TITLE 442. OKLAHOMA MEDICAL MARIJUANA AUTHORITY

CHAPTER 10. MEDICAL MARIJUANA REGULATIONS

SUBCHAPTER 1. GENERAL PROVISIONS

442:10-1-4. Definitions

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

"Actively operating" or **"Actively conducting business operations"** means a commercial licensee that possesses, sells, purchases or transfers medical marijuana and/or medical marijuana products to or from its licensed premises in a regular or seasonal capacity.

"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.

"Alcoholic beverage" means *alcohol, spirits, beer and wine and also includes every liquid or solid, patented or not, containing alcohol, spirits, wine or beer and capable of being consumed as a beverage by human beings* [37A O.S. § 1-103].

"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 issue 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.

"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 Authority to a medical marijuana dispensary, grower, processor, testing laboratory, or transporter.

"Canopy" means the total surface area within a cultivation area that is dedicated to the cultivation of flowering marijuana plants.

"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 medical marijuana patient license holder whom a physician attests 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); and

(B) 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.

"COA" means certificate of analysis.

"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.

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

"Decontamination" means a type of remediation 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, provided it is not processed into a solvent-based concentrate.

"Director" or **"Executive Director"** means the Executive Director of the Oklahoma Medical Marijuana Authority.

"Dispense" means the retail selling of medical marijuana or 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 Authority, 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 a licensed caregiver, and to the licensed patient's parent(s) or legal guardian(s) if licensed patient is a minor; to prepare and package noninfused pre-rolled medical marijuana with a net weight that does not exceed one (1) gram to sell to medical marijuana patients and caregivers; 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 samples to testing laboratories.

"Dispose" or **"Disposal"** means the disposition of medical marijuana waste by either a process which renders the waste unusable and unrecognizable 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 Authority;

(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 Authority; or

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

"Education facility" means an individual or entity that has been issued a license by the Authority 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 samples 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.

"Error in measurement" means a mistake made by the Authority or a municipality in the setback measurement process where either the distance between a medical marijuana dispensary and a school is miscalculated due to mathematical error or the methods used to measure the setback distance is inconsistent with 63 O.S. § 425(G).

"Error in measurement allowance" means an allowance of an error in measurements of the distance between a medical marijuana dispensary and a school up to and including five hundred (500) feet when remeasured after an original license has been issued.

"Exit package" means an opaque bag that is provided at the point of sale in which pre-packaged medical marijuana is placed.

"Final product" or **"Final medical marijuana product"** means any finished medical marijuana product that has been infused with a concentrate or that has been further processed and is in the form in which it will be sold to medical marijuana patients and caregivers, meaning no other ingredients or additives will be infused or otherwise added into the product. ~~Examples may include topicals, tinctures, cookies, brownies, candies, gummies, beverages, or chocolate.~~

"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 for consumption 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" means *articles used for food or drink for man, (2) chewing gum, and (3) articles used for components of any such article* [63 O.S. § 1-1101] and *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* [OAC 310:257-1-2 and OAC 310:260-1-6].

"Grower" or **"Commercial grower"** means an individual or entity that has been issued a medical marijuana business license by the Authority, which allows the grower to grow, harvest, dry, cure, package medical marijuana and noninfused pre-rolled medical marijuana with a net weight that does not exceed one (1) gram, to 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 samples to a testing laboratory, and includes the following:

(A) **"Indoor grow"** means an indoor, greenhouse, or light deprivation medical marijuana grow facility;

(B) **"Greenhouse"** means a structure located outdoors that is completely covered by a material that allows a controlled level of light transmission;

(C) **"Light deprivation"** means a structure that has concrete floors and the ability to manipulate natural light; and

(D) **"Outdoor grow"** means an outdoor medical marijuana grow facility that does not include any indoor, greenhouse, or light deprivation medical marijuana grow facilities.

"Harvest batch" means a specifically identified quantity of usable medical marijuana, not to exceed harvest batch sizes allowable under OAC 442:10-8-1(b), 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. For purposes of this Chapter, "harvested at the same time" refers to medical marijuana harvested during a single continuous harvest process that may exceed one (1) day.

"Hazardous processor license" means a license issued to a medical marijuana processor that performs an extraction method that utilizes chemicals considered hazardous by the OSHA Hazard Communication Standard under 29 CFR § 1910.1200.

"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" means 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."

"Infused pre-roll" means pre-rolled medical marijuana into which cannabis concentrate, extracts, derivatives, or other ingredients have been incorporated.

"Integration" or **"Integrated"** means a third-party vendor's software application or a software service

that has been fully validated to share inventory tracking or other data directly with the State inventory tracking system via a secure Application Programming Interface ("API").

"Inventory tracking system" or **"State inventory tracking system"** means the required tracking system established by the Authority that accounts for medical marijuana from either the seed or immature plant stage until the medical marijuana or medical marijuana product is sold to a patient at a medical marijuana dispensary, disposed of in accordance with these Rules, or used in a research project by a medical marijuana research facility, meaning that the State's inventory tracking system accounts for the entire life span of medical marijuana and medical marijuana products, including any testing samples thereof and medical marijuana waste.

"Kief" means the resinous trichomes of marijuana that have been separated from the marijuana plant.

"Label" means 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. § 422(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 and shall not include any plant or material containing delta-8 or delta-10 tetrahydrocannabinol which is grown, processed or sold pursuant to the provisions of the Oklahoma Industrial Hemp Program.

"Material change" means any change that would affect the qualifications for licensure of an applicant or licensee.

"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 Authority as a medical marijuana dispensary, grower, processor, testing laboratory, or transporter.

"Medical marijuana concentrate" or **"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 Authority oversight.

"Medical marijuana waste" means

(A) 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 seeds, roots, stems, stalks and fan leaves,

(B) all product which is deemed to fail laboratory testing and cannot be remediated or decontaminated, or

(C) all products and inventory from commercial licensees that:

(i) have gone out of business;

(ii) are not subject to the provisions of Section 1560 of Title 12 of the Oklahoma Statute; and

(iii) are unable to lawfully transfer or sell the product and inventory to another commercial licensee.

"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*."

"Nonhazardous processor license" means a license issued by the Authority to a processor that will not perform any processing or extraction methods that utilize a chemical considered hazardous by the OSHA Hazard Communication Standard under 29 CFR § 1910.1200.

"Noninfused pre-roll" means pre-rolled medical marijuana that consist only of flower, shake, or trim, and may include unflavored paper, a filter, tip, or cone. This product shall not include marijuana concentrates, extracts, derivatives, or any other ingredients.

"Nonliquid medical marijuana product" means a substance obtained by separating cannabinoids that have been extracted from plant material by physical or chemical means and is not a liquid, meaning that it does not conform to a container in which it is placed. Examples include wax, budder, shatter, and hash.

"Nonoperational" means a commercial licensee that cannot provide proof that it is actively operating or working towards operational status.

"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 *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* [11 O.S. § 1-102].

"Oklahoma resident" or **"Resident"** means an individual who can provide proof of residency as required by OAC 442:10-1-6 (relating to proof of residency) or OAC 442:10-5-3.1 (relating to proof of residency for commercial business licensees).

"Oklahoma uniform symbol" or **"Universal symbol"** means the image, established by the Authority 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 Authority.

"Openly in existence" means any building, location, or structure on a school site that has visible outward markings indicating the building, location, or structure was operating as a school which would serve as sufficient notice of the existence of the school or a reason for further inquiry on the part of the medical marijuana dispensary license applicant. "Openly in existence" shall not mean any school that operated secretly or discreetly without any signs or other markings on any building, location, or structure on the school site, undeveloped land or a structure owned by a school that was not openly used and marked as a school site, or any school site that was established after the medical marijuana dispensary had been established and licensed by the Authority.

"Organic" means the same as the term defined in the National Organic Program codified at 7 CFR §

205.2. This includes the terms "organically produced" as set forth in 7 U.S.C. § 6502(15) and "100 percent organic" and "made with organic (specified ingredients or food group(s))" as set forth in 7 CFR § 205.102.

"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 442:10-2-1 and OAC 442:10-2-2.

"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 an 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 Authority, 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 samples to a 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. Processors will receive either a hazardous processor license or a non-hazardous processor license based on the type of chemicals the processor will be utilizing in the extraction process in accordance with these Rules.

"Production batch" means

(A) Any amount of medical marijuana concentrate or nonliquid medical marijuana products, not to exceed production batch sizes allowable under OAC 442:10-8-1(b), 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 production batch sizes allowable under OAC 442:10-8-1(b), 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.

"Publicly traded company" means a business entity organized under the laws of the United States or Canada where the domicile for the business entity permits the sale of marijuana and such business entity has a class of securities that are registered and traded for investment pursuant to the Securities Exchange Act of 1934 or listed and traded for investment on a reputable recognized foreign stock exchange or foreign market.

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

"Public school" means an elementary, middle, high school, or technology center 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 Authority to conduct surveillance of testing laboratories for compliance purposes.

"Readily accessible" means that a licensee can immediately produce the documentation upon the Authority's request.

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

"Remediation" means the process by which a harvest batch or production batch that fails testing undergoes a procedure to remedy the harvest batch or production batch failure and is retested in accordance with Oklahoma law and 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 Authority to grow, cultivate, possess, and transfer samples 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 Oklahoma Medical Marijuana Authority as a medical marijuana dispensary.

"Revocation" means the Authority's final decision in accordance with the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq., that any license issued by the

Authority pursuant to Oklahoma law and this Chapter is rescinded.

~~**"RFID"** means Radio Frequency Identification.~~

"Rules" means, unless otherwise indicated, the rules as adopted and set forth in OAC 442:10.

"Sampler" means a person who is employed by or is an owner of a licensed laboratory, dispensary, 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.

"Seed-to-sale tracking system" means an electronic inventory tracking system utilized by a commercial licensee to track inventory, any steps through the process of cultivating or manufacturing medical marijuana and/or medical products, transactions with other licensees, testing, and other required information for the purpose of reporting that information to the Authority in accordance with Oklahoma law, rules, and regulations.

"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 name given to a particular variety of medical marijuana that is based on a combination of factors which may include, but is not limited to, botanical lineage, appearance, chemical profile, and accompanying effects. An example of a "strain" would be "OG Kush" or "Pineapple Express".

"Terpenoids" means isoprenes that are the aromatic compounds found in cannabis, including, but not limited to~~: limonene, myrcene, pinene, linalool, eucalyptol, delta-terpinene (Δ-terpinene), beta-caryophyllene (ß-caryophyllene), caryophyllene oxide, nerolidol and phytol~~ those listed at OAC 442:10-8-1(i)(7)(A).

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

"THC" means tetrahydrocannabinol, which is the primary psychotropic cannabinoid formed by decarboxylation of naturally occurring 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 Authority, which allows the transporter to transport, store, and distribute, but not take ownership of, medical marijuana and medical marijuana products to and from the licensed premises of commercial licensees. As used in this Chapter, "Transporter" or "Commercial Transporter" does not mean licensed commercial growers, processors, dispensaries, laboratories, research facilities, and education facilities who are automatic holders of transporter licenses.

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

"Transporter license" means a medical marijuana business license issued by the Authority either (A) automatically to commercial growers, processors, dispensaries, laboratories, research facilities, and education facilities 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 Authority to dispose of medical marijuana waste as authorized in Oklahoma

law and these Rules.

"Waste disposal facility license" means a license issued by the Authority 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 Authority.

"Waste disposal facility permit" means a permit issued by the Authority 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.

"Wholesale package" means medical marijuana from the same harvest batch or multiple units of medical marijuana product from the same production batch that are combined together as a single unit for the purpose of ~~RFID~~ inventory tracking system tagging and are transported to a single commercial licensee.

"Working towards operational status" means a commercial licensee that:

(A) Has applied for any additional permits, registrations, or licenses required by the Authority or another Oklahoma agency, organization, or political subdivision to lawfully conduct operations at the licensed premises and is awaiting issuance of such permit(s), registration(s), or other license(s);

(B) Is performing construction or other material changes to the licensed premises in preparation of operations at the licenses premises;

(C) Is onboarding or training initial staff in preparation of operations at the licensed premises;

(D) Is in the process of purchasing or is awaiting receipt of delivery of physical materials essential to operations at the licensed premises, such as furniture or equipment; or

(E) Any additional actions determined to be sufficient by the Authority.

442:10-1-5. Criminal history screening

(a) **Parties subject to screening.** Prior to issuance of any commercial license or transporter agent license, the following shall undergo ~~an Oklahoma state criminal history~~ a national fingerprint-based background check within thirty (30) days prior to the application for the license:

(1) Individual applicants applying on their own behalf;
(2) Individuals applying on behalf of an entity;
(3) All principal officers of an entity;
(4) All owners of an entity;
(5) For corporations seeking a business license, all officers, directors, and stockholders; and
(6) For public institutions seeking a research facility license, all principal investigators and co-principal investigators.

(b) **Disqualifying Criminal Conviction.** Any commercial applicant with a disqualifying criminal conviction is not qualified to receive or renew a commercial license.

(c) **OBNDD Registration**. Any commercial licensee issued a license authorized by this Chapter that is required under Oklahoma law to obtain an Oklahoma State Bureau of Narcotics and Dangerous Drugs Control ("OBNDD") registration shall do so prior to possessing or handling any marijuana or marijuana product.

(d) **Fees.** All applicable fees, including those charged by the Oklahoma State Bureau of Investigation vendor or OBNDD, are the responsibility of the applicant.

SUBCHAPTER 3. TRANSPORTER LICENSE

442:10-3-1. License for transportation of medical marijuana

(a) A medical marijuana transporter license shall be issued to qualifying applicants for grower, processor, dispensary, laboratory, research facility, or education facility licenses at the time of approval. This license shall enable licensed growers, processors, dispensaries, laboratories, research facilities, and education facilities to apply for and receive individual transporter agent licenses for agents, employees, officers or owners of the commercial licensed facility. Through their licensed transporter agents, licensed growers,

processors, dispensaries, laboratories, research facilities, and education facilities may transport medical marijuana or medical marijuana products to other commercial licensees. This license shall not authorize licensed growers, processors, dispensaries, laboratories, research facilities, or education facilities to transport, store, or distribute medical marijuana or medical marijuana products on behalf of other medical marijuana licensees.
(b) A medical marijuana commercial transporter license shall be issued as an independent business license to applicants meeting the requirements set forth in OAC 442:10-5-3, OAC 442:10-5-3.1, and OAC 442:10-5-3.2. This license shall be subject to the same restrictions and obligations as any commercial licensee and shall enable the commercial transporter to:

(1) transport, store, and distribute medical marijuana and medical marijuana products on behalf of other commercial licensees;
(2) contract with multiple commercial licensees; and
(3) maintain multiple warehouses at licensed premises that are approved by the Authority for the purpose of temporarily storing and distributing medical marijuana and medical marijuana products.

(c) A commercial transporter applicant or licensee must obtain and submit to the Authority for each warehouse location a certificate of compliance issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E), and the licensed premises shall meet security requirements applicable to a medical marijuana business.
(d) Pursuant to 63 O.S. § 427.3(D)(11), 63 O.S. § 427.14(L), 63 O.S. § 427.14(G)(2), and 63 O.S. § 427.14(J), for each warehouse location, a commercial transporter applicant or licensee must submit all Certificate(s) of Occupancy, Final Inspection Report(s), and Site Plan(s), issued from or approved by the organization, political subdivision, office, or individual responsible for enforcing the requirements of all building and fire codes adopted by the Oklahoma Uniform Building Code Commission pursuant to OAC 748:20. Pursuant to 74 O.S. § 324.11, in all geographical areas where the applicable Certificate(s) of Occupancy, Final Inspection Report(s), Site Plan(s) and/or permit(s) are not issued from and/or approved by local authorities, such documentation must be obtained from the Oklahoma Office of the State Fire Marshal.
~~(d)~~ (e) A commercial transporter applicant or licensee must have each warehouse location inspected and approved by the Authority prior to its use.
~~(e)~~ (f) A commercial transporter shall be responsible for any and all medical marijuana and medical marijuana products within its custody, control, or possession.
~~(f)~~ (g) No person or entity shall transport or otherwise transfer any medical marijuana or medical marijuana products without both a valid transporter license and a valid transporter agent license.

SUBCHAPTER 4. RESEARCH FACILITIES AND EDUCATION FACILITIES

442:10-4-3. Applications

(a) **Application fee**. An applicant for a research facility or education facility license, or renewal thereof, shall submit to the Authority a completed application on a form and in a manner prescribed by the Authority, along with the application fee as established in 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
(b) **Submission**. The application shall be on the Authority prescribed form and shall include the following information about the establishment:

(1) Name of the establishment;
(2) Physical address of the establishment, including the county in which any licensed premises will be located;
(3) GPS coordinates of the establishment;
(4) Phone number and email of the establishment; and
(5) Hours of operation for any licensed premises.

(c) **Individual applicant**. The application for a research facility or education facility license made by an individual on his or her own behalf shall be on the Authority prescribed form and shall include at a

minimum:

(1) The applicant's first name, middle name, last name, and suffix if applicable;

(2) The applicant's residence address and valid mailing address;

(3) The applicant's date of birth;

(4) The applicant's telephone number and email address;

(5) Indication of the type of research to be conducted;

(6) Indication of any public money involved in the research and/or curriculum, if applicable;

(7) An attestation that the information provided by the applicant is true and correct;

(8) An attestation that any licensed premises shall not be located on tribal lands;

(9) An attestation that the research project does not involve biomedical or clinical research subject to federal regulations and institutional oversight, which is exempt from Authority regulations, and that research facility and education facility licenses granted by the Authority are only issued for the research and/or curriculum described and approved in the application;

(10) An attestation that the use of any public funds or involvement of any public institution for research purposes must be disclosed at the time of application and that additional information and documentation regarding the research and/or curriculum may be required to be submitted during and after the application submission;

(11) An attestation that the applicant adheres to 45 CFR § 46 (Protection of Human Subjects under United States Law) regulations; and

(12) A statement signed by the applicant pledging not to divert marijuana to any individual or entity that is not lawfully entitled to possess marijuana.

(d) **Application on behalf of an entity**. In addition to requirements of Subsection (c), an application for a research facility or education facility license made by an individual on behalf of an entity shall include:

(1) An attestation that applicant is authorized to make application on behalf of the entity;

(2) Full name of organization;

(3) Trade name, if applicable;

(4) Type of business organization;

(5) Mailing address;

(6) Telephone number and email address;

(7) The name, residence address, and date of birth of each owner, if applicable; and

(8) The name and residence address of each principal investigator or principal officer, if applicable.

(e) **Supporting documentation for research facility applicants**. ~~Each~~ Pursuant to 63 O.S. § 427.3(D)(11), 63 O.S. § 427.14(L), 63 O.S. § 427.14(G)(2), and 63 O.S. § 427.14(J), each application for a research facility shall be accompanied by the following documentation:

(1) A certificate of compliance on a form prescribed or otherwise authorized by the Authority that is issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E);

(2) If applicable, official documentation from the Secretary of State establishing the applicant's trade name;

(3) If applicable, a list of all owners and principal officers of the applicant and supporting documentation, including, but not limited to: certificate of incorporation, bylaws, articles of organization, operating agreement, certificate of limited partnership, resolution of a board of directors, or other similar documents;

(4) If applicable, documents establishing the applicant; and the members, managers, and board members; and seventy-five percent (75%) of the applicant's ownership interests are Oklahoma residents as required in accordance with OAC 442:10-1-6. This requirement shall not apply to research facility applicants that are public institutions or Oklahoma non-profit entities registered with the Oklahoma Secretary of State;

(5) The applicant shall submit a full description of the research including the following:

(A) Defined protocol;

(B) Clearly articulated goals;
(C) Defined methods and outputs;
(D) Defined start and end date; and
(E) Funding source(s); ~~and~~

(6) If applicable, all Certificate(s) of Occupancy, Final Inspection Report(s), and Site Plan(s), issued from or approved by the organization, political subdivision, office, or individual responsible for enforcing the requirements of all building and fire codes adopted by the Oklahoma Uniform Building Code Commission pursuant to OAC 748:20. Pursuant to 74 O.S. § 324.11, in all geographical areas where the applicable Certificate(s) of Occupancy, Final Inspection Report(s), Site Plan(s) and/or permit(s) are not issued from and/or approved by local authorities, such documentation must be obtained from the Oklahoma Office of the State Fire Marshal; and

~~(6)~~ (7) Any further documentation or information the Authority determines is necessary to ensure the applicant is qualified under Oklahoma law and these Rules to obtain a research facility license.

(f) **Supporting documentation for education facility applicants.** Each application for an education facility license shall be accompanied by the following documentation:

(1) A certificate of compliance on a form prescribed or otherwise authorized by the Authority that is issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E);

(2) An application for an education facility must include non-profit registration with the Oklahoma Secretary of State;

(3) If applicable, official documentation from the Secretary of State establishing the applicant's trade name;

(4) If research is being conducted the applicant shall submit a full description of the research including the following:

(A) Defined protocol;
(B) Clearly articulated goals;
(C) Defined methods and outputs;
(D) Defined start and end date; and
(E) Funding source(s)

(5) If applicable, the education facility applicant must submit the curriculum and/or a description of the curricula that will be used; and

(6) Any further documentation or information the Authority determines is necessary to ensure the applicant is qualified under Oklahoma law and these Rules to obtain an education facility license.

(g) **Supporting documentation for public research or education**.

(1) Research facility and education facility licensees may contract to perform research and/or education in conjunction with a public higher education research institution. If the research will be conducted with a public institution or public money, the Authority shall review the research project and/or curriculum of the applicant to determine if it meets additional requirements in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq. The applicant shall supply all relevant information and documentation to establish that the research or education meets these additional requirements. The Authority shall review the research or education project to assess:

(A) The quality, study design, value, or impact of the project;
(B) Whether the applicant has the appropriate personnel, expertise, facilities, infrastructure, funding, and human, animal, or other approvals in place to successfully conduct the project; and
(C) Whether the amount of marijuana to be grown by the applicant is consistent with the scope and goals of the project.

(2) To assess these criteria, research facility and education facility applications for research or education involving public institutions or public money shall include:

(A) A description of how public institutions and public funds will be utilized in the research or education;

(B) A full description of the research project to include:
(i) Abstract;
(ii) Study problem or curriculum;
(iii) Rationale, including identification of the need, gaps, benefits, advance best practices, public policy or safety
(iv) Literature review, including a bibliography of all referenced materials;
(v) Study or curriculum objectives;
(vi) Research method; and
(vii) Ethical considerations.
(C) An overview of the amount of marijuana to be purchased, grown, or cultivated, and an explanation for the amount to be purchased or grown;
(D) Contract(s) and agreement(s) with public institutions involved in the research and sources of public funds supporting the research;
(E) Documentation of applicant's ability to successfully implement the research project and/or curriculum to include:
(i) Curriculum vitae or resumes for all principal investigators and co-principal investigators;
(ii) Organizational chart; and
(iii) Description of the funding source(s).
(F) Any further documentation or information the Authority determines is necessary to ensure the applicant is qualified under Oklahoma law and these Rules.

(h) **Incomplete application**. Failure to submit a complete application with all required information and documentation shall result in a rejection of the application. The Authority shall notify the applicant via email through the electronic application account of the reasons for the rejection, and the applicant shall have thirty (30) days from the date of notification to correct and complete the application without an additional fee. If the applicant fails to correct and complete the application within the thirty (30) day period, the application shall expire. Unless the Authority determines otherwise, an application that has been resubmitted but is still incomplete or contains errors that are not clerical or typographical in nature shall be denied.
(i) **Review process**. Research facility and education facility license approval shall be assessed by a procedural review process as determined by the Authority.
(j) **Application denial**. If the Authority determines that the research or education project does not meet the requirements of state law or these Rules, the application shall be denied.

