

641—154.26(124E) Quality assurance and control.

154.26(1) *Quality control program.* A manufacturer shall develop and implement a written quality assurance program that assesses the chemical and microbiological composition of medical cannabidiol. Assessment includes a profile of the active ingredients, including shelf life, and the presence of inactive ingredients and contaminants. A manufacturer shall use these testing results to determine appropriate storage conditions and product expiration dates.

154.26(2) *Sampling protocols.* A manufacturer shall develop and follow written procedures for sampling medical cannabidiol that require the manufacturer to:

- a. Conduct sample collection in a manner that provides analytically sound and representative samples;
- b. Document every sampling event and provide this documentation to the department upon request;
- c. Describe all sampling and testing plans in written procedures that include the sampling method and the number of units per lot to be tested;
- d. Ensure that random samples from each lot are:
 - (1) Taken in an amount necessary to conduct the applicable test;
 - (2) Labeled with the lot number; and
 - (3) Submitted for testing;
- e. Retain the results from the random samples for at least five years; and
- f. Notify the department at least two business days prior to sample collection and allow the department or its designees to be present to observe the sampling procedures when the samples are to be sent to a laboratory for testing.

154.26(3) *Sampling and testing.* A manufacturer shall:

- a. Work with the department and laboratory personnel to develop acceptance criteria for all potential contaminants based on the levels of metals, microbes, or other contaminants that the manufacturer uses in cultivating and producing medical cannabidiol;
- b. Conduct sampling and testing of plant material and medical cannabidiol lots using acceptance criteria that are protective of patient health. The sampling and testing results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol meet allowable health risk limits for contaminants. Testing of plant material and lots shall occur as described in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).
- c. Refrain from packaging or selling medical cannabidiol from a process lot that fails to meet established standards, specifications, and any other relevant quality control criteria. Medical cannabidiol from a process lot that fails quality assurance testing may be remixed and retested;
- d. Reject and destroy medical cannabidiol from a lot that fails to meet established standards, specifications, and any other relevant quality control criteria when remixing and retesting are not warranted;
- e. Develop and follow a written procedure for responding to results failing to meet established standards, specifications, and any other relevant quality control criteria, including:
 - (1) Criteria for when remixing and retesting are warranted;
 - (2) Instructions for destroying contaminated or substandard medical cannabidiol as provided in subrule 154.23(2) when remixing and retesting are not warranted; and
 - (3) Instructions for determining the source of contamination;
- f. Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

154.26(4) *Stability testing.*

- a. The quality assurance program shall include procedures for performing stability testing of each product type produced to determine product expiration dates. The procedures shall describe:
 - (1) Sample size and test intervals based on statistical criteria and departmental guidance pursuant to subrule 154.69(1) for each attribute examined to ensure valid stability estimates;
 - (2) Storage conditions for samples retained for testing; and
 - (3) Reliable and specific test methods.

b. Stability studies shall include:

- (1) Medical cannabidiol testing at appropriate intervals; and
- (2) Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed.

c. If product-expiration-date studies have not been completed before December 1, 2018, a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information. A manufacturer shall concurrently conduct stability studies to determine the actual product expiration date.

d. After a manufacturer verifies the tentative product expiration date, or determines the appropriate product expiration date, a manufacturer shall include that product expiration date on each lot of medical cannabidiol.

e. Stability testing shall be repeated if the manufacturing process or the product's chemical composition is changed.

154.26(5) Reserve samples.

a. A manufacturer shall retain a uniquely labeled reserve sample that represents each lot of medical cannabidiol and store the reserve sample under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the medical cannabidiol is marketed or in one that has similar characteristics. The reserve sample shall consist of at least twice the quantity necessary to perform all the required tests.

b. A manufacturer shall retain the reserve for at least two years from the date of manufacture.

c. After two years from the date of manufacture, reserve samples shall be destroyed as provided in subrule 154.23(2).

154.26(6) Retesting. If the department deems that public health may be at risk, the department may require the manufacturer to retest any sample of plant material or medical cannabidiol.

154.26(7) Disposal of substandard product. A manufacturer shall dispose of all medical cannabidiol as provided in subrule 154.23(2) when samples fail to meet established standards, specifications, and other relevant quality control criteria and when an adequate remedy for remixing and retesting as provided in paragraph 154.26(3) "c" is unavailable.

154.26(8) Recall and market withdrawal procedures. Each manufacturer shall establish a procedure for recalling or withdrawing from the market, as applicable, medical cannabidiol that has a reasonable probability of causing an unexpected or harmful response in a patient population, despite appropriate use, that outweighs the potential benefit of the medical cannabidiol. This procedure shall include:

a. Factors that make a recall or market withdrawal necessary;

b. Manufacturer's personnel who are responsible for overseeing the recall or market withdrawal; and

c. How to notify affected parties of a recall or market withdrawal.

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