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3796:4-1-01 Number of testing laboratory provisional licenses.

- (A) The director of the department of commerce or the director's designee may issue a provisional license to conduct laboratory testing of medical marijuana in accordance with the criteria listed in section 3796.09 of the Revised Code to an institution of higher learning that meets all of the following conditions:
- (1) The institution is public, and is located in the state of Ohio; and
 - (2) The institution has the facilities and resources necessary to conduct testing in accordance with the standards and procedures established in rules adopted by the department under section 3796.03 of the Revised Code.
- (B) Beginning on the date that occurs one year after the date on which the department begins accepting applications for licensure under section 3796.09 of the Revised Code, the director or the director's designee may issue a provisional license or certificate of operation to conduct laboratory testing of medical marijuana to a laboratory that is not part of an institution of higher learning as specified in paragraph (A) of this rule, in accordance with the criteria listed in section 3796.09 of the Revised Code and this Division.
- (C) In the event additional provisional licenses are deemed necessary, as determined by the director or the director's designee based on the volume of medical marijuana being produced and consumed by patients in the state of Ohio, the department will follow the license application procedures outlined in rule 3796:4-1-02 of the Administrative Code.

3796:4-1-02 Testing laboratory provisional license application.

- (A) The department shall provide advance notice to the public indicating the commencement date and time period for accepting applications. The director shall have the right to amend the notice prior to the deadline for submitting an application. The director shall publish such amended notice in the same manner as the original notice. The director shall also have the right to cancel a notice of open application prior to the award of a testing laboratory provisional license.
- (B) The provisional license application shall be submitted in accordance with Chapter 3796. of the Revised Code and this division. The application will include instructions for completion and submission. An applicant for a testing laboratory provisional license shall submit, in accordance with the application instructions, the following:
- (1) A non-refundable application fee as set forth in rule 3796:5-1-01 of the Administrative Code.
 - (2) A business plan, which, at a minimum, shall include:
 - (a) The legal name of the applicant;
 - (b) The type of business organization of the applicant, such as individual, corporation, partnership, limited liability company, association, cooperative, joint venture, or any other business organization;
 - (c) Confirmation that the applicant is registered with the secretary of state as the type of business submitted pursuant to paragraph (B)(2)(b) of this rule, a certificate of good standing issued by the secretary of state, and a copy of the applicable business documents governing the operations and administration of the business;
 - (d) The proposed physical address of the applicant's facility;

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- (e) An organizational chart of the company, including name, address, and date of birth of each principal officer and board member of the testing laboratory, provided that all those individuals shall be at least twenty-one years of age;
 - (f) All persons subject to the criminal records checks shall submit both an Ohio bureau of criminal identification and investigation criminal records check and a federal bureau of criminal investigation criminal records check pursuant to division (B) of section 3796.12 of the Revised Code;
 - (g) Any instance in which a business that any person associated with the applicant had managed or served on the board of the business and was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding;
 - (h) Evidence that the applicant owns the property on which the proposed testing laboratory will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the testing laboratory from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the testing laboratory from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
 - (i) A location area map of the area surrounding the proposed testing laboratory that establishes the facility is at least five hundred feet from the boundaries of a parcel of real estate having situated on it a prohibited facility, as measured under rule 3796:5-5-01 of the Administrative Code;
 - (j) For any instance in which an applicant or any person associated with the applicant is currently or was previously licensed or authorized in another state or jurisdiction to cultivate, produce, test, dispense, or otherwise deal in the distribution of medical marijuana in any form, the following:
 - (i) A copy of each such licensing or authorizing document verifying licensure in that state or jurisdiction;
 - (ii) A statement granting permission to contact the regulatory agency that granted the license, accompanied by the contact information, to confirm the information contained in the application; and
 - (iii) If the license, authorization, or application was ever warned, fined, denied, suspended, revoked, or otherwise sanctioned, a copy of documentation so indicating, or a statement that the applicant was so licensed and was never sanctioned; and
 - (k) Documentation that the applicant is currently in compliance, or will be in compliance prior to the issuance of a certificate of operation, with all building, fire, safety, and zoning statutes, local ordinances, and rules and regulations adopted by the locality in which the applicant's property is located, which are in effect at the time of the application, including but not limited to building department approval demonstrating compliance with rules adopted by the board of building standards pursuant to Chapters 3781. and 3791. of the Revised Code and any applicable zoning considerations.
- (3) An operations plan that establishes policies and procedures in accordance with the requirements of ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories," that the applicant will implement for the secure and proper analytical testing of medical marijuana,

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which, at a minimum, shall include:

- (a) Laboratory analysis techniques, including specific instrumentation and protocols necessary to perform the tests required by this division;
 - (b) Experience with the analytical testing of medical marijuana or other agricultural, horticultural, or pharmaceutical products;
 - (c) The implementation of standards and methods for conducting testing laboratory analysis of medical marijuana and medical marijuana products that will allow the applicant to obtain accreditation to the ISO/IEC 17025 standard within two years of issuance of a provisional license;
 - (d) Facility specifications, designating the areas in the facility where analytical testing will occur, and evidencing that the applicant will comply with the requirements of Chapter 3796. of the Revised Code and will operate in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code;
 - (e) Facility staffing and employment matters, which, at a minimum, shall include:
 - (i) Employee training standards for the safe operation and maintenance of any and all instrumentation that will be used in the analytical testing of medical marijuana conducted on an annual basis;
 - (ii) Employee training standards for the safe use, handling, storage and disposal of any and all chemicals that will be used in the analytical testing of medical marijuana, in accordance with OSHA protocols, conducted on an annual basis; and
 - (iii) Employee compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
 - (f) Compliance with the inventory tracking system implemented by the department; and
 - (g) Standards for the disposal of medical marijuana waste and other wastes.
- (4) A security plan that establishes policies and procedures to prevent theft, loss, or diversion from a testing laboratory and protect facility personnel, which, at a minimum, shall include:
- (a) Record keeping policies and procedures that will ensure the facility complies with rule 3796:4-2-06 of the Administrative Code;
 - (b) A security plan in accordance with rule 3796:4-2-07 of the Administrative Code;
 - (c) Transportation policies in accordance with rule 3796:4-2-10 of the Administrative Code; and
 - (d) A plot plan of the laboratory facility drawn to a reasonable scale that designates the different areas of operation, with mandatory access restrictions.
 - (i) If the building is in existence at the time of the application, the applicant shall submit plans and specifications drawn to scale for the interior of the building.
 - (ii) If the building is not in existence at the time of application, the applicant shall submit a plot plan and a detailed drawing to scale of the interior and the architect's drawing of the building to be constructed.

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- (5) A financial plan, which, at a minimum, shall include:
- (a) The identity and ownership interest of every person, association, partnership, other entity or corporation having a financial interest, direct or indirect, in the testing laboratory with respect to which licensure is sought;
 - (b) A cost breakdown of the applicant's anticipated costs in building the facility and implementing the policies and procedures submitted as part of the application and the source of funding for the associated costs;
 - (c) Documentation acceptable to the department that the individual or entity filing the application has at least two hundred fifty thousand dollars in liquid assets for a testing laboratory provisional license, which are unencumbered and can be converted within thirty days after a request to liquidate such assets;
 - (i) Documentation acceptable to the department includes a signed statement from an Ohio licensed certified public accountant attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying, if such a statement is available at the time of application.
 - (ii) The documentation must be dated within thirty calendar days before the date the application was submitted;
 - (d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule 3796:4-1-05 of the Administrative Code; and
 - (e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level in this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest of one percent or greater in the applicant for the five years before the filing of the application, unless the department determines that documentation should be submitted for all individuals and entities.
- (6) Any other information requested in the application instructions that the department deems necessary to evaluate and determine the applicant's suitability for a testing laboratory license.

3796:4-1-03 Testing laboratory application review.