442:10-4-4. Inspections

(a) Submission of an application for a medical marijuana research license and educational facility license constitutes permission for entry to and inspection of any licensed premises during hours of operation and other reasonable times. Refusal to permit or impeding such entry or inspection shall constitute grounds for administrative penalties, which may include but are not limited to fines as set forth in Appendix C and the denial, nonrenewal, suspension, ~~and/or~~ or revocation of a license.
(b) The Authority may perform two on-site inspections per calendar year of the licensed research facility or education facility to determine, assess, and monitor compliance with applicable Oklahoma law and these Rules or ensure qualifications for licensure. The Authority may perform an unannounced, on-site inspection of the operations and any facility of the medical marijuana research licensee or medical marijuana educational facility licensee.
(c) The Authority may conduct additional inspections to ensure correction of or investigate violations of applicable Oklahoma law and these Rules. If the Authority receives a complaint concerning noncompliance by a medical marijuana research licensee or a medical marijuana education facility licensee, the Authority may conduct additional unannounced, on-site inspections.
(d) The Authority shall refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities. Except for license information concerning licensed patients, the Authority may share

confidential information to assist other agencies in ensuring compliance with applicable laws, rules and regulations.
(e) If the Authority discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an inspection, the Authority may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation.
(f) The Authority may review any and all records of a licensee and may require and conduct interviews with such persons or entities and persons affiliated with such entities, for the purpose of determining compliance with Authority rules and applicable laws. Failure to make documents or other requested information available to the Authority and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include but are not limited to fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license. All records shall be kept on-site and readily accessible.
(g) If the Authority 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 inspection of the licensee, the Authority shall take administrative action in accordance with Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. §§ 250 et seq.
(h) Except as otherwise provided in Oklahoma law or these Rules, correctable violations identified during an inspection shall be corrected within thirty (30) days of receipt of a written notice of violations. If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.
(i) The Authority may assess fines in the amounts set forth in Appendix C and seek any other administrative penalties authorized by law against a licensee without providing opportunity to correct when the violation is not capable of being corrected.

442:10-4-5. Inventory tracking, records, reports, and audits
(a) **Monthly reports**. Research facility licensees shall submit monthly reports to the Authority, which shall include:
(1) The amount of marijuana purchased from medical marijuana businesses and research facilities in pounds;
(2) The amount of medical marijuana grown and used for research in pounds;
(3) The amount of marijuana waste in pounds;
(4) If necessary, a detailed explanation of why any marijuana cannot be accounted for as having been purchased, used for research, or maintained in current inventory; and
(5) Any information the Authority determines is necessary to ensure that all marijuana grown in Oklahoma is accounted for as required under 63 O.S. § 420 et seq. the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.
(6) Upon implementation, submission of information and data to the Authority through the State inventory tracking system will be required in accordance with the Oklahoma Medical Marijuana Protection Act, 63 O.S. § 427.1 et seq., and these Rules, and submission of information and data to the Authority through the State inventory tracking system shall be sufficient to satisfy monthly reporting requirements.
(b) **Transfer or sale**. A research facility licensee and an educational facility licensee may only transfer, by sale or donation, marijuana grown within its operation to medical marijuana research licensees. Research facility and education facility licensees shall keep records for every transaction related to the donation or sale of marijuana. Records related to the donation or sale shall include at a minimum the following:
(1) The name and license number of the medical marijuana researcher licensee that purchased or received the medical marijuana;
(2) The address and phone number of each recipient;
(3) The type of marijuana donated or sold;
(4) The amount of marijuana donated or sold in pounds; and

(5) The date of the donation or sale.

(c) **Records**. Pursuant to the Authority's audit and inspection responsibilities, research facility and education facility licensees 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 filed 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.

(d) **Inventory tracking system**. Pursuant to 63 O.S. § 427.3(D)(8) and 63 O.S. § 427.13(B), each commercial licensee shall use the State inventory tracking system by inputting inventory tracking data required to be reported to the Authority directly into the State inventory tracking system or by utilizing a seed-to-sale tracking system that integrates with the State inventory tracking system. All commercial licensees must have an inventory tracking system account activated to lawfully operate and must ensure all information is reported to the Authority accurately and in real time or after each individual sale in accordance with 63 O.S. § 427.13(B)(1) and these Rules. All commercial licensees shall ensure the following information and data are accurately tracked and timely reported to the Authority through the State inventory tracking system:

(1) The chain of custody of all medical marijuana and medical marijuana products, including every transaction with another licensee, patient, or caregiver including, but not limited to:

(A) The name address, license number, and phone number of the medical marijuana business that cultivated, manufactured, sold, purchased, or otherwise transferred the medical marijuana or medical marijuana product(s);

(B) The type, item, strain, and category of medical marijuana or medical marijuana product(s) involved in the transaction;

(C) The weight, quantity, or other metric required by the Authority, of the medical marijuana or medical marijuana product(s) involved in the transaction;

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

(E) The total amount spent in dollars;

(F) All point-of-sale records as applicable;

(G) Transportation information documenting the transport of medical marijuana or medical marijuana product(s) as required under OAC 442:10-3-6(b);
(H) Testing results and information;
(I) Waste records and information;
(J) Marijuana excise tax records, if applicable;
(K) ~~RFID~~ Inventory tracking system tag number(s);

(2) 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 or clones are planted;
(B) When medical marijuana plants are harvested and/or destroyed;
(C) When medical marijuana is transported, or otherwise transferred, sold, stolen, diverted, or lost;
(D) When medical marijuana changes form, including, but not limited to, when it is planted, cultivated, processed, and infused or otherwise processed into a final product or final form;
(E) A complete inventory of all medical marijuana; seeds; plant tissue; clones; useable marijuana; trim; shake; leaves; other plant matter; and medical marijuana products;
(F) All samples sent to a testing laboratory or used for internal quality testing or other purposes;

(3) Any further information the Authority determines is necessary to ensure all medical marijuana and medical marijuana products are accurately and fully tracked throughout the entirety of the lifespan of the plant and product.

(e) **Seed-to-sale tracking system.** A commercial licensee shall use a seed-to-sale tracking system or integrate its own seed-to-sale tracking system with the State inventory tracking system established by the Authority. If a commercial licensee uses a seed-to-sale tracking system that does not integrate with the State inventory tracking system, or does integrate but does not share all required information, the commercial licensee shall ensure all required information is reported directly into the State inventory tracking system.

(f) **Inventory tracking system requirements.**

(1) At a minimum, commercial licensees shall track, update, and report inventory after each individual sale to the Authority in the State inventory tracking system.

(2) All commercial licensees must ensure all on-premises and in-transit medical marijuana and medical marijuana product inventories are reconciled each day in the State inventory tracking system at the close of business, if not already done.

(3) Commercial licensees are required to use ~~RFID~~ inventory tracking system tags from an Authority-approved supplier for the State inventory tracking system. Each Licensee is responsible for the cost of all ~~RFID~~ inventory tracking system tags and any associated vendor fees.

(A) A commercial licensee shall ensure its inventories are properly tagged and that ~~a RFID~~ an inventory tracking system tag is properly assigned to medical marijuana, medical marijuana products, and medical marijuana waste as required by the Authority.

(B) A commercial licensee shall ensure it has an adequate supply of ~~RFID~~ inventory tracking system tags at all times. If a commercial licensee is unable to account for unused ~~RFID~~ inventory tracking system tags, the commercial licensee must report to the Authority and the State inventory tracking system vendor within forty-eight (48) hours.

(C) ~~RFID~~ Inventory tracking system tags must contain the legal name and correct license number of the commercial licensee that ordered them. Commercial licensees are prohibited from using another licensee's ~~RFID~~ inventory tracking system tags.

(D) ~~Prior to a plant reaching a point where it is able to support the weight of the RFID tag and attachment strap, the RFID tag may be securely fastened to the stalk or other similarly situated position approved by the Authority.~~ The inventory tracking system tag shall be placed on the container holding the medical marijuana plant and must remain physically near and clearly associated with the medical marijuana plant until the plant reaches twelve (12) inches in height. Clones must be tracked in the state seed-to-sale system and must be associated with a wholesale package tag, whether cut from a mother plant or transferred from another licensee, prior to reaching

twelve (12) inches in height.

(E) When the plant ~~becomes able to support the weight of the RFID tag, the RFID~~ reaches twelve (12) inches in height, the inventory tracking system tag shall be securely fastened to a lower supporting branch. The ~~RFID~~ inventory tracking system tag shall remain affixed for the entire life of the plant until disposal. If the plant changes forms, is removed from the original planting location after harvest, or is being trimmed, dried, or cured by the grower, the inventory tracking system tag shall be placed on the container holding the medical marijuana plants and/or must remain physically near and clearly associated with the medical marijuana plants until the plant is placed into a package in both the seed-to-sale tracking system and physically packaged and affixed with the inventory tracking system tag.

(F) Mother plants must be tagged before any cuttings or clones are generated therefrom.

(G) If ~~a RFID~~ an inventory tracking system tag gets destroyed, stolen, or falls off of a medical marijuana plant, the licensee must ensure a new ~~RFID~~ inventory tracking system tag is placed on the medical marijuana plant and the change of the ~~RFID~~ inventory tracking system tag is properly reflected in the State inventory tracking system.

(H) Commercial licensees shall not reuse any ~~RFID~~ inventory tracking system tag that has already been affixed to any regulated medical marijuana or medical marijuana products.

(4) Each wholesale package of medical marijuana must have ~~a RFID~~ an inventory tracking system tag during storage and transfer and may only contain one harvest batch of medical marijuana.

(5) Prior to transfer, commercial licensees shall ensure that each immature plant is properly affixed with an ~~RFID~~ inventory tracking system tag if the plant was not previously tagged in accordance with these Rules.

(6) Commercial licensees' inventory must have ~~a RFID~~ an inventory tracking system tag properly affixed to all medical marijuana products during storage and transfer in one of the following manners:

(A) Individual units of medical marijuana products shall be individually affixed with ~~a RFID~~ an inventory tracking system tag; or

(B) Medical marijuana products may only be combined in a single wholesale package using one ~~RFID~~ inventory tracking system tag if all units are from the same production batch.

(7) If any medical marijuana or medical marijuana products are removed from a wholesale package, each individual unit or new wholesale package must be separately tagged.

(8) All packages of medical marijuana waste shall have ~~a RFID~~ an inventory tracking system tag affixed and the contents of the waste package shall be reported in the State inventory tracking system.

(g) **Inventory tracking system administrators and users.**

(1) A commercial licensee must have at least one owner, or manager, who is an inventory tracking system administrator.

(2) The inventory tracking system administrator must attend and complete all required inventory tracking system training.

(3) If at any point, the inventory tracking system administrator for a licensee changes, the commercial licensee shall change or assign a new inventory tracking system administrator within thirty (30) business days.

(4) Commercial licensees shall maintain an accurate and complete list of all inventory tracking system administrators and employee users.

(5) Commercial licensees shall ensure that all owners and employees that are granted inventory tracking system account access for the purpose of conducting inventory tracking functions are trained and authorized before the owners or employees may access the State inventory tracking system.

(6) All inventory tracking system users shall be assigned an individual account in the State inventory tracking system.

(7) Any individual entering data into the State inventory tracking system shall only use the inventory tracking system account assigned specifically to that individual. Each inventory tracking system administrator and inventory tracking system user must have unique log-in credentials that shall not be

used by any other person.

(8) Within three (3) business days, commercial licensees must remove access for any inventory tracking system administrator or user from their accounts if any such individual no longer utilizes the State inventory tracking system or is no longer employed by the commercial licensee.

(h) **Loss access to State inventory tracking system.** If at any time a commercial licensee loses access to the State inventory tracking system due to circumstances beyond the commercial licensee's control, the commercial licensee shall keep and maintain records detailing all inventory tracking activities that were conducted during the loss of access. Once access is restored, all inventory tracking activities that occurred during the loss of access must be immediately entered into the State inventory tracking system. If a commercial licensee loses access to the State inventory tracking system due to circumstances within its control, the commercial licensee may not perform any business activities that would be required to be reported into the State inventory tracking system until access is restored and reporting is resumed; any transfer, sale, or purchase of medical marijuana or medical marijuana products shall be an unlawful sale.

(i) **Audits**. The Authority may perform on-site audits of all research facility and education facility licensees to ensure the accuracy of information and data reported to the Authority and to ensure that all marijuana grown in Oklahoma is accounted for. Submission of an application for a research facility or education facility license constitutes permission for entry to any licensed premises and auditing of the licensee during hours of operation and other reasonable times. Refusal to permit the Authority entry or refusal to permit the Authority to inspect all books and records shall constitute grounds for and administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license.

(1) The Authority may review any and all records and information of a research facility or education facility 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 Authority Rules and applicable laws. Failure to make documents or other requested information available to the Authority and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/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) Licensees shall comply with all written requests from the Authority to produce or provide access to records and information within ten (10) business days.

(3) If the Authority 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 licensee, the Authority shall take administrative action against the licensee in accordance with Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.

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

(5) If the Authority discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an audit, the Authority 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 in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.

(8) The Authority may assess fines in the amounts set forth in Appendix C and seek any other administrative penalties authorized by law against a licensee without providing opportunity to correct when the violation is not capable of being corrected.

442:10-4-6. Penalties

(a) **Failure to file timely reports.** If a research facility licensee fails to submit a timely, complete, and accurate required monthly report and fails to correct such deficiency within thirty (30) days of the Authority's written notice, the licensee shall be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.

(b) **Fraudulent reports**. Within any one (1) year period of time, if the licensee has submitted one (1) or more reports containing gross errors that cannot reasonably be attributed to normal human error, the licensee shall be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.

(c) **Unlawful purchase, ~~and~~ sale, or transfer**. Within any one (1) year period of time, if the licensee has made an unlawful purchase, ~~or~~ sale, or transfer of medical marijuana, the licensee shall be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.

(d) **Noncompliance and criminal activity**. A research facility or education facility ~~licenses~~ license shall be subject to revocation, suspension, monetary penalties, and any other penalty authorized by law upon a determination by the Authority that the licensee has not complied with applicable Oklahoma law or this Chapter, or upon official notification to the Authority that the licensee has engaged in criminal activity in violation of Oklahoma law.

(e) **Administrative penalties**. Procedures for administrative penalties against a licensee are stated in the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq. These procedures provide for the licensee to receive notice and to have the opportunity to be present at a hearing and to present evidence in his or her defense. The Executive Director or his or her designee may promulgate an administrative order revoking or suspending the license, dismissing the matter, or providing for other relief as allowed by law. At any time after the action is filed against the research facility or education facility licensee, the Authority and the licensee may dispose of the matter by consent order or stipulation. Orders are appealable in accordance with the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.

(f) **Fines.** Monetary penalties shall be assessed in the amounts set forth in Appendix C. Failure to pay any fine within thirty (30) days of assessment of the fine shall result in nonrenewal, suspension, and/or revocation of the license.

SUBCHAPTER 5. MEDICAL MARIJUANA BUSINESSES

442:10-5-1.1. Responsibilities of the license holder

Upon acceptance of the license issued by the Authority, the license holder in order to retain the license shall:

(1) Post the license or permit in a location in the licensed premises that is conspicuous;

(2) Comply with the provisions in this Chapter;

(3) Allow representatives of the Authority access to the medical marijuana business as specified under OAC 442:10-5-4 and OAC 442:10-5-6(i);

(4) Comply with directives of the Authority including time frames for corrective actions specified in inspection reports, audit reports, notices, orders, warnings, and other directives issued by the Authority in regard to the license holder's medical marijuana business or in response to community emergencies;

(5) Accept notices issued and served by the Authority according to law;

(6) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this Chapter or a directive of the Authority, including time frames for corrective actions specified in inspection reports, audit reports, notices, orders, warnings, and other directives;

(7) Ensure that all information and records maintained in the licensee's online OMMA license account—including the hours of operation for all licensed premises, trade name, and a valid mailing address, if applicable—are complete, accurate, and updated in a timely manner in accordance with these Rules;

(8) If applicable, submit the annual renewal application and pay all renewal license and late fees, if any;

(9) Bear the financial responsibility for all compliance and inventory tracking obligations and responsibilities set forth in Oklahoma statutes and these Rules. The Authority will not contribute to, fund, or subsidize any commercial licensee's compliance or tracking expenses. Nothing herein shall be construed to require the Authority to contribute to, subsidize, or fund in any way a commercial licensee's compliance or tracking expenses; and
(10) If multiple commercial licensees are located at the same location, each commercial license must ensure that all inventory is separately and properly tracked, accounted for, and physically and distinctly separated from the inventory of any other commercial licensee such that licensees and the Authority are readily able to distinguish as to which licensee each item of medical marijuana and medical marijuana products belongs.
(11) All medical marijuana commercial grower licensees who operate an outdoor medical marijuana production facility shall be required to register with the Oklahoma Department of Agriculture, Food, and Forestry as an environmentally sensitive crop owner. Registration shall provide notice to commercial and private pesticide applicators of the locations of medical marijuana crops and help minimize the potential for damaging pesticide drift. Medical marijuana commercial grower licensees shall provide their business name, address, Global Positioning System (GPS) coordinates for all outdoor medical marijuana production facilities, and any other information required by the Department when registering with the Environmentally Sensitive Area Registry.
(12) All medical marijuana commercial grower licensees shall file with the Authority a bond or attestation as required under OAC 442:10-5-3.3 and ensure that all information and records are complete, accurate, and updated in a timely manner in accordance with OAC 442:10-5-2(e)(3)
(13) Beginning January 1, 2024, the Authority shall require employees of a medical marijuana business licensee to apply for and receive a credential authorizing the employee to work in a licensed medical marijuana business.

(A) For purposes of this Section, "employee" means any natural person who:

(i) Grows, harvests, dries, cures, purchases, sells, transfers, transports, processes, produces, manufactures, creates, or packages medical marijuana, medical marijuana products, and/or medical marijuana waste on behalf of or for a medical marijuana licensed commercial grower, processor, or dispensary;

(ii) Samples, trains, or educates on behalf of or for a medical marijuana licensed education or research facility;

(iii) Disposes of or transports medical marijuana, medical marijuana products, and/or medical marijuana waste on behalf of a medical marijuana waste disposal facility licensee;

(iv) Tests and/or conducts research on medical marijuana and/or medical marijuana products on behalf of a medical marijuana licensed testing laboratory;

(v) Transports, stores, distributes, but does not take ownership of, medical marijuana and/or medical marijuana products on behalf of a medical marijuana licensed commercial transporter;

(vi) Tracks, traces, reports, and/or inputs any information into the State inventory tracking system on behalf of a medical marijuana commercial licensee; or

(vii) Conducts any other additional business for the benefit of a medical marijuana commercial licensee authorized under OAC 442:10.

(B) A credential will be issued to an individual employee and can be associated with multiple medical marijuana businesses or employers.

(C) A medical marijuana business license holder shall require all individuals employed under their license to have an active, unexpired credential prior to employment and must associate all employee credentials with the corresponding commercial license in a manner prescribed by the Authority.

(D) Employee credentials shall be valid from the date of issuance until January 31st of the following year.

(E) An employee may voluntarily surrender a credential to the Authority at any time.

(i) If an employee voluntarily surrenders a credential, the employee shall:

(I) Destroy or return the credential to the Authority;
(II) Submit a surrender employee credential form provided by the Authority; and
(III) Submit proof of the employee's identity through submission of documentation identified in OAC 442:10-1-7 (relating to Proof of Identity).
(ii) The surrender of a credential is effective upon written acceptance by the Authority.
(iii) Employee credential surrender forms and any other documentation or information submitted by an employee shall be confidential.

442:10-5-2. Licenses

(a) **Timeframe**. A medical marijuana business license shall be issued for a twelve (12) month period expiring one (1) year from the date of issuance. The license may be issued upon receipt of a completed application, payment of application fee, and verification by the Authority the individual or entity complies with the requirements set forth in Oklahoma law and this Chapter.

(b) **Location**. A business license issued to a grower, processor, dispensary, or testing laboratory shall only be valid for a single location at the address listed on the application. A transporter license shall only be valid at the physical locations that have been submitted to and approved by the Authority and are listed on the application.

(1) For a medical marijuana commercial grower that has a combination of both indoor and outdoor growing facilities at one (1) location, the medical marijuana commercial grower shall be required to obtain a separate license from the Authority for each type of grow operation and shall be subject to the licensing fees provided in 63 O.S. 427.14 and these Rules.

(2) Beginning June 1, 2023, no more than one (1) medical marijuana commercial grower license shall be issued for any one (1) property; a medical marijuana commercial grower holding a combination of both indoor and outdoor licenses at one (1) location shall be exempt from this requirement.

(c) **Renewal of license**.

(1) It is the responsibility of the license holder to renew the license, with all applicable documentation, prior to the date of expiration of the license by following the procedures provided in OAC 442:10-5-3.

(2) Before renewing a license, the Authority may require further information and documentation and may require additional background checks to determine the licensee continues to meet the requirements set forth in Oklahoma law and these Rules. Once a certificate of compliance is properly submitted showing full compliance, no additional certificate of compliance will be required for license renewal unless a change of use or occupancy occurs, or other change that would require additional inspection, licensure, or permitting by the state or municipality.

(3) The Authority may refuse to renew a license of a medical marijuana business for the following:

(A) Failure to meet the requirements for licensure set forth in 63 O.S. § 420 et seq; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or OAC 442:10.

(B) Noncompliance with 63 O.S. § 420 et seq.; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq.; or OAC 442:10.

(4) Upon the determination that a licensee has not met the requirements for renewal, the Authority shall provide written notice to the licensee. The notice shall provide an explanation for the denial of the renewal application.

(5) A commercial licensee that attempts to renew its license after the expiration date of the license shall pay a nonrefundable late renewal fee in the amount of $500.00 to reinstate the license once processed and approved by the Authority. A license that has been expired for more than ninety (90) days shall not be renewed.

(d) **Liquidation of products.** A medical marijuana business licensee whose license is not renewed, or whose license is revoked, suspended, or voluntarily surrendered, shall cease all operations immediately upon expiration of the license and shall dispose of any medical marijuana or medical marijuana products in accordance with OAC 442:10-5-10 that were not liquidated prior to licensure expiration in accordance with

Oklahoma law and these Rules.

(e) **Change in information**.

(1) Licensees shall notify the Authority in writing within fourteen (14) days of any changes in contact information by electronically submitting a change request in accordance with the Authority's instructions.

(2) Licensees shall obtain Authority approval for any material changes that affect the licensee's qualifications for licensure. No licensee shall operate under the conditions of a material change unless and until the Authority has approved in writing the material change. Licensees shall submit a material change request to the Authority in writing in advance of any material change that may affect the licensee's qualifications for licensure by electronically submitting a change request, along with any relevant documentation and fees, in accordance with the Authority's instructions. When submitting a material change request, the licensee will be required to pay a $500.00 nonrefundable fee. Except as is otherwise authorized by the Authority, licensees are limited to one location change request, one name change request, and one ownership change request per year of licensure.

