

INITIAL RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH

CHAPTER 681. MEDICAL MARIJUANA REGULATIONS

1. DESCRIPTION:

OAC 310:681-1-4. Definitions

- Adds definition of “remediation” (same definition set forth in 63 O.S. § 427.2).
- Adds definition of “decontamination.”

OAC 310:681-5-6. Inventory tracking, records, reports, and audits

- Subsection (b)(2): Clarifies that copies of sample field logs and documents related to transportation and sampling are included in the types testing records business licensees have to maintain. By including these documents in the list, they must be kept onsite and readily available for seven years.

OAC 310:681-5-10. Medical marijuana waste disposal

- Subsection (b)(1)-(3): Creates a new provision that would require commercial licensees to create and maintain (for five years) a disposal log that must be signed and attested to under penalty of perjury. Under current law, commercial licensees may dispose of root balls, stems, fan leaves, seeds, and stalks on their own but must send all other medical marijuana waste to a waste disposal facility. Documentation will help OMMA Compliance monitor disposal and dissuade diversion of plant material.

OAC 310:681-5-18. Prohibited Acts

- Subsection (k): Clarifies that licensees shall only sell or otherwise transfer medical marijuana to Oklahoma-licensed medical marijuana businesses and that licensee shall not sell medical marijuana to out-of-state individuals or entities.

OAC 310:681-7-1. Labeling and Packaging

- Subsection (d): Adds prohibition that packages and labels cannot contain the OSDH or OMMA logo. Compliance inspectors have found several instances where this is occurring.
- Subsection (e): Adds requirements for labels of non-edible products so they are more uniform with edibles and provide important information such as name, license number, batch number, quantity, and ingredients. These items are essential information for a patient to have access to in the event of a recall.
- Subsection (f): Adds basic labeling requirements for wholesale transfers between growers and/or processors, which include name, license number, batch number, date of harvest or production, and a statement that the medical marijuana has passed testing or failed testing and is being transferred for remediation purposes only.
- Subsection (g): Adds requirement that growers and processors store medical marijuana and products under conditions and in manner that protects against contamination and deterioration. Also requires it to be stored in fully sealed/closed receptacles when not in use.

OAC 310:681-8-1. Testing standards and thresholds

- Subsections (c): Clarifies that samples must be collected and labeled in accordance with applicable statutes and these Rules. Strikes duplicative language that was intended to be struck during prior rulemaking.
- Subsection (d): Authorizes growers to sell/transfer and processors to purchase/process a harvest batch that has failed microbiological testing for remediation purposes only. Strikes and moves language requiring dispensaries to maintain copies of Certificates of Analysis (COAs).
- Subsection (h): Expands and clarifies the duty of growers, processors, and dispensaries to obtain and retain (for two years) copies of COAs for all medical marijuana and products they purchase. Requires growers and processors to provide these copies to the Department immediately upon request and to other licensees who request copies in order to be in compliance with these requirements. Also requires growers and processors to notify the Department when their medical marijuana or products fail testing.
- Subsection (j): Establishes process for retesting harvest and production batches that fail testing. Requires the reserve sample to be used for retesting and outlines protocol for collection of a new sample if the reserve sample is not sufficient. Allows retesting to be limited to the category of analyte that failed initial testing; limits costs by not requiring full panel retesting. If retest gives passing results, requires second retest to confirm safety and suitability of medical marijuana or product. Requires any batch that does not have two successful tests for each analyte to be remediated, decontaminated, or disposed.
- Subsection (k): Allows for harvest or production batches that have been remediated or decontaminated and have failed testing to be retested in accordance with the new retesting procedures established in (j). Prohibits further decontamination of production batches that failed retesting and allows for harvest batches that have been decontaminated and failed testing for microbials to be disposed of or remediated.
- Subsection (l): Authorizes growers to sell/transfer to a processor and processor to purchase/process a harvest batch that has failed microbiological testing for remediation purposes only. Clarifies that the production batch must be fully tested. Prohibits processors from selling medical marijuana from the harvest batch that failed testing.
- Subsections (m)-(r): Changes term “remediation” to “decontamination” to reflect the fact that the definition of “remediation” in 63 O.S. § 427.2 limits the definition of remediation to the processing of a harvest batch that has failed microbiological testing into a solvent-based concentrate.

OAC 310:681-8-2. General operating requirements and procedures

- Subsection (b): Establishes requirement that a testing laboratory shall only report COAs for analytes the laboratory conducted that are within the scope of the testing laboratory’s accreditation; clarifies laboratories may outsource testing and report those results on a COA but must identify the laboratory that conducted the testing.

OAC 310:681-8-3. Sampling requirements and procedures.

- Subsection (a)(1)(A) and (a)(11): Establishes requirement that samplers must be trained on the testing laboratory’s sampling protocols and that commercial licensees must document such training.
- Subsection (a)(6): Requires samples to be clearly labeled with the following information: “Primary Sample” or “Reserve Sample”; name, license number, and batch number.
- Subsection (a)(9): Requires the sample field log to list the title and version of the laboratory’s standard operating procedure that was followed when collecting the sample.
- Subsection (e)(2): Prohibits a laboratory from withholding from a commercial licensee a COA reporting a failed test.

- Subsection (e)(3): Clarifies that COAs must contain the required information even in “electronic form” and requires COAs to contain definitions of any abbreviated terms.
- Subsection (e)(4): Requires COAs to clearly and conspicuously list “Pass” or “Fail” in font size no smaller than the size of 12 point Times New Roman font. Cannot be listed in fine print or footnotes. Also requires actual limits of analytes detected to be listed, even if below allowable threshold.
- Subsection (e)(6): Requires laboratory to immediately notify the Department in the form and manner prescribed by Department of any failed testing.

OAC 310:681-9-9. Waste disposal

- Subsection (a): Requires commercial licensees to submit waste to a waste disposal facility within 90 days.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

The changes proposed are intended to ensure the safety of medical marijuana and medical marijuana products sold to consumers and to prevent diversion and unlawful distribution of medical marijuana. The Department anticipates that the majority of persons impacted from the regulatory changes will be medical marijuana businesses.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:

The classes of persons who are likely to benefit from the proposed rules include the population of patients consuming medical marijuana and medical marijuana products. Despite the rise of use of cannabis for medical purposes, conclusive evidence regarding the short- and long-term health effects of cannabis use remains elusive. In order to best protect the public health and the health of licensed patients, the proposed emergency rules set forth additional requirements for the sampling, testing, labeling, and disposal of medical marijuana and medical marijuana products.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:

There are no fee changes. It is anticipated that some the changes will result in increased costs to businesses. The full economic impact and costs are unknown but the proposed emergency rules were drafted with consideration and intent to not create any unnecessary or burdensome costs. The Department will accept public comments from the persons who may potentially be impacted by costs as a result of compliance when the emergency rules are presented for permanent rule consideration.

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY.

There are no costs associated with implementation.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

7. ADVERSE EFFECT ON SMALL BUSINESS:

The full economic impact and costs are unknown but the proposed emergency rules were drafted with consideration and intent to not create any unnecessary or burdensome costs. The Department will accept public comments from the persons who may potentially be impacted by costs as a result of compliance when the emergency rules are presented for permanent rule consideration.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:**

There are no less costly means currently identified.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY**

These emergency rules seek to fulfill core public health functions of protecting Oklahomans from potential harms through known evidence-based policies and promising practices, while staying within the authority provided by enabling law. Evidence remains limited on the beneficial uses of cannabis and concern remains on its effects on specific populations. The Department has identified public health concerns with the implementation of a medical marijuana program and has proposed emergency rules that will help ensure the health and safety of the medical marijuana and medical marijuana products sold to consumers. These rules include, but are not limited to, making label requirements for medical marijuana and medical marijuana edibles the same; requiring a business take reasonable steps to store medical marijuana where it will be protected from contamination; setting basic label requirements for samples and batches being transferred between businesses; and outlining process for retesting of medical marijuana that will ensure product that initially fails testing is safe for consumption.

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**

As noted in the prior sections, a full assessment of potential effects on public health and safety without adoption is unknown; however, the proposed emergency rules are intended to address issues identified during OSDH's investigation of several recalls of medical marijuana.

11. **PREPARATION AND MODIFICATION DATES:**

This rule impact statement was prepared on September 8, 2020.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 681. MEDICAL MARIJUANA REGULATIONS**

RULEMAKING ACTION:

EMERGENCY adoption

RULES:

Subchapter 1. General Provisions [AMENDED]
310:681-1-4 [AMENDED]
Subchapter 5. Medical Marijuana Businesses [AMENDED]
310:681-5-6 [AMENDED]
310:681-5-10 [AMENDED]
310:681-5-18 [AMENDED]
Subchapter 7. Packaging, Labeling, and Advertising [AMENDED]
310:681-7-1 [AMENDED]
Subchapter 8. Laboratory Testing [AMENDED]
310:681-8-1 [AMENDED]
310:681-8-2 [AMENDED]
310:681-8-3 [AMENDED]
Subchapter 9. Waste Disposal Facilities [AMENDED]
310:681-9-9 [AMENDED]
APPENDIX A [REVOKED]
APPENDIX A [NEW]

AUTHORITY:

Oklahoma State Commissioner of Health; Title 63 O.S. Section 1-104

ADOPTION:

September 24, 2020

EFFECTIVE:

Immediately upon Governor's approval

EXPIRATION:

Effective through September 14, 2021, unless superseded by another rule or disapproved by the Legislature

SUPERSEDED EMERGENCY ACTIONS:

n/a

INCORPORATIONS BY REFERENCE:

n/a

FINDING OF EMERGENCY:

These emergency rules seek to fulfill core public health functions of protecting Oklahomans from potential harms through known evidence-based policies and promising practices, while staying within the authority provided by enabling law. Evidence remains limited on the beneficial uses of cannabis and concern remains on its effects on specific populations. The Department has identified public health concerns with the implementation of a medical marijuana program and has proposed emergency rules that will help ensure the health and safety of the medical marijuana and medical marijuana products sold to consumers. These rules include, but are not limited to, making label requirements for medical marijuana and medical marijuana edibles the same; requiring a business take reasonable steps to store medical marijuana where it will be protected from contamination; setting basic label requirements for samples and batches being transferred between

businesses; and outlining process for retesting of medical marijuana that will ensure product that initially fails testing is safe for consumption.