- (A) The department, an independent contractor selected by the department, or a combination of the two shall review the submitted applications as described in this chapter and the application instructions. In order to receive consideration under paragraph (B) of this rule, an applicant shall:
- (1) Demonstrate sufficient liquid capital pursuant to rule 3796:4-1-02 of the Administrative Code and an ability to meet the financial responsibility requirements under rule 3796:4-1-05 of the Administrative Code;
 - (2) Certify in writing at the time of application that an owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent or other person has not been:
 - (a) Convicted of a disqualifying offense, as defined in rule 3796:1-1-01 of the Administrative Code; or

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- (b) Issued a certificate to recommend or applied for certification under section 4731.30 of the Revised Code;
- (3) Verify that the proposed facility is not located within five hundred feet from a prohibited facility, which shall be measured in accordance with rule 3796:5-5-01 of the Administrative Code;
- (4) Certify that the local jurisdiction where the facility is proposed has not passed a moratorium or taken other action that would prohibit the applicant from operating as a medical marijuana testing laboratory;
- (5) Certify that an owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent, or other person who may significantly influence or control the activities of the testing laboratory does not have a direct or indirect ownership or investment interest, a compensation arrangement with, or share any corporate officers or employees with any of the following:
 - (a) A cultivator, processor, or dispensary licensed under Chapter 3796. of the Revised Code;
 - (b) An applicant for a cultivator, processor, or dispensary license;
- (6) Provide documentation sufficient to establish that the applicant is in compliance with the applicable tax laws of this state and any jurisdiction where the applicant operates and conducts business;
- (7) Submit an application with the applicable fee under rule 3796:5-1-01 of the Administrative Code during the established application submission period established under paragraph (A) of rule 3796:4-1-02 of the Administrative Code. The application shall be submitted in accordance with the application instructions and forms issued by the department. The department may remove an application from consideration for any of the following:
 - (a) Failure or refusal to submit information required under rule 3796:4-1-02 of the Administrative Code or requested by the department during the application submission or review process;
 - (b) Inclusion of information in the application that misleads the department, misrepresents a material fact, or fails to disclose a material fact to the department;
 - (c) Submission of an application that is in violation of the application instructions issued by the department, or includes forms issued by the department that have been altered.
- (B) The applicants shall be ranked using an impartial and numerical process taking into account the criteria identified in rule 3796:4-1-02 of the Administrative Code, as developed by the department, an independent contractor selected by the department, or a combination of the two. The applicants will be ranked based on the following criteria, at a minimum:
 - (1) A business plan, which, at a minimum, shall include:
 - (a) A proposed business model demonstrating a likelihood of success, a sufficient business ability and experience on the part of the applicant;
 - (b) An organizational chart of the company, including name, address, and date of birth of each principal officer and board member of the testing laboratory, provided that all those individuals shall be at least twenty-one years of age;
 - (c) Experience, which includes information on licenses held by any person affiliated with the applicants,

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regardless if said license is active or expired. If expired, applicant shall provide the grounds behind the expiration. The information provided on business licenses shall include the type of license, the licensing agency, the date the license was obtained, and a summary of any negative actions taken against each license.

- (d) Evidence that the applicant owns the property on which the proposed testing laboratory will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the testing laboratory from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the testing laboratory from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
 - (e) Documentation that the applicant is currently in compliance, or will be in compliance prior to the issuance of a certificate of operation, with any local ordinances, rules or regulations adopted by the locality in which the applicant's property is located, which are in effect at the time of the application. Such documentation may include, but is not limited to, local building department approval demonstrating compliance with rules adopted by the board of building standards pursuant to Chapters 3781. and 3791. of the Revised Code to construct the proposed facility, local approval to operate as a medical marijuana cultivation facility, and evidence that the applicant's proposed location is in compliance with local ordinances, rules or regulations adopted by the locality in which the applicant's property is located, which are in effect at the time of the application.
- (2) An operations plan, which shall include but not be limited to:
- (a) Documentation of testing laboratory analysis protocols and instrumentation;
 - (b) A list of proposed analytical services to be offered;
 - (c) Facility plans and specifications evidencing that the applicant will comply with the requirements of Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
 - (d) Staffing and training guidelines, which shall include, but not be limited to:
 - (i) Employee training standards for the safe operation and maintenance of any and all instrumentation that will be used in the testing of medical marijuana;
 - (ii) Employee training standards for the safe use, handling, storage, and disposal of any and all chemicals that will be used in the testing of medical marijuana, in accordance with OSHA protocols; and
 - (iii) Employee compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
 - (e) Compliance with the inventory tracking system implemented by the department; and
 - (f) Standards for the destruction and disposal of medical marijuana waste and other wastes.
- (3) A security plan, which shall include but not be limited to:

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- (a) Policies and procedures to ensure a secure, safe facility to prevent theft, loss, or diversion and protect facility personnel;
 - (b) Physical equipment used to monitor the facility and meet the security requirements under Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
 - (c) Emergency notification procedures with the department, local law enforcement, and emergency response professionals;
 - (d) A plot plan of the laboratory facility drawn to a reasonable scale that designates the different areas of operation, with the mandatory access restrictions; and
 - (e) Transportation policies and procedures, which includes the transportation of medical marijuana from a cultivator or processor licensed by the department to the proposed testing laboratory in the state of Ohio, in accordance with rule 3796:4-2-10 of the Administrative Code.
- (4) A financial plan, which, at a minimum, shall include:
- (a) The identity and ownership interest of every person, association, partnership, other entity, or corporation having a financial interest, direct or indirect, in the testing laboratory with respect to which licensure is sought;
 - (b) A cost breakdown of the applicant's anticipated costs in building the facility and implementing the policies and procedures submitted as part of the application and the source of funding for the associated costs;
 - (c) Documentation acceptable to the department that the individual or entity filing the application has secured at least two hundred fifty thousand dollars in liquid assets for a testing laboratory provisional license are unencumbered and can be converted within thirty days after a request to liquidate such assets;
 - (i) Documentation acceptable to the department includes a signed statement from an Ohio licensed certified public accountant attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying, if such a statement is available at the time of application.
 - (ii) The documentation must be dated within thirty calendar days before the date the application was submitted.
 - (d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule 3796:4-1-05 of the Administrative Code; and
 - (e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level in this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest of one percent or greater in the applicant for the five years before the filing of the application, unless the department determines that documentation should be submitted for all individuals and entities.
- (5) Any other information that the department deems necessary to evaluate and determine the applicant's suitability to operate as a medical marijuana testing laboratory.

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- (C) In addition to the criteria established in paragraph (B) of this rule, the department may also consider the following when awarding a provisional license:
- (1) Principal place of business;
 - (a) The applicant must provide documentation establishing that its principal place of business is headquartered in Ohio. The applicant may also provide the names, addresses, and verification of any persons associated with the applicant that have established residency in Ohio.
 - (b) The applicant may also provide a plan for generating Ohio-based jobs and economic development.
 - (2) Employment practices, in which the applicant must demonstrate a plan of action to inform, hire, and educate minorities, women, veterans, disabled persons, and Ohio residents;
 - (3) Verification of economically disadvantaged groups; and
 - (a) The applicant must demonstrate the following:
 - (i) It is owned and controlled by a United States citizen who is a resident of this state and is a member of one of the economically disadvantaged groups set forth in division (C) of section 3796.09 of the Revised Code. As used in this section, "owned and controlled" means that at least fifty-one percent of the business, including corporate stock if a corporation, is owned by persons who belong to one or more of the groups set forth in this rule, and that those owners have control over the management and day-to-day operations of the business and an interest in the capital, assets, and profits and losses of the business proportionate to their percentage of ownership; or
 - (ii) It is owned and controlled as a woman-owned business by a United States citizen who is a resident of this state. For purpose of the paragraph, "owned and controlled" has the same ownership and control requirements as listed in subparagraph (i) above.
 - (4) Research plan, in which the applicant must provide the department with a detailed proposal to conduct or facilitate a scientific study or studies related to the medicinal use of marijuana. Such a proposal shall address any applicable regulatory restrictions and compliance therewith.
- (D) The department may request additional information as part of the application review process from an applicant that otherwise meets all of the requirements under paragraph (A) of this rule. The applicant shall have thirty calendar days from the date the applicant receives the department's request to provide the information. If the applicant fails to provide the requested information within thirty calendar days, it will result in an abandoned application. An abandoned application shall not receive further consideration.
- (E) An applicant forfeits all fees associated with an abandoned application. The department shall not be required to act on an abandoned application and the application may be destroyed by the department. An abandoned application will not prevent an applicant from applying for a provisional license in the future if the department issues additional provisional licenses pursuant to rule 3796:4-1-01 of the Administrative Code.