(A) Medical marijuana business licensees submitting a location change must provide the information and documentation required in OAC 442:10-5-3 relating to locations, including but not limited to the following:

(i) If applicable, proof as required in OAC 442:10-5-3(e)(6) that the location of the dispensary or grower is at least one thousand (1,000) feet from any public and private school;

(ii) A certificate of compliance as required in OAC 442:10-5-3(e)(8) on a form prescribed or otherwise authorized by the Authority that is issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E); ~~and~~

(iii) If applicable, all Certificate(s) of Occupancy, Final Inspection Report(s), and Site Plan(s), issued from or approved by the organization, political subdivision, office, or individual responsible for enforcing the requirements of all building and fire codes adopted by the Oklahoma Uniform Building Code Commission pursuant to OAC 748:20. Pursuant to 74 O.S. § 324.11, in all geographical areas where the applicable Certificate(s) of Occupancy, Final Inspection Report(s), Site Plan(s) and/or permit(s) are not issued from and/or approved by local authorities, such documentation must be obtained from the Oklahoma Office of the State Fire Marshal;

(iv) If applicable, a bond or attestation as required under OAC 442:10-5-3.3 certifying compliance with 63 O.S. § 427.26; and

(v) Any further documentation the Authority determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.

~~(iv)~~ (vi) Upon written acceptance of a location change by the Authority, commercial licensees must carry a physical copy of the written location change approval while transporting medical marijuana products from location to location.

(B) Medical marijuana business licensees submitting an ownership change request must provide the information and documentation required in OAC 442:10-5-3 relating to owners, including but not limited to the following:

(i) A list of all owners and principal officers of the commercial applicant and supporting documentation as set forth in OAC 442:10-5-3(e)(1);

(ii) An affidavit of lawful presence for each new owner;

(iii) Documents required under OAC 442:10-5-3(e)(7) establishing that the applicant; and the members, managers, and board members if applicable; and seventy-five percent (75%) of the commercial applicant's ownership interests are Oklahoma residents as required in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.;

(iv) A background check in accordance with OAC 442:10-1-5; ~~and~~

(v) If applicable, a bond or attestation as required under OAC 442:10-5-3.3 certifying

compliance with 63 O.S. § 427.26; and

(vi) Any further documentation the Authority determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.

(C) A medical marijuana business licensee submitting a name change request must provide the information and documentation required in OAC 442:10-5-3 relating to the business name, including, but not limited to, the following:

(i) A certificate of good standing from the Oklahoma Secretary of State issued within thirty (30) days of submission of the application;

(ii) If applicable, official documentation from the Secretary of State establishing the applicant's trade name;

(iii) If applicable, an electronic copy or digital image in color of a sales tax permit issued by the Oklahoma Tax Commission;

(iv) A list of all owners and principal officers of the licensee under the new name and supporting documentation as set forth in OAC 442:10-5-3(e)(1);

(v) Documents establishing that seventy-five (75%) of the ownership of the licensee under the new name are Oklahoma residents in accordance with OAC 442:10-5-3(e)(7); ~~and~~

(vi) If applicable, a bond or attestation as required under OAC 442:10-5-3.3 certifying compliance with 63 O.S. § 427.26; and

(vii) Any further documentation the Authority determines is necessary to ensure the business licensee is still qualified under Oklahoma law and this Chapter to obtain a business license.

(D) Medical marijuana growers, processors, or commercial transporters that have held a valid medical marijuana business license for at least eighteen (18) months and are operating in good standing may submit an ownership change request to add a publicly traded company as an owner. The publicly traded company shall not own more than forty percent (40%) of the equity in the existing medical marijuana grower, processor, or commercial transporter. The following documentation must be provided:

(i) If applicable, a certificate of good standing from the Oklahoma Secretary of State issued within thirty (30) days of submission of the application.

(ii) A list of all owners, excluding all shareholders of the publicly traded company, and principal officers of the commercial applicant and supporting documentation as set forth in OAC 442:10-5-3(e)(1);

(iii) Documents required under OAC 442:10-5-3(e)(7) establishing that the applicant; and the members, managers, and board members if applicable; and seventy-five percent (75%) of the grower, processor, or transporter applicant's ownership interests, excluding the publicly traded company, are Oklahoma residents as required in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

(3) Upon cancellation or expiration of a bond, commercial grower licensees shall provide proof to the Authority on forms and in a manner prescribed by the Authority of a new alternate bond or attestation and accompanying documentation meeting the requirements of OAC 442:10-5-3.3 before the date of cancellation or expiration of the previous bond. Any grower that fails to comply with this section shall be subject to disciplinary action including, but not limited to, revocation, nonrenewal, or monetary penalties.

(f) **Transfer of license**. Licenses may not be changed from one license type to another.

(g) **Surrender of license**.

(1) A licensee may voluntarily surrender a license to the Authority at any time.

(2) If a licensee voluntarily surrenders a license, the licensee shall:

(A) Return the license to the Authority;

(B) Submit on a form prescribed by the Authority a report to the Authority including the reason for surrendering the license; contact information following the close of business; the person or persons responsible for the close of the business; and where business records will be retained;

(C) Submit proof of the licensee's identity through submission of documentation identified in OAC 442:10-1-7 (relating to Proof of Identity); and
(D) Liquidate or dispose of any medical marijuana or medical marijuana products remaining in the possession of the licensee in accordance with OAC 442:10-5-2(d) and OAC 442:10-5-10.

442:10-5-3. Applications

(a) **Application fee**. An applicant for a medical marijuana business, or renewal thereof, shall submit to the Authority a completed application on a form and in a manner prescribed by the Authority, along with the application fee as established in 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

(b) **Submission**. Applications for a business license will be accepted by the Authority no earlier than sixty (60) days from the date that the State Question is approved by the voters of the State of Oklahoma. The application shall be on the Authority prescribed form and shall include the following information about the establishment:

(1) Name of the establishment;
(2) Physical address of the establishment, including the county in which any licensed premises will be located;
(3) GPS coordinates of the establishment;
(4) Phone number and email of the establishment; and
(5) Hours of operation for any licensed premises.

(c) **Individual applicant**. The application for a business license made by an individual on his or her own behalf shall be on the Authority prescribed form and shall include at a minimum:

(1) The applicant's first name, middle name, last name and suffix if applicable;
(2) The applicant's residence address and valid mailing address;
(3) The applicant's date of birth;
(4) The applicant's telephone number and email address;
(5) An attestation that the information provided by the applicant is true and correct;
(6) An attestation that any licensed premises shall not be located on tribal lands;
(7) An attestation that the business has obtained all applicable local licenses and permits for all licensed premises;
(8) An attestation that no individual with ownership interest in the business is a sheriff, deputy sheriff, police officer, prosecuting officer, an officer or employee of OMMA, or an officer or employee of a municipality in which the commercial entity is located; and
(9) A statement signed by the applicant pledging not to divert marijuana to any individual or entity that is not lawfully entitled to possess marijuana.

(d) **Application on behalf of an entity**. In addition to requirements of Subsection (c), an application for a business license made by an individual on behalf of an entity shall include:

(1) An attestation that applicant is authorized to make application on behalf of the entity:
(2) Full name of organization;
(3) Trade name, if applicable;
(4) Type of business organization;
(5) Mailing address;
(6) Telephone number and email address; and
(7) The name, residence address, and date of birth of each owner and each member, manager, and board member, if applicable.

(e) **Supporting documentation**. ~~Each~~ Pursuant to 63 O.S. § 427.3(D)(11), 63 O.S. § 427.14(L), 63 O.S. § 427.14(G)(2), and 63 O.S. § 427.14(J), each application shall be accompanied by the following documentation:

(1) A list of all owners and principal officers of the business applicant and supporting documentation, including, but not limited to: certificate of incorporation, bylaws, articles of organization, operating

agreement, certificate of limited partnership, resolution of a board of directors, or other similar documents;
(2) If applicable, a certificate of good standing from the Oklahoma Secretary of State issued within thirty (30) days of submission of the application;
(3) If applicable, official documentation from the Secretary of State establishing the applicant's trade name;
(4) If applicable, an electronic copy or digital image in color of a sales tax permit issued by the Oklahoma Tax Commission;
(5) An Affidavit of Lawful Presence for each owner;
(6) If a licensed dispensary or grower, proof that the location of the facility is at least one thousand (1,000) feet from a public or private school. For a dispensary, the distance specified shall be measured in a straight line from the nearest property line of such public school or private school to the nearest perimeter wall of the licensed premise of such medical marijuana dispensary. For a grower, the distance specified shall be measured in a straight line from the nearest property line of such public school or private school to the nearest property line of the licensed premises of such medical marijuana commercial grower. For the purposes of this subsection, a school shall not include a property owned, used, or operated by a public or private school that is not used for classroom instruction on core curriculum, such as an administrative building, athletic facility, ballpark, field, or stadium, unless such property is located on the same campus as a building used for classroom instruction on core curriculum;
(7) Documents establishing the applicant; and the members, managers, and board members if applicable; and seventy-five percent (75%) of the commercial applicant's ownership interests are Oklahoma residents as required in the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

(A) Applicants seeking to renew a commercial license issued prior to the enactment of the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., shall submit documentation establishing proof of residency in accordance with OAC 442:10-1-6 (relating to proof of residency);

(B) All other applicants shall submit documentation establishing proof of residency in accordance with OAC 442:10-5-3.1 (relating to proof of residency for business licenses).

(8) If applicable, a certificate of compliance on a form prescribed or otherwise authorized by the Authority that is issued by the political subdivision where the licensed premises is to be located certifying compliance with the categories listed in 63 O.S. § 426.1(E);
(9) If applicable, all Certificate(s) of Occupancy, Final Inspection Report(s), and Site Plan(s), issued from or approved by the organization, political subdivision, office, or individual responsible for enforcing the requirements of all building and fire codes adopted by the Oklahoma Uniform Building Code Commission pursuant to OAC 748:20. Pursuant to 74 O.S. § 324.11, in all geographical areas where the applicable Certificate(s) of Occupancy, Final Inspection Report(s), Site Plan(s) and/or permit(s) are not issued from and/or approved by local authorities, such documentation must be obtained from the Oklahoma Office of the State Fire Marshal;
~~(9)~~ (10) If applicable, accreditation documentation, including documentation of enrollment in analyte-specific proficiency testing results, showing applicants meet requirements stated in OAC 442:10-8-2(a);
~~(10)~~ (11) If a licensed grower, processor or transporter has added or is seeking to add a publicly traded company as an owner, additional documentation as required under OAC 442:10-5-2(e)(2)(C) to show the grower, processor, or transporter applicants meet the requirements stated in 63 O.S. § 427.15a;
~~(11)~~ (12) If applicable, a list of all chemicals a processor will utilize to process marijuana;
~~(12)~~ (13) If applicable, safety data sheets for every chemical a processor will utilize to process marijuana; ~~and~~
~~(13)~~ (14) If applicable, a bond or attestation as required under OAC 442:10-5-3.3 certifying compliance with 63 O.S. § 427.26;
(15) Supplemental application materials to be submitted by the applicant and utilized by the Authority to

determine medical marijuana business licensing fees pursuant to 63 O.S. 427.14; and

(16) Any further documentation the Authority determines is necessary to ensure the commercial applicant is qualified under Oklahoma law and this Chapter to obtain a commercial license.

(f) **Incomplete application**. Failure to submit a complete application with all required information and documentation shall result in a rejection of the application. The Authority shall notify the applicant via email through the electronic application account of the reasons for the rejection, and the applicant shall have thirty (30) days from the date of notification to correct and complete the application without an additional fee. If the applicant fails to correct and complete the application within the thirty (30) day period, the application shall expire. Unless the Authority determines otherwise, an application that has been resubmitted but is still incomplete or contains errors that are not clerical or typographical in nature shall be denied.

(g) **Status update letter**. If a delay in processing has occurred, the Authority shall notify the applicant via email of the delay and the reason for the delay.

(h) **Moratorium.** Beginning August ~~1,~~ 26, 2022, and ending August 1, ~~2024~~ 2026, there shall be a moratorium on processing and issuing new medical marijuana business licenses for dispensaries, processors, and growers. The Authority will review and process applications received on or before August ~~1,~~ 26, 2022. The Executive Director of the Authority may terminate the moratorium prior to August 1, ~~2024~~ 2026, upon a determination that all pending license reviews, inspections, or investigations have been completed. The moratorium shall not apply to:

(1) The renewal of a medical marijuana business license for dispensaries, processors, or growers;

(2) The issuance of a medical marijuana business license necessitated by a change in the ownership or location of a dispensary, processor, or grower; or

(3) The issuance or renewal of a testing laboratory, transporter, education facility, research, or waste disposal license.

442:10-5-3.3. Commercial grower bond required

All medical marijuana commercial grower licensees shall file with the Authority either a bond covering the permit area upon which the business licensee will initiate and conduct commercial growing operations or an attestation that the permit area on which the licensee operates the commercial growing operation has been owned by the licensee for at least a five (5) year period prior to submission of application. For the purposes of this section, "permit area" means the "licensed premises" as defined in OAC 442:10-1-4:

(1) All commercial grower license applicants shall submit on forms prescribed by the Authority:

(A) a bond covering the area of land within the permit area upon which the business licensee will initiate and conduct commercial growing operations, or

(B) an attestation and accompanying documentation showing that the permit area on which the licensee will initiate or conduct commercial growing operations has been owned by the licensee for at least a five (5) year period prior to submission of application.

(2) The bond shall be in an amount no less than fifty thousand dollars ($50,000.00) for each license sought or held and shall be issued by a surety company qualified to do business in the State of Oklahoma as a surety. For purposes of this section, “qualified” means a business that has a Certificate of Authority, License, or other formal authorization from the Oklahoma Insurance Department authorizing the surety to transact business in Oklahoma. The Authority may require a higher amount depending on the reclamation requirements to assure the completion of the reclamation plan or to defray the cost of restoration of the property including removing equipment, destruction of waste, remediation of environmental hazards, prohibiting public access, addressing improperly coded buildings, or determination of the final disposition of any seized property.

(3) Bonds that expire shall be renewed prior to thirty (30) days before the expiration date of the bond. Upon expiration of a bond, commercial grower licensees shall provide proof to the Authority on forms and in a manner prescribed by the Authority of a new alternate bond or attestation and accompanying documentation meeting the requirements of OAC 442:10-5-3.3 before the date of expiration of the previous bond.

(4) A surety may cancel the bond prior to expiration of the bond by providing written notice to the Authority on forms and in a manner prescribed by the Authority thirty (30) days prior to the date of cancellation. Upon cancellation of a bond, the commercial grower shall provide proof to the Authority of a new, alternate bond or attestation and accompanying documentation meeting the requirements of 63 O.S. § 427.26 and this section on forms and in a manner prescribed by the Authority before the date of cancellation of the previous bond.
(5) The Authority may recall the bond up to one (1) year after revocation or surrender of the license or cancellation or expiration of the bond.
(6) Any grower that fails to comply with this section shall be subject to disciplinary action including, but not limited to, revocation, nonrenewal, or monetary penalties.

442:10-5-4. Inspections

(a) Submission of an application for a medical marijuana commercial license constitutes permission for entry to and inspection of any licensed premises and any vehicles on the licensed premises used for the transportation of medical marijuana and medical marijuana products during hours of operation and other reasonable times. Refusal to permit or impeding such entry or inspection shall constitute grounds for administrative penalties, which may include but are not limited to fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license.
(b) The Authority may perform two on-site inspections per calendar year of each licensed grower, processor, dispensary, or commercial transporter to determine, assess, and monitor compliance with applicable Oklahoma law and these Rules or ensure qualifications for licensure.
(c) The Authority shall conduct one on-site inspection of a testing laboratory applicant prior to licensure and up to two (2) on-site inspection annually thereafter. The inspection prior to initial licensure may include proficiency testing, and shall be conducted to ensure all application materials are accurate and the applicant meets all requirements in 63 O.S. § 427.17 and these Rules. The inspection prior to initial licensure may include verification that applicant can achieve analyte-specific testing thresholds showing applicants meet requirements stated in OAC 442:10-8-2.
(d) The Authority shall conduct one (1) on-site inspection of each warehouse location of a medical marijuana transporter applicant or licensee prior to approving the location for use to ensure all information and documentation is true and correct and to determine if the proposed warehouse location meets all requirements of 63 O.S. § 427.16 and these Rules.
(e) The Authority may conduct additional inspections to ensure correction of or investigate violations of applicable Oklahoma law and these Rules.
(f) The Authority shall refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.
(g) If the Authority discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an inspection, the Authority may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation. Except for license information concerning licensed patients, the Authority may share confidential information to assist other agencies in ensuring compliance with applicable laws, Rules, and regulations.
(h) The Authority may review any and all records of a licensee and may require and conduct interviews with such persons or entities and persons affiliated with such entities, for the purpose of determining compliance with Authority Rules and applicable laws. Failure to make documents or other requested information available to the Authority and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license. All records shall be kept on-site and readily available.
(i) If the Authority 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., and these Rules during an inspection of the licensed business,

the Authority shall take administrative action in accordance with Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.
(j) The Authority may assess fines in the amounts set forth in Appendix C and seek any other administrative penalties authorized by law against a licensee without providing opportunity to correct when the violation is not capable of being corrected. The Authority may suspend or revoke a license for failure to pay any fine or monetary penalty lawfully assessed by the Authority against the licensee.
(k) Except as otherwise provided in Oklahoma law or these Rules, correctable violations identified during an inspection shall be corrected within thirty (30) days of receipt of a written notice of violations. If a licensee fails to correct violations within thirty (30) days, the licensee will be subject to a fine in the amount set forth Appendix C for each violation and any other administrative action and penalty authorized by law.
(l) The Authority may employ secret shoppers to inspect licensed commercial medical marijuana businesses. Secret shoppers may purchase medical marijuana or medical marijuana products for compliance testing or attempt to purchase medical marijuana or marijuana products in order to prove compliance with the Oklahoma Medical Marijuana and Patient Protection Act or any rule determined by the Authority. In the absence of unanimous confirmation of test results with safety failures for contaminants, the Authority may investigate, embargo, or recall any medical marijuana or medical marijuana products. Nothing in this section otherwise prohibits the Authority from conducting investigations resulting from a secret shopper inspection.

442:10-5-6. 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 Authority. These reports shall be deemed untimely if not received by the Authority 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 Authority 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 Authority 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 Authority 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) Upon implementation, submission of information and data to the Authority through the State inventory tracking system will be required in accordance with the Oklahoma Medical Marijuana Protection Act, 63 O.S. § 427.1 et seq., and these Rules, and submission of the information and data to the Authority through the State inventory tracking system shall be sufficient to satisfy monthly reporting requirements.

(b) **Records**. Pursuant to the Authority'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 cultivation, processing, preparation, transportation, sampling, and/or testing of medical marijuana and medical marijuana products, including but not limited to sample field logs, patient processing logs, safety data sheets and inventory for each chemical utilized by a processor, inventory manifests, transporter agent licenses, COAs, testing records, equipment inspections, training materials, and standard operating procedures.

(3) Except as otherwise provided in this Subsection, 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 commercial licensees involved in each transaction, and the name and license number of all patient licensees involved in each transaction;
(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) For processors processing medical marijuana directly on behalf of a patient or caregiver, a log documenting each instance in which the processor processed medical marijuana received from a licensed patient into a concentrate form on behalf of the licensed patient, which shall include, but is not limited to, the following information:

(A) The patient and, if applicable, caregiver license number;
(B) The date the processor received the medical marijuana from the patient or caregiver;
(C) The weight of medical marijuana received from the patient;
(D) The weight or amount of concentrate produced, along with the weight of any excess medical marijuana, if applicable; and
(E) The date the concentrate was returned to the patient or caregiver.

(5) Any and all documents relating to the disposal or destruction of medical marijuana, medical marijuana products, and medical marijuana waste.
(6) Commercial licensees must also have the following documentation readily available on the licensed premise:
(A) the square footage or total acres of the licensed premises;
(B) a diagram of the licensed premises;
(C) if applicable, the number and type of lights at the licensed premise of a commercial grower;
(D) if applicable, the number, type and production capacity of equipment located at the licensed premise of a commercial processor;
(E) the names, addresses and telephone numbers of employees or agents of a medical marijuana business;
(F) employment manuals and standard operating procedures for the medical marijuana business; and
(G) any other information the Authority deems reasonably necessary.

(c) **Patient information.** Records containing private patient or caregiver information retained by a commercial licensee shall comply with all relevant state and federal laws. "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~~ accurately reported to the Authority ~~upon request~~ in the State inventory tracking system for all transactions to ensure compliance and protect public health ~~purposes~~ and safety, including the verification of lawful sales or patient traceability in the event of product recall.

(d) **Inventory tracking system**. Pursuant to 63 O.S. § 427.3(D)(8) and 63 O.S. § 427.13(B), each commercial licensee shall use the State inventory tracking system by inputting inventory tracking data required to be reported to the Authority directly into the State inventory tracking system or by utilizing a seed-to-sale tracking system that integrates with the State inventory tracking system All commercial licensees must have an inventory tracking system account activated to lawfully operate and must ensure all information is reported to the Authority accurately and in real time or after each individual sale in accordance with 63 O.S. § 427.13(B)(1) and these Rules. All commercial licensees shall ensure the following information and data are accurately tracked and timely reported to the Authority though the State inventory tracking system:

(1) The chain of custody of all medical marijuana and medical marijuana products, including every transaction with another commercial licensee, patient, or caregiver, including but not limited to:
(A) The name, address, license number, and phone number of the medical marijuana business that cultivated, manufactured, sold, purchased, or otherwise transferred the medical marijuana or medical marijuana product(s);
(B) The complete, accurate, and valid patient or caregiver license number of all patient or caregiver licensees involved in each transaction;
(C) The type, item, strain, and category of medical marijuana or medical marijuana product(s) involved in the transaction;
~~(C)~~ (D) The weight, quantity, or other metric required by the Authority, of the medical marijuana or medical marijuana product(s) involved in the transaction;
~~(D)~~ (E) The batch number of the medical marijuana or medical marijuana product(s);
~~(E)~~ (F) The total amount spent in dollars;
~~(F)~~ (G) All point-of-sale records as applicable;
~~(G)~~ (H) Transportation information documenting the transport of medical marijuana or medical marijuana product(s) as required under OAC 442:10-3-6(b);
~~(H)~~ (I) Testing results and information;
~~(I)~~ (J) Waste records and information;
~~(J)~~ (K) Marijuana excise tax records, if applicable;
~~(K)~~ (L) ~~RFID~~ Inventory tracking system tag number(s);

(2) The entire life span of a licensee's stock of medical marijuana and medical marijuana products, including, at a minimum, notifying the Authority:

(A) When medical marijuana seeds or clones are planted;

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

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

(D) When medical marijuana changes form, including, but not limited to, when it is planted, cultivated, processed, and infused or otherwise processed into a final ~~form~~ product or final form;

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

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

(3) Any further information the Authority determines is necessary to ensure all medical marijuana and medical marijuana products are accurately and fully tracked throughout the entirety of the lifespan of the plant and product.

(e) **Seed-to-sale tracking system**. A commercial licensee shall use a seed-to-sale tracking system or integrate its own seed-to-sale tracking system with the State inventory tracking system established by the Authority. If a commercial licensee uses a seed-to-sale tracking system that does not integrate with the State inventory tracking system, or does integrate but does not share all required information, the commercial licensee shall ensure all required information is reported directly into the State inventory tracking system.

(f) **Inventory tracking system requirements.**

(1) At a minimum, commercial licensees shall track, update, and report inventory after each individual sale to the Authority in the State inventory tracking system.

(2) All commercial licensees must ensure all on-premises and in-transit medical marijuana and medical marijuana product inventories are reconciled each day in the State inventory tracking system at the close of business, if not already done.

