

4770.0500 MEDICAL CANNABIS MANUFACTURER; QUALITY CONTROL; ASSURANCE PROGRAM.

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

Subp. 2. **Sampling protocols.** A medical cannabis manufacturer must develop and follow written procedures for sampling medical cannabis 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 commissioner upon request;

C. describe all sampling and testing plans in written procedures that include the sampling method and the number of units per batch to be tested;

D. ensure that random samples from each batch are:

- (1) taken in an amount necessary to conduct the applicable test;
- (2) labeled with the batch unique identifier; and
- (3) submitted for testing; and

E. retain the results from the random samples for at least five years.

Subp. 3. **Sampling; testing levels.** A medical cannabis manufacturer must:

A. 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 cannabis. The testing levels are subject to approval by the commissioner;

B. conduct sampling and testing using acceptance criteria that are protective of patient health. The sampling and testing results must ensure that batches of medical cannabis meet allowable health risk limits for contaminants;

C. reject a medical cannabis batch that fails to meet established standards, specifications, and any other relevant quality-control criteria;

D. develop and follow a written procedure for responding to results indicating contamination. The procedure must include destroying contaminated medical cannabis and determining the source of contamination; and

E. retain documentation of test results, assessment, and destruction of medical cannabis for at least five years.

Subp. 4. Quality assurance program; stability testing.

A. The quality assurance program must include procedures for performing stability testing of each product type produced to determine product shelf life that addresses:

- (1) sample size and test intervals based on statistical criteria 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 must include:

- (1) medical cannabis testing at appropriate intervals;
- (2) medical cannabis testing in the same container-closure system in which the drug product is marketed; and
- (3) testing medical cannabis for reconstitution at the time of dispensing, as directed in the labeling, and after the samples are reconstituted.

C. If shelf-life studies have not been completed before July 1, 2015, a medical cannabis manufacturer may assign a tentative expiration date, based on any available stability information. The manufacturer must concurrently conduct stability studies to determine the actual product expiration date.

D. After the manufacturer verifies the tentative expiration date, or determines the appropriate expiration date, the medical cannabis manufacturer must include that expiration date on each batch of medical cannabis.

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

Subp. 5. Reserve samples.

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

B. A medical cannabis manufacturer must retain the reserve for at least one year following the batch's expiration date.

Subp. 6. **Retesting.** If the commissioner deems that public health may be at risk, the commissioner may require the manufacturer to retest any sample of plant material or medical cannabis.

Statutory Authority: *MS s 14.389; 152.25; 152.26*

History: *39 SR 1080*

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