results from the certificate of analysis under § 1171.27 (relating to test results
3 and reporting).
- 4 (10) The date the testing results were provided to the grower/processor or the
5 Department under § 1171.30 (relating to Department request for testing).
- 6 (b) A laboratory shall keep a paper or electronic copy of the test results performed on
7 samples submitted by a grower/processor or the Department. A laboratory shall provide a copy
8 of any test result within 2 days of a request made by the Department.

9

10 **§ 1171.32. Advertising.**

- 11 (a) A laboratory may not advertise its services to the general public. A laboratory may
12 advertise its services to a grower/processor as provided in this section.
- 13 (b) Advertising materials proposed to be used by a laboratory shall be reviewed and
14 approved by the Department prior to circulation or other use.
- 15 (c) Personal solicitation by an employee, representative, or agent of a laboratory to a
16 grower/processor shall be considered advertising for the purposes of this section.
- 17 (d) A laboratory may only advertise testing services that are performed onsite at the
18 laboratory.
- 19 (e) A sign of a descriptive character that is designed to identify the laboratory or access to
20 the laboratory is permissible as long as the sign meets local zoning requirements and the
21 requirements of this section.

22

23 **§ 1171.33. Ownership prohibition.**

1 (a) The following individuals shall not have a management or a direct or indirect financial or
2 other ownership interest in a laboratory that tests medical marijuana:

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

5 (2) A practitioner who is registered with the Department to issue certifications to
6 patients with serious medical conditions.

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

9 (4) Any other person, other than a patient, who may receive a direct or indirect
10 financial benefit from the growing, processing, sale, purchase or use of medical
11 marijuana.

12 (b) An individual who is employed by a medical marijuana organization shall not also be
13 employed by or affiliated with a laboratory that has a contract with the medical marijuana
14 organization where the individual is employed.

15
16 **§ 1171.34. Approval, suspension or revocation of a laboratory approval.**

17 (a) A laboratory approval may be issued by the Department under this chapter if the
18 Department determines that the laboratory applicant is financially and professionally suitable to
19 conduct testing of medical marijuana as required by the act and this part.

20 (b) An existing laboratory approval may be suspended or revoked for any of the following:

21 (1) Failure to maintain proper standards of accuracy.

22 (2) Engaging in unethical practices.

1 (3) Failure to submit the reports required under § 1171.31 (relating to laboratory
2 reporting).

3 (4) Failure to follow the act and this part.

4 (c) An existing laboratory approval may be revoked for any of the following:

5 (1) Dishonest reporting or repeated errors by the laboratory.

6 (2) Allowing unauthorized persons to perform testing or to sign reports.

7 (3) Including false statements in the application for laboratory approval.

8 (4) Advertising medical marijuana laboratory testing services to the public.

9 (5) Knowingly accepting a sample of medical marijuana from a person other than a
10 grower/processor.

11 (6) Failing to maintain standard operating procedures approved by the Department.

12 (7) Failing to properly enter test results into the electronic tracking system.

13 (8) Violating the act or this part.

14 (d) A laboratory applicant may appeal a determination made by the Department under this
15 section in accordance with 2 Pa.C.S. Chapter 5 (relating to practice and procedure).

16

17 **§ 1171.35. Renewal of a laboratory approval.**

18 A laboratory may renew its laboratory approval by submitting to the Department:

19 (1) An application under § 1171.22 (relating to approval of laboratories).

20 (2) A copy of its most recent:

21 (i) Assessment by an accreditation body.

22 (ii) Quality assurance standards.

23

1 **§ 1171.36. Stability testing and retention sampling.**

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

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

6 (c) The laboratory shall retain a sample from each harvest batch sufficient to provide for
7 follow-up testing, if necessary, and to properly store the sample for 1 year from the date of
8 expiration of the batch.

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