GIST/ANALYSIS:

The changes proposed are intended to ensure the safety of medical marijuana and medical marijuana products sold to consumers and to prevent diversion and unlawful distribution of medical marijuana. In order to best protect the public health and the health of licensed patients, the proposed emergency rules set forth additional requirements for the sampling, testing, labeling, and disposal of medical marijuana and medical marijuana products. These rules include, but are not limited to, making label requirements for medical marijuana and medical marijuana edibles the same; requiring a business take reasonable steps to store medical marijuana where it will be protected from contamination; setting basic label requirements for samples and batches being transferred between businesses; and outlining process for retesting of medical marijuana that will ensure product that initially fails testing is safe for consumption.

CONTACT PERSON:

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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING EMERGENCY RULES ARE CONSIDERED PROMULGATED AND EFFECTIVE UPON APPROVAL BY THE GOVERNOR AS SET FORTH IN 75 O.S., SECTION 253(F):

SUBCHAPTER 1. GENERAL PROVISIONS

310:681-1-4. Definitions

The following words and terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"**Advertising**" means the act of providing consideration for the publication, dissemination, solicitation, or circulation of visual, oral, or written communication to induce directly or indirectly any person to patronize a particular medical marijuana business or to purchase any particular medical marijuana or medical marijuana products. "Advertising" includes marketing but does not include packaging and labeling.

"**Applicant**" means the natural person or entity in whose name a license would be issued.

"**Application status**" means the status of a submitted application and includes the following:

- (A) "Submitted" means the application has been submitted but a review is not yet complete;
- (B) "Rejected" means the application has been reviewed but contains one or more errors requiring correction by the applicant at no additional fee before a final determination on the application can be made. "Rejected" does not mean the application is denied;
- (C) "Approved" means the application has been approved and that a

license will be issued and mailed to the applicant; and

(D) "Denied" means the applicant does not meet the qualifications under Oklahoma law and this Chapter for a license.

"**Authority**" or "**OMMA**" means the Oklahoma Medical Marijuana Authority, a division of the Oklahoma State Department of Health.

"**Batch number**" means a unique numeric or alphanumeric identifier assigned prior to any testing to allow for inventory tracking and traceability.

"**Business license**" means a license issued by the Department to a medical marijuana dispensary, grower, processor, testing laboratory, or transporter.

"**Cannabinoid**" means any of the chemical compounds that are active principles of marijuana.

"**Caregiver**" means a family member or assistant who regularly looks after a licensed patient whom a physician certifies is homebound or needs assistance.

"**CFR**" means the Code of Federal Regulations, the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which is published by the U.S. Government Printing Office. Citations in this Chapter to the CFR refer sequentially to the Title, Part and Section numbers.

"**Child-resistant**" means packaging that is:

(A) Designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for normal adults to use properly as defined by 16 CFR § 1700.15 (1995) and 16 CFR § 1700.20 (1995);

(B) Opaque so that the outermost packaging does not allow the product to be seen without opening the packaging material; and

(C) Resealable to maintain its child-resistant effectiveness for multiple openings for any product intended for more than a single use or containing multiple servings.

"**Clone**" means a non-flowering plant cut from a mother plant that is capable of developing into a new plant and has shown no signs of flowering.

"**Commercial license**" means any license issued to an individual or entity that is not a patient, caregiver, or transporter agent.

"**Commercial licensee**" means an individual or entity issued a commercial license and does not mean a patient, caregiver, or transporter agent.

"**Commissioner**" means the State Commissioner of Health of the Oklahoma State Department of Health.

"**Complete(d) application**" means a document prepared in accordance with Oklahoma law, these Rules, and the forms and instructions provided by the Department, including any supporting documentation required by the Department and the license fee.

"**Decontamination**" means a process that attempts to remove or reduce to an acceptable level a contaminant exceeding an allowable threshold set forth in these Rules in a harvest batch or production batch.

"**Department**" means the Oklahoma State Department of Health or its agent or designee.

"**Dispense**" means the retail selling of medical marijuana medical

marijuana products that are packaged and labeled in accordance with the law to a licensed patient, the licensed patient's parent(s) or legal guardian(s) if licensed patient is a minor, or a licensed caregiver.

"Dispensary" or **"Commercial Dispensary"** means an individual or entity that has been issued a medical marijuana business license by the Department, which allows the dispensary to purchase medical marijuana or medical marijuana products from a licensed processor, grower, or dispensary; to sell medical marijuana and medical marijuana products to a licensed patient, to the licensed patient's parent(s) or legal guardian(s) if licensed patient is an minor, and a licensed caregiver; and to sell, transfer, and transport or contract with a commercial transporter to transport medical marijuana or medical marijuana products to another licensed dispensary, a research facility, and an educational facility; and to transfer to testing laboratories.

"Dispose" or **"Disposal"** means the final disposition of medical marijuana waste by either a process which renders the waste unusable through physical destruction or a recycling process.

"Disqualifying criminal conviction" means:

(A) Any non-violent felony conviction within last two (2) years of submitting an application to the Department;

(B) Any violent felony conviction for an offense listed in 57 O.S. § 571(2) within last five (5) years of submitting an application to the Department; or

(C) Incarceration for any reason during submission of application to the Department.

"Education facility" means an individual or entity that has been issued a license by the Department to operate a facility providing training and education to individuals involving the cultivation, growing, harvesting, curing, preparing, packaging, or testing of medical marijuana, or the production, manufacture, extraction, processing, packaging, or creation of medical-marijuana-infused products or medical marijuana products for the limited education and research purposes permitted under state and federal law and these Rules; to transfer, by sale or donation, medical marijuana grown within its operation to licensed research licensees; and to transfer to licensed testing laboratories.

"Entity" means an individual, sole proprietorship, a general partnership, a limited partnership, a limited liability company, a trust, an estate, an association, a corporation, or any other legal or commercial entity.

"Entrance to a private or public school" means an opening, such as a door, passage, or gate, that allows access to any public or private schools, including school buildings, facilities, or other indoor and outdoor properties utilized for classes or school activities.

"Flower" means the reproductive organs of the marijuana or cannabis plant referred to as the bud or parts of the plant that are harvested and used to consume in a variety of medical marijuana products.

"Flowering" means the reproductive state of the marijuana or cannabis plant in which there are physical signs of flower or budding out of the nodes of the stem.

"Food" has the same meaning as set forth in 63 O.S. § 1-1101 (*'food' means (1) articles used for food or drink for man, (2) chewing gum, and (3) articles used for components of any such article*) and set forth in the Oklahoma Administrative Code ("OAC") OAC 310:257-1-2 and OAC 310:260-1-6 (*"'food' means any raw, cooked, or processed edible substance, ice, beverage or ingredient used or intended for use or for sale in whole or in part for human consumption"*).

"Grower" or **"Commercial grower"** means an individual or entity that has been issued a medical marijuana business license by the Department, which allows the grower to grow, harvest, dry, cure, package, sell, transfer, and transport or contract with a commercial transporter for the transport of medical marijuana in accordance with Oklahoma law and this Chapter to a dispensary, processor, grower, research facility, education facility, or testing laboratory.

"Harvest Batch" means a specifically identified quantity of usable medical marijuana, no greater than ten (10) pounds, that is uniform in strain, cultivated utilizing the same cultivation practices, harvested at the same time from the same location, and dried or cured under uniform conditions.

"Immature plant" means a nonflowering marijuana plant that has not demonstrated signs of flowering.

"Indirect beneficial owner" means an individual or entity who indirectly, through any contract, arrangement, understanding, relationship or otherwise, owns ten percent (10%) or more of the equity interests of a grower, processor, or dispensary.

"Information panel" has the same definition as set forth in 21 CFR § 101.2 and means *"that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel."*

"Inventory tracking system" means a required tracking system that accounts for the entire life span of medical marijuana, from either the seed or immature plant stage until the medical marijuana or medical marijuana product is consumed, used, disposed of or otherwise destroyed.

"Label" carries the same definition as set forth in 63 O.S. § 1-1101 and means *a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this article that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if there be any, of the retail package of such article, or is easily legible through the outside container or wrapper.*

"License" means a state issued license or other state issued documentation proving the holder of such license is a member of a state-regulated medical marijuana program.

"License number" means the unique multi-character identifier issued and printed upon each license.

"Licensee" means any natural born person or entity that holds a medical marijuana license provided for in this Chapter, excluding inmates of any local, county, state, or federal correctional facility or jail.

"Licensed Packager" means as used in 63 O.S. § 422A(C) a processor.

"Licensed premises" means the premises specified in an application for a medical marijuana business, research facility, education facility, or waste disposal facility that is owned or in lawful possession of the licensee and within which the licensee is authorized to operate.

"Lot" means the food produced during a period of time indicated by a specific code.

"Marijuana" means the same as the term that is defined in 63 O.S. § 2-101.

"Mature plant" means harvestable female marijuana plant that is flowering.

"Medicaid" means the program that is also commonly known in Oklahoma as "SoonerCare."

"Medical marijuana" means marijuana that is grown, processed, dispensed, tested, possessed, or used for a medical purpose.

"Medical marijuana business" means an individual or entity licensed by the Department as a medical marijuana dispensary, grower, processor, testing laboratory, or transporter.

"Medical marijuana concentrate" ("Concentrate") means a substance obtained by separating cannabinoids from any part of the marijuana plant by physical or chemical means, so as to deliver a product with a cannabinoid concentration greater than the raw plant material from which it is derived. Categories of concentrate include water-based medical marijuana concentrate, food-based medical marijuana concentrate, solvent-based concentrate, and heat- or pressure-based medical marijuana concentrate as those terms are defined in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

"Medical marijuana product" means a product that contains cannabinoids that have been extracted from plant material or the resin therefrom by physical or chemical means and is intended for administration to a licensed patient, including but not limited to concentrates, oils, tinctures, edibles, pills, topical forms, gels, creams, and other derivative forms, except that this term does not include live plant forms.

"Medical marijuana research" means research on medical marijuana and medical marijuana products for public purposes, including the advancement of (A) Public health policy and public safety policy, (B) Agronomic and horticultural best practices, and C) Medical and pharmacopoeia best practices. For purposes of this Chapter, this term does not include biomedical and clinical research that is subject to federal regulations and institutional oversight and shall not be subject to Department oversight.

"Medical marijuana waste" means unused, surplus, returned or out-of-date marijuana; recalled marijuana; unused marijuana; plant debris of the plant of the genus cannabis, including dead plants and all unused plant parts, except the term shall not include roots, stems, stalks and fan leaves.

"Minor" means any natural person younger than eighteen (18) years of age.

"Mother plant" means a marijuana plant that is grown or maintained

for the purpose of generating clones, and that will not be used to produce plant material for sale to a processor or dispensary.

