641—154.29(124E) Quality assurance and control.

154.29(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 stability studies, and the presence of inactive ingredients and contaminants. A manufacturer shall use these testing results to determine appropriate storage conditions and product expiration dates.

154.29(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.

154.29(3) *Sampling and testing.* A manufacturer shall:

a. Work with the department and laboratory personnel to develop acceptance criteria for contaminants, including but not limited to cannabinoid content, metals, microbiological impurities, solvents, 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. Sampling method results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol are homogenous and representative of the process or package lot;

c. Reject and destroy medical cannabidiol from a lot that fails to meet established standards, and any other relevant quality control criteria, when remixing and retesting are not warranted;

d. Develop and follow a written procedure for responding to results failing to meet established standards, 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 when remixing and retesting are not warranted; and

(3) Instructions for determining the source of contamination;

e. Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

154.29(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 departmental guidance pursuant to subrule 154.47(1);

(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, a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information.

d. If a manufacturer determines a product expiration date beyond one year, a manufacturer shall submit justification to the department, and receive approval, prior to labeling a product with an expiration date beyond one year.

154.29(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 one year from the date of manufacture.

c. After one year from the date of manufacture, reserve samples shall be destroyed.

154.29(6) *Retesting.* If the department deems that public health may be at risk, the department may require the manufacturer to retest any sample of medical cannabidiol.

154.29(7) *Disposal of substandard product.* A manufacturer shall dispose of all medical cannabidiol when samples fail to meet established standards, and other relevant quality control criteria.

154.29(8) *Recall procedures.* Each manufacturer shall establish a procedure for recalling product from the market 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 necessary;

b. Manufacturer’s personnel who are responsible for overseeing the recall; and

c. How to notify affected parties of a recall.

[**ARC 8124C**, IAB 7/10/24, effective 8/14/24]