3796:4-1-04 Testing laboratory provisional license award.

- (A) A provisional license shall be issued to the qualified applicant receiving at least the minimum required score in each category and the highest total score overall as compared to the other applicants.

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- (B) If no qualified applicants are found during the process described in rule 3796:4-1-03 of the Administrative Code, a provisional licensee fails to fulfill the conditions in the application, a certificate of operation is revoked, or no license is issued or active for any other reason, the department may, at the discretion of the director, announce another period to submit an application in accordance with rule 3796:4-1-02 of the Administrative Code.
- (C) No person shall hold or be granted more than one testing laboratory provisional license or testing laboratory certificate of operation at any time. No person shall hold a financial interest in or be an owner, partner, officer, director, shareholder, member, or other person who may significantly influence or control the activities of more than one testing laboratory. No corporation, partnership, limited liability partnership, limited liability company, or other entity or subsidiary thereof shall hold a financial interest in or be an owner, officer, partner, shareholder, member, or other person who may significantly influence or control the activities of more than one testing laboratory.

3796:4-1-05 Testing laboratory financial responsibility.

- (A) A provisional licensee shall provide evidence of financial responsibility before a certificate of operation can be issued, which may be payable to the department for any of the following reasons:
- (1) A testing laboratory fails to adhere to the security plan approved by the department or otherwise operates the facility in a manner that allows for or results in theft, loss, or diversion of medical marijuana;
 - (2) A testing laboratory engages in activities prohibited under rule 3796:4-2-08 of the Administrative Code;
or
 - (3) A testing laboratory has its certification of operation fined, suspended, or revoked, resulting from activities prohibited under rule 3796:5-6-02 of the Administrative Code.
- (B) Evidence of financial responsibility shall be provided by the following:
- (1) Providing and maintaining at its own expense any insurance coverage and terms of insurance required and approved by the department, including, but not limited to, products liability and general liability, prior to the issuance of a certificate of operation, if such products are in existence at the time of issuance or the time of renewal for the certificate of operation; and
 - (2) Establishing and maintaining an escrow account in a chartered financial institution in Ohio in the amount of seventy-five thousand dollars, with escrow terms, approved by the department, that it shall be payable to the department in the event of circumstances outlined in paragraph (A) of this rule. A financial institution may not return money in an escrow or surety account to the testing laboratory that established the account or a representative of the testing laboratory unless the testing laboratory or representative presents a statement issued by the department indicating that the account may be released; or
 - (3) Providing a surety bond naming the testing laboratory as principal of the bond, upon terms approved by the department, in the amount of seventy-five thousand dollars, payable to the department in the event of circumstances outlined in paragraph (A) of this rule. Bond terms include the following:
 - (a) The business name and registration number on the bond must correspond exactly with the business name and registration number in the department's records.
 - (b) A copy of the bond must be received by the department before a certificate of operation is issued.

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- (c) The bond shall not be canceled by a surety on less than thirty days' notice in writing to the department. If a bond is canceled and the Testing laboratory fails to file a new bond with the department in the required amount on or before the effective date of cancellation, the testing laboratory's license shall be revoked. The total and aggregate liability of the surety on the bond is limited to the amount specified on the bond.
- (4) The department shall permit a testing laboratory to reduce the escrow or surety bond by twenty-five thousand dollars upon the successful achievement of each of the following milestones, resulting in a potential elimination of the escrow account or surety bond:
 - (a) A determination by the department that the testing laboratory remained fully operational without substantial interruption and demonstrates an ability to comply with the requirements of Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796, as determined by the department, for a period of one year;
 - (b) A determination by the department that the testing laboratory remained fully operational without substantial interruption and demonstrates an ability to comply with the requirements of Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796, as determined by the department, for two consecutive years; and
 - (c) A determination by the department that the testing laboratory remained fully operational without substantial interruption and demonstrates an ability to comply with the requirements of Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796, as determined by the department, for three consecutive years.
- (5) A testing laboratory will not be held in default should the failure to comply be the direct result of an event or effect that cannot be reasonably anticipated or controlled, such as an act of God or nature and not the result of a lack of good faith effort.
- (C) The required insurance policy and surety bond shall be written by an insurance company formed, licensed or eligible, and authorized or approved to write such insurance in the state of Ohio under Title XXXIX of the Revised Code.

3796:4-1-06 Testing laboratory certificate of operation.

- (A) A provisional licensee is prohibited from operating as a licensed testing laboratory and performing any analytical testing activities until a certificate of operation is issued by the department. The information and plan submitted by a provisional licensee shall become mandatory conditions that must be met before a certificate of operation can be awarded.
- (B) A provisional licensee shall have six months from the date they are notified of selection to obtain a certificate of operation. A certificate of operation shall be issued once all applicable inspections are passed and the provisional licensee demonstrates that it conforms to the specifications of the application, as well as the requirements imposed by law and rules. If a certificate of operation is issued, the provisional license becomes null and void.
- (C) The department shall not award a certificate of operation to a provisional licensee if the provisional licensee has not met all of the specifications in the application and passed all applicable inspections under rule 3796:4-3-01 of the Administrative Code within six months of written or electronic notification of the

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applicant's selection. If the provisional licensee fails to remedy the deficiencies in accordance with rule 3796:4-3-01 of the Administrative Code or otherwise satisfy the six-month time period established under paragraph (B) of this rule, the director, at his or her discretion, may extend the time period for the testing laboratory to obtain a certificate of operation or take action pursuant to rule 3796:5-6-01 of the Administrative Code.

- (D) The certificate of operation, along with a copy of the current certificate of occupancy for the facility and any other certificate, business license, or other authorization required to conduct testing activities, shall be posted in a conspicuous place within the facility and made available to the department and all fire code and building officials upon request.

3796:4-1-07 Testing laboratory transfer of ownership or location.

- (A) A provisional license issued pursuant to this rule is nontransferable.
- (B) A certificate of operation shall be issued for the specific testing laboratory and location identified on the application, and is valid only for the owner, premises, and name designated on the certificate of operation, and the location for which it is issued. A certificate of operation may only be transferred or assigned if the department determines that the proposed ownership or location change meets all the requirements of this division and Chapter 3796. of the Revised Code and the following requirements are met:
- (1) Upon any request for a change in ownership, the testing laboratory shall:
- (a) Notify the department in writing of the proposed ownership change;
 - (b) Facilitate the submission of both an Ohio bureau of criminal identification and investigation criminal records check and a federal bureau of investigation criminal records check pursuant to division (B) of section 3796.12 of the Revised Code;
 - (c) Demonstrate to the department that the person acquiring the interest meets the requirements under rules 3796:4-1-02 and 3796:4-1-03 of the Administrative Code and that the testing laboratory will remain in compliance with its application for a provisional license, Chapter 3796. of the Revised Code, and the rules promulgated in accordance with Chapter 3796. of the Revised Code, under the proposed ownership structure; and
 - (d) Submit a new application in accordance with rule 3796:4-1-02 of the Administrative Code if the transfer of ownership would result in a new controlling shareholder or shareholders outside of the current ownership structure approved by the department. For purposes of calculating a controlling interest, the department will consider all transfers of ownership that occur in a given calendar year and calculate such transfers in the aggregate.
- (2) Upon a request for a change in location, a testing laboratory shall:
- (a) Notify the department in writing of the proposed location change;
 - (b) Submit plans and specifications for the new facility in accordance with rule 3796:4-1-02 of the Administrative Code; and
 - (c) Demonstrate to the department that the new location meets the applicable requirements of rule 3796:4-1-02 of the Administrative Code and that the testing laboratory will remain in compliance

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with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code at the new location.