"Municipality" means the same definition as set forth in the Oklahoma Municipal Code, 11 O.S. § 1-102, and *"means any incorporated city or town."*

"Officer of a corporate entity" or **"Principal officer"** means an officer identified in the corporate bylaws, articles of organization or other organizational documents, or in a resolution of the governing body.

"Officer of a municipality" means the same definition as set forth in the Oklahoma Municipal Code, 11 O.S. § 1-102, and *means any person who is elected to an office in municipal government or is appointed to fill an unexpired term of an elected office, and the clerk and the treasurer whether elected or appointed.*

"Oklahoma resident" or **"Resident"** means an individual who can provide proof of residency as required by OAC 310:681-1-6 (relating to proof of residency) or OAC 310:681-5-3.1 (relating to proof of residency for commercial business licensees).

"Oklahoma uniform symbol" or **"Universal symbol"** means the image, established by the Department and made available to commercial licensees through the OMMA website, which indicates the package contains medical marijuana or medical marijuana products with THC and must be printed at least one-half inch in size by one-half inch in size in the color designated by the Department.

"Out-of-state medical marijuana patient license" means an unexpired medical marijuana patient license issued by another U.S. state, which is the substantial equivalent of the Oklahoma medical marijuana patient license issued pursuant to OAC 310:681-2-1 and OAC 310:681-2-2.

"Owner" means, except where the context otherwise requires, a direct beneficial owner, including, but not limited to, all persons or entities as follows:

- (A) All shareholders owning an interest of a corporate entity and all officers of a corporate entity;
- (B) All partners of a general partnership;
- (C) All general partners and all limited partners that own an interest in a limited partnership;
- (D) All members that own an interest in a limited liability company;
- (E) All beneficiaries that hold a beneficial interest in a trust and all trustees of a trust;
- (F) All persons or entities that own interest in a joint venture;
- (G) All persons or entities that own an interest in an association;
- (H) The owners of any other type of legal entity; and
- (I) Any other person holding an interest or convertible note in any entity which owns, operates, or manages a licensed medical marijuana facility.

"Package" or **"Packaging"** means any container or wrapper that a medical marijuana business may use for enclosing or containing medical marijuana or medical marijuana products, except that "package" or "packaging" shall not include any carry-out bag or other similar

container.

"Patient" or **" Licensed patient"** means a person that has been properly issued a medical marijuana license pursuant to Oklahoma law and these Rules.

"Pesticide" means

- (A) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or
- (B) any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant. "Pesticide" shall not include any article that is a "new animal drug" as designated by the United States Food and Drug Administration.

"Physician" or **"Oklahoma Physician"** means a doctor of medicine, a doctor of osteopathic medicine, or a doctor of podiatric medicine who holds a valid, unrestricted and existing license to practice in the State of Oklahoma.

"Plant material" means the leaves, stems, buds, and flowers of the marijuana plant, and does not include seedlings, seeds, clones, stalks, or roots of the plant or the weight of any non-marijuana ingredients combined with marijuana.

"Political subdivision" means any county or municipal governments.

"Preschool" means a public early childhood education program offered under 70 O.S. §§ 11-103.7 and 1-114 (B) or similar program offered by a private school whose primary purpose is to offer educational (or academic) instruction. Preschool does not include a homeschool, daycare, or child care facility licensed under the Oklahoma Child Care Facilities Licensing Act, 10 O.S. § 401 et seq.

"Principal display panel" has the same definition as set forth in 21 CFR § 101.1 and "means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale."

"Private school" means a preschool, elementary, middle, or high school maintained by private individuals, religious organizations, or corporations, funded, at least in part, by fees or tuition, and open only to pupils selected and admitted based on religious affiliations or other particular qualifications. "Private school" shall not include a homeschool, daycare, or child care facility licensed under the Oklahoma Child Care Facilities Licensing Act, 10 O.S. § 401 et seq.

"Process" means to distill, extract, manufacture, prepare, or otherwise produce a medical marijuana product.

"Processor" or **"Commercial Processor"** means an individual or entity that has been issued a medical marijuana business license by the Department, which allows the processor to: purchase medical marijuana or medical marijuana products from a grower or processor; process, package, sell, transfer, and transport or contract with a commercial transporter to transport medical marijuana and medical marijuana products that they processed to a licensed dispensary, processor, or testing laboratory in accordance with Oklahoma law and this Chapter; and process medical marijuana received from a licensed patient into a medical marijuana concentrate, for a fee.

"Production batch" means

- (A) Any amount of medical marijuana concentrate, not to exceed ten (10) pounds, of the same category and produced using the same

extraction methods, standard operating procedures, and an identical group of harvest batch of medical marijuana; and
(B) Any amount of finished medical marijuana product, not to exceed ten (10) pounds, of the same exact type, produced using the same ingredients, standard operating procedures, and same production batch of medical marijuana concentrate or same harvest batch of medical marijuana.

"Public institution" means any entity established or controlled by the federal government, state government, or a local government or municipality, including, but not limited, institutions of higher education and related research institutions.

"Public money" means any funds or money obtained from any governmental entity, including, but not limited to, research grants.

"Public school" means a preschool, elementary, middle, or high school established under state law, regulated by the local state authorities in the various political subdivisions, funded and maintained by public taxation, and open and free to all children of the particular district where the school is located.

"Quality assurance laboratory" means a laboratory designated by the Department to conduct surveillance of testing laboratories for compliance purposes.

"Registered to conduct business" means any individual or entity that is required under Oklahoma law to register with the Oklahoma Secretary of State and/or the Oklahoma Tax Commission and has provided sufficient proof to the Department of its good standing with such.

"Remediation" means the process by which the medical marijuana flower or trim, which has failed microbial testing, is processed into solvent-based medical marijuana concentrate and tested in accordance with these Rules.

"Research project" means a discrete scientific endeavor to answer a research question or a set of research questions related to medical marijuana and is required for a medical marijuana research license.

"Research facility" means an individual or entity that has been issued a license by the Department to grow, cultivate, possess, and transfer to testing laboratories, and to transfer by sale or donation to other licensed research facilities, medical marijuana for the limited research purposes permitted under state and federal law and these Rules.

"Retailer" or **"Retail marijuana establishment"** as used in 63 O.S. § 420 et seq. means an entity licensed by the State Department of Health as a medical marijuana dispensary.

"Revocation" means the Department's final decision in accordance with the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq., that any license issued by the Department pursuant to Oklahoma law and this Chapter is rescinded.

"Rules" means, unless otherwise indicated, the rules as adopted and set forth in OAC 310:681.

"Sampler" means a person who is employed by or is an owner of a licensed laboratory, grower, or processor and is authorized by that employer to collect samples in accordance with the testing laboratory's standard operating procedures and these Rules.

"Seedling" means a marijuana plant that has no flowers.

"Shipping container" means a hard-sided container with a lid or other enclosure that can be secured into place. A shipping container is used solely for the transport of medical marijuana, medical marijuana concentrate, or medical marijuana products between medical marijuana businesses, a medical marijuana research facility, or a medical marijuana education facility.

"State question" means Oklahoma State Question No. 788 and Initiative Petition Number 412.

"Strain" means the classification of marijuana or cannabis plants in either pure sativa, indica, afghanica, ruderalis, or hybrid varieties.

"Terpenoids" means isoprenes that are the aromatic compounds found in cannabis, including, but not limited to: limonene, myrcene, pinene, linalool, eucalyptol, Δ -terpinene, β -caryophyllene, caryophyllene oxide, nerolidol and phytol.

"Testing laboratory" or **"Laboratory"** means a public or private laboratory licensed pursuant to state law and these Rules to conduct testing and research on medical marijuana and medical marijuana products.

"THC" means tetrahydrocannabinol, which is the primary psychotropic cannabinoid formed by decarboxylation of naturally tetrahydrocannabinolic acid, which generally occurs by exposure to heat.

"Transporter" or **"Commercial Transporter"** means an individual or entity issued a medical marijuana commercial license by the Department, which allows the transporter to transport, store, and distribute medical marijuana and medical marijuana products to and from the licensed premises of commercial licensee. As used in this Chapter, "Transporter" or "Commercial Transporter" does not mean licensed commercial growers, processors, and dispensaries who are automatic holders of transporter licenses.

"Transporter Agent" means an agent, employee, officer, or owner of commercial transporter, grower, processor, or dispensary who has been issued a transporter agent license by the Department to transport medical marijuana and medical marijuana products on behalf of the said commercial transporter, grower, processor, or dispensary.

"Transporter license" means a medical marijuana business license issued by the Department either (A) automatically to commercial growers, processors, and dispensaries upon approval of a business license, or (B) to commercial transporters solely for the transportation, storage, and distribution of medical marijuana and medical marijuana products.

"Usable medical marijuana" means the dried leaves, flowers, oils, vapors, waxes, and other portions of the marijuana plant and any mixture or preparation thereof, excluding seed, roots, stems, stalks, and fan leaves.

"Waste disposal facility" means an individual or entity that has been issued a medical marijuana waste disposal facility license by the Department to dispose of medical marijuana waste as authorized in Oklahoma law and these Rules.

"Waste disposal facility license" means a license issued by the Department to possess, transport, and dispose of medical marijuana waste. The waste disposal facility license shall be issued to the

location submitted by the applicant that is first approved by the Department.

"Waste disposal facility permit" means a permit issued by the Department to a waste disposal licensee to possess, transport, and dispose of medical marijuana waste at the location submitted on the permit application. Waste disposal facility permits shall be required for each approved facility operated by a waste disposal facility licensee.

SUBCHAPTER 5. MEDICAL MARIJUANA BUSINESSES

310:681-5-6. Inventory tracking, records, reports, and audits

(a) **Monthly reports.** Licensed growers, processors, and dispensaries shall complete a monthly report on a form and in a manner prescribed by the Department. These reports shall be deemed untimely if not received by the Department by the fifteenth (15th) of each month for the preceding month.