(3) Commercial licensees are required to use ~~RFID~~ inventory tracking system tags from an Authority-approved supplier for the State Inventory Tracking System. Each Licensee is responsible for the cost of all ~~RFID~~ inventory tracking system tags and any associated vendor fees.

(A) A commercial licensee shall ensure its inventories are properly tagged and that ~~a RFID~~ an inventory tracking system tag is properly assigned to medical marijuana, medical marijuana products, and medical marijuana waste as required by the Authority.

(B) A commercial licensee shall ensure it has an adequate supply of ~~RFID~~ inventory tracking system tags at all times. If a commercial licensee is unable to account for unused ~~RFID~~ inventory tracking system tags, the commercial licensee must report to the Authority and the State inventory tracking system vendor within forty-eight (48) hours.

(C) ~~RFID~~ Inventory tracking system tags must contain the legal name and correct license number of the commercial licensee that ordered them. Commercial licensees are prohibited from using another licensee's ~~RFID~~ inventory tracking system tags.

(D) ~~Prior to a plant reaching a point where it is able to support the weight of the RFID tag and attachment strap, the RFID tag may be securely fastened to the stalk or other similarly situated position approved by the Authority.~~ The inventory tracking system tag shall be placed on the container holding the medical marijuana plant and must remain physically near and clearly associated with the medical marijuana plant until the plant reaches twelve (12) inches in height. Clones must be tracked in the state seed-to-sale system and must be associated with a wholesale package tag, whether cut from a mother plant or transferred from another licensee, prior to reaching twelve (12) inches in height.

(E) When the plant ~~becomes able to support the weight of the RFID tag, the RFID~~ reaches twelve (12) inches in height, the inventory tracking system tag shall be securely fastened to a lower supporting branch. The ~~RFID~~ inventory tracking system tag shall remain affixed for the entire life of the plant until disposal. If the plant changes forms, is removed from the original planting location after harvest, or is being trimmed, dried, or cured by the grower, the inventory tracking system tag

shall be placed on the container holding the medical marijuana plants and/or must remain physically near and clearly associated with the medical marijuana plants until the plant is placed into a package in both the seed-to-sale tracking system and physically packaged and affixed with the inventory tracking system tag.

(F) Mother plants must be tagged before any cuttings or clones are generated therefrom.

(G) If ~~a RFID~~ an inventory tracking system tag gets destroyed, stolen, or falls off of a medical marijuana plant, the licensee must ensure a new ~~RFID~~ inventory tracking system tag is placed on the medical marijuana plant and the change of the ~~RFID~~ inventory tracking system tag is properly reflected in the State inventory tracking system.

(H) Commercial licensees shall not reuse any ~~RFID~~ inventory tracking system tag that has already been affixed to any regulated medical marijuana or medical marijuana products.

(4) Each wholesale package of medical marijuana must have ~~a RFID~~ an inventory tracking system tag during storage and transfer and may only contain one harvest batch of medical marijuana.

(5) Prior to transfer, commercial licensees shall ensure that each immature plant is properly affixed with an ~~RFID~~ inventory tracking system tag if the plant was not previously tagged in accordance with these Rules.

(6) Commercial licensees' inventory must have ~~a RFID~~ an inventory tracking system tag properly affixed to all medical marijuana products during storage and transfer in one of the following manners:

(A) Individual units of medical marijuana products shall be individually affixed with ~~a RFID~~ an inventory tracking system tag; or

(B) Medical marijuana products may only be combined in a single wholesale package using one ~~RFID~~ inventory tracking system tag if all units are from the same production batch.

(7) If any medical marijuana or medical marijuana products are removed from a wholesale package, each individual unit or new wholesale package must be separately tagged.

(8) All packages of medical marijuana waste shall have ~~a RFID~~ an inventory tracking system tag affixed and the contents of the waste package shall be reported in the State inventory tracking system.

(g) **Inventory tracking system administrators and users.**

(1) A commercial licensee must have at least one owner, or manager, who is an inventory tracking system administrator.

(2) The inventory tracking system administrator must attend and complete all required inventory tracking system training.

(3) If at any point, the inventory tracking system administrator for a commercial licensee changes, the commercial licensee shall change or assign a new inventory tracking system administrator within thirty (30) business days.

(4) Commercial licensees shall maintain an accurate and complete list of all inventory tracking system administrators and employee users.

(5) Commercial licensees shall ensure that all owners and employees that are granted inventory tracking system account access for the purpose of conducting inventory tracking functions are trained and authorized before the owners or employees may access the State inventory tracking system.

(6) All inventory tracking system users shall be assigned an individual account in the State inventory tracking system.

(7) Any individual entering data into the State inventory tracking system shall only use the inventory tracking system account assigned specifically to that individual. Each inventory tracking system administrator and inventory tracking system user must have unique log-in credentials that shall not be used by any other person.

(8) Within three (3) business days, commercial licensees must remove access for any inventory tracking system administrator or user from their accounts if any such individual no longer utilizes the State inventory tracking system or is no longer employed by the commercial licensee.

(h) **Loss of use of the State inventory tracking system.** If at any time a commercial licensee loses access to the State inventory tracking system due to circumstances beyond the commercial licensee's control, the

commercial licensee shall keep and maintain records detailing all inventory tracking activities that were conducted during the loss of access. Once access is restored, all inventory tracking activities that occurred during the loss of access must be immediately entered into the State inventory tracking system. If a commercial licensee loses access to the State inventory tracking system due to circumstances within its control, the commercial licensee may not perform any business activities that would be required to be reported into the State inventory tracking system until access is restored and reporting is resumed; any transfer, sale, or purchase of medical marijuana or medical marijuana products shall be an unlawful sale.

(i) **Audits**. The Authority shall perform on-site audits of all commercial licensees to ensure the accuracy of information and data reported to the Authority 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 Authority entry or refusal to permit the Authority to inspect all books and records shall constitute grounds for and administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license.

(1) The Authority 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 Authority Rules and applicable laws. Failure to make documents or other requested information available to the Authority 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 onsite and readily accessible.

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

(3) If the Authority 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 Authority 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 Authority 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 Authority discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an audit, the Authority may refer the matter to appropriate Oklahoma state or local law enforcement or regulatory authorities for further investigation. Except for license information concerning licensed patients, the Authority may share confidential information to assist other agencies in ensuring compliance with applicable laws, Rules and regulations.

(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.

(j) **Confidential records.** All monthly report, inventory tracking and seed-to-sale information, data, and records submitted to the Authority are treated as confidential records and are exempt from the Oklahoma Open Records Act.

442:10-5-6.1. Penalties

(a) **Failure to file timely reports**. If a commercial licensee fails to submit a timely, complete, and accurate required monthly report and fails to correct such deficiency within thirty (30) days of the Authority's written notice, the licensee shall be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.

(b) **Inaccurate reports**. Within any two (2) year period of time, if a licensee has submitted one (1) or more

reports containing gross errors that cannot reasonably be attributed to normal human error, licensee shall be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.

(c) **Unlawful purchase, ~~and~~ sale, or transfer**.

(1) Within any one (1) year period of time, if the licensee has made an unlawful purchase, ~~or~~ sale, or transfer of medical marijuana, the licensee shall be subject to a fine in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.

(2) The Authority may revoke the license at any time regardless of the number of the offense upon a showing that the violation was willful or grossly negligent.

(d) **Noncompliance and criminal activity**. Commercial licenses and transporter agent licenses shall be subject to nonrenewal, revocation, suspension, monetary penalties, and any other penalty authorized by law upon a determination by the Authority that the licensee has not complied with applicable Oklahoma law or this Chapter, or upon official notification to the Authority that the licensee has engaged in criminal activity in violation of Oklahoma law.

(e) **Administrative penalties**. Procedures for administrative penalties against a licensee are stated in the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq. These procedures provide for the licensee to receive notice and to have the opportunity to be present at a hearing and to present evidence in his or her defense. The Executive Director or his or her designee may promulgate an administrative order revoking or suspending the license, dismissing the matter, or providing for other relief as allowed by law. At any time after the action is filed against the commercial licensee, the Authority and the licensee may dispose of the matter by consent order or stipulation. Orders are appealable in accordance with the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.

(f) **Fines.** Monetary penalties shall be assessed in the amounts set forth in Appendix C. Failure to pay any fine within thirty (30) days of assessment of the fine shall result in nonrenewal, suspension, and/or revocation of the license.

(g) **Administrative Order.** In addition to any other remedies provided by law, the Authority may issue a written order to any licensee the Authority has reason to believe has violated Oklahoma law or these regulations, and to whom the Authority has served, not less than thirty (30) days previously, a written notice of violation of such statutes or rules.

(1) The written order shall state with specificity the nature of the violation. The Authority may impose any disciplinary action authorized under by law including, but not limited, nonrenewal, suspension, revocation and the assessment of monetary penalties.

(2) Any order issued pursuant to the provisions of this section shall become a final order unless, not more than thirty (30) days after the order is served to the licensee, the licensee requests an administrative hearing in accordance with these Rules. Upon such request, the Authority shall promptly initiate administrative proceedings.

(h) ~~**Emergency Cease and Desist.** If the Authority finds that an emergency exists requiring immediate action in order to protect the health or welfare of the public, the Authority may issue an order, without providing notice or hearing, stating the existence of said emergency and requiring that action be taken by the commercial licensee as the Authority deems necessary to meet the emergency. Such action may include, but is not limited to, ordering the commercial licensee to immediately cease and desist operations. The order shall be effective immediately upon issuance and commercial licensees shall immediately comply with the provisions of the order. The Authority may assess a penalty not to exceed ten thousand dollars ($10,000.00) per day of noncompliance with the order. In assessing such penalty, the Authority shall consider the seriousness of the violation and efforts taken by the commercial licensee to comply with applicable requirements. Upon application to the Authority, the licensee shall be offered a hearing within ten (10) days of issuance of the order.~~ **Remitting taxes.** If any medical marijuana business licensee intentionally does not remit the taxes as required by 68 O.S. § 1354 of Oklahoma Statutes, the Authority shall permanently revoke the medical marijuana business license of the business licensee and the business licensee shall be permanently ineligible to receive any other type of medical marijuana business license issued by the

Authority, including licenses for a dispensary, commercial grower operation, processing facility, transporter, research, education facility, and waste disposal facility.

442:10-5-7. Tax on retail medical marijuana sales

(a) The tax on retail medical marijuana sales by a dispensary is established at seven percent (7%) of the gross dollar amount received by the dispensary for the sale of any medical marijuana or medical marijuana product. This tax will be collected by the dispensary from the customer who must be a licensed medical marijuana patient or caregiver.

(b) A dispensary shall either hold or obtain an Oklahoma sales tax permit from the Oklahoma Tax Commission in compliance with OAC 710:65-19-216.

(c) Reports and payments on gross sales, tax collected, and tax due shall be remitted to the Oklahoma Tax Commission by every dispensary on a monthly basis. No additional reporting regarding gross sales, tax collected, and tax due shall be made to the Authority.

(d) Dispensary reporting and remittance shall be made to the Oklahoma Tax Commission on a monthly basis. Reports and remittances are due to the Oklahoma Tax Commission no later than the 20th day of the month following the month for which the report and remittances are made.

(e) All dispensaries required to report and remit medical marijuana tax shall remit the tax and file their monthly tax report in accordance with the manner prescribed by the Tax Commission.

(f) The report shall contain the following information:

(1) Dispensary name, address, telephone number and dispensary license number;

(2) Reporting month and year;

(3) Total gross receipts for the preceding month from sales of medical marijuana or any medical marijuana product;

(4) The amount of tax due as described in (a) of this Section; and

(5) Such other reasonable information as the Tax Commission may require.

(g) If a due date for the tax reporting and remittance falls on a Saturday, Sunday, a holiday, or dates when the Federal Reserve Banks are closed, such due date shall be considered to be the next business date.

(h) Pursuant to 63 O.S. § 426, the Legislature receives all monies from sales tax proceeds collected on medical marijuana to be appropriated at the discretion of the Legislature to fund substance abuse programs and common education, including redbud school grants. The Legislature receives all monies collected from fines and fees to be appropriated at the discretion of the Legislature to fund the Oklahoma Medical Marijuana Authority. ~~proceeds from the sales tax levied shall first be distributed to the Oklahoma Medical Marijuana Authority for the annual budgeted amount for administration of the Oklahoma Medical Marijuana Authority Program. All distributions will be made monthly to the Authority until full reimbursement is reached for the annual budgeted cost of the program. If tax levies are not sufficient to reimburse the Authority for the full annual budgeted cost, then all tax levies collected during the fiscal shall be remitted to the Authority.~~

442:10-5-16. 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 licensed premises, except that if the licensed premises is a residence, a commercial licensee shall only be prohibited from consuming alcohol or the smoking or vaping of medical marijuana in areas of the licensed premises where operations of the business are conducted.

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

(c) No commercial licensee 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 advertising prohibited under OAC 442:10-7-3.

(f) No commercial licensee shall sell or offer to sell medical marijuana or medical marijuana product 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 Authority.
(h) No commercial licensee shall threaten or harm a patient, medical practitioner, or an employee of the Authority.
(i) No commercial licensee shall fail to adhere to any acknowledgment, verification, or other representation made to the Authority.
(j) No licensed grower shall possess, sell or otherwise transfer, or offer to sell or otherwise transfer medical marijuana products.
(k) 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.
(l) Licensees shall not sell or otherwise transfer, purchase, obtain, or otherwise accept the transfer of medical marijuana or medical marijuana products from an any individual or entity that is not an Oklahoma-licensed medical marijuana business, except that licensed dispensaries may sell medical marijuana and medical marijuana products to licensed patients and caregivers and a processor may process medical marijuana directly on behalf of a licensed patient or caregiver in accordance with OAC 442:10-5-5. No licensee shall purchase or sell medical marijuana or medical marijuana products to or from any unlicensed individual or entity.
(m) After implementation of the State inventory tracking system, no licensee shall sell or otherwise transfer, purchase, obtain or otherwise accept the transfer of medical marijuana or otherwise accept the transfer of medical marijuana or medical marijuana products that are not properly inputted and tracked in the State inventory tracking system in accordance with Oklahoma law and regulations.
(n) Medical marijuana growers and dispensaries shall not make or package infused pre-rolls.
(o) Medical marijuana growers and dispensaries shall not make or package pre-rolls that exceed one (1) gram in net weight.
(p) Licensees shall not allow any other entity or person to use their OMMA license number who is not an owner, employee, or authorized contractor of the commercial licensee while conducting business on behalf of that commercial licensee.
(q) No commercial licensee shall make, sell, transfer, or offer to sell any alcoholic beverage that has been infused with medical marijuana or medical marijuana products.
(r) Growers shall not purchase, make, sell, transfer, or otherwise obtain any medical marijuana products except growers may package and sell noninfused pre-rolls and kief in accordance with these Rules.
(s) Dispensaries shall not package or alter packaging or labeling of medical marijuana or medical marijuana products except for the following reasons:

(1) Dispensaries are authorized to package and sell noninfused pre-rolled marijuana;
(2) Dispensaries, or employees thereof, may handle loose or nonpackaged medical marijuana to be placed in packaging for retail sale consistent with Oklahoma law and these Rules, including packaging and labeling requirements in OAC 442:10-7-1(d)-(e);
(3) Dispensaries may apply barcodes, qr codes, or other inventory tracking tags and labels. These items shall not obscure required label and packaging requirements; and
(4) Dispensaries must place medical marijuana or medical marijuana products into a child-resistant exit package at the point of transfer to a patient or caregiver if those items are not already in child-resistant packaging.

(t) Growers shall not engage in any commercial growing operations without a bond or attestation as required under OAC 442:10-5-3.3 certifying compliance with 63 O.S. § 427.26.
(u) No licensed medical marijuana commercial grower shall knowingly hire or employ undocumented immigrants to perform work inside a medical marijuana commercial grow facility or anywhere on the property of the medical marijuana commercial grower operation. A licensed medical marijuana commercial

grower that violates the provisions of this subsection shall be subject to penalties including but not limited to, license revocation and denial of future license applications.
(v) No commercial licensee shall employ any employee without a credential issued pursuant to OAC 442:10-5-1.1(13). For purposes of this Section, "employee" shall have the same meaning as OAC 442:10-5-1.1(13).

SUBCHAPTER 7. PACKAGING, LABELING, AND ADVERTISING

442:10-7-1. 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." and "For use by licensed medical marijuana patients only. "
(3) All medical marijuana and medical marijuana products must be packaged in child-resistant containers, although the containers may be clear in order to allow licensed medical marijuana patient and licensed medical marijuana caregivers the ability to view the product inside the container, and placed into an exit package 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 deceptive, false or misleading statements. For purposes of this section, information that is deceptive, false, or misleading includes:

(A) Any indication that the medical marijuana or medical marijuana product is organic, unless the National Organic Program (Section 6517 of the federal Organic Foods Production Act of 1990 (7 U.S.C. Section 6501 et seq.)) authorizes organic certification and designation for marijuana and

marijuana products. This includes variants of the word "organic" such as "organix" and "organique."

(B) Any indication that the medical marijuana or medical marijuana product is "Pesticide-free," unless the medical marijuana or a medical-marijuana product was grown, harvested, processed, and dispensed without any pesticide.

(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 Medical Marijuana Authority.

(10) Packages and labels shall not contain any universal symbols from another state, any statements that the medical marijuana was grown in another state, or any depictions, symbols, or other information that could cause a reasonable patient to be confused as to the state of origin of the medical marijuana or medical marijuana product.

(11) Labels shall be designed and applied in a manner that does not cause patient confusion regarding the package's contents, potency, or other required information. In the event that any package or immediate container of medical marijuana or medical marijuana product is relabeled, all prior labels must be removed in entirety prior to the new label being applied. Covering an initial label with an updated label is prohibited.

(12) All packaging and labeling must contain current and accurate information on file with the Authority, including, but not limited to, the licensee's legal name, trade name, and license number.

(13) Packages and labels shall be considered inaccurate if the difference in percentage of the cannabinoid and/or total THC claimed to be present on a package or label is plus or minus fifteen percent (15%) of the percentage on the COA. For example, bulk order packaging that identifies a THC amount as 100mg would be inaccurate if the COA for that production batch indicated a THC content of less than 85mg or more than 115mg.

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

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

(A) The name and license number of the grower, dispensary, 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;

(F) The Oklahoma Uniform Symbol in the manner and form prescribed by the Authority;

(G) THC potency on the COA for that batch;

(H) Total terpenoid content in the manner prescribed by the Authority; and

(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 442:10-5-8.

(3) As applicable, ~~RFID~~ inventory tracking system tags shall not obscure required label and packaging requirements.

(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, and dispensaries.**

(1) Growers, ~~and~~ processors, and dispensaries 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 tagged and stored in receptacles that are capable of being fully closed and sealed and are kept fully closed and sealed.
(3) When any storage receptacle is in use and contains medical marijuana or medical marijuana products, commercial licensees shall identify the batch number and tag on the storage receptacle of all medical marijuana and medical marijuana products so that an inspector can easily identify to which batch the medical marijuana and medical marijuana products belong.

SUBCHAPTER 8. LABORATORY TESTING

442:10-8-1. 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 concentration, terpenoid type and concentration, 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 Authority. A licensed laboratory shall only send samples for testing to another Oklahoma licensed laboratory.

(b) **Batches**.

(1) **Batch size.** Growers shall separate all harvested medical marijuana into harvest batches ~~not to exceed~~ that weigh less than or equal to fifteen ~~(15)~~ (≤ 15) pounds with the exception of any plant material to be sold to a licensed processor for the purposes of turning the plant material into concentrate which may be separated into harvest batches ~~of no more than~~ that weigh less than or equal to fifty ~~(50)~~ (≤ 50) pounds. Processors shall separate all medical marijuana product into production batches ~~not to exceed~~ that contain a volume that is less than or equal to four ~~(4)~~ (≤ 4) liters of liquid medical marijuana concentrate or that weigh less than or equal to nine ~~(9)~~ (≤ 9) pounds for nonliquid medical marijuana products, and for final medical marijuana products ~~no greater than~~ shall contain less than or equal to one-thousand ~~(1,000)~~ (≤ 1,000) grams of ~~THC~~ total delta-9-tetrahydrocannabinol (Δ-9-THC).

(2) **Research and Development ("R&D") testing.** Growers and processors may submit samples for research and development testing. R&D testing may be performed by a licensed laboratory in accordance with these Rules:

(A) Passing R&D test results. If a sample submitted to a laboratory passes a R&D test, it shall not constitute a pass for the purposes of compliance with required testing under OAC 442:10-8-1(i);
(B) Failing R&D test results. If a sample submitted to a laboratory fails a R&D test, laboratories shall clearly note in the State's inventory tracking system and on any COA created for an R&D sample that the test results are for R&D purposes only; and
(C) Growers and processors shall ensure that any R&D testing done under this subsection is appropriately documented and identified in the State's inventory tracking system.

(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.

(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 testing to processors for decontamination or remediation in accordance with OAC 442:10-8-1(l)(2). Growers may transfer medical marijuana from harvest batches to processors for decontamination prior to testing, so long as decontaminated medical marijuana is not processed into a solvent-based concentrate and is returned to the originating licensed commercial grower. Decontaminated harvest batches must successfully pass all tests in accordance with this Subchapter prior to transfer or sale.

(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 442:10-8-1(l)(2).

(3) Dispensaries shall not purchase, accept transfer of, sell, or otherwise transfer any medical marijuana or medical marijuana products that have not passed all tests in accordance with this Subchapter.

(e) **Authority required testing**. The Authority 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 or the quality assurance laboratory upon demand when the Authority has reason to believe the medical marijuana is unsafe for patient consumption or inhalation or has not been tested in accordance with Oklahoma law and these regulations. The Authority may also require a medical marijuana business to periodically submit samples of medical marijuana or medical marijuana products to the quality assurance laboratory for quality assurance purposes. The licensee shall provide the samples or units of medical marijuana or medical marijuana products at its own expense but shall not be responsible for the costs of testing.

(f) **Prohibited transfers.** Except as is authorized in these Rules, growers, 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) **Embargo and recall.**

(1) **Embargo.** In the event that any medical marijuana or medical marijuana product is found by an authorized agent of the Authority to fail to meet the requirements of 63 O.S. § 420 et al., or the Oklahoma Medical Marijuana and Patient Protection Act as it relates to health and safety, the medical marijuana or medical marijuana product is handled in violation of applicable laws or rules and regulations promulgated by the Executive Director of the Authority, or the medical marijuana or medical marijuana product may be poisonous, deleterious to health or is otherwise unsafe, the following shall occur:

(A) All such medical marijuana and medical marijuana products in the possession of a commercial licensee shall be immediately affixed with an electronic tag, physical tag and/or other appropriate marking or hold, including a hold in the State's inventory tracking system, giving notice of the reason that the medical marijuana or medical marijuana product is subject to embargo. The affixed tag(s) and/or electronic hold shall further warn all persons not to remove or dispose of the medical marijuana or medical marijuana product by sale, donation, or otherwise transfer without permission of the Authority. It shall be unlawful for any person to remove or dispose of the embargoed medical marijuana or medical marijuana products without permission of the Authority.

(B) The Authority, upon determination that any medical marijuana or medical marijuana product embargoed is in violation of applicable laws, rules or regulations, or is otherwise poisonous, deleterious to health or unsafe for consumption may institute an action in a district court of competent jurisdiction for the condemnation and destruction of the medical marijuana or medical marijuana product in accordance with 63 O.S. § 427.24.