- (C) A testing laboratory requesting a change in ownership or location shall submit the applicable fee under rule 3796:5-1-01 of the Administrative Code. A proposed change in ownership or request for a change in location shall not be effective until approved in writing by the department.
- (D) A testing laboratory receiving approval from the department for a change in location shall have ninety days from the date of approval, unless an extension is granted at the discretion of the department, to transfer samples and begin operations at the new location, subject to the following restrictions:
 - (1) The transition period shall not begin until the new location is ready to begin testing and has passed an inspection by the department under rule 3796:4-3-01 of the Administrative Code.
 - (2) No medical marijuana samples may be transferred to or tested at the new location prior to the beginning date of the approved transition period.
 - (3) Any medical marijuana samples at the original location past the ninety-day transition period shall be destroyed in accordance with rule 3796:4-2-06 of the Administrative Code.
 - (4) The testing laboratory shall notify the department in writing or by electronic transmission once the transfer of medical marijuana sample inventory is complete and testing has begun at the new location.
- (E) Upon inspection and verification by the department that the new location is in compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, the department shall issue a license modification reflecting the new location. The modified license shall have the same expiration date as the previously issued license.

3796:4-1-08 Testing laboratory certificate of operation renewal.

- (A) Every testing laboratory certificate of operation issued by the department under this chapter shall expire annually on the date it was issued. A renewal application for a testing laboratory, accompanied by the proper renewal fee established under rule 3796:5-1-01 of the Administrative Code, shall be filed with the department at least thirty days prior to the expiration date of the certificate of operation.
- (B) The department shall grant a renewal application if the application is filed in a timely manner, the testing laboratory submits the corresponding renewal fee, the department confirms that nothing warrants the denial of the renewal under rule 3796:5-6-01 of the Administrative Code, and the testing laboratory passes a full inspection, unless a full inspection was passed within three months before the renewal date.
- (C) If a renewal application is not filed prior to the expiration date of the certificate of operation, the certificate of operation shall be suspended for a maximum of thirty days, at which point it will be deemed expired if the testing laboratory has not successfully renewed the certificate of operation under paragraph (B) of this rule. Upon expiration of the certificate of operation, the testing laboratory shall not engage in any testing activities in furtherance of the business of the testing of medical marijuana. The department shall not renew the certificate of operation and the facility shall permanently cease its operations.

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3796:4-1-09 Winding down.

- (A) If a testing laboratory decides to voluntarily surrender or not renew its certificate of operation and permanently discontinue business operations, the testing laboratory shall provide written notice to the department at least ninety days prior to the effective date of the closure. If the closure is the result of an eviction notice, the testing laboratory shall immediately notify the department of the eviction notice and the effective date of the notice. This notice shall be provided prior to the testing laboratory taking any steps to wind down and discontinue business operations.
- (B) A testing laboratory that notifies the department of its intent to voluntarily surrender or not renew its certificate of operation under paragraph (A) of this rule shall submit, within sixty days of the effective date, a written plan of closure for approval by the department. This plan shall include, at a minimum:
- (1) The destruction of medical marijuana samples on hand at the facility on the effective date of the closure;
 - (2) The sale or removal of equipment and products ancillary to the testing of medical marijuana;
 - (3) The retention of all records required to be maintained in accordance with the applicable records retention schedules;
 - (4) The removal or disposal of any solvents or other chemicals used in the testing of medical marijuana, which shall be carried out in accordance with all applicable local, state, and federal laws.
 - (5) The steps that will be taken to maintain compliance with Chapter 3796. of the Revised Code, the rules promulgated in accordance with Chapter 3796. of the Revised Code, and any other conditions required by the director until the approved closure date; and
 - (6) The closure and intended use of the premises in which the testing laboratory was located.
- (C) The director shall approve or deny a testing laboratory's plan of closure within thirty days of receipt. The director may request additional information if approval or denial of the plan cannot be determined based on the information provided.

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:

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- (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

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- (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.

3796:4-2-02 Testing laboratory proficiency testing and certification.

- (A) Within two calendar years of the date of issuance of a provisional license by the department, a testing laboratory shall become accredited to the ISO/IEC 17025 standard by a non-profit accreditation body that is signatory to the "International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA)" and which operates in accordance with ISO/IEC 17011 "General Requirements for accreditation Bodies Accrediting Conformity Assessment Bodies," and shall consent to have all inspections and reports pertaining to certification and accreditation made available to the department.
 - (1) If the director believes that a testing laboratory has failed to meet the requirements of paragraph (A) of this rule, the director may issue a notice of noncompliance to a licensed testing laboratory. The notice shall include the factual basis for the director's belief, including any appropriate supporting documentation.
 - (2) Upon a notice issued pursuant to paragraph (B) of this rule, a testing laboratory may respond with any evidence sufficient to prove that the testing laboratory has met, and continues to meet, the standards established by paragraph (A) of this rule.
 - (3) If a testing laboratory fails to respond to a notice issued, or the director determines the evidence provided is insufficient to establish that the conditions in paragraph (A) of this rule have been met, the director shall move to fine, suspend, or revoke the testing laboratory certificate of operation pursuant to rule 3796:5-6-01 of the Administrative Code.
 - (4) At any time prior to the issuance of a notice of noncompliance under this rule, a testing laboratory may petition the director to toll computation of the time frames provided in paragraph (A) of this rule. Such a petition shall provide the following:
 - (a) An explanation of the facts and circumstances that will not allow the testing laboratory to become certified and accredited as required in paragraph (A) of this rule; and
 - (b) A plan for how and when the testing laboratory will be able to meet the requirement of paragraph (A) of this rule, with specific attention to how such a plan will allow the testing laboratory to meet the standards established in paragraph (A).
 - (5) Upon receipt of a petition under paragraph (E) of this rule, the director may stay the requirement of paragraph (A) of this rule for a testing laboratory. A director's order staying the requirement of paragraph (A) of this rule shall state the date upon which the stay is lifted using information provided by the testing laboratory in accordance with paragraph (E)(2) of this rule.
- (B) The department may require a testing laboratory to participate in third party proficiency testing programs

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administered by organizations accredited to ISO/IEC 17043 "Conformity Assessment - General Requirements for Proficiency Testing."

3796:4-2-03 Testing laboratory sample procurement.

- (A) A testing laboratory shall collect samples of harvested plant material for analysis from a cultivator. Samples must be taken from each segregated, homogenized batch of harvested marijuana, as defined in rule 3796:1-1-01 of the Administrative Code, in such a manner as to ensure that a random sample is selected.
- (B) A testing laboratory shall collect samples of medical marijuana products for analysis from a processor. Samples must be taken from each lot of medical marijuana products, as defined in rule 3796:1-1-01 of the Administrative Code, in such a manner as to ensure that a random sample is selected.
- (C) A testing laboratory may collect samples of marijuana-derived ingredients, including but not limited to extracts, intended for use in the manufacture of medical marijuana products, if analysis is requested by a processor. Samples must be taken from each batch of marijuana-derived ingredients in such a manner as to ensure that a random sample is selected. Tests performed on medical marijuana extract may satisfy the requirements set forth in paragraph (C) of rule 3796:4-2-04 of the Administrative Code for the following analyses:
 - (1) Mycotoxin contamination;
 - (2) Heavy metal contamination;
 - (3) Pesticide and fertilizer residue contamination; or
 - (4) Residual solvent contamination.
- (D) A testing laboratory may collect samples of plant material at any phase of cultivation for the purposes of assisting cultivators in research and development regarding new strains of medical marijuana or cultivation techniques, if analysis is requested by a cultivator. Tests performed pursuant to this paragraph must be reported to the department in accordance with rule 3796:4-2-05 of the Administrative Code, and the resulting certificate of analysis must be clearly marked with the phrase "For research and development only. Not for sale."
- (E) A testing laboratory shall transport all samples in accordance with rule 3796:4-2-10 of the Administrative Code.