(1) Dispensary reports shall include:

- (A) The amount of marijuana purchased in pounds;
- (B) The amount of marijuana sold or otherwise transferred in pounds;
- (C) The amount of marijuana waste in pounds;
- (D) If necessary, a detailed explanation of why any medical marijuana product purchased by the licensee cannot be accounted for as having been sold or still remaining in inventory;
- (E) Total dollar amount of all sales to medical marijuana patients and caregivers;
- (F) Total dollar amount of all taxes collected from sales to medical marijuana patients and caregivers; and
- (G) Any information the Department determines is necessary to ensure that all marijuana grown in Oklahoma is accounted for as required under 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

(2) Grower reports shall include:

- (A) The amount of marijuana harvested in pounds;
- (B) The amount of marijuana purchased in pounds;
- (C) The amount of marijuana sold or otherwise transferred in pounds;
- (D) The amount of drying or dried marijuana on hand;
- (E) The amount of marijuana waste in pounds;
- (F) If necessary, a detailed explanation of why any marijuana cannot be accounted for as having been sold, disposed of, or maintained in current inventory;
- (G) Total dollar amount of all sales; and
- (H) Any information the Department determines is necessary to ensure that all marijuana grown in Oklahoma is accounted for as required under 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

(3) Processor reports shall include:

- (A) The amount of marijuana purchased in pounds;
- (B) The amount of marijuana sold or otherwise transferred in pounds;

(C) The amount of medical marijuana manufactured or processed in pounds;

(D) If necessary, a detailed explanation of why any marijuana cannot be accounted for as having been purchased, sold, processed, or maintained in current inventory;

(E) The amount of marijuana waste in pounds; and

(F) Any information the Department determines is necessary to ensure that all marijuana grown in Oklahoma is accounted for as required under 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

(4) Submission of information and data to the Department through the seed-to-sale tracking system established by the Department, or a seed-to-sale tracking system that integrates with the Department-established system, in accordance with the Oklahoma Medical Marijuana Protection Act, 63 O.S. § 427.1 et seq., and these Rules shall be sufficient to satisfy monthly reporting requirements.

(b) **Records.** Pursuant to the Department's audit and inspection responsibilities, medical marijuana business shall keep onsite and readily accessible, either in paper or electronic form, a copy of the records listed below. Except as otherwise specifically provided in Oklahoma law and this Chapter, all records shall be maintained for at least seven (7) years from the date of creation.

(1) Business records, which may include but are not limited to employee records, organizational documents or other records relating to the governance and structure of the licensee, manual or computerized records of assets and liabilities, monetary transactions, tax records, journals, ledgers, and supporting documents, including agreements, checks, invoices, receipts, and vouchers.

(2) As applicable, any documents related to the processing, preparation, transportation, sampling, and/or testing of medical marijuana and medical marijuana products, including but not limited to sample field logs, lab reports, testing records, equipment inspections, training materials, and standard operating procedures.

(3) Documentation of every instance in which medical marijuana was sold or otherwise transferred to or purchased or otherwise obtained from another licensee, which shall include, but is not limited to:

(A) The name, license number, address, and phone number of all licensees involved in each transaction; and

(B) The quantity and type of medical marijuana or medical marijuana products involved in each transaction;

(C) The batch number of the medical marijuana or medical marijuana products involved in each transaction;

(D) The date of each transaction;

(E) The monetary value of the medical marijuana or medical marijuana products involved in each transaction, including the total sale or purchase amounts;

(F) All point-of-sale and tax records; and

(G) All inventory manifests and other documentation relating to the transport of medical marijuana and medical marijuana products.

(4) Any and all documents relating to the disposal or destruction of

medical marijuana, medical marijuana products, and medical marijuana waste.

(c) **Patient information.** Records containing private patient information shall not be retained by a medical marijuana business for more than sixty (60) days without the patient's or caregiver's consent. "Private patient information" means personally identifiable information, such as the patient name, address, date of birth, social security number, telephone number, email address, photograph, and financial information. This term does not include the patient's medical marijuana license number, which shall be retained by the business and provided to the Department upon request for compliance and public health purposes, including the verification of lawful sales or patient traceability in the event of product recall.

(d) **Inventory.** Each business licensee shall use the seed-to-sale tracking system established by the Department or a seed-to-sale tracking system that integrates with the Department-established system at the time of its implementation. The system utilized by each licensee shall be a system that:

(1) Documents the chain of custody of all medical marijuana and medical marijuana products, including every transaction with another commercial licensee, patient, or caregiver;

(2) Establishes ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of medical marijuana and medical marijuana products for traceability which shall enable the licensee to detect any diversion, theft, or loss in a timely manner;

(3) Identifies and allows for tracking and documentation of the entire life span of a licensee's stock of medical marijuana and medical marijuana products, including, at a minimum:

(A) When medical marijuana seeds are planted;

(B) When medical marijuana plants are harvested and/or destroyed;

(C) When medical marijuana is transported, sold, stolen, diverted, or lost;

(D) A complete inventory of all medical marijuana; seeds; plant tissue; clones; usable marijuana; trim; leaves; other plant matter; and medical marijuana products;

(E) All samples sent to a testing laboratory or used for internal quality testing or other purposes;

(4) In event of a serious adverse event or recall, is capable of tracking medical marijuana or medical marijuana product from a patient back to the source of the medical marijuana or medical marijuana product; and

(5) Tracks medical marijuana using an assigned batch number and bar code.

(e) **Audits.** The Department may perform on-site audits of all commercial licensees to ensure the accuracy of the monthly reports and to ensure that all marijuana grown in Oklahoma is accounted for. Submission of an application for a medical marijuana commercial license constitutes permission for entry to any licensed premises and auditing of the commercial licensee during hours of operation and other reasonable times. Refusal to permit the Department entry or refusal to permit the Department to inspect all books and records

shall constitute grounds for the nonrenewal, suspension, or revocation of a license.

(1) The Department may review any and all records and information of a commercial licensee and may require and conduct interviews with such persons or entities and persons affiliated with such licensees, for the purpose of determining compliance with Department rules and applicable laws. Failure to make documents or other requested information available to the Department and/or refusal to appear or cooperate with an interview shall constitute grounds for nonrenewal, suspension, or revocation of a license or any other remedy or relief provided under law. All records shall be kept on-site and readily accessible.

(2) Commercial licensees shall comply with all written requests from the Department to produce or provide access to records and information within ten (10) business days.

(3) If the Department identifies a violation of 63 O.S. § 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or these Rules during an audit of the commercial licensee, the Department shall take administrative action against the licensee in accordance with the Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.

(4) The Department may refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a commercial licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.

(5) If the Department discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an audit, the Department may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation.

(6) Except as is otherwise provided in Oklahoma law or these Rules, correctable violations identified during an audit shall be corrected within thirty (30) days of receipt of a written notice of violation.

(7) If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine of \$500.00 for each violation and any other administrative action and penalty authorized by law.

310:681-5-10. Medical marijuana waste disposal

(a) All medical marijuana plant material and waste generated during the cultivation, production, processing, handling, and testing of medical marijuana and medical marijuana products must be stored, managed, and disposed of in accordance with these Rules, the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and any other applicable Oklahoma statutes and rules, except that medical marijuana waste shall not be subject to the provisions of the Uniform Controlled Dangerous Substances Act, 63 O.S. § 2-101 et seq.

(b) Licensees may dispose of root balls, stems, fan leaves, seeds, and the mature stalks or fiber produced from such stalks at the license premises by open burning, incineration, burying, mulching, composting or any other technique approved by the Department of Environmental Quality.

(1) Commercial licensees engaged in the disposal of root balls, stems, fan leaves, seeds, and the mature stalks or fiber produced from such stalks shall create and maintain a disposal log that contains, at a minimum, the following information:

- (A) Name and license number of the commercial licensee;
- (B) A description of the plant material being disposed;
- (C) A brief description of the method used for disposal;
- (D) Date and time of the disposal; and
- (E) Names of employee(s) conducting the disposal.

(2) The waste disposal log shall contain a signed statement from the commercial licensee, or authorized representative of the commercial licensee, attesting to the lawful disposal of these plant parts under penalty of perjury.

(3) All disposal records shall be maintained by commercial licensees for a period of five (5) years and shall be subject to inspection and auditing by the Authority.

310:681-5-18. Prohibited acts

(a) No commercial licensee shall allow the consumption of alcohol or the smoking or vaping of medical marijuana, or medical marijuana products on the premises.

(b) No commercial licensee shall employ any person under the age of eighteen (18).

(c) No dispensary shall allow for or provide the delivery of medical marijuana or medical marijuana products to licensed patients or caregivers.

(d) No dispensary shall allow any physician to be located, maintain an office, write recommendations, or otherwise provide medical services to patients at the same physical address as a dispensary.

(e) No commercial licensee shall engage in false advertising.

(f) No commercial licensee shall sell or offer to sell medical marijuana products by means of any advertisement or promotion that includes any statement, representation, symbol, depiction, or reference, directly or indirectly, which would reasonably be expected to induce minors to purchase or consume marijuana or medical marijuana products.

(g) No commercial licensee shall falsify or misrepresent any documents, forms, or other materials or information submitted to the Department.

(h) No commercial licensee shall threaten or harm a patient, medical practitioner, or an employee of the Department.

(i) No commercial licensee shall fail to adhere to any acknowledgment, verification, or other representation made to the Department.

(j) No licensee shall operate or otherwise use any extraction equipment or processes utilizing butane, propane, carbon dioxide or any potentially hazardous material in residential property.

(k) Licensees shall only sell or otherwise transfer, purchase, obtain, or otherwise accept the transfer of medical marijuana or medical marijuana products from an Oklahoma-licensed medical marijuana business. No licensee shall purchase or sell medical marijuana or medical marijuana products from any unlicensed or out-of-state individual or entity.

SUBCHAPTER 7. PACKAGING, LABELING, AND ADVERTISING

310:681-7-1. Labeling and packaging

(a) **Prohibition on sale or transfer.** Commercial licensees shall not sell, distribute, or otherwise transfer medical marijuana and medical marijuana products that are not packaged and labeled in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules.

(b) **Nonacceptance or return.** A dispensary shall refuse to accept or shall return to the licensee transferring medical marijuana or medical marijuana products to the dispensary, any medical marijuana or medical marijuana products that are not packaged and labeled in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules. The business licensee who sold or otherwise transferred the nonconforming medical marijuana or medical marijuana products shall accept such return. If circumstances are such that the dispensary cannot return or refuse to accept the nonconforming medical marijuana or medical marijuana products, the dispensary shall dispose of the nonconforming medical marijuana and medical marijuana products in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

(c) **Documentation.** A dispensary shall document any such return, nonacceptance, or disposal, and such documentation shall include at a minimum:

- (1) The license number, name, contact information, and address of the licensee who sold or otherwise transferred the nonconforming medical marijuana or medical marijuana products to the dispensary;
- (2) A complete inventory of the medical marijuana and medical marijuana products to be returned or disposed, including the batch number;
- (3) The reason for the nonacceptance, return, or disposal; and
- (4) The date of the nonacceptance, return, or disposal.