(C) The Authority, upon determination that any medical marijuana or medical marijuana product meets the requirements of applicable laws, rules or regulations, or otherwise is not poisonous, deleterious to health or unsafe shall remove the embargo.
(D) In the event any medical marijuana or medical marijuana products subject to an embargo ~~is~~ are sold or otherwise transferred, such embargoed medical marijuana or medical marijuana products shall be recalled in accordance with these Rules.
(E) Every commercial licensee who is in possession or has ever had possession of such embargoed medical marijuana or medical marijuana products shall assist in the embargo.

(2) **Recall.** ~~In the event that~~ If any medical marijuana or medical marijuana products ~~that exceed~~ test above allowable ~~testing~~ thresholds, are the subject of an embargo, ~~or a derivative thereof,~~ are otherwise determined to be unsafe, or that otherwise fail to meet standards set forth in this Subchapter ~~are sold or otherwise transferred~~, the following shall occur:
(A) Any commercial licensee with knowledge of such event shall immediately notify the Authority;
(B) All such medical marijuana and medical marijuana products shall be immediately recalled and cannot be sold or otherwise transferred; and
(C) 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, including, but not limited to, the following:
(i) Undertake necessary measures to ensure any affected medical marijuana or medical marijuana products are not transferred;
(ii) Create a distribution list of all commercial licensees that received the medical marijuana or medical marijuana products subject to the recall, including the licensee's name, license number, address and contact information;
(iii) Create a list identifying all medical marijuana or medical marijuana products subject to the recall, including the category of medical marijuana or medical marijuana products, product description, net contents, batch number, and, if applicable, the name and license number of the commercial licensee that cultivated or manufactured the medical marijuana or medical marijuana product subject to the recall;
(iv) Provide notice to all affected licensees and consumers once identified;
(v) Communicate with the Authority regarding the status of the recall and provide all required information and documentation to the Authority within two (2) weeks unless granted additional time by the Authority.
(vi) The Licensee's failure to timely comply with the provisions of this subsection and/or provide required information and documentation to the Authority may result in revocation, suspension, and monetary penalties. The Authority may also issue a public recall notice, at any time, if it determines it is necessary to protect the public's health safety and welfare.
(D) The commercial licensee whose harvest or production batch is being recalled, and who bears responsibility for the recall, shall bear the costs for disposal of all medical marijuana waste subject to the recall in accordance with Oklahoma law and these Rules.

(h) **Retention of test results and records**.
(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 any and all COAs for at least seven (7) years and these records must be kept onsite and readily accessible.
(6) Growers and processors shall immediately provide copies of COAs to the Authority 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 Authority, provide notification to the Authority of any medical marijuana or medical marijuana products that have failed testing. Such notification shall include copies of the applicable COAs.
(8) For the purposes of this subsection, submission of a COA by the laboratory into the State's inventory tracking system is sufficient to meet a commercial licensee's requirements to report and maintain such records.

(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. The in-sample limit of quantification (LOQ) must be less than or equal to fifty percent (≤ 50%) of the allowable thresholds listed in this Section.

(1) ~~**Microbiological**~~ **Microbial testing**. Harvest batch samples and production batch samples shall be tested for microbial ~~limits as set forth in Appendix A.~~ analytes in accordance with the following:

(A) **Allowable thresholds.** Samples shall be tested for the following microbial analytes and must be less than (<) the allowable thresholds, in colony forming units found in one gram (CFU/ g), listed below:

(i) All medical marijuana, medical marijuana products and medical marijuana concentrates, excluding pressurized metered dose inhaler products, metered dose nasal spray products, vaginal administration products or rectal administration products, shall be tested for the following microbial analytes and shall be less than the associated allowable threshold:

(I) Total yeast and mold microbials < 10^4 CFU/g;
(II) Shiga toxin-producing Escherichia coli (STEC) < 1 CFU/g;
(III) Pathogenic Salmonella spp. < 1 CFU/g;
(IV) Aspergillus flavus < 1 CFU/g;
(V) Aspergillus fumigatus < 1 CFU/g;
(VI) Aspergillus niger < 1 CFU/g; and
(VII) Aspergillus terreus < 1 CFU/g.

(ii) Pressurized metered dose inhaler and metered dose nasal spray medical marijuana and medical marijuana products shall be tested for the following microbial analytes and shall be less than the associated allowable threshold:

(I) Total yeast and mold microbials < 10^1 CFU/g;
(II) Total aerobic microbials < 10^2 CFU/g;
(III) Staphylococcus aureus < 1 CFU/g; and
(IV) Bile tolerant gram-negative bacteria < 1 CFU/g.

(iii) Vaginal administration products shall be tested for the following microbial analytes and shall be less than the associated allowable threshold:

(I) Total yeast and mold microbials < 10^1 CFU/g;
(II) Total aerobic microbials < 10^2 CFU/g;
(III) Staphylococcus aureus < 1 CFU/g;
(IV) Pseudomonas aeruginosa < 1 CFU/g; and
(V) Candida albicans < 1 CFU/g.

(iv) Rectal administration products shall be tested for the following microbial analytes and shall be less than the associated allowable threshold;

(I) Total yeast and mold microbials < 10^2 CFU/g; and
(II) Total aerobic microbials < 10^3 CFU/g.

(B) **Instrumentation.** Testing laboratories shall use a genetically based assay or agar plate culture to

perform microbial testing. The manufacturer's instructions for use, including recommendations, must be followed, unless otherwise specified by these rules.

(C) **Methodologies**. The method employed by a testing laboratory must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known microbial contamination values. Passing values must demonstrate the expected result.

(D) **Genetically based assay.** Genetically based assay testing requirements are as follows:

(i) **Sample preparation.** Sample must weigh greater than or equal to one gram (≥ 1 g). Methods of microbial sample preparation that reduce or kill the targeted microbes, such as cryogenic grinding or heat introduction, shall not be used. If the manufacturer does not offer instructions or recommendations regarding enrichment and incubation, then the primary sample must be enriched and incubated for at least twenty-four (24) hours using enrichment media suitable for identification of the target organism

(ii) **Laboratory quality control (LQC) samples.** The following LQC samples must be run every twenty (20) samples in an analytic run and must include:

(I) A positive control, for each targeted organism, that shall result in detection of amplification. If amplification of the target organism is not detected, all samples in the associated batch shall be reanalyzed. A positive control shall be a positive template control that contains the DNA sequence of the targeted analyte or a positive extraction control that contains a sample of the live microbial analyte, that was extracted using the same process as the samples; and

(II) A negative control that shall not result in amplification. If amplification is detected, all samples in the associated batch shall be re-analyzed;

(III) A laboratory replicate sample that demonstrates repeatability of the initial sample; and

(IV) An internal control, in each sample, that contains a non-targeted DNA sequence that is co-amplified with the targeted sequences and results in detection of amplification. If amplification is not detected that sample shall be reprepared and reanalyzed in a different batch. If amplification is not detected a second time, the sample shall be re-extracted and reprepared for new analysis.

(iii) **Reporting results**. Microbial analytes shall be reported to the nearest whole number, in CFU. All results shall include the sample weight in grams (g).

(E) **Agar plate culture.** If using agar plate culture methodologies, the following requirements apply:

(i) **Sample preparation**. The primary sample must weigh greater than or equal to one gram (≥ 1 g). Methods of microbial sample preparation that may reduce or kill targeted microbes, such as cryogenic grinding or heat introduction, shall not be used. For non-quantitative testing, the primary sample must be enriched and incubated for at least twenty-four (24) hours using enrichment media suitable for identification of the target organism. The primary sample must be used for all additional analysis. If the primary sample has been depleted prior to additional analysis, the reserve sample must be enriched and incubated for forty-eight (48) hours, using enrichment media suitable for identification of the target organism.

(ii) **Laboratory quality control (LQC) samples for qualitative agar plating.** Plating techniques shall undergo an initial validation to determine an appropriate dilution factor. The following LQC samples must be run every twenty (20) samples and must include:

(I) A positive control, for each targeted microorganism, that shall result in detectable growth, or a positive reaction if the method uses a reaction to identify an organism;

(II) A negative control that shall not detect the presence of a microbial organism;

(III) An environmental negative control, a duplicate of the negative control, except that the plate shall remain open to the environment during the sample preparation period; and

(IV) A laboratory replicate sample with results that match the initial sample results, detecting the presence or absence of a microbial organism.

(iii) **Laboratory quality control (LQC) samples for quantitative agar plating.** Plating techniques shall undergo an initial validation to determine an appropriate dilution factor. The following LQC samples must be run every twenty (20) samples and must include:

(I) A positive control, for each targeted microorganism, that shall result in detectable growth;

(II) A negative control that shall not result in detectable microbial growth; and

(III) An environmental negative control, a duplicate of the negative control, except that the plate shall remain open to the environment during the sample preparation period.

(iv) **Reporting Results**. Microbial analytes shall be reported to the nearest whole number, in CFU. All results shall include the sample weight in grams (g). A result that exceeds the allowable thresholds for a microbial analyte must be verified in duplicate using the original enrichment from the primary sample. If the primary sample has been depleted prior to additional analysis, the reserve sample must be enriched and incubated for forty-eight (48) hours, using enrichment media suitable for identification of the target organism. Upon re-analysis, any result that exceeds allowable thresholds shall be considered a failure the entire batch.

(2) **Mycotoxins**. Production batch samples shall be tested for ~~mycotoxins as set forth in Appendix A.~~ mycotoxin analytes in accordance with the following:

(A) **Allowable thresholds.** Samples shall be tested for the following mycotoxin analytes and shall be less than (<) the allowable threshold, in parts per billion (ppb), listed below:

(i) [Aflatoxin B1 + Aflatoxin B2 + Aflatoxin G1 + Aflatoxin G2] < 20 ppb; and

(ii) Ochratoxin A < 20 ppb.

(B) **Instrumentation.** For mycotoxin analyte testing, laboratories shall use Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) with Electrospray Ionization (ESI), LC-MS/MS with Atmospheric Pressure Chemical Ionization (APCI), or Enzyme Linked Immunosorbent Assay (ELISA).

(C) **Methodologies.** A testing laboratory's method must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known analyte concentration values. Passing values must be within plus or minus two and a half on a standard deviation index (± 2.5 SDI).

(D) **Sample preparation.** Sample must weigh greater than or equal to five tenths of a gram (≥ 0.5 g). Sample preparation solvents must be Liquid Chromatography Mass Spectrometry (LC-MS) grade. Solid form samples shall be homogenized by blending, using a food processor or similar apparatus, or cryogrinding. Liquid form samples shall be homogenized by stirring. Analytes shall be extracted from the sample using the following techniques: solid-liquid extraction or solid phase extraction.

(E) **Laboratory quality control (LQC) requirements.**

(i) **LQC samples.** The following LQC samples must be run with each analytic run, and repeated every twenty (20) samples in an analytic run and must include:

(I) A method blank with a resulting value that is less than or equal to the limit of quantification (≤LOQ);

(II) A laboratory control sample (LCS) with an acceptable limit that shall be plus or minus twenty percent (± 20%) of the known analyte concentration, in accordance with the following requirements. The LCS shall be spiked at or near the allowable thresholds for all required analytes to be reported and shall be determined with the correction factor applied. The LCS shall be carried through preparation and analysis as if it were a sample. A percent recovery calculation will be performed using the following mathematical formula: the resulting LCS concentration shall be divided by the known analyte concentration, which will then be multiplied by one hundred [(LCS concentration / known analyte concentration) * 100]. If the LCS results fall outside of the acceptance limits, then a testing laboratory cannot verify that it is able to acceptably perform the analysis in a clean matrix. A failing LCS may

be re-analyzed once. If the results of the re-analysis also fall outside of the acceptance limits, then all samples associated with the LCS must be re-prepared and re-analyzed, along with all other appropriate analysis batch QC samples;

(III) A matrix spike with a recovery greater than or equal to seventy percent (≥ 70%) and less than or equal to one hundred and thirty percent (≤ 130%) of expected values;

(IV) A matrix spike duplicate that results in a relative percent difference that is less than or equal to thirty percent (RPD ≤ 30%) for all mycotoxin analytes resulting in concentrations greater than (>) the LOQ; and

(V) Continuing calibration verification (CCV) with a recovery greater than or equal to seventy percent (≥ 70%) and less than or equal to one hundred and thirty percent (≤ 130%) of expected values. A CCV sample is required at the beginning of an analytic run, every twenty (20) samples, and at the end of the run.

(ii) **Instrument QC.** New calibrations must be accurately verified in the lower twenty-five percent (25%) of the calibration curve using second source certified reference materials (CRM) or a second preparation. Recoveries must be greater than or equal to seventy percent (≥ 70%) and less than or equal to one hundred and thirty percent (≤ 130%) of expected values.

(F) **Calibration criteria.** Calibrations shall include the following requirements:

(i) Testing laboratories may use commercially available CRM calibration standards or those prepared by the laboratory. Commercially available calibration standards shall only be used according to the manufacturer's instructions. All calibration standards shall be used before their date of expiration;

(ii) Data that is above the highest retained calibrator shall not be reported without qualification;

(iii) Gravimetric dilution shall be used to determine dilution factors for standards and shall be reported in grams per gram (g/g);

(iv) Matrix matching or surrogate matrix shall be used in calibration standards;

(v) Five (5) levels of linear or weighted linear regression, or six (6) levels of quadradic regression, using an average response factor;

(vi) A coefficient of determination that is greater than or equal to ninety-nine hundredths ($R^2 \geq 0.99$) and a relative standard error that is less than thirty percent (RSE < 30%); and

(vii) The calibration curve shall not be manipulated so that it artificially passes through zero.

(G) **Reporting results.** Mycotoxin analytes shall be reported to three (3) significant figures, using the unit parts per billion (ppb).

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

(A) **Allowable thresholds.** Samples shall be tested for the following residual solvent analytes and shall be less than (<) the allowable threshold, in parts per million (ppm), listed below. If the cannabis concentrate used to make an infused product was tested for residual solvents and test results indicate the lot was within established limits, then the infused product does not require additional testing for residual solvent analytes.

(i) Acetone < 1000 ppm;

(ii) Benzene < 2 ppm;

(iii) Butane < 1000 ppm;

(iv) Ethanol < 5000 ppm (required for inhaled products only);

(v) Ethyl acetate < 1000 ppm;

(vi) Heptane < 1000 ppm;

(vii) Hexane < 60 ppm;

(viii) Methanol < 600 ppm;

(ix) Pentane < 1000 ppm;

(x) Propane < 1000 ppm;
(xi) Isopropyl Alcohol < 1000 ppm;
(xii) Toluene < 180 ppm; and
(xiii) Total Xylenes (m, p, o-xylenes) < 430 ppm.

(B) **Instrumentation.** For residual solvent testing, laboratories shall use Headspace Gas Chromatography Flame Ionization Detection (GC-FID) or Headspace Gas Chromatography Mass Spectrometry (GC-MS).

(C) **Methodologies**. A testing laboratory's method must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known analyte concentration values. Passing values must be within plus or minus two and a half on a standard deviation index (± 2.5 SDI).

(D) **Sample preparation.** Sample must weigh greater than or equal to two tenths of a gram (≥ 0.2 g). The extraction and/or dilution solvent chosen for preparation of standards and samples shall not be included on the analyte list of residual solvents tested for in OAC 442:10-8-1(i)(3)(A). All analytes shall be soluble in the extraction and/or dilution solvent. Background levels of contamination from laboratory solvents shall be controlled and shall be below the allowable threshold for each solvent.

(E) **Laboratory quality control (LQC) requirements.**

(i) **LQC samples.** The following LQC samples must be run with each analytic run, and repeated every twenty (20) samples in an analytic run and must include:

(I) A method blank with a resulting value that is less than or equal to the limit of quantification (≤ LOQ);

(II) A laboratory control sample (LCS) with an acceptable limit that shall be plus or minus twenty percent (± 20%) of the known analyte concentration, in accordance with the following requirements. The LCS shall be spiked at or near the allowable thresholds for all required analytes to be reported and shall be determined with the correction factor applied. The LCS shall be carried through preparation and analysis as if it were a sample. A percent recovery calculation will be performed using the following mathematical formula: the resulting LCS concentration shall be divided by the known analyte concentration, which will then be multiplied by one hundred [(LCS concentration / known analyte concentration) * 100]. If the LCS results fall outside of the acceptance limits, then a testing laboratory cannot verify that it is able to acceptably perform the analysis in a clean matrix. A failing LCS may be re-analyzed once. If the results of the re-analysis also fall outside of the acceptance limits, then all samples associated with the LCS must be re-prepared and re-analyzed, along with all other appropriate analysis batch QC samples;

(III) A matrix spike with a recovery greater than or equal to seventy percent (≥70%) and less than or equal to one hundred and thirty percent (≤ 130%) of expected values;

(IV) A matrix spike duplicate that results in a relative percent difference that is less than or equal to twenty percent (RPD ≤ 20%) for all residual solvent analytes resulting in concentrations greater than (>) the LOQ; and

(V) Continuing calibration verification (CCV) with a recovery that is greater than or equal to eighty percent (≥ 80%) and less than or equal to one hundred and twenty percent (≤ 120%) of expected values. A CCV sample is required at the beginning of an analytic run, every twenty (20) samples, and at the end of the run.

(ii) **Instrument QC.** New calibrations must be accurately verified using second source certified reference materials (CRM) or a second preparation in the lower twenty-five percent (25%) of the calibration curve. Recoveries must be greater than or equal to eighty percent (≥ 80%) and less than or equal to one hundred and twenty percent (≤ 120%).

(F) **Calibration criteria.** Calibrations shall include the following requirements:

(i) Testing laboratories may use commercially available CRM calibration standards or those

prepared by the laboratory. Commercially available calibration standards shall only be used according to the manufacturer's instructions. All calibration standards shall be used before their date of expiration;

(ii) Data that is above the highest retained calibrator shall not be reported without qualification;

(iii) Gravimetric dilution shall be used to determine dilution factors for standards and shall be reported in grams per gram (g/g);

(iv) Five (5) levels of linear or weighted linear regression, or six (6) levels of quadradic regression, using an average response factor;

(v) A coefficient of determination that is greater than or equal to nine hundred and ninety-five thousandths ($R^2 \geq 0.995$) and a relative standard error that is less than twenty-five percent (RSE < 25%); and

(vii) The calibration curve shall not be manipulated so that it artificially passes through zero (0).

(G) **Reporting results.** Residual solvent analytes shall be reported to three (3) significant figures using the unit parts per million (ppm). Integration type and QC integration must correspond to the calibration integration. Peaks shall be integrated from baseline to baseline and non-resolved peaks shall be split peak at the valley minimum.

(4) **Metals**. Harvest batch samples and production batch samples shall be tested for heavy metal analytes in accordance with the following:

~~(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 with accepted limits determined by the product form submitted at testing.~~

~~(C) If the cannabis concentrate used to make an infused product was tested for metals and test results indicate the batch was within established limits, then the infused product does not require additional testing for metals. However, noninfused pre-rolls and infused pre-rolls must still undergo additional testing for metals.~~

(A) **Allowable thresholds.** Samples shall be tested for the following heavy metal analytes and shall be less than (<) the allowable threshold, in parts per million (ppm), as determined by the product form listed below:

(i) Inhaled product, administration by metered dose nasal spray, or pressurized metered dose inhaler medical marijuana and medical marijuana products shall be tested for the following heavy metal analytes and shall be less than the associated allowable thresholds:

(I) Arsenic < 0.2 ppm;

(II) Cadmium < 0.2 ppm;

(III) Lead < 0.5 ppm; and

(IV) Mercury < 0.1 ppm.

(ii) Topical and transdermal medical marijuana and medical marijuana products shall be tested for the following heavy metal analytes and shall be less than the associated allowable thresholds:

(I) Arsenic < 3 ppm;

(II) Cadmium < 3 ppm;

(III) Lead < 10 ppm; and

(IV) Mercury < 1 ppm.

(iii) Oral consumption, rectal, or vaginal administration medical marijuana and medical marijuana products shall be tested for the following heavy metal analytes and shall be less than the associated allowable thresholds:

(I) Arsenic < 1.5 ppm;

(II) Cadmium < 0.5 ppm;

(III) Lead < 1 ppm; and

(IV) Mercury < 1.5 ppm.

(B) **Instrumentation.** For heavy metal analyte testing, laboratories shall use Inductively Coupled Plasma Mass Spectrometry (ICP-MS) equipped with collision reaction cell technology. For sample preparation, a closed vessel microwave digestion system capable of reaching two hundred and ten degrees Celsius (210 °C), or a hot plate capable of reaching ninety-five degrees Celsius (95 °C) for one (1) hour, are required.

(C) **Methodologies.** A testing laboratory's method must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known analyte concentration values. Passing values must be within plus or minus two and a half on a standard deviation index (± 2.5 SDI). All internally developed methods shall comply with AOAC Standard Method Performance Requirements (SMPR) 2020.001. For Determination of Heavy Metals in a Variety of Cannabis and Cannabis-Derived Products. (2020);

(D) **Sample preparation.** Samples must weigh greater than or equal to five tenths of a gram (≥ 0.5 g). Internal Standards must be used for all analytes. Recovery of internal standards must be greater than or equal to fifty percent (≥ 50%) and less than or equal to two hundred percent (≤ 200%). A fifteen (15) minute pre-digestion is required to initiate the breakdown of hydrocarbons. If microwave digestion is used, a determination of seal integrity is required. If the post weight loss of the sample exceeds one percent (1%) of the pre-weight of the sample and reagents, the sample is considered compromised, and a new digestion must be performed. Glass vials must be acid washed before use. Concentrated ultrapure, or equivalent nitric acid (HNO_3) shall be used for sample digestion and concentrated ultrapure, or equivalent hydrochloric acid (HCl) shall be used for mercury stabilization. The diluent for sample preparation shall be determined by the following formula: one to five percent volume per volume HNO_3 and five tenths percent volume by volume HCl solution in deionized water with a resistance greater than eighteen megaohms per centimeter [1% - 5% (v/v) HNO_3 / 0.5% (v/v) HCl solution in DI Water (Resistance > 18 MΩ•cm)]. The rinse blank solution shall be prepared on the same day as analysis and shall be determined by the following formula: one to five percent volume per volume HNO_3 and five tenths percent HCl solution in deionized water with a resistance greater than eighteen megaohms per centimeter [1% - 5% (v/v) HNO3 / 0.5% HCl solution in DI Water (Resistance > 18 MΩ•cm)]. When mercury analysis is performed, gold shall be added to the rinse blank, calibrators, samples, and LQC samples to a concentration of a hundred micrograms per liter (100 µg/L).