3796:4-2-04 Testing laboratory analysis requirements.

- (A) A testing laboratory shall analyze a sample of at least one half of one percent of the net weight of the batch from each batch of dried, cured plant material intended to be sold to a dispensary licensed by the state of Ohio board of pharmacy for, at minimum:
 - (1) Moisture content
 - (2) Cannabinoid potency including, at minimum:
 - (a) Delta-9-tetrahydrocannabinolic acid (THCA);

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(b) Delta-9-tetrahydrocannabinol (THC);

(c) Cannabidiolic acid (CBDA); and

(d) Cannabidiol (CBD);

(3) Foreign matter contamination;

(4) Microbial contamination;

(5) Mycotoxin contamination;

(6) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and

(7) Pesticide and fertilizer residue.

(B) A testing laboratory shall analyze a sample of at least one half of one percent of the net weight of the batch from each batch of plant material intended to be sold to a processor licensed by the department for use in the manufacture of medical marijuana products for, at minimum:

(1) Pesticide and fertilizer residue; and

(2) Cannabinoid potency for, at a minimum:

(a) Delta-9-tetrahydrocannabinolic acid (THCA);

(b) Delta-9-tetrahydrocannabinol (THC);

(c) Cannabidiolic acid (CBDA); and

(d) Cannabidiol (CBD);

(C) A testing laboratory shall analyze a sample of one unit of the same size, weight, and volume intended to be packaged and sold to a licensed dispensary from each lot of medical marijuana products prior to sale to a dispensary licensed by the state of Ohio board of pharmacy for, at minimum:

(1) Cannabinoid potency including, at minimum:

(a) Delta-9-tetrahydrocannabinolic acid (THCA);

(b) Delta-9-tetrahydrocannabinol (THC);

(c) Cannabidiolic acid (CBDA); and

(d) Cannabidiol (CBD);

(2) Foreign matter contamination;

(3) Microbial contamination;

(4) Mycotoxin contamination, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for mycotoxin contamination by a licensed testing laboratory;

(5) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury, if a medical

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marijuana extract was used in the manufacture of the product that was not previously tested for heavy metal contamination by a licensed testing laboratory;

- (6) Pesticide and fertilizer residue, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for pesticide or fertilizer residue contamination by a licensed testing laboratory; and
 - (7) Residual solvents, if a hydrocarbon-based medical marijuana extract was used in the manufacture of the product that was not previously tested for residual solvent contamination by a licensed testing laboratory.
- (D) A testing laboratory may perform analysis on marijuana-derived ingredients used in the manufacture of medical marijuana products, including but not limited to medical marijuana extract. When performing analysis on medical marijuana-derived ingredients, the following sample sizes and required tests shall apply:
- (1) A sample of at least one half of one percent of the net weight of the batch from a batch of medical marijuana extract derived from a system utilizing hydrocarbon solvents for, at minimum:
 - (a) Pesticide and fertilizer residue; and
 - (b) Cannabinoid potency including, at minimum:
 - (i) Delta-9-tetrahydrocannabinolic acid (THCA);
 - (ii) Delta-9-tetrahydrocannabinol (THC);
 - (iii) Cannabidiolic acid (CBDA); and
 - (iv) Cannabidiol (CBD);
 - (c) Mycotoxin contamination;
 - (d) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and
 - (e) Residual solvents.
 - (2) A sample of at least one half of one percent of the net weight of the batch from a batch of medical marijuana extract derived from a system utilizing carbon dioxide for, at minimum:
 - (a) Pesticide and fertilizer residue; and
 - (b) Cannabinoid potency for, at a minimum:
 - (i) Delta-9-tetrahydrocannabinolic acid (THCA);
 - (ii) Delta-9-tetrahydrocannabinol (THC);
 - (iii) Cannabidiolic acid (CBDA); and
 - (iv) Cannabidiol (CBD);
 - (c) Mycotoxin contamination; and
 - (d) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury.

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- (3) A sample of at least one half of one percent of the net weight of the batch from a batch of medical marijuana extract derived from a method that does not involve the use of a hydrocarbon or carbon dioxide as a solvent for, at a minimum:
- (a) Cannabinoid potency including, at minimum:
 - (i) Delta-9-tetrahydrocannabinolic acid (THCA);
 - (ii) Delta-9-tetrahydrocannabinol (THC);
 - (iii) Cannabidiolic acid (CBDA); and
 - (iv) Cannabidiol (CBD);
 - (b) Foreign matter contamination;
 - (c) Microbial contamination;
 - (d) Mycotoxin contamination;
 - (e) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and
 - (f) Pesticide and fertilizer residue.
- (E) The department shall establish rules for laboratory testing of any forms of medical marijuana approved by the state of Ohio board of pharmacy pursuant to division (A)(6) of section 3796.06 of the Revised Code, including required analytical tests and the sample size associated therewith, prior to the manufacture or sale of forms not listed in this rule.
- (F) A testing laboratory may request additional sample material in excess of the amounts listed in this rule if necessary for completion of the required quality assurance tests.
- (G) For the purposes of microbial contamination analysis, a sample provided to a testing laboratory shall be deemed to have passed if it satisfies the standards set forth in Table 9 of the "Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control" (2014) monograph.
- (1) If a batch of plant material is not deemed to have passed testing for microbial contamination, that batch may be designated for extraction by hydrocarbon-based or carbon dioxide-based methods
 - (2) Medical marijuana extract derived from a batch of plant material not deemed to have passed testing for microbial contamination must be tested for microbial contamination prior to use in the manufacture of medical marijuana products.
- (H) For the purposes of mycotoxin contamination analysis, a sample provided to a testing laboratory pursuant to this section shall be deemed to have passed if:
- (1) The total of the detected amounts, if any, of aflatoxin B1, aflatoxin B2, aflatoxin G1, and aflatoxin G2 is less than twenty micrograms per kilogram; and
 - (2) The detected amount, if any, of ochratoxin A is less than twenty micrograms per kilogram.
- (I) For the purposes of heavy metal contamination analysis, a sample provided to a testing laboratory shall be deemed to have passed if:

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- (1) The detected amount of arsenic, if any, is less than 0.14 micrograms per kilogram.
 - (2) The detected amount of cadmium, if any, is less than 0.09 micrograms per kilogram.
 - (3) The detected amount of lead, if any, is less than 0.29 micrograms per kilogram.
 - (4) The detected amount of mercury, if any, is less than 0.29 micrograms per kilogram.
- (J) For the purposes of pesticide residue analysis, a sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for an approved pesticide chemical residue in a food item as set forth in Subpart C of 40 C.F.R. Part 180. A sample shall automatically be deemed to have failed if residue is detected from any pesticide not on the approved pesticide list maintained by the department, regardless of the detected level of residue.
- (K) Except as provided in paragraph (G)(1) of this rule, if a sample is deemed to have failed tests for any contaminants listed in this rule, the cultivator or processor that provided the sample must immediately destroy the corresponding batch of plant material or extract or lot of medical marijuana products and document the destruction in the inventory tracking system.

3796:4-2-05 Testing laboratory reporting.