(d) **General requirements.** The following general label and packaging requirements, prohibitions, and exceptions shall apply to all medical marijuana and medical marijuana products being transferred or sold to a dispensary or by a dispensary:

- (1) Labels, packages, and containers shall not be attractive to minors and shall not contain any content that reasonably appears to target children, including toys, cartoon characters, and similar images. Packages should be designed to minimize appeal to children and shall not depict images other than the business name logo of the medical marijuana producer and image of the product.
- (2) Packaging must contain a label that reads: "Keep out of reach of children."
- (3) All medical marijuana and medical marijuana products must be packaged in child-resistant containers at the point of sale or other transfer to a patient, a patient's parent or legal guardian if patient is a minor, or a caregiver.
- (4) Label must contain a warning that states "Women should not use marijuana or medical marijuana products during pregnancy because of

the risk of birth defects."

(5) Packages and labels shall not contain any false or misleading statements.

(6) No medical marijuana or medical marijuana products shall be intentionally or knowingly packaged or labeled so as to cause a reasonable patient confusion as to whether the medical marijuana or medical marijuana product is a trademarked product.

(7) No medical marijuana or medical marijuana products shall be packaged or labeled in a manner that violates any federal trademark law or regulation.

(8) Packages and labels shall not make any claims or statements that the medical marijuana or medical marijuana products provide health or physical benefits to the patient.

(9) Packages and labels shall not contain the logo of the Oklahoma State Department of Health or the Oklahoma Medical Marijuana Authority.

(e) **Label requirements for sales to dispensaries or by dispensaries.**

(1) Labels on Medical medical marijuana and medical marijuana product products being transferred or sold to a dispensary or by a dispensary labels shall contain, at a minimum, the following information:

(A) The name and license number of the grower or processor who is selling or otherwise transferring the medical marijuana or medical marijuana products to the dispensary;

(B) Name of the medical marijuana or medical marijuana product;

(C) The batch number of the medical marijuana or medical marijuana product;

(D) Net quantity or weight of contents;

(E) Ingredients list;

~~(A)~~ (F) The Oklahoma Uniform Symbol in the manner and form prescribed by the Department;

~~(B)~~ (G) THC potency;

~~(C)~~ (H) Terpenoid potency; and

~~(D)~~ (I) The statement, "This product has been tested for contaminants."

(2) Labels for edible medical marijuana products shall also meet the requirements set forth in OAC 310:681-5-8.1.

(f) **Label requirements for sales between growers and/or processors.**

All medical marijuana and medical marijuana products sold or otherwise transferred between growers and/or processors shall be labeled and the label shall contain, at a minimum, the following information:

(1) Name and license number of the grower or processor who is selling or otherwise transferring the medical marijuana or medical marijuana product;

(2) The batch number of the medical marijuana or medical marijuana product;

(3) Date of harvest or production; and

(4) A statement that the medical marijuana or medical marijuana products have passed testing or statement that the medical marijuana failed testing and is being transferred to a processor for purposes of remediation.

(g) **Storage requirements for growers and processors.**

(1) Growers and processors shall store medical marijuana and medical marijuana products under conditions and in a manner that protects the medical marijuana and medical marijuana products from physical and microbial contamination and deterioration;

(2) When not in use, medical marijuana and medical marijuana products shall be stored in receptacles that are capable of being fully closed and sealed and are kept fully closed and sealed.

SUBCHAPTER 8. LABORATORY TESTING

310:681-8-1. Testing standards and thresholds

(a) **Purpose.** To ensure the suitability and safety for human consumption of medical marijuana and medical marijuana products, growers and processors are required to test medical marijuana and medical marijuana products for microbials, mycotoxins, residual solvents, pesticides, THC and cannabinoid potency, terpenoid potency, heavy metals, foreign materials and filth, and water activity and moisture content in accordance with the following standards and thresholds. No laboratory may test medical marijuana without a valid, unexpired testing laboratory license issued by the Department. A licensed laboratory shall only send samples for testing to another licensed laboratory.

(b) **Batches.** Growers shall separate all harvested medical marijuana into harvest batches not to exceed ten (10) pounds. Processors shall separate all medical marijuana product lots into production batches not to exceed ten (10) pounds.

(c) **Frequency.** Growers and processors shall ensure samples from each harvest batch and production batch are collected, labeled, and tested in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules. ~~Growers shall not sell or otherwise transfer any medical marijuana from any medical marijuana harvest batch until samples of the harvest batch have passed all tests in accordance with this Subchapter. Processors shall not process, sell, or otherwise transfer any medical marijuana products from any medical marijuana production batch until samples of the production batch have passed all tests in accordance with this Subchapter.~~

(d) **Prohibitions.**

(1) Growers shall not sell or otherwise transfer any medical marijuana from any medical marijuana harvest batch until samples of the harvest batch have passed all tests in accordance with this Subchapter, except that growers may sell or otherwise transfer harvest batches that have failed microbiological testing to processors for remediation in accordance with OAC 310:681-8-1(1)(2).

(2) Processors shall not purchase or otherwise obtain, process, sell, or otherwise transfer any medical marijuana or medical marijuana products from any medical marijuana harvest batch or production batch until samples of the harvest batch or production batch have passed all tests in accordance with this Subchapter, except that processors may purchase or otherwise obtain and process harvest batches that have failed testing for the purpose of

remediation only in accordance with OAC 310:681-8-1(1)(2).

~~(3) Dispensaries shall not purchase, accept transfer of, or sell any medical marijuana or medical marijuana products that have not passed all tests in accordance with this Subchapter. Dispensaries shall obtain and maintain copies of the certificate of analysis (COAs) for all medical marijuana and medical marijuana products the dispensary purchases. Growers and processors shall provide dispensaries with copies of certificates of analysis upon request.~~

(e) **Department required testing.** The Department may require a medical marijuana commercial business to submit a sample of medical marijuana, medical marijuana concentrate, or medical marijuana product to a licensed testing laboratory upon demand. The costs for all sampling and tests conducted pursuant to these rules shall be the financial responsibility of the business licensee.

(f) **Prohibited transfers.** Except as is authorized in these Rules, ~~Growers growers, and processors, and dispensaries~~ shall dispose of and shall not use, sell, or otherwise transfer any medical marijuana or medical marijuana products that exceed any testing thresholds or fail to meet any other standards or requirements set forth in this Subchapter.

(g) **Recall.** In the event that any medical marijuana or medical marijuana products that exceed allowable testing thresholds or that otherwise fail to meet standards set forth in this Subchapter are sold or otherwise transferred, the following shall occur:

- (1) Any commercial licensee with knowledge of such event shall immediately notify the Department;
- (2) All such medical marijuana and medical marijuana products shall be immediately recalled; and
- (3) Every commercial licensee who is in possession or has ever had possession of such medical marijuana or medical marijuana products shall assist in the immediate recall.

(h) **Retention of test results and records.** ~~Processors and growers shall retain all test results and related records for at least two (2) years.~~

(1) Prior to accepting any sale or transfer of any medical marijuana, growers shall obtain copies of any and all certificates of analysis (COAs) for every test conducted on the harvest batch(es) of the medical marijuana.

(2) Prior to accepting any sale or transfer of any medical marijuana or medical marijuana products, processors shall obtain copies of any and all COAs for every test conducted on the harvest batch(es) of the medical marijuana or production batch(es) of the medical marijuana products.

(3) Prior to accepting any sale or transfer of medical marijuana, dispensaries shall obtain copies of any and all COAs for every test conducted on the harvest batch(es);

(4) Prior to accepting any sale or transfer of medical marijuana products, dispensaries shall obtain copies of any and all COAs for every test conducted on the production batch(es);

(5) Commercial licensees shall maintain copies of all COAs for at least two (2) years and these records must be kept onsite and readily accessible.

(6) Growers and processors shall immediately provide copies of COAs to the Department upon request and to any medical marijuana licensee upon request when the purpose of such request is compliance with this Section.

(7) Growers and processors shall, in the manner and form prescribed by the Department, provide notification to the Department of any medical marijuana or medical marijuana products that have failed testing. Such notification shall include copies of the applicable COAs.

(i) **Allowable thresholds.** If changes to this Subsection require a change in methodology, proficiency testing enrollment, or accreditation the medical marijuana testing laboratory has up to ninety (90) days to comply.

(1) **Microbiological testing.** Harvest batch samples and production batch samples shall be tested for microbial limits as set forth in Appendix A.

(2) **Mycotoxins.** Production batch samples shall be tested for mycotoxins as set forth in Appendix A.

(3) **Residual solvents and chemical residue.** Production batch samples shall be tested for residual solvents and chemical residue as set forth in Appendix A. If the cannabis concentrate used to make an infused product was tested for solvents and chemical residue and test results indicate the lot was within established limits, then the infused product does not require additional testing for solvents and chemical residue.

(4) **Metals.**

(A) All harvest batch and production batch samples shall be tested for heavy metals, which shall include but is not limited to lead, arsenic, cadmium, and mercury.

(B) Test results shall meet thresholds set forth in Appendix A.

(C) If the cannabis concentrate used to make an infused product was tested for metals and test results indicate the lot was within established limits, then the infused product does not require additional testing for metals.

(5) **Pesticide residue.** All harvest batch and production batch samples shall be tested for the following pesticides, and shall not exceed the associated limits:

(A) Spiromesifen < 0.2 ppm

(B) Spirotetramat < 0.2 ppm

(C) Tebuconazole < 0.4 ppm

(D) Etoxazole < 0.2 ppm

(E) Imazalil < 0.2 ppm

(F) Imidacloprid < 0.4 ppm

(G) Malathion < 0.2 ppm

(H) Myclobutanil < 0.2 ppm

(I) Azoxystrobin < 0.2 ppm

(J) Bifenazate < 0.2 ppm

(K) Abamectin (Avermectins: Bla & Blb) < 0.5 ppm

(L) Permethrin (mix of isomers) < 0.2 ppm

(M) Spinosad (Mixture of A and D) < 0.2 ppm

(6) **Potency.** Processors and growers shall test harvest batch and production batch samples for levels of total THC and terpenoid

potency.

(7) **Foreign materials and filth.** Growers and processors shall inspect all medical marijuana and medical marijuana products for contaminants and filth.

(A) Contaminants include any biological or chemical agent, foreign matter, or other substances not intentionally added to medical marijuana or medical marijuana products that may compromise safety or suitability.

(B) The surface area of each sample shall not contain more than two percent (2%) of foreign organic material.

(C) Samples shall not contain any presence of inorganic material, including but not limited to plastic, glass, and metal shavings.

(D) Inspection records shall indicate a continual process of physical inspection has taken place for all batches.