(E) **Laboratory quality control (LQC) requirements.**

(i) **LQC samples.** The following LQC samples must be run with each analytic run, and repeated every twenty (20) samples in an analytic run and must include:

(I) A method blank with a resulting value that is less than the limit of quantification (< LOQ);

(II) A laboratory control sample (LCS) with an acceptable limit that shall be plus or minus twenty percent (± 20%) of the known analyte concentration, in accordance with the following requirements. The LCS shall be spiked at or near the allowable thresholds for all required analytes to be reported and shall be determined with the correction factor applied. The LCS shall be carried through preparation and analysis as if it were a sample. A percent recovery calculation will be performed using the following mathematical formula: the resulting LCS concentration shall be divided by the known analyte concentration, which will then be multiplied by one hundred [(LCS concentration / known analyte concentration) * 100]. If the LCS results fall outside of the acceptance limits, then a testing laboratory cannot verify that it is able to acceptably perform the analysis in a clean matrix. A failing LCS may be re-analyzed once. If the results of the re-analysis also fall outside of the acceptance limits, then all samples associated with the LCS must be re-prepared and re-analyzed, along with all other appropriate analysis batch QC samples;

(III) A matrix spike with a recovery greater than or equal to eighty percent (≥ 80%) and less than or equal to one hundred twenty percent (≤ 120%) of expected values;

(IV) A matrix spike duplicate that results in a relative percent difference that is less than or equal to twenty percent (RPD ≤ 20%) for all heavy metal analytes resulting in concentrations greater than (>) the LOQ; and

(V) Continuing calibration verification (CCV) with a recovery greater than or equal to eighty-five percent (≥ 85%) and less than or equal to one hundred and fifteen percent (≤ 115%) of expected values. A CCV sample is required at the beginning of an analytic run, every twenty (20) samples, and at the end of the run.

(ii) **Instrument QC.** New calibrations must be accurately verified using second source certified reference materials (CRM) or a second preparation targeting the lower twenty-five percent (25%) of the calibration curve. Recoveries must be greater than or equal to eighty-five percent (≥ 85%) and less than or equal to one hundred and fifteen percent (≤ 115%).

(F) **Calibration criteria.** Calibrations shall include the following requirements:

(i) Testing laboratories may use commercially available CRM calibration standards or those prepared by the laboratory. Commercially available calibration standards shall only be used according to the manufacturer's instructions. All calibration standards shall be used before their date of expiration;

(ii) A minimum of three replicate integrations are required for each analyte;

(iii) Data that is above the highest retained calibrator shall not be reported without qualification;

(iv) Gravimetric dilutions shall be used to determine dilution factors for standards and shall be reported in grams per gram (g/g);

(v) Five (5) levels of linear or weighted linear regression; and

(vi) A coefficient of determination that is greater than or equal to nine hundred and ninety-five thousandths ($R^2 \geq 0.995$) and a relative standard error that is less than twenty-five percent (RSE < 25%).

(G) **Reporting results.** Heavy metal analytes shall be reported to three (3) significant figures, using the unit ppm and on a dry weight basis, for samples that require reporting moisture results, as determined by the following equation: the moisture concentration of the sample as it was received, divided by the percent moisture of the sample subtracted from one hundred, multiplied by one hundred, equals the corrected moisture concentration dry weight ([("As received" concentration) / (100 - % moisture)] x 100 = corrected moisture concentration dry weight).

(5) **Pesticide residue**. ~~All harvest~~ Harvest batch samples and production batch samples shall be tested for ~~the following pesticides, and shall not exceed the associated limits:~~ pesticide analytes in accordance with the following:

~~(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: B1a & B1b) < 0.5 ppm~~

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

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

(A) **Allowable thresholds**. Samples shall be tested for the following pesticide analytes and shall be less than (<) the allowable threshold, in parts per million (ppm), listed below:

(i) Abamectin (B1a & B1b) < 0.5 ppm;

(ii) Azoxystrobin < 0.2 ppm;

(iii) Bifenazate < 0.2 ppm;
(iv) Etoxazole < 0.2 ppm;
(v) Imazalil < 0.2 ppm;
(vi) Imidacloprid < 0.4 ppm;
(vii) Malathion < 0.2 ppm;
(viii) Myclobutanil < 0.2 ppm;
(ix) Permethrins (cis & trans) < 0.2 ppm;
(x) Spinosad (mixture of A and D) < 0.2 ppm;
(xi) Spiromesifen < 0.2 ppm;
(xii) Spirotetramat < 0.2 ppm; and
(xiii) Tebuconazole < 0.4 ppm.

(B) **Instrumentation.** For pesticide analyte testing, laboratories shall use LC-MS/MS with ESI or LC-MS/MS with APCI.

(C) **Methodologies.** The method employed by a testing laboratory must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known analyte concentration values. Passing values must be within plus or minus two and a half on a standard deviation index (± 2.5 SDI).

(D) **Sample preparation.** Sample must weigh greater than or equal to five tenths of a gram (≥ 0.5 g). Sample preparation solvents must be LC-MS grade. Internal standards must be used for all analytes. Solid form samples shall be homogenized by blending, using a food processor or similar apparatus, or cryogrinding. Liquid form samples shall be homogenized by stirring. Analytes shall be extracted from the sample using the following techniques: solid-liquid extraction or solid phase extraction.

(E) **Laboratory quality control (LQC) requirements.**

(i) **LQC samples.** The following LQC samples must be run with each analytic run, and repeated every twenty (20) samples in an analytic run and must include:

(I) A method blank with a resulting value that is less than or equal to the limit of quantification (≤ LOQ);

(II) A laboratory control sample (LCS) with an acceptable limit that shall be plus or minus twenty percent (± 20%) of the known analyte concentration, in accordance with the following requirements. The LCS shall be spiked at or near the allowable thresholds for all required analytes to be reported and shall be determined with the correction factor applied. The LCS shall be carried through preparation and analysis as if it were a sample. A percent recovery calculation will be performed using the following mathematical formula: the resulting LCS concentration shall be divided by the known analyte concentration, which will then be multiplied by one hundred [(LCS concentration / known analyte concentration) * 100]. If the LCS results fall outside of the acceptance limits, then a testing laboratory cannot verify that it is able to acceptably perform the analysis in a clean matrix. A failing LCS may be re-analyzed once. If the results of the re-analysis also fall outside of the acceptance limits, then all samples associated with the LCS must be re-prepared and re-analyzed, along with all other appropriate analysis batch QC samples;

(III) A matrix spike with a recovery greater than or equal to seventy percent (≥ 70%) and less than or equal to one hundred thirty percent (≤ 130%) of expected values;

(IV) A matrix spike duplicate that results in a relative percent difference that is less than or equal to thirty percent (RPD ≤ 30%) for all pesticide residue analytes resulting in concentrations greater than (>) the LOQ; and

(V) Continuing calibration verification (CCV) with a recovery greater than or equal to seventy percent (≥ 70%) and less than or equal to one hundred and thirty percent (≤ 130%) of expected values. A CCV sample is required at the beginning of an analytic run, every twenty (20) samples, and at the end of the run.

(ii) **Instrument QC.** New calibrations must be accurately verified using second source certified reference materials (CRM) or a second preparation targeting the lower twenty-five percent (25%) of the calibration curve. Recoveries must be greater than or equal to seventy percent (≥ 70%) and less than or equal to one hundred and thirty percent (≤ 130%) of expected values.

(F) **Calibration criteria.** Calibrations shall include the following requirements:

(i) Testing laboratories may use commercially available CRM calibration standards or those prepared by the laboratory. Commercially available calibration standards shall only be used according to the manufacturer's instructions. All calibration standards shall be used before their date of expiration;

(ii) Data that is above the highest retained calibrator shall not be reported without qualification;

(iii) Gravimetric dilution shall be used to determine dilution factors for standards and shall be reported in grams per gram (g/g);

(iv) Matrix matching or a surrogate matrix shall be used in calibration standards; and

(v) Internal standards with a correction factor that is greater than or equal to fifty percent (≥ 50%) and less than or equal to two hundred percent (≤ 200%);

(vi) Five (5) levels of linear or weighted linear regression, or six (6) levels of quadratic regression;

(vii) A coefficient of determination that is greater than or equal to ninety-nine hundredths ($R^2 \geq 0.99$) and a relative standard error that is less than thirty percent (RSE < 30%); and

(viii) The calibration curve shall not be manipulated so that it artificially passes through zero (0).

(G) **Reporting results.** Pesticide analytes shall be reported to three (3) significant figures, using the unit parts per million. Samples that require moisture analysis shall be reported on a dry weight basis as determined by the following equation: the moisture concentration of the sample as it was received, divided by the percent moisture of the sample subtracted from one hundred, multiplied by one hundred, equals the corrected moisture concentration dry weight ([("As received" concentration) / (100 - % moisture)] x 100 = corrected moisture concentration dry weight).

(H) **Positive identification**. Positive identification of pesticide analytes using LC-MS/MS shall be deemed accurate only if there is a qualifier ion in transition; and the peak area ratio (quantitation transition/qualification transition) of the samples is within plus or minus fifty percent (± 50%) of the peak area ratio (quantitation transition/qualification transition) of the calibrator.

(6) ~~**Potency**.~~ **THC and cannabinoid concentration.** ~~Processors and growers shall test harvest batch and production batch samples for levels of total THC and terpenoid type and concentration and terpenoid type and concentration, including but not limited to:~~ Harvest batch samples and production batch samples shall be tested for THC and cannabinoid concentration in accordance with the following:

~~(A) THC and cannabinoid concentration, including but not limited to:~~

~~(i) Total cannabidiol (CBD)~~

~~(ii) Total cannabinoids~~

~~(iii) Tetrahydrocannabinolic acid (THCa)~~

~~(iv) Delta-9-tetrahydrocannabinol (Delta-9-THC)~~

~~(v) Delta-8-tetrahydrocannabinol (Delta-8-THC)~~

~~(vi) Cannabidiolic acid (CBDA)~~

~~(vii) Cannabidiol (CBD)~~

~~(viii) Cannabinol (CBN)~~

~~(ix) Cannabigerolic acid (CBGa)~~

~~(x) Cannabigerol (CBG)~~

~~(xi) Tetrahydrrocannabivarin (THCV)~~

~~(xii) Cannabichromene (CBC)~~

~~(B) Terpenoid type and concentrate, including but not limited to:~~

~~(i) Limonene~~

~~(ii) Myrcene~~
~~(iii) Pinene~~
~~(iv) Linalool~~
~~(v) Eucalyptol~~
~~(vi) Delta-terpinene (Δ-terpinene)~~
~~(vii) Beta-caryophyllene (ß-caryophyllene)~~
~~(viii) Caryophyllene oxide~~
~~(ix) Nerolidol~~
~~(x) Phytol~~

(A) **Cannabinoid analytes**. Samples shall be tested for cannabinoid analytes including, but not limited to, the following:

(i) Cannabichromene (CBC);
(ii) Cannabidiol (CBD);
(iii) Cannabidiol acid (CBDA);
(iv) Cannabigerol (CBG);
(v) Cannabigerolic acid (CBGA);
(vi) Cannabinol (CBN);
(vii) Delta-8-tetrahydrocannabinol (Δ-8-THC);
(viii) Delta-9-tetrahydrocannabinol (Δ-9-THC);
(ix) Tetrahydrocannabinolic acid (THCA); and
(x) Tetrahydrocannabivarin (THCV).

(B) **Total cannabinoid concentrations**. Samples shall be tested for total cannabinoid analyte concentrations in accordance with the following:

(i) Total Δ-9-THC concentration shall be determined by combining the THCA and Δ-9-THC concentrations using the following calculation: the THCA concentration as expressed in milligrams per gram multiplied by eight hundred and seventy-seven thousandths plus the Δ-9-THC concentration expressed in milligrams per gram is equal to the total Δ-9-THC concentration as expressed in milligrams per gram [(THCA concentration (mg/g) x 0.877) + Δ-9-THC concentration (mg/g) = total Δ-9-THC concentration (mg/g)]; and

(ii) When the acidic form and the decarboxylated form of a cannabinoid are both detected, the total concentration for that cannabinoid shall be determined using the following calculation: the concentration of the cannabinoid's acidic form, expressed in milligrams per gram, multiplied by eight hundred and seventy-seven thousandths plus the concentration of the decarboxylated form, expressed in milligrams per gram equals the total concentration, as expressed in milligrams per gram, for that cannabinoid. [(acidic form [cannabinoid] concentration (mg/g) × 0.877) + decarboxylated form [cannabinoid] concentration (mg/g) = total [cannabinoid] concentration (mg/g)].

(C) **Instrumentation.** For THC and cannabinoid concentration testing, laboratories shall use Liquid Chromatography Diode Array Detection (LC-DAD), LC-MS or Liquid Chromatography Ultraviolet (LC-UV).

(D) **Methodologies.** The method employed by a testing laboratory must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known analyte concentration values. Passing values must be within plus or minus two and a half on a standard deviation index (± 2.5 SDI).

(E) **Laboratory quality control (LQC) requirements.**

(i) **LQC samples.** The following LQC samples must be run with each analytic run, and repeated every twenty (20) samples in an analytic run and must include:

(I) A method blank with a resulting value that is less than or equal to the limit of quantification (≤ LOQ);

(II) A laboratory control sample (LCS) with an acceptable limit that shall be plus or minus

twenty percent (± 20%) of the known analyte concentration, in accordance with the following requirements. The LCS shall be spiked at or near the allowable thresholds for all required analytes to be reported and shall be determined with the correction factor applied. The LCS shall be carried through preparation and analysis as if it were a sample. A percent recovery calculation will be performed using the following mathematical formula: the resulting LCS concentration shall be divided by the known analyte concentration, which will then be multiplied by one hundred [(LCS concentration / known analyte concentration) * 100]. If the LCS results fall outside of the acceptance limits, then a testing laboratory cannot verify that it is able to acceptably perform the analysis in a clean matrix. A failing LCS may be re-analyzed once. If the results of the re-analysis also fall outside of the acceptance limits, then all samples associated with the LCS must be re-prepared and re-analyzed, along with all other appropriate analysis batch QC samples;

(III) A matrix spike with a recovery greater than or equal to eighty percent (≥ 80%) and less than or equal to one hundred and twenty percent (≤ 120%) of expected values;

(IV) A matrix spike duplicate that results in a relative percent difference that is less than or equal to twenty percent (RPD ≤ 20%) for all cannabinoid analytes resulting in concentrations greater than (>) the LOQ; and

(V) Continuing calibration verification (CCV) with a recovery greater than or equal to eighty-five percent (≥ 85%) and less than or equal to one hundred and fifteen percent (≤ 115%) of expected values. A CCV sample is required at the beginning of an analytic run, every twenty (20) samples, and at the end of the run.

(ii) **Instrument QC**. New calibrations must be accurately verified using second source certified reference materials (CRM) or a second preparation. Recoveries must be greater than or equal to eighty-five percent (≥ 85%) and less than or equal to one hundred and fifteen percent (≤ 115%) of expected values.

(F) **Calibration criteria.** Calibrations shall include the following requirements:

(i) Testing laboratories may use commercially available CRM calibration standards or those prepared by the laboratory. Commercially available calibration standards shall only be used according to the manufacturer's instructions. All calibration standards shall be used before their date of expiration;

(ii) Data that is above the highest retained calibrator shall not be reported without qualification;

(iii) Gravimetric dilution shall be used to determine dilution factors for standards and shall be reported in grams per gram (g/g);

(iv) Five (5) levels of linear or weighted linear regression;

(v) A coefficient of determination that is greater than or equal to nine hundred and ninety-five thousandths ($R^2 \geq 0.995$) and a relative standard error that is less than twenty-five percent (RSE < 25%).

(G) **Reporting results.** Cannabinoid analytes shall be reported to three (3) significant figures. Samples that require moisture analysis shall be reported on a dry weight basis as determined by the following equation: the moisture concentration of the sample as it was received, divided by the percent moisture of the sample subtracted from one hundred, multiplied by one hundred, equals the corrected moisture concentration dry weight ([("As received" concentration) / (100 - % moisture)] x 100 = corrected moisture concentration dry weight).

(H) **Peak integration.** Integration type and QC integration must correspond to the calibration integration. Peaks shall be integrated from baseline to baseline and non-resolved peaks shall be split peak at the valley minimum.

(I) **Total Δ-9-THC concentration acceptance criteria.** If a sample of medical marijuana flower has a total Δ-9-THC concentration of greater than or equal to thirty percent (≥ 30%) or if a distillate sample has a total Δ-9-THC concentration of greater than or equal to ninety percent (≥ 90%), the following requirements shall apply before those results are reported:

(i) For medical marijuana flower with a total Δ-9-THC concentration that is:

(I) Greater than or equal to thirty percent (≥ 30%) total Δ-9-THC concentration, and less than thirty-two and five tenths percent (< 32.5%) total Δ-9-THC concentration, it must be retested using the primary sample. If the retest results are within plus or minus fifteen percent (± 15%) of the original results, the higher of the two results shall be reported. If the retest results are not within plus or minus fifteen percent (± 15%) of the original results, a third test must be performed. A median value of all three (3) test results shall be reported. If retesting under this subsection results in a value greater than or equal to thirty-two and five tenths percent (≥ 32.5%) total Δ-9-THC concentration, results may not be reported under this subunit and (II) of this unit applies; or

(II) Greater than or equal to thirty-two and five tenths percent (≥ 32.5%) Δ-9-THC concentration, the Authority will collect a new primary and reserve sample from the source batch. The Authority will conduct testing for total Δ-9-THC concentration using the original reserve sample and the new primary sample. If both retest results are within plus or minus fifteen percent (± 15%) original results, the original results shall be reported. If the retest on the original reserve sample results in a value that is not within plus or minus fifteen percent (± 15%) of the original concentration, the Authority may refer the matter for further investigation. If the retest on the new primary sample results in a value that is not within plus or minus fifteen percent (± 15%) of the original results, the testing laboratory must retest using the new reserve sample and report those results. Testing values generated by the Authority shall not be reported in place of testing laboratory results.

(ii) For medical marijuana distillate with a total Δ-9-THC concentration that is:

(I) Greater than or equal to ninety percent (≥ 90%) and less than ninety-five percent (< 95%) total Δ-9-THC concentration, it must be retested using the primary sample. If the retest results are within plus or minus ten percent (± 10%) of the original results, the higher of the two results shall be reported. If the retest results are not within plus or minus ten percent (± 10%) of the original results, a third test must be performed. A median value of all three (3) test results shall be reported. If retesting under this subsection results in a value that is greater than or equal to ninety-five percent (≥ 95%) total Δ-9-THC concentration, results may not be reported under this subunit and (II) of this unit applies; or

(II) Greater than or equal to ninety-five percent (≥ 95%) Δ-9-THC concentration, the Authority will collect a new primary and reserve sample from the source batch. The Authority will conduct testing for total THC concentration using the original reserve sample and the new primary sample. If both retest results are within plus or minus ten percent (± 10%) original results, the original results shall be reported. If the retest on the original reserve sample results in a value that is not within plus or minus ten percent (± 10%) of the original concentration, the Authority may refer the matter for further investigation. If the retest on the new primary sample results in a value that is not within plus or minus ten percent (± 10%) of the original results, the testing laboratory must retest using the new reserve sample and report those results. Testing values generated by the Authority shall not be reported in place of testing laboratory results.

(7) **Terpenoid type and concentration.** Harvest batch samples and production batch samples shall be tested for terpenoid type and concentration in accordance with the following:

(A) **Terpene analytes**. Samples shall be tested for terpene analytes including, but not limited to, the following:

(i) alpha-Bisabolol (α-Bisabolol);

(ii) beta-Caryophyllene (β-Caryophyllene);

(iii) Caryophyllene oxide;

(iv) Eucalyptol;

(v) alpha-Humulene (α-Humulene);

(vi) Limonene;
(vii) Linalool;
(viii) beta-Myrcene (β-Myrcene);
(ix) cis-Nerolidol;
(x) trans-Nerolidol;
(xi) alpha-Pinene (α-Pinene);
(xii) beta-Pinene (β-Pinene); and
(xiii) alpha-Terpinene (α-Terpinene).

(B) **Instrumentation.** For terpene analyte testing, laboratories shall use GC-MS or GC-FID.

(C) **Sample preparation.** Sample must weigh greater than or equal to two tenths of a gram (≥ 0.2 g).

(D) **Methodologies**. The method employed by a testing laboratory must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known analyte concentration values. Passing values must be within plus or minus two and a half on a standard deviation index (± 2.5 SDI).

(E) **Laboratory quality control (LQC) requirements.**

(i) **LQC samples.** The following LQC samples must be run with each analytic run, and repeated every twenty (20) samples in an analytic run and must include:

(I) A method blank with a resulting value that is less than or equal to the limit of quantification (≤ LOQ);

(II) A laboratory control sample (LCS) with an acceptable limit that shall be plus or minus twenty percent (± 20%) of the known analyte concentration, in accordance with the following requirements. The LCS shall be spiked at or near the allowable thresholds for all required analytes to be reported and shall be determined with the correction factor applied. The LCS shall be carried through preparation and analysis as if it were a sample. A percent recovery calculation will be performed using the following mathematical formula: the resulting LCS concentration shall be divided by the known analyte concentration, which will then be multiplied by one hundred [(LCS concentration / known analyte concentration) * 100]. If the LCS results fall outside of the acceptance limits, then a testing laboratory cannot verify that it is able to acceptably perform the analysis in a clean matrix. A failing LCS may be re-analyzed once. If the results of the re-analysis also fall outside of the acceptance limits, then all samples associated with the LCS must be re-prepared and re-analyzed, along with all other appropriate analysis batch QC samples;

(III) A matrix spike with a recovery greater than or equal to eighty percent (≥ 80%) and less than or equal to one hundred and twenty percent (≤ 120%) of expected values;

(IV) A matrix spike duplicate that results in a relative percent difference that is less than or equal to twenty percent (RPD ≤ 20%) for all terpenoid analytes resulting in concentrations greater than (>) the LOQ; and

(V) Continuing calibration verification (CCV) with a recovery greater than or equal to eighty-five percent (≥ 85%) and less than or equal to one hundred and fifteen percent (≤ 115%) of expected values. A CCV sample is required at the beginning of an analytic run, every twenty (20) samples, and at the end of the run.

(ii) **Instrument QC**. New calibrations must be accurately verified using second source certified reference materials (CRM) or a second preparation that targets the lower twenty-five percent (25%) of the calibration curve. Recoveries must be greater than or equal to eighty-five percent (≥ 85%) and less than or equal to one hundred and fifteen percent (≤ 115%) of expected values.

(F) **Calibration criteria.** Calibrations shall include the following requirements:

(i) Testing laboratories may use commercially available CRM calibration standards or those prepared by the laboratory. Commercially available calibration standards shall only be used according to the manufacturer's instructions. All calibration standards shall be used before their

date of expiration;

(ii) Data that is above the highest retained calibrator shall not be reported without qualification;

(iii) Gravimetric dilution shall be used to determine dilution factors for standards and shall be reported in grams per gram (g/g);

(iv) Five (5) levels of linear regression or six (6) levels of quadratic regression;

(v) A coefficient of determination that is greater than or equal to ninety-eight hundredths ($R2 \geq 0.98$) for linear regression. For quadratic regression, a coefficient of determination that is greater than or equal to ninety-nine hundredths ($R^2 \geq 0.99$) is required; and

(iv) The calibration curve shall not be manipulated so that it artificially passes through zero (0).

(G) **Reporting results.** Terpenoid analytes shall be reported to three (3) significant figures. Samples that require moisture analysis shall be reported on a dry weight basis as determined by the following equation: the moisture concentration of the sample as it was received, divided by the percent moisture of the sample subtracted from one hundred, multiplied by one hundred, equals the corrected moisture concentration dry weight ([("As received" concentration) / (100 - % moisture)] x 100 = corrected moisture concentration dry weight).

(H) **Positive identification.** The standard addition method or analyzing the sample on a secondary column shall be used to demonstrate analyte recovery for GC-FID methods. Positive identification of a terpenoid analyte using GC-MS requires the presence of the target ions and all qualifier ions.