- (A) A testing laboratory performing analysis on medical marijuana shall submit in portable document format (.pdf) an electronic copy of the results of analysis of all batches and lots tested to the department via an email address specified and maintained by the department and input the results of analysis into the inventory tracking system.
- (B) A testing laboratory performing analysis on medical marijuana shall create a unique certificate of analysis for each batch or lot tested, which shall include, at minimum:
- (1) The name and license number of the testing laboratory where the analysis was performed;
 - (2) The name and license number of the cultivator or processor from whom the sample was received;
 - (3) The registered name of the medical marijuana strain or medical marijuana product that was registered with the department;
 - (4) A unique batch or lot number as defined in rule 3796:1-1-01 of the Administrative Code that will match the sample of medical marijuana or medical marijuana products with a batch or lot, in order to facilitate any warnings or recalls the department deems appropriate;
 - (5) The date or dates on which each test was performed;
 - (6) A grid or table listing all tests performed, and indicating "pass" or "fail" for each, as defined in rule 3796:4-2-04 of the Administrative Code.
 - (7) The cannabinoid profile of the sample, including the percentage content by weight for, at minimum:
 - (a) Delta-9-tetrahydrocannabinol (THC);
 - (b) Delta-9-tetrahydrocannabinolic acid (THCA);

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(c) Cannabidiol (CBD); and

(d) Cannabidiolic acid (CBDA);

(8) Moisture content;

(9) Results of analysis for foreign matter contamination;

(10) Quantitative results of analysis for microbial contamination;

(11) Quantitative results of analysis for heavy metal contamination;

(12) Quantitative results of analysis for pesticide and fertilizer residue;

(13) Quantitative results of analysis for mycotoxins;

(14) Quantitative results of analysis for residual solvents; and

(15) The signature of the laboratory manager or scientific director certifying the analysis.

(C) The certificate of analysis may contain the following:

(1) Results of quantitative analysis of additional cannabinoids for which the laboratory is able to obtain a standard for comparison;

(2) Results of quantitative analysis of terpenes for which the laboratory is able to obtain a standard for comparison;

(D) A certificate of analysis shall not contain any sum totals of cannabinoids or terpenes, except THC content as defined in paragraph rule 3796:1-1-01 of the Administrative Code.

3796:4-2-06 Testing laboratory waste disposal.

(A) Upon completion of the required analysis performed on any given sample, a licensed testing laboratory shall immediately dispose of any medical marijuana waste or excess medical marijuana not used during the sample analysis in accordance with the testing laboratory's disposal plan, under the supervision of a type 1 employee, as defined in paragraph (H) of rule 3796:5-2-01 of the Administrative Code, and in such a manner as to render the medical marijuana unusable.

(B) The disposal procedures established by the testing laboratory and submitted as part of the application process shall be sufficient to render unusable any medical marijuana waste or excess medical marijuana not used during the sample analysis. Medical marijuana waste or excess medical marijuana that is rendered unusable shall be discarded into a locked dumpster or other approved, locked container for removal from the facility by a waste removal company selected by the testing laboratory. Medical marijuana waste or excess medical marijuana shall be rendered unusable by grinding and incorporating the medical marijuana waste with one or more of the non-consumable, solid wastes listed in this paragraph, such that the resulting mixture is at least fifty-one per cent non-marijuana waste:

(1) Paper waste;

(2) Cardboard waste;

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- (3) Food waste;
 - (4) Yard waste;
 - (5) Soil or other growth media;
 - (6) Other wastes approved by the department.
- (C) The disposal of medical marijuana waste and excess medical marijuana not used during the sample analysis shall be performed by a type 1 key employee under video surveillance from the time the destruction begins to when it is placed in a locked dumpster or other approved, locked container and removed from the facility.
- (D) The type 1 employee overseeing the disposal of excess medical marijuana shall maintain and make available in accordance with this Chapter a separate record of every disposal indicating:
- (1) The date and time of disposal;
 - (2) The manner of disposal;
 - (3) The volume and weight of the excess medical marijuana;
 - (4) The solid waste used to render the excess medical marijuana unusable; and
 - (5) The signature of the type 1 employee overseeing the disposal of the medical marijuana.
- (E) The disposal of other waste from the testing laboratory that does not include medical marijuana, including hazardous waste and liquid waste, shall be performed in a manner consistent with federal and state law.

3796:4-2-07 Testing laboratory security.

- (A) The department shall determine the appropriate security requirements for all testing laboratory facilities, and may require additional safeguards to ensure the security of medical marijuana. A testing laboratory shall comply with the security plan submitted as part of its testing laboratory provisional license application. At a minimum, the testing laboratory shall:
- (1) Install an adequate security alarm system around the perimeter, utilizing commercial grade equipment, to prevent and detect diversion, theft, or loss of medical marijuana;
 - (2) Utilize a video surveillance recording system installed by a vendor that is approved by the department and that meets the standards required by the department to prevent and detect diversion, theft, or loss of medical marijuana;
 - (3) Maintain all security system equipment and video surveillance systems in a secure location so as to prevent theft, loss, destruction, or alteration;
 - (a) A testing laboratory shall limit access to surveillance areas to a type 1 key employees that are essential to surveillance operations, law enforcement agencies, security system service employees, the department, and others when approved by the department; and
 - (b) A testing laboratory shall make available to the department, upon request, a current list of Type 1 employees and contractors who have access to the surveillance room. A testing laboratory shall keep

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all on-site surveillance rooms locked and shall not use such rooms for any other functions.

- (4) Keep all approved safes, approved vaults, or any other approved equipment or areas used for storing medical marijuana samples securely locked and protected from unauthorized access;
 - (5) Ensure the outside perimeter of the facility is well-lit and in accordance with the testing laboratory's plan in its license application;
 - (6) Restrict access to any area within the facility containing medical marijuana samples to all persons except licensed employees and agents or an individual permitted to access the facility under the supervision of a licensed employee or agent in accordance with the visitor authorization procedures set forth in rule 3796:5-2-01 of the Administrative Code.
 - (7) Limit the use of combination numbers, passwords, or electronic or biometric security systems to licensed, authorized employees, and prevent the sharing of any employee-specific access credentials; and
 - (8) Not allow keys to be left in the locks and not store or place keys or badges in a location accessible to persons other than licensed, authorized employees.
- (B) The testing laboratory shall install a security alarm system and a video surveillance recording system under paragraph (A) of this rule. A security alarm system and video surveillance recording system shall, at a minimum, contain the following:
- (1) A system designed to detect motion and identify unauthorized access to the facility;
 - (2) Video cameras in all areas that may contain medical marijuana samples, and at all points of entry and exit to capture a clear and certain identification of any person entering or exiting the facility, which shall be appropriate for the normal lighting conditions of the area under surveillance;
 - (3) Video cameras shall be directed at all approved safes, approved vaults, any other area where medical marijuana samples are being stored or handled;
 - (4) The security alarm system and video surveillance recording system shall comply with the following minimum capabilities:
 - (a) Provide a direct feed and login capabilities to the department to allow for real-time access and monitoring of the facility via the live video surveillance recording system.
 - (b) A display monitor with a minimum screen size of twelve inches shall be connected to the electronic recording security system at all times.
 - (c) Installed in a manner that will prevent cameras from being readily obstructed, tampered with, or disabled.
 - (d) The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded).
 - (e) A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture.
 - (f) Cameras installed outdoors and in low-light interior areas shall be day/night cameras with a minimum resolution of six hundred lines per inch (analog) or D1 (IP) and a minimum light factor requirement

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of 0.7 LUX. The installation of additional lighting may be required to increase picture clarity and brightness. Cameras shall be calibrated and focused to maximize the quality of the recorded image.