(8) **Water activity and moisture content.**

(A) All harvest batch samples shall be tested to determine the level of water activity and the percentage of moisture content. This subsection shall not apply to harvest batches that are flash frozen.

(B) A harvest batch sample shall be deemed to have passed water activity testing if the water activity does not exceed 0.65 Aw. The laboratory shall report the result of the water activity test, to two significant figures, on the certificate of analysis (COA) and indicate "pass" or "fail" on the COA.

(C) A harvest batch sample shall be deemed to have passed moisture content testing if the moisture content does not exceed fifteen percent (15.0%). The laboratory shall report the result of the moisture content test to the nearest tenth of one percent, by weight, of the dry sample on the COA and indicate "pass" or "fail" on the COA.

(j) Retesting. If a harvest or production batch fails any analyte testing, the harvest or production batch may be retested in accordance with the following:

(1) The reserve sample shall be used first for all retesting. If there is not enough reserve sample for any additional tests required under this Subsection, a new sample may be collected. The new sample must be a representative sample of the batch and shall be gathered in accordance with these Rules.

(2) The retest may be limited to testing for the category of analyte that has failed testing. For example, if a primary sample fails pesticide testing, testing of the reserve sample may be limited to pesticide testing.

(3) If the first retest fails testing for the same analyte that failed the initial test, the harvest or production batch must either be remediated or decontaminated in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules, or must be disposed of in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. and these Rules.

(4) If the first retest(s) passes testing, a second retest shall be conducted to confirm the product does not exceed allowable thresholds and is safe to consume. If the second retest also passes

for the same analyte, the batch may be processed, sold or otherwise transferred. If the second retest fails for the same analyte that failed the initial test, the harvest or production batch must either be remediated or decontaminated in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules, or must be disposed of in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. and these Rules.

(5) If during the first retest, a harvest batch or production batch fails testing for an analyte that passed initial testing, the harvest batch or production batch must pass testing for that analyte during the second retest.

(6) Any harvest batch or production batch that is retested and does not have two (2) successful tests for each analyte must either be remediated or decontaminated in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules, or must be disposed of in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. and these Rules.

—(j)—(k) **Remediation, decontamination, and retesting, general.**

(1) If a sample fails testing under this Subchapter, the harvest batch or production batch from which the sample was taken:

(A) May be remediated or decontaminated in accordance with these Rules; or

(B) If it is not or cannot be remediated or decontaminated under these Rules, it must be disposed in accordance with the Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. and these Rules.

(2) A harvest batch or production batch that ~~has failed testing and~~ has been remediated or decontaminated must be ~~re-tested~~ fully tested and successfully pass all the analyses required under this Subchapter. If the harvest batch or ~~product~~ production batch fails to pass testing after remediation or decontamination, the harvest batch or production batch must be either disposed of in accordance with the Waste Management Act, 63 O.S. § 427a et seq. and these Rules or retested in accordance with OAC 310:681-8-1(j) with the following exceptions:

(A) Any harvest batch that has been decontaminated and fails retesting for microbials must be either remediated or disposed of in accordance with these Rules.

(B) Any production batch that has been decontaminated and fails retesting shall not be further decontaminated.

(3) Growers and processors may remediate failed harvest batches or production batches providing the remediation method does not impart any toxic or deleterious substance to the usable medical marijuana or medical marijuana products. Any remediation methods or remediation solvents used on medical marijuana or medical marijuana products must be disclosed to the testing laboratory.

(4) Growers and processors must, as applicable:

(A) Have detailed procedures for remediation and decontamination processes to remove microbiological contaminants and foreign materials, and for reducing the concentration of solvents.

(B) Prior to retesting, provide to the testing laboratory a document specifying how the product was remediated or decontamination. This document shall be retained by the laboratory together with other testing documentation.

(C) Document all re-sampling, re-testing, decontamination, remediation, and/or disposal of marijuana or marijuana-derived products that fail laboratory testing under these Rules.

(5) At the request of the grower or processor, the Department may authorize a re-test to validate a failed test result on a case-by-case basis. All costs of the re-test will be borne by the grower or the processor requesting the re-test.

(6) Growers and processors must inform a laboratory prior to samples being taken that the harvest batch or production batch has failed testing and is being re-tested after undergoing remediation or decontamination.

~~(k)~~ **(1) Remediation, decontamination, and retesting, microbiological impurities testing.**

(1) If a sample from a harvest batch or production batch fails microbiological contaminant testing, the batch may be used to make a cannabinoid concentrate or extract if the processing method effectively decontaminates the batch.

(2) A grower may only sell or otherwise transfer a harvest batch that has failed microbiological contaminant testing to a processor and only for the purpose of remediation. The processor shall either remediate the harvest batch by processing it into a solvent-based concentrate or shall dispose of the batch in accordance with these Rules. Any production batches resulting from the remediation must be tested in accordance with OAC 310:681-8-1(k). Processors shall not sell any medical marijuana from any harvest batch that has failed testing.

~~(2)~~ (3) If a sample from a batch of a cannabinoid concentrate or extract fails microbiological contaminant testing, the batch may be further processed, if the processing method effectively decontaminates the batch, such as a method using a hydrocarbon-based solvent or a CO2 closed-loop system.

~~(3)~~ (4) A batch that is remediated or decontaminated in accordance with this subsection (1) or (2) Subsection of this section must be sampled and tested in accordance with these rules and must be tested, if not otherwise required for that product, for microbiological contaminants, residual solvents and processing chemicals and residual pesticides.

~~(4)~~ (5) A batch that fails microbiological contaminant testing after undergoing a decontamination process in accordance with subsection (1) or (2) of this section must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

~~(l)~~ **(m) Remediation Decontamination and retesting, residual solvent and processing chemicals testing.**

(1) If a sample from a batch fails residual solvent and processing chemicals testing, the batch may be ~~remediated~~ decontaminated using procedures that would reduce the concentration of solvents to less than the action level.

(2) A batch that is ~~remediated~~ decontaminated in accordance with subsection (1) ~~of this section~~ must be sampled and retested for solvents in accordance with these Rules and must be tested, if not otherwise required for that product under these rules, for pesticides.

(3) A batch that fails residual solvent and processing chemicals testing and is not ~~remediated~~ decontaminated or is ~~remediated~~ decontaminated and fails retesting must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

~~(m)~~ **(n) Remediation, decontamination and retesting, foreign materials testing.**

(1) If a sample from a batch of usable marijuana fails foreign materials testing, the batch from which the sample was taken may be remediated to reduce the amount of foreign materials to below action levels.

(2) A batch that undergoes ~~remediation~~ decontamination as described in subsection (1) ~~of this section~~ must be sampled and tested in accordance with these Rules.

~~(n)~~ **(o) Remediation, decontamination and retesting, residual pesticide testing.**

(1) If a sample from a batch fails residual pesticide testing, the batch may not be remediated or decontaminated and must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

(2) The Department may report to the Oklahoma Department of Agriculture all test results showing samples failing residual pesticide testing.

~~(o)~~ **(p) Remediation, decontamination and retesting, heavy metals testing.**

(1) If a sample from a batch fails heavy metals testing, the batch may not be remediated or decontaminated and must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

(2) The Department may report to the Oklahoma Department of Environmental Quality all test results showing samples failing heavy metals testing.

~~(p)~~ **(q) Remediation, decontamination and retesting, mycotoxin testing.**

(1) If a sample from a batch fails mycotoxins testing, the batch may not be remediated or decontaminated and must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

~~(q)~~ **(r) Remediation, decontamination and ~~testing~~ retesting, water activity and moisture content.**

(1) If a harvest batch sample fails water activity and/or moisture content testing, the harvest batch may be further dried and cured by the grower.

(2) A harvest batch that undergoes ~~remediation~~ decontamination as described in subsection (1) ~~of this section~~ must be sampled and tested in accordance with these Rules. If the harvest batch passed initial testing for residual solvents and chemical residue, metals, and/or pesticides, then the harvest batch does not require

additional testing for those testing categories.

310:681-8-2. General operating requirements and procedures

(a) **Laboratory accreditation.** A laboratory that submits an application to become a licensed testing laboratory prior to January 1, 2020 must have made application for accreditation to ANSI/ASQ National Accreditation Board, American Association for Laboratory Accreditation (A2LA), Perry Johnson Laboratory Accreditation (PJLA), or any other accrediting entity using the ISO/IEC Standard 17025, at the time of application. Application for accreditation must be made to one of these entities in both chemistry and biology, or cannabis. A laboratory that submits an application to become a licensed testing laboratory on or after January 1, 2020 must be accredited by ANSI/ASQ National Accreditation Board, American Association for Laboratory Accreditation (A2LA), Perry Johnson Laboratory Accreditation (PJLA), or any other accrediting entity using the ISO/IEC Standard 17025. The accreditation must be from one of these entities in both chemistry and biology, or cannabis.

(b) **Testing limited to scope of accreditation.** Upon accreditation, a testing laboratory shall only report test results on COAs for the testing of analytes the laboratory conducted that are within the scope of the testing laboratory's accreditation. A lab may outsource testing and report those results on a COA but must identify the testing laboratory that actually conducted the testing.

~~(b)~~(c) **Proficiency testing.** The laboratory shall be subject to proficiency testing by the Department or its designee at a frequency and at times to be determined by the Department or its designee.

(1) The laboratory shall cooperate with the Department or its designee for purposes of conducting proficiency testing. The Department or its designee may require submission of samples from the licensed laboratory for purposes of proficiency testing.

(2) The quality assurance laboratory shall obtain reserve samples from licensed laboratories for the purposes of proficiency testing, which shall occur at a minimum of three (3) times per year for regular monitoring. The Department or the quality assurance laboratory may require additional proficiency tests to ensure correction of or investigate violations of Oklahoma law and these Rules.

(3) If the Department determines on the basis of a proficiency testing that the laboratory has not satisfactorily identified the presence, quantity, or other relevant factor(s) pertaining to a given analyte, the Department may revoke the license, require additional tests, and/or require remedial actions to be taken by the laboratory.

(4) If a laboratory fails its proficiency testing for an analyte, the batch testing results since the last proficiency test for that analyte must be re-evaluated. The laboratory director shall assess and implement necessary procedures to ensure risks to public safety are mitigated following failed proficiency testing results.

~~(c)~~(d) **Conflict of interest.** A person who is a direct beneficial owner or an indirect beneficial owner of a licensed dispensary, commercial grower, or processor shall not be an owner of a licensed laboratory. A

licensed testing laboratory shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the testing processes or results of the laboratory. At a minimum, employees, owners, or agents of a licensed laboratory who participate in any aspect of the analysis and results of a sample are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any ongoing financial, employment, personal, or business relationship with the medical marijuana business licensee that provided the sample.

