

3796:4-2-01

Testing laboratory operations.

(A) A testing laboratory shall establish, maintain, and comply with the policies and procedures contained in the operations plan submitted by the testing laboratory as part of the application that was approved by the department. The operations plan shall include policies and procedures for the analysis, storage, sample inventory tracking, and transportation of plant material, medical marijuana extract, and medical marijuana products. At a minimum, a facility's operations plan shall accomplish the following:

- (1) Designate areas in the facility that are compartmentalized based on function, including any areas to which access is restricted;
- (2) Implement policies and procedures that provide best practices for safe, secure, and proper testing of medical marijuana;
- (3) Establish training and safety policies and procedures to ensure that any person involved in analytical testing of medical marijuana:
 - (a) Has been fully trained in the safe operation and maintenance of any and all instrumentation that will be used in the testing of medical marijuana, with supporting documentation of the training;
 - (b) Has been fully trained in the safe use, handling, and storage of any and all chemicals that will be used in the testing of medical marijuana, in accordance with OSHA protocols, with supporting documentation of the training;
 - (c) Has direct access to applicable material safety data sheets and labels; and
 - (d) Has been fully trained regarding compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code.
- (4) Document the chain of custody for all medical marijuana in the inventory tracking system;
- (5) Establish a standard for the facility to be maintained in a clean and orderly condition, which includes free from infestation by rodents, insects, birds, and other animals of any kind; and
- (6) Maintain a facility with adequate lighting, ventilation, temperature, sanitation, equipment, and security for the testing of medical marijuana, including the following:
 - (a) A testing laboratory shall keep all floors and benches free of debris, dust, and any other potential contaminants;

- (b) A testing laboratory shall use chemicals, cleaning solutions, and other sanitizing agents generally accepted for laboratory use, and shall store them in a manner that protects against contamination;
 - (c) A testing laboratory shall keep its equipment in a clean, professional environment and maintain a cleaning and equipment maintenance log at the facility;
 - (d) A testing laboratory shall have its scales, balances, or other weight and/or mass measuring devices routinely calibrated using "National Institute of Standards and Technology" (NIST)-traceable reference weights, at least once each calendar year; and
 - (e) A testing laboratory shall standardize all analytical test instrumentation using reference materials traceable to reference material producers accredited to ISO/IEC 17034 "General Requirements for the Competence of Reference Material Producers" or the national metrology institute (NMI), where available.
- (B) A testing laboratory shall employ a scientific director who will be responsible for supervision of all laboratory staff and for ensuring that the laboratory achieves and maintains quality standards of practice. The scientific director shall meet the following qualifications, at minimum:
 - (1) A doctorate degree in chemical or biological sciences from an accredited college or university and two years of post-degree laboratory experience; or
 - (2) A master's degree in chemical or biological sciences from an accredited college or university and four years of post-degree laboratory experience.
- (C) A testing laboratory shall employ the following methods of analysis:
 - (1) Methods established in accordance with "Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control" (2014) monograph published by the "American Herbal Pharmacopoeia"; or
 - (2) Alternative methods that have been reviewed and approved by the department. If the proposed methods are approved, the department may require the testing laboratory to have the methods validated by an independent third party, at the expense of the testing laboratory, prior to the testing laboratory using the proposed methods to conduct testing services.
- (D) A testing laboratory shall track and submit into the inventory tracking system any information the department determines necessary for tracking medical marijuana, including, but not limited to, transportation of samples, sample inventory, and results of analysis.

Effective:

Five Year Review (FYR) Dates:

Certification

Date

Promulgated Under:	119.03
Statutory Authority:	R.C. 3796.03
Rule Amplifies:	R.C. 3796.03, R.C. 3796.09