- (g) Allow for the exporting of still images in an industry standard image format, including .jpg, .bmp and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. All recordings shall be erased or destroyed prior to disposal.
 - (h) Security recordings shall provide an image resolution of at least D1, and the image frame rate shall be at least three frames per second during alarm or motion based recording.
 - (i) Repair and/or replace any failed component of the video surveillance recording system within twenty-four hours, unless notice is provided to the department and an extension is approved.
- (5) Twenty-four hour live feed with motion-activated recording capabilities from all video cameras, which the testing laboratory shall make available for immediate viewing by the department upon request and shall retain for at least forty-five days. If a testing laboratory is aware of a pending criminal, civil or administrative investigation, or legal proceeding for which a recording may contain relevant information, the testing laboratory shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the testing laboratory manager that it is not necessary to retain the recording;
- (6) A silent alarm, which can be utilized in the event of a holdup or other instances of duress, which notifies law enforcement;
- (7) Panic alarm, which for purposes of this subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;
- (8) Automatic voice dialer, which for purposes of this subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety, or emergency services agency requesting dispatch;
- (9) A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the testing laboratory within five minutes of the failure, either by telephone, email, or text message; and
- (10) The ability to comply with the security requirements of this rule for a period of at least forty-eight hours during a power outage.
- (C) In addition to the requirements listed in paragraph (B) of this rule, each testing laboratory shall have a back-up alarm system approved by the department that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.
- (D) A testing laboratory shall keep all security equipment in good-working order and the systems shall be inspected and all devices tested on annual basis.

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3796:4-2-08 Testing laboratory prohibited activities.

- (A) A testing laboratory shall not cultivate, process, manufacture, distribute, provide, or sell medical marijuana in any form.
- (B) A testing laboratory shall not permit the consumption of medical marijuana in any form on the premises.
- (C) A testing laboratory shall not share a facility with a cultivator, processor, or dispensary licensed under Chapter 3796. of the Revised Code.
- (D) A testing laboratory shall not falsify, change, modify, or otherwise alter in any way the results of quantitative or other analyses performed on medical marijuana samples or the corresponding certificates of analysis.
- (E) A testing laboratory shall not employ any sampling methods that do not ensure that a random sample is collected for analysis, or that could provide results that are not representative of a batch or lot from which a sample is taken.
- (F) A testing laboratory shall not prepare medical marijuana samples in such a manner as to provide results that are not representative of a batch or lot from which a sample is taken.
- (G) A testing laboratory shall not store medical marijuana in quantities greater than that which is necessary to perform required analyses.
- (H) A testing laboratory shall not transport medical marijuana in quantities greater than that which is necessary to perform required analyses.
- (I) A testing laboratory shall not perform analyses on any medical marijuana that has not been obtained from a cultivator or processor licensed under Chapter 3796. of the Revised Code.
- (J) A testing laboratory shall not perform analyses on any medical marijuana that has not been identified in the inventory tracking system.
- (K) A testing laboratory shall not endorse, advertise, or make claims on behalf of any cultivator, processor, dispensary, brand or strain of medical marijuana, or brand or type of medical marijuana product.
- (L) A testing laboratory shall not publish or otherwise release to the public the results of any tests performed pursuant to paragraph (D) of rule 3796:4-2-03 of the Administrative Code.
- (M) An owner, officer, board member, administrator, employee, agent, or other person who may significantly influence or control the activities of a testing laboratory shall not:
 - (1) Have a direct or indirect financial interest in a cultivator, processor, or dispensary licensed under Chapter 3796. of the Revised Code; or
 - (2) Serve as an officer, board member, administrator, employee, agent, or other person who may significantly influence or control the activities of a cultivator, processor, or dispensary licensed under Chapter 3796. of the Revised Code.
- (N) A physician certified or who has applied for certification by the state of Ohio medical board under section 4731.30 of the Revised Code to recommend medical marijuana shall not:

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- (1) Have a direct or indirect financial interest in a testing laboratory; or
- (2) Serve as an officer, board member, administrator, employee, agent, or other person who may significantly influence or control the activities of a testing laboratory.

3796:4-2-09 Testing laboratory record keeping requirements.

- (A) Each testing laboratory shall keep and maintain upon the licensed premises for a five-year period true, complete, legible, and current books and records. All required records must be made available for inspection if requested by the department. The following records shall be maintained:
- (1) Records relating to the disposal of excess medical marijuana and medical marijuana waste in accordance with paragraph (E) of this rule and paragraph (D) of rule 3796:4-2-06 of the Administrative Code;
 - (2) Transportation records in accordance with rule 3796:4-2-10 of the Administrative Code;
 - (3) Records of all samples analyzed and the corresponding certificates of analysis;
 - (4) Security records in accordance with paragraph (B) of rule 3796:4-2-07 of the Administrative Code;
 - (5) Sample inventory tracking records and sample inventory records maintained in the inventory tracking system, as well as any records maintained by the facility outside the inventory tracking system;
 - (6) Financial records in accordance with paragraph (C) of this rule;
 - (7) Employee records in accordance with paragraph (D) of this rule; and
 - (8) Records of any theft, loss, or other unaccountability of any medical marijuana as described in rule 3796:5-4-01 of the Administrative Code.
- (B) A testing laboratory may use an electronic system for the storage and retrieval of records required by Chapter 3796. of the Revised Code or the rules promulgated under Chapter 3796. of the Revised Code or other records relating to medical marijuana. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this rule. A testing laboratory shall use a system that:
- (1) Guarantees the confidentiality of the information stored in the system;
 - (2) Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the testing laboratory;
 - (3) Is capable of placing a litigation hold or enforcing a records retention hold for purposes of conducting an investigation or pursuant to ongoing litigation; and
 - (4) Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.
- (C) A testing laboratory shall maintain financial records, which shall include the following:
- (1) Records that clearly reflect all financial transactions and the financial condition of the business, including contracts for services performed or received that relate to the testing laboratory;
 - (2) Purchase invoices, bills of lading, manifests, sales records, copies of bills of sale, and any supporting

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documents, including the items and/or services purchased, from whom the items were purchased, and the date of purchase;

(3) Bank statements and canceled checks for all accounts relating to the testing laboratory, if applicable; and

(4) Accounting and tax records related to the testing laboratory and all investors in the facility.

(D) A testing laboratory shall maintain employee records, which shall include the following:

(1) All records relating to the hiring of employees, including applications, documentation of verification of references, and any other related materials;

(2) An employee log that includes the following information for every current and former employee:

(a) Employee name, address, phone number, and emergency contact information;

(b) Registration number and access credential designation;

(c) Date of hire and date of separation from employment, if applicable, and the reason for the separation;

(d) All training, education, and disciplinary records; and

(e) Salary and wages paid to each employee, and any executive compensation, bonus, benefit, or item of value paid to any individual affiliated with any medical marijuana entity, including members of a non-profit corporation, if any.

(E) Medical marijuana analysis and disposal records may be stored at the facility and shall include all of the following:

(1) The registered strain or product name, form, and quantity of marijuana involved;

(2) The date the sample was taken from the cultivator or processor and arrived at the testing laboratory;

(3) The date and time of testing, transporting, or disposing of the medical marijuana; and

(4) If the medical marijuana is destroyed, the testing laboratory shall maintain records in accordance with paragraph (D) of rule 3796:4-2-06 of the Administrative Code.

3796:4-2-10 Testing laboratory transportation of medical marijuana samples.