~~(d)~~ **(e) Safety standards.** Licensed laboratories must comply with Occupational Safety and Health Administration (OSHA) Standard 29 CFR § 1910.1450.

~~(e)~~ **(f) Personnel.** A licensed laboratory shall not operate unless a medical laboratory director is on site during operational hours. Personnel of a licensed laboratory shall meet the following minimum requirements:

(1) A medical laboratory director must possess a bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least twenty-four (24) college semester credit hours in chemistry and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory will be performing. A master's degree or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience. The medical laboratory director shall be responsible for the development of and adherence to all pre-analytic, analytic, and post-analytic procedures, and the implementation of a quality system that assures reliable test results and regulatory compliance.

(2) Analysts must possess a bachelor's degree applicable to a laboratory testing environment, with a minimum of two (2) years of experience, or an associate's degree and five (5) years of applicable experience.

(3) Ancillary personnel must possess a high school diploma or equivalent.

~~(f)~~ **(g) Equipment.**

(1) Equipment used for analysis must have a Limit of Detection (LOD) capable of detecting the thresholds listed in OAC 310:681-8-1(h) and Appendix A.

(2) Equipment used for the analysis of test samples shall be adequately inspected, cleaned, and maintained. Equipment used for the generation or measurement of data shall be adequately tested and calibrated on an appropriate schedule, as applicable.

(3) Laboratory operations shall document procedures setting forth in sufficient detail the methods and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment, and shall specify, as appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The procedures shall designate the personnel responsible for the performance of each operation.

(4) Records shall be maintained of all inspection, maintenance, testing, and calibrating operations. These records shall include the

date of the operation, the person who performed it, the written procedure used, and any deviations from the written procedure. All deviations must be reviewed and approved by the medical laboratory director. Records shall be kept of non-routine repairs performed on equipment. Such records shall document the nature of the repair, how and when the need for the repair was discovered, and any remedial action taken in response to the repair. A written assessment of the validity of the results obtained previous to the failure must be made. Documentation of any repeat testing performed must also be maintained. Any non-routine repair must be reported to and reviewed by the quality assurance laboratory.

(5) Computer systems used for the analysis of samples, retention of data, sample tracking, calibration scheduling, management of reference standards, or other critical laboratory management functions shall ensure that electronic records, electronic signatures, and handwritten signatures executed to electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

~~(g)~~ **(h) Data storage.**

(1) The laboratory shall ensure that all raw data, documentation, protocols, and final reports associated with analysis of a test sample are retained for at least two (2) years from the date of completion of analysis.

(2) The laboratory shall designate an individual as responsible for records maintenance. Only authorized personnel may access the maintained records.

(3) The laboratory shall maintain the records identified in this section:

(A) In a manner that allows retrieval, as needed;

(B) Under conditions of storage that minimize deterioration throughout the retention period; and

(C) In a manner that prevents unauthorized alteration.

~~(h)~~ **(i) Materials to be maintained on premises.** The laboratory shall maintain on its premises, and shall promptly present to the Department upon request:

(1) Personnel documentation including, but not limited to employment records, job descriptions, education, and training requirements of the laboratory, and documentation of education and training provided to staff for the purpose of performance of assigned functions;

(2) Policies concerning laboratory operations, business licensing, and security procedures;

(3) Any policies, protocol, or procedures for receipt, handling, and disposition of samples of usable marijuana;

(4) Equipment information detailing the type of equipment used, inspection policies and practices, testing and calibration schedules and records, and standards for cleaning and maintenance of equipment;

(5) Reagents, solutions, and reference policies including, but not limited to standards for labeling, storage, expiration, and re-qualification dates and records;

(6) Reference standards, acquired or internally produced, including the certificate of analysis;

(7) Sample analysis procedures including, but not limited to procedures for the use of only primary or secondary standards for quantitative analyses;

(8) Documentation demonstrating that the analytical methods used by the laboratory are appropriate for their intended purpose; that staff is competent in the process; and that deviations from approved standards of practice do not occur without proper authorization;

(9) Policies for data recording, review, storage, and reporting that include, but are not limited to standards to ensure that:

(A) Data are recorded in a manner consistent with applicable Oklahoma law and these Rules, and are reviewed to verify that applicable standards of practice, equipment calibration, and reference standards were applied before reporting;

(B) All data, including raw data, documentation, protocols, and reports are retained in accordance with applicable Oklahoma law and these rules; and

(C) Reports are the property of the business or individual who provided the sample, and reports meet the requirements of this rule.

(10) Documentation showing the laboratory complies with OSHA Standard 29 CFR § 1910.1450; and

(11) Such other materials as the Department may require.

~~(i)~~(j) **Department access to materials and premises.** The laboratory shall promptly provide the Department or the Department's designee access to a report of a test, and any underlying data, that is conducted on a sample. The laboratory shall also provide access to the Department or the Department's designee to laboratory premises, and to any material or information requested by the Department, for the purpose of determining compliance with the requirements of applicable Oklahoma law and these rules.

310:681-8-3. Sampling requirements and procedures

General requirements.

(a) **General requirements.** Samples must be collected in accordance with OAC 310:681-8-3(a)-(c). Individuals collecting samples are called "Samplers."

(1) Samplers must:

(A) Follow the approved ~~sampling policies and~~ standard operating procedures of the laboratory that will be testing the samples collected. Samplers must be trained on how to collect samples in accordance with the standard operating procedures of the laboratory(ies) that will be conducting the testing on the samples collected and shall have access to a copy of the laboratory's standard operating procedures while they are collecting the samples; and

(B) Follow inventory manifest requirements set forth in these Rules.

(2) Samplers shall collect samples at the location of the grower or processor.

(3) A licensed laboratory must either utilize a licensed commercial transporter to transport samples or obtain a commercial transporter license in order to transport samples from the grower or processor

to the laboratory.

(4) All commercial transporters, growers, or processors transporting samples to a laboratory shall be prohibited from storing samples at any location other than the laboratory facility. All samples must be delivered the day of collection.

(5) Samples shall only be collected from harvest batches and production batches in final form. For purpose of this Subsection, "final form" means the form medical marijuana or a medical marijuana product is in when sold or transferred.

(6) The sampler shall collect both a primary sample and a reserve sample from each harvest batch and production batch. The sample shall be clearly and conspicuously labeled and the label shall include at least the following information:

(A) Whether the sample is "Primary Sample" or "Reserve Sample";

(B) Name and license number of grower or processor from whom the sample was taken; and

(C) The batch number of harvest batch or production batch from which the sample was taken.

(7) The primary sample and reserve sample shall be stored separately and analyzed separately. The reserve sample is used for quality control purposes only.

(8) Samples shall be transported and subsequently stored at the laboratory in a manner that prevents degradation, contamination, and tampering. If the medical marijuana or medical marijuana product specifies on the label how the product shall be stored, the laboratory shall store the sample as indicated on the label.

(9) The sampler shall create and use a sample field log to record the following information for each ~~sampler batch~~ sample:

(A) Laboratory's name, address, and license number;

(B) Title and version of the laboratory's standard operating procedure(s) followed when collecting the sample;

~~(B)~~ (C) Sampler's name(s) and title(s) and the names of others onsite;

~~(C)~~ (D) Date and time sampling started and ended;

~~(D)~~ (E) Grower's or processor's name, address, and license number;

~~(E)~~ (F) Batch number of the batch from which the sample was obtained;

~~(F)~~ (G) Sample matrix;

~~(G)~~ (H) Total batch size, by weight or unit count;

~~(H)~~ (I) Total weight or unit count of the primary sample;

~~(I)~~ (J) Total weight or unit count of the reserve sample;

~~(J)~~ (K) The unique sample identification number for each sample;

~~(K)~~ (L) Name, business address, and license number of the person who transports the samples to the laboratory;

~~(L)~~ (M) Requested analyses;

~~(M)~~ (N) Sampling conditions, including temperature;

~~(N)~~ (O) Problems encountered and corrective actions taken during the sampling process, if any; and

~~(O)~~ (P) Any other observations from sampling, including major inconsistencies in the medical marijuana color, size, or smell.

(10) The laboratory shall maintain inventory manifest documentation listed in OAC 310:681-3-6 and utilize an electronic inventory

management system that meets the requirements set forth in OAC 310:681-5-6(d) for each sample that the laboratory collects, transports, and analyzes.

(11) Commercial licensees shall document all employee training on a testing laboratory's standard operating procedures.

~~(11)~~(12) A laboratory Commercial licensees must maintain the documentation required in these rules for at least two (2) years and must provide that information to the Department upon request.

(b) Sample size.

(1) To obtain a representative sample of a harvest batch, a total of 0.5% of the batch is collected from different areas of the batch following the laboratory's approved protocol. The sample is then homogenized and aliquoted into a primary sample and reserve sample, which shall be equal in amounts. The primary sample and reserve sample shall be in the amounts specified in the laboratory's standard operating procedure. Any amounts left over after aliquoting may be returned to the harvest batch.

(2) To obtain a representative sample of a processed batch that is well mixed or homogeneous by its nature, obtain an amount sufficient to be aliquoted into a primary sample and a reserve sample, which shall be equal in amounts. If the batch is of not homogeneous or is of unknown homogeneity, then 0.5% of the batch shall be collected from different portions of the batch following the laboratory's approved protocol. The sample is then homogenized and aliquoted into a primary sample and reserve sample, which shall be equal in amounts. The primary sample and reserve sample shall be in the amounts specified in the laboratory's standard operating procedure. Any amounts left over after aliquoting may be returned to the harvest batch.

(c) Sampling standard operating procedures.

(1) Samples collected must be representative of the entire batch to ensure accurate microbiological analysis and foreign material assessments.

(2) Sample protocol shall be approved by the laboratory director. The laboratory shall develop and implement written sampling policies and procedures that are appropriate for each test method and each type of matrix to be tested and that are consistent with these regulations. Sampling procedures must describe the laboratory's method for collection, preparation, packaging, labeling, documentation, and transport of samples from each matrix type the laboratory tests.

(3) The sampling standard operating procedures (SOP) shall include at least the following information:

(A) A step-by-step guide for obtaining samples from each matrix type the laboratory samples;

(B) Protocols for ensuring that contaminants are not introduced during sampling, including protocols relating to the sanitizing of equipment and tools, protective garb, and sampling containers;

(C) Accepted test sample types;

(D) Minimum test sample size;

(E) Recommended test sample containers;

(F) Test sample labeling;

(G) Transport and storage conditions, such as refrigeration, as appropriate to protect the physical and chemical integrity of the sample;

(H) Other requirements, such as use of preservatives, inert gas, or other measures designed to protect sample integrity; and

(I) Chain-of-custody documentation for each sample in accordance with OAC 310:681-5-6.