~~(7)~~ (8) **Foreign materials and filth**. ~~Growers and processors shall inspect all medical marijuana and medical marijuana products for contaminants and filth.~~ Harvest batch samples and production batch samples shall be tested for foreign materials and filth in accordance with the following:

(A) ~~Contaminants~~ **Allowable thresholds.** Foreign materials and filth are contaminants that 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. Samples shall be tested for foreign material and filth contaminants in accordance with the following:

(i) **Organic contaminants.** Foreign organic material shall be less than or equal to two percent (≤ 2%) by weight of each sample; and

(ii) **Inorganic contaminants.** Inorganic material, including but not limited to plastic, glass, and metal shavings, shall not be present in a sample.

(B) ~~The surface area of each sample shall not contain more than two percent (2%) of foreign organic material.~~ **Methodologies.** The method employed by a testing laboratory must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known analyte concentration values. Passing values must be within plus or minus two and a half on a standard deviation index (± 2.5 SDI).

(C) ~~Samples shall not contain any presence of inorganic material, including but not limited to plastic, glass, and metal shavings.~~ **Reporting results.** Results shall be reported as passing or failing.

~~(8)~~ (9) **Water activity and moisture content.** Harvest batch samples shall be tested to determine the level of water activity and the percentage of moisture content in accordance with this subsection. This subsection shall not apply to harvest batches that are flash frozen.

(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.~~ **Sample preparation.** Sample must weigh greater than or equal to five tenths of a gram (≥ 0.5 g).

(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.~~ **Water activity.** Samples shall be tested to determine the level of water activity in accordance with the following:

(i) **Allowable thresholds.** A harvest batch sample shall be deemed to have passed water activity

testing if the water activity is less than or equal to sixty-five hundredths (≤ 0.65 a_w).

(ii) **Instrumentation.** Testing laboratories shall use a water activity calibrated measurement system capable of a measurement resolution of one thousandth water activity (0.001 a_w) with an accuracy of plus or minus five thousandths water activity (±0.005 a_w), with a measurement range of at least four tenths to eight tenths water activity (0.40 to 0.80 a_w), and capable of a temperature measurement resolution of one tenth degree Celsius (0.1 °C) with an accuracy of one tenth degree Celsius (0.1 °C).

(iii) **Methodologies.** The method employed by a testing laboratory must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known analyte concentration values. Passing values must be within plus or minus two and a half on a standard deviation index (± 2.5 SDI).

(iv) **Laboratory quality control (LQC) samples.** The following LQC samples must be run once per day in an analytic run and must include:

(I) A sample replicate that results in a relative percent difference that is less than or equal to five percent (RPD ≤ 5%); and

(II) Continuing calibration verification (CCV) with a recovery greater than or equal to ninety-five percent (≥ 95%) and less than or equal to one hundred and five percent (≤ 105%) of expected values.

(v) **Reporting results.** Results shall be reported to two (2) decimal places, using the unit water activity (a_w).

(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.~~ **Moisture content.** Samples shall be tested to determine the percentage (%) of moisture content in accordance with the following:

(i) **Allowable thresholds.** A harvest batch sample shall be deemed to have passed moisture content testing if the moisture content is less than or equal to fifteen percent (≤ 15.0%) of the dry weight of the sample.

(ii) **Instrumentation.** To test the moisture content of a sample, laboratories shall use an oven for the loss on drying technique, a moisture analyzer, or the Karl Fischer technique.

(iii) **Methodologies.** The method employed by a testing laboratory must pass a matrix proficiency test as required by the Authority. The Authority will conduct the matrix proficiency test and will supply medical marijuana samples with known analyte concentration values. Passing values must be within plus or minus two and a half on a standard deviation index (± 2.5 SDI).

(iv) **Laboratory quality control (LQC) samples when using the loss on drying technique or a moisture analyzer.** The following LQC samples shall be run once per day in an analytic run and shall include:

(I) A laboratory duplicate sample that results in a relative percent difference that is less than or equal to twenty percent (RPD ≤ 20%); and

(II) A continuing calibration verification (CCV) to verify the laboratory balance used by using a calibrated weight set, result must be less than or equal to one tenth percent (≤ 0.1%) difference from assigned mass.

(v) **Laboratory quality control (LQC) sample**s when using the Karl Fischer technique. The following LQC samples shall be run once per day in an analytic run and shall include:

(I) A method blank with a resulting value that is less than or equal to the limit of quantification (≤ LOQ);

(II) A laboratory duplicate sample that results in a relative percent difference that is less than or equal to ten percent (RPD ≤ 10%);

(III) A continuing calibration verification (CCV) that shows that the water standard is within the stated criteria for the standard used; and

(IV) Instrument QC, titer shall be determined following the manufacturer's instructions and recommendations.

(vi) **Reporting results.** Results shall be reported to three (3) significant figures indicating the percentage of moisture content by dry weight in the sample.

(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) Any retesting of a reserve sample requested by the originating licensee must be requested within thirty (30) days. 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.

(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 of 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 been remediated or decontaminated must be fully tested and successfully pass all the analyses required under this Subchapter and as set forth in Appendix F. If the harvest batch or 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 442:10-8-1(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 processers must, as applicable:

(A) Have detailed procedures for remediation and decontamination processes to remove ~~microbiological~~ microbial 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~~ decontaminated. 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 Authority 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.

(l) **Remediation, decontamination, and retesting, ~~microbiological impurities~~ microbial testing.**

(1) If a sample from a harvest batch or production batch fails ~~microbiological contaminant~~ microbial 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~~ microbial 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 442:10-8-1(k). Processors shall not sell any medical marijuana from any harvest batch that has failed testing. Harvest batches that have failed microbial testing may be sent to a processor for decontamination of microbial contaminants and returned to the grower, provided the harvest batch was not processed into a solvent-based concentrate.

(3) If a sample from a batch of a cannabinoid concentrate or extract ~~fails microbiological contaminant testing~~ exceeds a microbial analyte allowable threshold, 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.

(4) A batch that is remediated or decontaminated in accordance with this Subsection of this section must be sampled and tested in accordance with these rules in the following manner:

(A) A batch that has failed microbial testing at a testing laboratory, that is decontaminated in accordance with this Subsection must be tested for microbials, heavy metals, THC and cannabinoid concentration, terpenoid type and concentration, ~~microbiological contaminants, heavy metals, and residual pesticides~~ and must be tested for pesticide residue, foreign material and filth, and water activity and moisture content if not previously tested ~~prior to decontamination~~.

(B) A batch that has failed for microbials during a grower's inspection, that is decontaminated in accordance with this Subsection must be tested for microbials, heavy metals, pesticide residue, THC and cannabinoid concentration, terpenoid type and concentration, foreign materials and filth, and water activity and moisture content.

~~(B)~~ (C) A batch that is remediated in accordance with this Subsection by processing into a solvent based concentrate must be tested for THC and cannabinoid concentration, terpenoid type and

concentration, ~~microbiological contaminant~~ microbials, mycotoxins, residual solvents, heavy metals, and residual pesticides.

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

(m) **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 decontaminated using procedures that would reduce the concentration of solvents to less than the action level.

(2) A batch that is decontaminated in accordance with ~~subsection (1)~~ this section must be sampled and retested for residual solvents in accordance with these Rules.

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

(n) **Decontamination and retesting, foreign materials and filth testing.**

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

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

(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 of in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

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

(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 of in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

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

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

(r) **Decontamination and 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 decontamination as described in ~~subsection (1)~~ this section must be sampled and tested in accordance with these Rules. If the harvest batch passed initial testing for residual solvents, metals, and/or pesticides, then the harvest batch does not require additional testing for those testing categories.

(3) If a harvest batch that fails microbial testing and water activity and/or moisture content testing, the harvest batch does not need to be further dried and cured by the grower before being transferred to a processor for remediation in accordance with OAC 442:10-8-1(l).

(s) **Testing of pre-rolls, kief, shake and trim.**

(1) **~~Noninfused~~ Pre-rolls.** ~~Growers, processors and dispensaries~~ Pre-rolls may ~~create noninfused pre-rolls~~ be created in accordance with ~~Oklahoma law and these Rules.~~ the following:

(A) **Noninfused pre-rolls.** Growers, processors and dispensaries may create noninfused pre-rolls

from flower, shake, or trim collected from single harvest or multiple harvest batches. For multiple harvest batches, provided all harvest batches have passed all testing requirements under this ~~Subchapter. The~~ Subchapter, the plant material must be homogenized into a new batch ~~not exceed~~ that weighs less than or equal to fifteen ~~(15)~~ (≤ 15) pounds. ~~Noninfused~~ Multiple harvest batch noninfused pre-rolls created by a grower, processor or dispensary are subject to the same testing requirements of a harvest batch under OAC 442:10-8-1(i). For single harvest batch noninfused pre-rolls made from flower, shake or trim that has passed full compliance testing, growers, processors, or dispensaries must conduct additional testing on the pre-rolls only for heavy metals, THC and cannabinoid concentration, and foreign materials and filth.

(B) ~~Growers, processors and dispensaries may create noninfused pre-rolls from flower, shake, or trim collected from a single harvest batch. If the noninfused flower, shake or trim come from a single harvest that has passed full compliance testing, growers, processors or dispensaries must conduct additional testing on the pre-rolls only for heavy metals, filth and contaminants, and THC and cannabinoid concentration.~~ **Infused pre-rolls.** Only processors may create infused pre-rolls. Infused pre-rolls must be tested for microbials, mycotoxins, residual solvents, heavy metals, pesticide residue, THC and cannabinoid concentration, terpenoid type and concentration, foreign material and filth, and water activity and moisture content. If medical marijuana concentrate, that has previously passed residual solvent testing, is used to infuse the pre-roll, residual solvent testing is not required.

(2) **Kief.** Growers and processors may collect kief from multiple harvest batches, provided ~~all~~ those harvest batches have passed all testing requirements under this Subchapter. The kief must be homogenized into a new batch ~~not exceed~~ that weighs less than or equal to fifteen ~~(15)~~ (≤ 15) pounds. Kief collected by a grower or processor is subject to the same testing requirements of a harvest batch under OAC 442:10-8-1(i).

(3) ~~Infused Pre-rolls.~~ ~~Only processors may create infused pre-rolls. Infused pre-rolls shall be tested in the same manner as noninfused pre-rolls in accordance with OAC 442:10-8-1(s)(1).~~

~~(4)~~ Shake and trim. Growers and processors may collect shake and trim from multiple harvest batches provided ~~all~~ those harvest batches have passed all testing requirements under this Subchapter. The shake and trim must be homogenized into a new batch ~~not exceed~~ that weighs less than or equal to fifty ~~(50)~~ (≤ 50) pounds. Shake and trim collected by a grower or processor is subject to the same testing requirements of a harvest batch under OAC 442:10-8-1(i).

(4) Medical marijuana concentrate and medical marijuana infused products. Medical marijuana concentrate and medical marijuana infused products, excluding infused pre-rolls, must be tested for microbials, mycotoxins, residual solvents, heavy metals, pesticide residue, THC and cannabinoid concentration, terpenoid type and concentration, and foreign material and filth. If the medical marijuana product is made from medical marijuana concentrate that has previously passed residual solvents and heavy metals testing then testing for residual solvents and heavy metals are not required for that product. If a licensee produces both the medical marijuana concentrate and the medical marijuana infused product from that concentrate, the licensee may forgo testing the medical marijuana concentrate, provided the medical marijuana infused product successfully passes all testing requirements under OAC 442:10-8-1(i).

442:10-8-2. General operating requirements and procedures

(a) **Laboratory accreditation**. All medical marijuana testing laboratories shall obtain accreditation by any accrediting entity approved by the Authority and subscribing to the International Laboratory Accreditation Cooperation ("ILAC"), prior to applying for and receiving a medical marijuana testing laboratory license. The accreditation must be from one of these entities in both chemistry and biology, or cannabis and must be specific to the procedure used in the laboratory. Renewal of any medical marijuana testing laboratory license shall be contingent upon maintaining accreditation in accordance with these Rules.

(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. Laboratories must notify the Authority of any change in scope of the testing laboratory's accreditation and the Authority may verify that the applicant can achieve analyte-specific testing thresholds showing applicants meet requirements stated in this section. A lab may outsource testing and report those results on a COA but must identify the testing laboratory that actually conducted the testing.

(c) **External quality control program testing**. The laboratory shall be subject to an external quality control program administered by the Authority or its designee. Frequency of external quality control testing is to be determined by the Authority or its designee.

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

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

(3) A result outside of the target range of any analyte in an external quality control sample event shall be deemed an unsatisfactory result. Each unsatisfactory result shall be evaluated by the licensed laboratory and corrective measure identified. The evaluation and completion of corrective measures shall be documented and signed by the laboratory director. The laboratory must then demonstrate its ability to achieve the target value.

(4) More than ~~20%~~ twenty percent (20%) unsatisfactory results in any external quality control testing event shall be deemed unsuccessful participation in the external quality control program. Unsuccessful participation in external quality control testing for two (2) testing events in a row, or ~~2~~ two (2) out of ~~3~~ three (3) events, may result in suspension or revocation of a laboratory license.

(5) Failure to participate in any external quality control testing shall be deemed unsuccessful participation in the external quality control program.

(6) If a laboratory fails its external quality control testing for an analyte, the batch testing results since the last external quality control 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 external quality control testing results.

(d) **Conflict of interest**. A person who is a direct 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. A medical marijuana testing laboratory shall not test samples for any medical marijuana business in which an owner, employee or agent of the medical marijuana testing laboratory has any form of ownership or financial interest in the medical marijuana business.

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

(f) **Personnel**. A licensed laboratory shall not operate unless a medical laboratory director is on site during operational hours; in his or her absence, the medical laboratory director may delegate in writing the duties and responsibilities to a qualified designee that meets all requirements of a laboratory director required by applicable Oklahoma law and these rules. 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.

(4) A licensed laboratory shall notify the Authority within seven (7) business days after any change of the laboratory's director occurs.

(g) **Equipment**.

(1) Equipment used for analysis must have ~~a~~ an in sample Limit of ~~Detection (LOD)~~ Quantification (LOQ) capable of detecting quantities at or below ~~50%~~ fifty percent (50%) of the thresholds listed in ~~OAC 442:10-8-1(h) and Appendix A~~ OAC 442:10-8-1(i).

(2) Equipment used for the analysis of test samples shall be adequately inspected, cleaned, and maintained. Preventive maintenance shall be carried out in accordance with the requirements and recommendations of the manufacturer. Equipment used for the generation or measurement of data shall be adequately tested and calibrated on an appropriate schedule, as applicable. Any modification or repair of an instrument shall undergo verification that it can meet the quality control requirements of these Rules.

(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 used in preparation or analysis of laboratory samples, storage of samples, reagents, calibrators and controls, 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 and shall be readily accessible to all personnel who operate the equipment.

(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 in writing 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 to bring the instrument into compliance with the quality control requirements of these Rules. 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.

(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.

(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 seven (7) 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.

(i) **Materials to be maintained on premises**. The laboratory shall maintain on its premises, and shall promptly present to the Authority 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~~ protocols, 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 including traceability from current container to original container; all reagents must be traceable from current container to original container;
(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 deviations from approved standards of practice do not occur without documented authorization in writing; method performance is verified each time a new analyst performs the test; and that staff is competent in the process; including but not limited to:
(A) Direct observations of routine test performance, including sample preparation, handling, processing and testing as appropriate;
(B) Monitoring recording and reporting of test results;
(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records;
(D) Direct observation of instrument maintenance and function checks;
(E) Test performance using previously analyzed specimens, blind sample testing, and external proficiency testing results;
(F) Assessment of problem-solving skills;
(G) Initial assessment within the first six (6) months of employment, with annual assessments thereafter unless a change in methodology occurs; and
(H) Documentation must be complete before reporting results~~; and~~.
(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 Authority may require.

(j) **Authority access to materials and premises**. The laboratory shall promptly provide the Authority or the Authority'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 Authority or the Authority's designee to laboratory premises, and to any material or information requested by the Authority, for the purpose of determining compliance with

the requirements of applicable Oklahoma law and these rules.
(k) **Reporting of accreditation and proficiency testing results**. The laboratory must submit to the Authority, within thirty (30) days of an accrediting entity's assessment, the results of any proficiency testing or an accrediting entity's audit, including the findings and any corrective action required following the assessment.
(l) **Licensed premises standards.** The laboratory must be constructed, arranged and maintained in a way that ensures the laboratory premises, ventilation and utilities are sufficient for conducting all phases of the testing process:

(1) Work area ~~should~~ shall be arranged to minimize problems in specimen handling, examination and testing, and reporting of test results. Workbench space must be sufficient for the performance of testing, including, but not limited to, adequate lighting, water, gas, vacuum, and electrical outlets. Instruments, equipment, and computer systems ~~should~~ shall be placed in locations where their operation is not affected adversely by physical or chemical factors, such as heat, humidity, direct sunlight, vibrations, power fluctuations, or fumes from acid or alkaline solutions. Equipment tops ~~should~~ shall not be used as a workbench space;
(2) Lighting or backgrounds as appropriate for visual interpretation of test results;
(3) There is a system in place which ensures that the ventilation system properly removes vapors, fumes, and excessive heat as appropriate for the type of testing done in the laboratory;
(4) There is an adequate, stable electrical source maintained at each testing location that meets the power requirements for each piece of equipment;
(5) The Laboratory is designed to minimize contamination of samples, equipment, instruments, reagents and supplies. Laboratories performing molecular amplification procedures must have a mechanism to detect cross-contamination of specimens; and
(6) Reagents must be prepared in an area that is separate, as applicable, from where specimens are processed, prepared, amplified, and detected to prevent contamination.

442:10-8-3. Sampling requirements and procedures
(a) **General requirements**. Samples must be collected, handled, stored, and disposed of in accordance with this Section. Individuals collecting samples are called "Samplers."

(1) Samplers shall:
(A) Follow the approved standard operating procedures of the laboratory that will be testing the samples collected
(B) 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;
(C) Have access to a copy of the laboratory's standard operating procedures while they are collecting the samples; and
(D) Follow inventory manifest requirements set forth in these Rules.
(2) Samplers shall collect samples at the location of the grower, processor or dispensary and must affix the samples with a tamper-proof seal at the time of collection.
(3) All commercial transporters, growers, processors or dispensaries 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.
(4) For transfer or sale of harvest batches or production batches, samples must be collected in the 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.~~ following:
(A) For all medical marijuana and medical marijuana products excluding medical marijuana products that are administered via inhalation, "final form" means the form medical marijuana or a medical marijuana product is in when sold or transferred.
(B) For medical marijuana products that are administered via inhalation, "final form" means the form the medical marijuana product is in after being placed into any physical glass, metal, or plastic

cartridge or container used to smoke, vaporize, vape, or e-cigarette the product.

(5) 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 the "Primary Sample" or "Reserve Sample";

(B) The name and license number of grower, processor or dispensary from whom the sample was taken; and

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

(6) The primary sample and reserve sample shall be stored separately and analyzed separately. The reserve sample shall only be used for quality control purposes or for retesting in accordance with OAC 442:10-8-1(j).

(7) 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.

(8) The sampler shall create and use a sample field log to record the following information for each sample, and copies of the sample field log shall be maintained by both the laboratory and the commercial licensee from which the samples are being collected. The field log shall include, at a minimum, the following information:

(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;

(C) Sampler's name(s) and title(s);

(D) Date and time sampling started and ended;

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

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

(G) Sample matrix;

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

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

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

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

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

(M) Requested analyses;

(N) Sampling conditions, including temperature;

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

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

(9) The laboratory shall maintain inventory manifest documentation listed in OAC 442:10-3-6 and utilize an electronic inventory management system that meets the requirements set forth in OAC 442:10-5-6(d) for each sample that the laboratory collects, transports, and analyzes.

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

(11) Commercial licensees must maintain the documentation required in these rules for at least seven (7) years and must provide that information to the Authority upon request.

(b) **Sample size**.

(1) To obtain a representative sample of a harvest batch or non-infused pre-rolls, a total of ~~0.5%~~ one-half of one percent (0.5%) of the batch shall be collected from different areas of the batch following the laboratory's approved protocol. The sample shall then be ~~homogenized~~ well mixed and aliquoted into a primary sample and reserve sample~~, which shall be equal in amounts~~. The primary sample and the

reserve sample shall ~~be in the amounts specified in the laboratory's standard operating procedure~~ each weigh greater than or equal to seven grams (≥ 7 g). Any amounts left over after aliquoting may be returned to the harvest or production batch.

(2) To obtain a representative sample of a ~~processed~~ production batch that is a well mixed ~~or homogeneous by its nature~~ liquid, a sampler shall obtain a primary sample and a reserve sample that shall each weigh greater than or equal to seven grams (≥ 7 g) ~~an amount sufficient to be aliquoted into a primary sample and a reserve sample, which shall be equal in amount. If the batch is~~ To obtain a representative sample of infused pre-rolls or a non-liquid production batch, ~~not homogeneous or is of unknown homogeneity, then 0.5%~~ one-half of one percent (0.5%) of the batch shall be collected from different portions of the batch following the laboratory's approved protocol. The sample shall then be ~~homogenized~~ well mixed and aliquoted into a primary sample and reserve sample, which shall be equal in amount. The primary sample and reserve sample shall ~~be in the amounts specified in the laboratory's standard operating procedure~~ each weigh greater than or equal to seven grams (≥ 7 g). Any amount left over after aliquoting may be returned to the production batch.

~~(3) To obtain a representative sample of a final medical marijuana product batch, samples shall be collected in accordance with the table in Appendix D.~~

~~(4) To obtain a representative sample of pre-rolls, samples shall be collected in accordance with the table in Appendix E~~.

(c) **Sampling standard operating procedures**.

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

(2) ~~Sample~~ Sampling 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 442:10-5-6.

(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~~ not accept a test sample that is less than the minimum amount listed in OAC 442:10-8-3(b);

(2) The laboratory shall store each test sample under the appropriate conditions appropriate to protect

the physical and chemical integrity of the sample;
~~(2)~~ (3) 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)~~ (4) Reserve samples shall be maintained and properly stored by the laboratory for at least thirty (30) days. Any retesting requested by the originating licensee must be requested within thirty (30) days to ensure the retesting occurs within the required thirty (30) day storage period for reserve samples.
~~(4)~~ (5) After the required thirty (30) day storage period, 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 442:10-5-10 (relating to medical marijuana waste disposal).

(e) **Data reporting**.
(1) The laboratory shall generate a certificate of analysis (COA) for each 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. Any amendments to a COA shall include a revision identifier or report number, an explanation of the amendment, and shall identify all changes included in the amendment.
(3) 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;
(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;
(L) Definitions of any abbreviated terms; and
(M) The state inventory tracking system tag number, the sample tag number, and the source package tag number.
(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;

(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

(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 Authority immediately and shall submit to the Authority a copy of the COA containing those compounds as required in OAC 442:10-8-3(e)(3)(I). The Authority may require a processor, grower, or dispensary to submit samples for additional testing, including testing for analytes that are not required by these Rules. The licensee shall provide the samples or units of medical marijuana or medical marijuana products at its own expense but shall not be responsible for the costs of testing.

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

442:10-8-4. Laboratory quality assurance and quality control

(a) **Laboratory Quality Assurance (LQA) program**. The medical laboratory director shall develop and implement an LQA program to ensure the reliability and validity of the analytical data produced by the laboratory.