(A) Prior to transporting any medical marijuana samples, regardless of form, a testing laboratory licensed by the department shall maintain a transportation log, in writing, that contains the following information:

(1) The name and address of the medical marijuana entity from which the sample is taken;

(2) The name and registration number of the registered testing laboratory employee transporting the medical marijuana samples;

(3) The license plate number and vehicle type that will transport the shipment;

(4) The time of departure and estimated time of arrival;

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- (5) The specific travel route, which includes street names and distances; and
 - (6) The total weight of the samples collected, a description of each sample, and the total number of samples being transported.
- (B) The testing laboratory transporting medical marijuana under paragraph (A) of this rule shall enter the information required in the inventory tracking system in accordance with section 3796.07 of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code. The transportation log shall be made available to law enforcement agencies upon request. A testing laboratory shall maintain all transportation logs in accordance with the record keeping requirements established under the rules promulgated in accordance with Chapter 3796. of the Revised Code, and make them available at the request of the department.
- (C) The vehicle transporting the medical marijuana samples or any product containing medical marijuana shall meet the following requirements:
- (1) Be insured as required by law;
 - (2) Store the medical marijuana samples in a locked, safe, and secure storage compartment that is part of the motor vehicle, or in a locked storage container that has a separate key or combination pad;
 - (3) Ensure that any medical marijuana samples are not visible from the outside of the vehicle;
 - (4) Be staffed by a testing laboratory employee registered with the department;
 - (5) Have access to a secure form of communication with personnel at the testing laboratory and the ability to contact law enforcement through the 911 emergency system at all times that the vehicle contains medical marijuana samples, unless notification is impractical under the circumstances; and
 - (6) Not contain any marks, logos, brands, or other illustrations on the exterior of the vehicle, other than those affixed to the vehicle by the vehicle manufacturer or dealership.
- (D) Any vehicle transporting medical marijuana samples shall travel directly from the facility from which the samples were collected to the testing laboratory, and shall not make any stops in between except to other medical marijuana entities listed on the transportation log for the purpose of collecting samples, to refuel the vehicle, or to notify the medical marijuana entities, the department and law enforcement in the event of an emergency. In the event of an emergency, the employees will report the emergency immediately to law enforcement through the 911 emergency system and to the medical marijuana entities, which will immediately notify the department, unless the notification is impractical under the circumstances.
- (E) A registered testing laboratory employee transporting medical marijuana samples shall do the following:
- (1) Display his or her department issued employee identification card at all times when transporting medical marijuana samples and shall produce it for the department or department's authorized representative or law enforcement official upon request;
 - (2) Ensure delivery times vary and routes are randomized;
 - (3) Report any vehicle accident that occurs during the transportation to the management staff of the testing laboratory within two hours after the accident occurs;
 - (4) Report any loss or theft of medical marijuana that occurs during the transportation of medical marijuana in

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accordance with rule 3796:5-4-01 of the Administrative Code; and

- (5) Carry a copy of the transportation log completed pursuant to paragraph (A) of this rule for the duration of the trip.

3796:4-3-01 Testing laboratory enforcement.

- (A) The submission of an application that results in the issuance of a provisional license or certificate of operation for a testing laboratory irrevocably gives the department consent to conduct all inspections necessary to ensure compliance with the testing laboratory's application, state law, Chapter 3796. of the Revised Code and the rules promulgated under Chapter 3796. of the Revised Code. The department may conduct the inspection independently, or may work with other departments, state agencies, or local authorities, including the department of agriculture, the department of industrial compliance and the state fire marshal, to ensure compliance with the testing laboratory's application, state law, Chapter 3796. of the Revised Code and the rules promulgated under Chapter 3796. of the Revised Code.
- (B) An inspector conducting an inspection pursuant to this rule does not need to be accompanied by a licensed employee during the inspection. During an inspection, the inspector may:
 - (1) Review and make copies of all records maintained in accordance with rule 3796:4-2-07 of the Administrative Code;
 - (2) Enter any room in the facility;
 - (3) Inspect facility vehicles;
 - (4) Review the policies and procedures of the testing laboratory, including methods of operating;
 - (5) Survey the premises and any off-site facilities;
 - (6) Inspect all equipment, instruments, tools, materials, machinery or any other resource used to analyze medical marijuana;
 - (7) Request access to locked areas in the facility; and
 - (8) Question licensed employees at the location;
- (C) A pre-approval inspection of a testing laboratory that is required before the department issues a certificate of operation to a testing laboratory possessing a provisional license under rule 3796:4-1-06 of the Administrative Code shall occur at a mutually agreeable time. The department shall rely on the facility's application, Chapter 3796. of the Revised Code and the rules promulgated under Chapter 3796. of the Revised Code to facilitate the inspection and ensure compliance of the facility. Upon the completion of the pre-approval inspection, the department may issue:
 - (1) A certificate of operation in accordance with rule 3796:4-1-06 of the Administrative Code, at which point the facility will be permitted to begin operations; or
 - (2) A written statement listing the deficiencies identified during the inspection that must be remedied before a certificate of operation will be issued by the department.
 - (a) Upon receipt of a statement of deficiencies, the testing laboratory shall develop a plan of correction

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for each deficiency and submit the plan in writing to the department for approval within ten business days after receipt of the statement of deficiencies and request for a plan, unless a written extension is issued by the department.

- (b) The plan of correction must include specific requirements for corrective action that will be performed within thirty calendar days after the department's acceptance of the plan of correction, or the remaining time period under paragraph (B) of rule 3796:4-1-06 of the Administrative Code, whichever is greater.
 - (c) If the plan of correction submitted is not acceptable to the department or would prevent the facility from obtaining a certificate of operation in accordance with rule 3796:4-1-06 of the Administrative Code, the department may either direct the medical marijuana licensee to resubmit a plan of correction or the department may develop a directed plan of correction with which the testing laboratory must comply. Upon acceptance of the written plan of correction, the department and the testing laboratory will sign a mutually binding agreement defining the terms under which the testing laboratory will be issued a certificate of operation. If the parties are unable to come to terms on the written plan of correction, the department may take any action permitted under rule 3796:5-6-01 of the Administrative Code.
 - (d) The department shall re-inspect a testing laboratory upon the completion of the written plan of correction. If the corrective measures meet the department's satisfaction, the department shall issue a certificate of operation. If the corrective measures do not meet the requirements of the written plan of correction, the department shall take action in accordance with rule 3796:5-6-01 of the Administrative Code.
- (D) The department may, at any time it determines an inspection is needed, with or without notice, conduct an inspection of a testing laboratory to ensure compliance with the facility's application, state law, Chapter 3796. of the Revised Code and the rules promulgated under Chapter 3796. of the Revised Code of the Administrative Code in accordance with paragraph (A) of this rule. An inspection of a testing laboratory may include, without limitation, investigation of standards for safety from fire on behalf of the department by the local fire protection agency. If a local fire protection agency is not available, the state fire marshal may conduct the inspection after the medical marijuana testing laboratory pays the appropriate fee to the state fire marshal for such inspection.
- (E) Following an inspection conducted pursuant to paragraph (D) of this rule, the department shall issue an inspection report that documents the following:
- (1) The observations and findings of the inspection;
 - (2) The outcome of the inspection;
 - (3) Any suggestions for the testing laboratory to take into consideration; and
 - (4) If applicable, a written statement listing the deficiencies identified during the inspection.
 - (a) Upon receipt of a request for a written plan of correction, the testing laboratory shall develop a plan of correction for each deficiency and submit the plan to the department for approval within ten business days after receipt of the statement of deficiencies, unless a written extension is issued by the department.
 - (b) The plan of correction must include specific requirements for corrective action that will be performed

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within thirty calendar days. If the plan submitted is not acceptable to the department, the department may either direct the medical marijuana licensee to resubmit a plan of correction or the department may develop a directed plan of correction with which the testing laboratory must comply. Upon acceptance of the written plan of correction, the department and the testing laboratory will sign a mutually binding agreement defining the terms agreed upon by the parties. If the parties are unable to come to terms on the written plan of correction, the department may take any action permitted under rule 3796:5-6-01 of the Administrative Code.

- (c) The department shall re-inspect a testing laboratory upon the completion of the written plan of correction. If the corrective measures meet the department's satisfaction, the department shall indicate such on the inspection report and conclude the inspection. If the corrective measures do not meet the requirements of the written plan of correction, the department shall take action in accordance with rule 3796:5-6-01 of the Administrative Code.
- (F) If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, risk to public health or the occurrence of a prohibited activities under rule 3796:5-6-02 of the Administrative Code, the department may take immediate action authorized under rule 3796:5-6-01 of the Administrative Code.
- (G) To prevent destruction of evidence, diversion or other threats to public safety, the department may order an administrative hold of medical marijuana or medical marijuana product or any books and records of any licensee. The department may assess the costs of an investigation, including travel and the time of any and all employees, to a licensee.