(4) The sampling SOP shall be signed and dated by the medical laboratory director and shall include any revision dates and authors. The laboratory director's signature denotes approval of the plan.

(5) The laboratory shall retain a controlled copy of the sampling SOP on the laboratory premises and ensure that the sampling SOP is accessible to the sampler in the field during sampling.

(d) **Sample handling, storage and disposal.** A laboratory shall establish sample handling procedures for the tracking of test samples through the analytical process (by weight, volume, number, or other appropriate measure) to prevent diversion.

(1) The laboratory shall store each test sample under the appropriate conditions appropriate to protect the physical and chemical integrity of the sample.

(2) Analyzed test samples consisting of medical marijuana or medical marijuana products shall be held in a controlled access area pending destruction or other disposal.

(3) Any portion of a medical marijuana or medical marijuana product test sample that is not destroyed during analysis shall be:

(A) Returned to the licensed individual or entity that provided the sample after the required retention period for reserve samples;

(B) Transported to a state or local law enforcement office; or

(C) Disposed of in accordance with OAC 310:681-5-10 (relating to medical marijuana waste disposal).

(e) **Data reporting.**

(1) The laboratory shall generate a certificate of analysis (COA) for each primary sample that the laboratory analyzes.

(2) The laboratory shall issue the COA to the requester within two (2) business days after technical and administrative review of analysis has been completed. A laboratory shall not withhold a COA reporting a failed test from the requester for any reason.

(3) ~~The COA~~ All COAs, whether in paper or electronic form, shall contain, at minimum, the following information:

(A) The name, address, license number, and contact information of the laboratory that conducted the analysis;

(B) If the laboratory sends a sample to another laboratory for testing, the reference laboratory must be identified as having performed that test;

(C) The name, address, and license number of the requester;

(D) The description of the type or form of the test sample (leaf, flower, powder, oil, specific edible product, etc.) and its total primary sample weight in grams, reported to the nearest gram;

(E) The unique sample identifier;

(F) Batch number of the batch from which the sample was obtained;

(G) Sample history, including the date collected, the date received by the laboratory, and the date(s) of sample analyses and corresponding testing results, including units of measure where applicable;

(H) The analytical methods used, including at a minimum identification of the type of analytical equipment used (e.g., GC, HPLC, UV, etc.);

(I) The reporting limit for each analyte tested;

(J) Any compounds detected during the analyses of the sample that are not among the targeted analytes and are unknown, unidentified, tentatively identified or known and injurious to human health if consumed, if any; ~~and~~

(K) The identity of the supervisory or management personnel who reviewed and verified the data and results and ensured that data quality, calibration, and other applicable requirements were met; and

(L) Definitions of any abbreviated terms.

(4) The laboratory shall report test results for each primary sample on the COA as follows:

(A) When reporting quantitative results for each analyte, the laboratory shall use the appropriate units of measurement as required under this chapter and indicate "pass" or "fail";

(B) When reporting qualitative results for each analyte, the laboratory shall indicate "pass" or "fail";

(C) "Pass" and "Fail" must be clear, conspicuous, and easily identifiable in a font size no less than the size of 12 pt font in Times New Roman and shall not be in fine print or footnotes;

~~(C)~~ (D) When reporting results for any analytes that were detected below the analytical method limit of quantitation (LOQ), indicate "<LOQ"> and list the results for analytes that were detected above the LOQ but below the allowable limit; and

~~(D)~~ (E) Indicate "NT" for not tested for any test that the laboratory did not perform.

(5) Upon detection of any compounds during the analyses of the sample that are not among the targeted analytes and are unknown, unidentified, tentatively identified, or known and injurious to human health if consumed, laboratories shall notify the Department immediately and shall submit to the Department a copy of the COA containing those compounds as required in OAC 310:681-8-3(e) (3) (I). The Department may require a processor or grower to submit samples for additional testing, including testing for analytes that are not required by these Rules, at the licensee's expense.

(6) When a laboratory determines that a harvest batch or production batch has failed any required testing, the laboratory shall immediately notify the Department in the manner and form prescribed by the Department on its website and shall submit a copy of the COA to the Department within two (2) business days. Submission of this information to the Department through the seed-to-sale tracking system established by the Department or a seed-to-sale tracking system that integrates with the Department-established system shall be sufficient to satisfy this reporting requirement.

SUBCHAPTER 9. WASTE DISPOSAL FACILITIES

310:681-9-9. Waste disposal

(a) **Frequency.** Commercial licensees shall transfer medical marijuana waste to a medical marijuana waste facility for disposal within ninety (90) days.

~~(a)~~(b) **Permissible methods.** Waste shall be disposed through either a process which renders the waste unusable through physical destruction or a recycling process that the waste disposal facility is authorized to conduct pursuant to Oklahoma law.

~~(b)~~(c) **Unusable and unrecognizable.**

(1) Medical marijuana waste facilities shall render medical marijuana waste (except hazardous waste) unusable and unrecognizable through one of the following methods. Other methods to render marijuana waste unusable and unrecognizable must be approved by the Department before implementation.

(A) Grinding and incorporating the medical marijuana waste with the non-consumable, solid wastes listed below such that the resulting mixture is at least 50 percent non-marijuana waste, and such that the resulting mixture cannot easily be separated and sorted:

- (i) Paper waste;
- (ii) Plastic waste;
- (ii) Cardboard waste;
- (iii) Food waste;
- (iv) Grease or other compostable oil waste;
- (v) Bokashi, or other compost activators;
- (vi) Soil;
- (vii) Sawdust; and
- (viii) Other wastes approved by the Department that will render the medical marijuana waste unusable and unrecognizable.

(B) Disposal of hazardous waste shall be conducted in a manner consistent with federal, state and local laws, regulations, rules or other requirements.

(2) Medical marijuana waste facilities shall only use methods or materials permitted under their licensure with the Oklahoma Department of Environmental Quality or the Oklahoma Department of Agriculture and any applicable laws.

~~(c)~~(d) **Applicable laws apply.** Medical marijuana waste, including any hazardous waste, shall be stored, secured, managed, and disposed in accordance with all applicable state and local statutes, rules, regulations, ordinances, or other requirements.

APPENDIX A. TESTING THRESHOLDS [REVOKED]

APPENDIX A. TESTING THRESHOLDS [NEW]

MICROBIOLOGICAL TESTING		
Substance	Acceptable Limits	Product to be Tested
Shiga-Toxin producing E. coli (STEC)-Bacteria	< 1 Colony forming Unit (CFU) per gram	Medical Marijuana; Medical Marijuana Products, including medical marijuana concentrates but not including rectal administration products, vaginal administration products, pressurized metered dose inhaler products, and metered dose nasal spray products
Salmonella species-Bacteria	< 1 Colony forming Unit (CFU) per gram	
Aspergillus niger	< 1 Colony forming Unit (CFU) per gram	
Aspergillus fumigatus	< 1 Colony forming Unit (CFU) per gram	
Aspergillus terreus	< 1 Colony forming Unit (CFU) per gram	
Aspergillus flavus	< 1 Colony forming Unit (CFU) per gram	
Total	<10 ⁴ Colony forming Unit (CFU) per gram	
Yeast/Mold	<10 ¹ Colony forming Unit (CFU) per gram or milliliter	Metered dose nasal spray products; pressurized metered dose inhaler products; and vaginal administration products
	< 10 ² Colony forming Unit (CFU) per gram or milliliter	Rectal Administration products
Total aerobic microbial count	< 10 ² Colony forming Unit (CFU) per gram or milliliter	Metered dose nasal spray products; pressurized metered dose inhaler products; or vaginal administration products
	< 10 ³ Colony forming Unit (CFU) per gram or milliliter	Rectal Administration products
Staphylococcus aureus	< 1 Colony forming Unit (CFU) per gram or milliliter	Metered dose nasal spray products; pressurized metered dose inhaler products; or vaginal administration products
Pseudomonas aeruginosa	< 1 Colony forming Unit (CFU) per gram or milliliter	Vaginal administration products

Bile tolerant gram negative bacteria	< 1 Colony forming Unit (CFU) per gram or milliliter	Metered dose nasal spray products; and pressurized metered dose inhaler products
Candida albicans	< 1 Colony forming Unit (CFU) per gram or milliliter	Vaginal administration products

MYCOTOXINS

Substance	Acceptable Limits	Product to be Tested
Aflatoxins (B1, B2, G1, and G2)	< 20 ppb (total of B1 + B2 + G1 + G2)	Medical Marijuana Products
Ochratoxin A	< 20 ppb	

RESIDUAL SOLVENTS AND CHEMICAL RESIDUE

Substance	Acceptable Limits	Product to be Tested
Acetone	< 1,000 ppm	Medical Marijuana Products
Butanes	< 1,000 ppm	
Heptanes	< 1,000 ppm	
Isopropyl Alcohol	< 1,000 ppm	
Propane	< 1,000 ppm	
Benzene	< 2 Parts ppm	
Toluene	< 180 ppm	
Pentane	< 1,000 ppm	
Hexane	< 60 ppm	
Total Xylenes (m,p,o-xylenes)	< 430 ppm	
Methanol	< 600 ppm	
Ethyl Acetate	< 1000 ppm	Medical marijuana products that are administered via inhalation.
Ethanol	< 5,000 ppm	

METALS

Substance	Acceptable Limits Based on Intended Use	Product to be Tested
Metals (Arsenic, Cadmium, Lead, and Mercury)	Inhaled Product or administration by metered dose nasal spray or pressurized metered dose inhaler: Lead - Max Limit: < 0.5 ppm Arsenic - Max Limit: < 0.2 ppm Cadmium - Max Limit: < 0.2 ppm Mercury - Max Limit: < 0.1 ppm	Medical Marijuana and Medical Marijuana Products
	Topical and/or Transdermal: Lead - Max Limit: < 10 ppm Arsenic - Max Limit: < 3 ppm Cadmium - Max Limit: < 3 ppm Mercury - Max Limit: < 1 ppm	

	Oral Consumption, rectal or vaginal administration: Lead - Max Limit: < 1 ppm Arsenic - Max Limit: < 1.5 ppm Cadmium - Max Limit: < 0.5 ppm Mercury - Max Limit: < 1.5 ppm	
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