(1) The LQA program shall, at minimum, include a written LQA manual that addresses the following:

(A) Quality control procedures, including remedial actions;

(B) Laboratory organization and employee training and responsibilities;

(C) LQA criteria for acceptable performance;

(D) Traceability of data and analytical results;

(E) Instrument maintenance, calibration procedures, and frequency;

(F) Performance and system audits;

(G) Steps to change processes when necessary;

(H) Record retention;

(I) Test procedure standardization; and

(J) Method validation, including, but not limited to, accuracy, precision, sensitivity, cross-over, ~~LOD~~ Limit of Detection (LOD), Limit of Quantitation (LOQ), linearity, and measurement of uncertainty. For chromatographic methods, accuracy measurements must include statistical determination of an acceptable retention time window for identification of an analyte;

(K) Method verification of all externally validated methods, including but not limited to the laboratory's ability to achieve the validated method's performance criteria, analyst demonstration of competency, and a passing score for sample proficiency testing in an appropriate matrix;

(L) Any material alteration of a validated method, whether developed externally or internally, causes the method to become a laboratory developed method and subject to full validation;

(M) Validation or verification of a method following non-routine maintenance, repair of an instrument, or relocation of an analytical piece of equipment.

(2) The laboratory director shall annually review, amend if necessary, and approve the LQA program and manual when:

(A) The LQA program and manual are created; and

(B) There is a change in methods, laboratory equipment, or the supervisory or management laboratory employee overseeing the LQA program.

(b) **Laboratory quality control samples.**

(1) The laboratory shall use laboratory quality control (LQC) samples in the performance of each

analysis ~~according to the specifications in this section~~ as required by OAC 442:10-8-1(i).

(2) The laboratory shall analyze LQC samples in the same manner as the laboratory analyzes samples of medical marijuana and medical marijuana products.

(3) ~~The laboratory shall use negative and positive controls for microbial testing.~~

~~(4) The following quality control samples must be run every 20 samples in an analytic run:~~

~~(A) Method blank;~~

~~(B) Continuing calibration verification (CCV);~~

~~(C) Laboratory replicate sample; and~~

~~(D) Matrix spike sample or matrix spike duplicate sample.~~

~~(5)~~ If the result of the analyses is outside the specified acceptance criteria in ~~Appendix B~~ OAC 442:10-8-1(i), the laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria. Samples after the last acceptable run must be re-tested.

~~(6)~~ (4) The laboratory shall generate a LQC sample report for each analytical run that includes LQC parameters, measurements, analysis date, and matrix. The results must fall within the criteria set forth in ~~Appendix B~~ OAC 442:10-8-1(i).

(c) **Reagents, solutions, and reference standards**.

(1) Reagents, solutions, and reference standards shall be:

(A) Secured in accordance with the laboratory's storage policies; labeled to indicate identity of the reagent, identity of the preparer, date received or prepared, and expiration or requalification date; and labeled with, where applicable, concentration or purity, storage requirements, lot tracking number, and date opened;

(B) Stored under appropriate conditions to minimize degradation or deterioration of the material; and

(C) Used only within the item's expiration or requalification date.

(2) Deteriorated or outdated reagents and solutions shall be properly disposed of, in compliance with all federal, state and local regulations.

(3) The laboratory may acquire commercial reference standards for cannabinoids and other chemicals or contaminants, for the exclusive purpose of conducting testing for which the laboratory is approved. The laboratory may elect to produce reference standards in-house (internally). When internally produced, the laboratory shall utilize standard analytical techniques to document the purity and concentration of the internally produced reference standards. The laboratory is authorized to obtain marijuana or marijuana-derived product from a licensed non-profit producer for this purpose.

(4) The laboratory shall obtain or, for internally-produced standards, shall create a certificate of analysis (COA) for each lot of reference standard. Each COA shall be kept on-file and the lot number of the reference standard used shall be recorded in the documentation for each analysis, as applicable.

442:10-8-5. Quality assurance laboratory

(a) **Purpose.** The Authority is authorized to operate a quality assurance laboratory or to contract with a private laboratory for the purpose of evaluating the day-to-day operations of licensed laboratories. Any such contracted laboratory is prohibited from conducting any other commercial medical marijuana testing in this state.

(b) **Accreditation.** The quality assurance laboratory must be accredited by or 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. Accreditation or application for accreditation must be from one of these entities in both chemistry and biology or cannabis.

(c) **Duties.** The Authority shall utilize the quality assurance laboratory to: ~~On behalf of the Authority, a contracted private laboratory shall have the authority to:~~

(1) Conduct Inter-Laboratory Control Testing of laboratory licensees and applicants in a manner and frequency approved by the Authority;

(2) Provide recommendations for all equipment and standards to be utilized by licensed medical marijuana testing laboratories when testing samples of medical marijuana, medical marijuana concentrate, and medical marijuana products; ~~Inspect and assess testing equipment of licensed testing laboratories;~~

(3) Provide standardized operating procedures when procuring, collecting, extracting, and testing medical marijuana, medical marijuana concentrate, and medical marijuana products; ~~Access and test LQC samples;~~

(4) Procure, handle, transfer, transport, and test samples taken from medical marijuana licensed businesses; ~~Inspect and obtain copies of all laboratory documents and records, including but not limited to SOPs, COAs, testing reports, policies, and manuals;~~

(5) Implement the secret shopper program pursuant to 63 O.S. 427.25 of the Oklahoma Statutes; ~~Interview laboratory employees, owners, and agents for the purpose of evaluating compliance with Oklahoma law and these Rules; and~~

(6) Detect and analyze any compounds that are not among the targeted analytes and are unknown, unidentified, tentatively identified, or known and injurious to human health if consumed; and

(7) Other actions as deemed appropriate by the Authority to ensure compliance with Oklahoma law and these Rules.

(d) In order to fulfill the duties of the quality assurance laboratory, the Authority may:

(1) Enter into interlocal agreements with any other government agency pursuant to 74 O.S. 1001 et seq of the Oklahoma Statutes;

(2) Select a laboratory information system through a competitive bidding process pursuant to 74 O.S. 85.7 of the Oklahoma Statutes; or

(3) Collect samples from harvest batches that failed testing.

(e) The quality assurance laboratory may transport and transfer medical marijuana, medical marijuana concentrate, and medical marijuana product for testing between the originating medical marijuana business, the quality assurance laboratory, and other licensed medical marijuana testing laboratories pursuant to this section.

(f) The quality assurance laboratory shall comply with the provisions of the Oklahoma Medical Marijuana and Patient Protection Act when transporting samples of medical marijuana, medical marijuana concentrate, and medical marijuana product for testing between the originating medical marijuana business, the quality assurance laboratory, and other licensed medical marijuana testing laboratories pursuant to this section.

(g) Nothing in this section shall require the quality assurance laboratory to apply for and receive a license.

(h) The Authority shall submit an annual report to the Legislature on quality assurance activities and results.

SUBCHAPTER 9. WASTE DISPOSAL FACILITIES

442:10-9-3. License applications

(a) **Application fee**. An applicant for a waste disposal facility license, or renewal thereof, shall submit to the Authority a completed application on a form and in a manner prescribed by the Authority, along with the application fee as established in 63 O.S. § 420 et seq. and the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq.

(b) **Submission**. The application shall be on the Authority prescribed form and shall include the following information about the establishment:

(1) Name of the establishment;

(2) Physical address of the establishment, including the county in which any licensed premises will be located;

(3) GPS coordinates of the establishment;

(4) Phone number and email of the establishment;

(5) Hours of operation for any licensed premises;

(6) Type of waste facility; and

(7) Proposed number and location of additional waste disposal facilities associated with the applicant.

(c) **Individual applicant**. The application for a waste disposal facility license made by an individual on his or her own behalf shall be on the Authority prescribed form and shall include at a minimum:

(1) The applicant's first name, middle name, last name, and suffix if applicable;

(2) The applicant's residence address and valid mailing address;

(3) The applicant's date of birth;

(4) The applicant's telephone number and email address;

(5) An attestation that the information provided by the applicant is true and correct;

(6) An attestation that any licensed premises shall not be located on tribal lands; and

(7) A statement signed by the applicant pledging not to divert marijuana to any individual or entity that is not lawfully entitled to possess marijuana.

(d) **Application on behalf of an entity**. In addition to requirements of Subsection (c), an application for a waste facility license made by an individual on behalf of an entity shall include:

(1) An attestation that applicant is authorized to make application on behalf of the entity;

(2) Full name of organization;

(3) Trade name, if applicable;

(4) Type of business organization;

(5) Mailing address;

(6) Telephone number and email address; and

(7) The name, residence address, and date of birth of each owner and each member, manager, and board member, if applicable.

(e) **Supporting documentation**. ~~Each~~ Pursuant to 63 O.S. § 427.3(D)(11), 63 O.S. § 427.14(L), 63 O.S. § 427.14(G)(2), and 63 O.S. § 427.14(J), each application shall be accompanied by the following documentation:

(1) A list of all persons and/or entities that have an ownership interest in the entity;

(2) If applicable, a certificate of good standing from the Oklahoma Secretary of State;

(3) If applicable, official documentation from the Secretary of State establishing the applicant's trade name;

(4) An Affidavit of Lawful Presence for each owner;

(5) Proof that the proposed location of the waste disposal facility is a least one thousand (1,000) feet from a public or private school. The distance specified shall be measured from any entrance of the school to the nearest front entrance of the facility;

(6) Documents establishing the applicant, the members, managers, and board members, if applicable, and seventy-five percent (75%) of the ownership interests are Oklahoma residents as established in 63 O.S. § 420 et seq., and OAC 442:10-1-6 (relating to proof of residency);

(7) Proof of sufficient liability insurance. Liability insurance or a letter of insurability from the insurance company shall be provided by the applicant and shall apply to sudden and nonsudden bodily injury and property damage on, below, and above the surface of the facility. Such insurance shall be maintained for the period of operation of the facility during operation and after closing. Sufficient liability insurance means that the licensee shall maintain at all times insurance coverage with at least the following minimum limits:

(A) Commercial General Liability: $5,000,000.00 each occurrence;

(B) Pollution Legal Liability: $5,000,000.00 each occurrence;

(8) Relevant waste permit(s) from the Oklahoma Department of Environmental Quality or the Oklahoma Department of Agriculture; ~~and~~

(9) If applicable, all Certificate(s) of Occupancy, Final Inspection Report(s), and Site Plan(s), issued from or approved by the organization, political subdivision, office, or individual responsible for enforcing the requirements of all building and fire codes adopted by the Oklahoma Uniform Building Code Commission pursuant to OAC 748:20. Pursuant to 74 O.S. § 324.11, in all geographical areas

where the applicable Certificate(s) of Occupancy, Final Inspection Report(s), Site Plan(s) and/or permit(s) are not issued from and/or approved by local authorities, such documentation must be obtained from the Oklahoma Office of the State Fire Marshal; and

~~(9)~~ (10) Any further documentation the Authority determines is necessary to ensure the applicant is qualified under Oklahoma law and this Chapter to obtain a waste disposal facility license.

(f) **Incomplete application**. Failure to submit a complete application with all required information and documentation shall result in a rejection of the application. The Authority shall notify the applicant via email through the electronic application account of the reasons for the rejection.

442:10-9-7. Audits and inventory

(a) **Audits**. The Authority may perform on-site audits of all waste disposal facility licensees and permitted locations to ensure that all marijuana grown in Oklahoma is accounted for. Submission of an application for a medical marijuana waste disposal facility license constitutes permission for entry to any licensed premises and auditing of the licensee during hours of operation and other reasonable times. Refusal to permit the Authority entry or refusal to permit the Authority to inspect all books and records shall constitute grounds for administrative penalties, which may include, but is not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license or permit.

(1) The Authority may review any and all records and information of a waste disposal facility 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 Authority rules and applicable laws. Failure to make documents or other requested information available to the Authority and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/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) Waste disposal facility licensees shall comply with all written requests from the Authority to produce or provide access to records and information within ten (10) business days.

(3) If the Authority identifies a violation of the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., other applicable Oklahoma law, or these Rules during an audit of the licensee, the Authority 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 Authority may refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a waste disposal licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.

(5) If the Authority discovers what it reasonably believes to be criminal activity or other violations of Oklahoma law during an audit, the Authority 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 in the amount set forth in Appendix C for each violation and any other administrative action and penalty authorized by law.

(8) The Authority may assess fines in the amounts set forth in Appendix C and seek any other administrative penalties authorized by law against a licensee without providing opportunity to correct when the violation is not capable of being corrected.

(b) **Inventory tracking system.** Pursuant to 63 O.S. § 427.3(D)(8) and 63 O.S. § 427.13(B), each commercial licensee shall use the State inventory tracking system by inputting inventory tracking data required to be reported to the Authority directly into the State inventory tracking system or by utilizing a seed-to-sale tracking system that integrates with the State inventory tracking system. All commercial licensees must have an inventory tracking system account activated to lawfully operate and must ensure all

information is reported to the Authority accurately and in real time or after each individual sale in accordance with 63 O.S. § 427.13(B)(1) and these Rules. All commercial licensees shall ensure the following information and data are accurately tracked and timely reported to the Authority through the State inventory tracking system

(1) The chain of custody of all medical marijuana and medical marijuana products, including every transaction with another commercial licensee, patient or caregiver, including but not limited to:

(A) The name, address, license number and phone number of the medical marijuana business that cultivated, manufactured, sold, purchased, or otherwise transferred the medical marijuana or medical marijuana product(s);

(B) The type, item, strain, and category of medical marijuana or medical marijuana product(s) involved in the transaction;

(C) The weight, quantity, or other metric required by the Authority, of the medical marijuana or medical marijuana product(s) involved in the transaction;

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

(E) The total amount spent in dollars;

(F) All point-of-sale records as applicable;

(G) Transportation information documenting the transport of medical marijuana or medical marijuana product(s) as required under OAC 442:10-3-6(b);

(H) Testing results and information;

(I) Waste records and information;

(J) Marijuana excise tax records, if applicable;

(K) ~~RFID~~ Inventory tracking system tag number(s);

(2) The entire life span of a licensee's stock of medical marijuana and medical marijuana products, including, at a minimum, notifying the Authority:

(A) When medical marijuana seeds or clones are planted;

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

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

(D) When medical marijuana changes form, including, but not limited to, when it is planted, cultivated, processed, and infused or otherwise processed into a final ~~form~~ product or final form;

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

(3) Any further information the Authority determines is necessary to ensure all medical marijuana and medical marijuana products are accurately and fully tracked throughout the entirety of the life span of the plant and product.

(c) **Seed-to-sale tracking system.** A commercial licensee shall use a seed-to-sale tracking system or integrate its own seed-to-sale tracking system with the State inventory tracking system established by the Authority. If a commercial licensee uses a seed-to-sale tracking system that does not integrate with the State inventory tracking system, or does integrate but does not share all required information, the commercial licensee shall ensure all required information is reported directly into the State inventory tracking system.

(d) **Inventory tracking system requirements.**

(1) At a minimum, commercial licensees shall track, update and report its inventory after each individual sale to the Authority in the State inventory tracking system.

(2) All commercial licensees must ensure all on-premises and in-transit medical marijuana and medical marijuana product inventories are reconciled each day in the State inventory tracking system at the close of business, if not already done.

(3) Commercial licensees are required to use ~~RFID~~ inventory tracking system tags from an Authority-approved supplier for the State Inventory Tracking System. Each Licensee is responsible for the cost of all ~~RFID~~ inventory tracking system tags and any associated vendor fees.

(A) A commercial licensee shall ensure its inventories are properly assigned to medical marijuana, medical marijuana products, and medical marijuana waste as required by the Authority.

(B) A commercial licensee shall ensure it has an adequate supply of ~~RFID~~ inventory tracking system tags at all times. If a commercial licensee is unable to account for unused ~~RFID~~ inventory tracking system tags, the commercial licensee must report to the Authority and the State inventory tracking system vendor within forty-eight (48) hours.

(C) ~~RFID~~ Inventory tracking system tags must contain the legal name and correct license number of the commercial licensee that ordered them. Commercial licensees are prohibited from using another licensee's ~~RFID~~ inventory tracking system tags.

(D) ~~Prior to a plant reaching a point where it is able to support the weight of the RFID tag and attachment strap, the RFID tag may be securely fastened to the stalk or other similarly situated position approved by the Authority.~~ The inventory tracking system tag shall be placed on the container holding the medical marijuana plant and must remain physically near and clearly associated with the medical marijuana plant until the plant reaches twelve (12) inches in height. Clones must be tracked in the state seed-to-sale system and must be associated with a wholesale package tag, whether cut from a mother plant or transferred from another licensee, prior to reaching twelve (12) inches in height.

(E) When the plant ~~becomes able to support the weight of the RFID tag, the RFID~~ reaches twelve (12) inches in height, the inventory tracking system tag shall be securely fastened to a lower supporting branch. The ~~RFID~~ inventory tracking system tag shall remain affixed for the entire life of the plant until disposal. If the plant changes forms, is removed from the original planting location after harvest, or is being trimmed, dried, or cured by the grower, the inventory tracking system tag shall be placed on the container holding the medical marijuana plants and/or must remain physically near and clearly associated with the medical marijuana plants until the plant is placed into a package in both the seed-to-sale tracking system and physically packaged and affixed with the inventory tracking system tag.

(F) Mother plants must be tagged before any cuttings or clones are generated therefrom.

(G) If ~~a RFID~~ an inventory tracking system tag gets destroyed, stolen, or falls off of a medical marijuana plant, the licensee must ensure a new ~~RFID~~ inventory tracking system tag is placed on the medical marijuana plant and the change of the ~~RFID~~ inventory tracking system tag is properly reflected in the State inventory tracking system.

(H) Commercial licensees shall not reuse any ~~RFID~~ inventory tracking system tag that has already been affixed to any regulated medical marijuana or medical marijuana products.

(4) Each wholesale package of medical marijuana must have ~~a RFID~~ an inventory tracking system tag during storage and transfer and may only contain one harvest batch of medical marijuana.

(5) Prior to transfer, commercial licensees shall ensure that each immature plant is properly affixed with an ~~RFID~~ inventory tracking system tag if the plant was not previously tagged in accordance with these Rules.

(6) Commercial licensees' inventory must have ~~a RFID~~ an inventory tracking system tag properly affixed to all medical marijuana products during storage and transfer in one of the following manners:

(A) Individual units of medical marijuana products shall be individually affixed with ~~a RFID~~ an inventory tracking system tag; or

(B) Marijuana products may only be combined in a single wholesale package using one ~~RFID~~ inventory tracking system tag if all units are from the same production batch.

(7) If any medical marijuana or medical marijuana products are removed from a wholesale package, each individual unit or new wholesale package must be separately tagged.

(8) All packages of medical marijuana waste shall have ~~a RFID~~ an inventory tracking system tag affixed and the contents of the waste package shall be reported in the State inventory tracking system.

(e) **Inventory tracking system administrators and users.**

(1) The inventory tracking system administrator must attend and complete all required inventory tracking system training.

(2) If at any point, the inventory tracking system administrator for a licensee changes, the commercial

licensee shall change or assign a new inventory tracking system administrator within thirty (30) business days.
(3) Commercial licensees shall maintain an accurate and complete list of all inventory tracking system administrators and employee users.
(4) Commercial Licensees shall ensure that all owners and employees that are granted inventory tracking system account access for the purpose of conducting inventory tracking functions are trained and authorized before the owners or employees may access the State inventory tracking system.
(5) All inventory tracking system users shall be assigned an individual account in the State inventory tracking system.
(6) Any individual entering data into the State inventory tracking system shall only use the inventory tracking system account assigned specifically to that individual. Each inventory tracking system administrator and inventory tracking system user must have unique log-in credentials that shall not be used by any other person.
(7) Within three (3) business days, commercial licensees must remove access for any inventory tracking system administrator or user from their accounts if any such individual no longer utilizes the State inventory tracking system or is no longer employed by the commercial licensee.

(f) **Loss of access to State inventory tracking system**. If at any time a commercial licensee loses access to the State inventory tracking system due to circumstances beyond the commercial licensee's control, the commercial licensee shall keep and maintain records detailing all inventory tracking activities that were conducted during the loss of access. Once access is restored, all inventory tracking activities that occurred during the loss of access must be immediately entered into the State inventory tracking system. If a commercial licensee loses access to the inventory tracking system due to circumstances within its control, the commercial licensee may not perform any business activities that would be required to be reported into the State inventory tracking system until access is restored and reporting is resumed; any transfer, sale, or purchase of medical marijuana or medical marijuana products would be an unlawful sale.

SUBCHAPTER 11. PROCESS VALIDATION

442:10-11-1. Standards and requirements to achieve process validation

(a) Purpose. The Authority is authorized to establish process validation requirements. Process validation shall be voluntary, and no licensee shall be required to validate their process.

(b) Definitions. The following words and terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Certified Process Validation Testing Laboratory" means a testing laboratory certified by the Authority to conduct testing and research on samples of medical marijuana and medical marijuana products for medical marijuana businesses pursuing or operating under process validation.

"Process change" means any alteration or modification to a process that previously underwent process validation and has the potential to affect the quality, safety, or integrity of a final product. This includes, but is not limited to, changes in raw material sources or suppliers, alterations in equipment type, scale, or location, modifications in process parameters, methods, or procedures, implementation of new technologies or techniques, changes in the facility or environment where the process occurs, or alterations in the sequence, duration, or conditions of process steps.

"Process validated" means a licensed medical marijuana business operating in accordance with this Subchapter.

"Process validation" means the documented data and objective evidence that a particular process, when operated according to standard operating procedures, will consistently produce medical marijuana and medical marijuana products that meet predetermined quality attributes and specifications and are adequate for an intended use.

"Process Validation Report" means a document that provides a detailed account of the approach, intentions, and activities to be conducted during a validation activity and the results and findings from a

validation activity.

"Process validation self-assessment" means a systematic evaluation tool provided by the Authority, designed to allow medical marijuana businesses to assess and quantify their adherence to the requirements in this Subchapter.

"Process verification" means the continual and documented monitoring, evaluation, and/or assessment of whether or not a particular process complies with these Rules and a medical marijuana licensee's standard operating procedures.

"Standard operating procedures" or **"SOPs"** means written procedures produced by a medical marijuana licensee that provides detailed instructions on how to perform activities to ensure consistency, quality, and safety of medical marijuana and medical marijuana products and demonstrates compliance with Oklahoma law and these Rules.

(c) General requirements. Licensees seeking to achieve process validation and licensees maintaining process validation must meet the ongoing requirements listed below.

(1) Applicable laws apply. Licensees must comply with all requirements of Oklahoma law and these Rules in addition to any additional requirements to operate under process validation.

(2) Seed to sale tracking system. All licensees must track their marijuana and marijuana product inventory with the Authority's designated seed-to-sale system. This requirement for compliance with the seed-to-sale system shall be mandatory for licensees seeking to achieve process validation whether or not compliance with a seed-to-sale system is mandatory for all licensees.

(3) Initial requirements to achieve process validation. Licensees seeking to achieve process validation must submit every harvest batch or production batch for testing to a Certified Process Validation Testing Laboratory and must successfully pass all required testing with no failures over a three (3) month period.

(4) Ongoing requirements to maintain process validation. Licensees maintaining process validation must continue to submit every harvest batch or production batch for testing to a Certified Process Validation Testing Laboratory and must successfully pass all required testing with no failures. Any testing failures under process validation will require the licensee to revalidate the process. Licensees shall immediately notify the Authority in the manner and form prescribed by the Authority on its website and shall submit a copy of the COA to the Authority within two (2) business days. Further, the licensee must perform and document a corrective action and preventative action (CAPA) investigation to determine the root cause of the failure. The report shall be made available to the Authority upon request.

(5) Process validated laboratory. Licensees seeking to achieve process validation and licensees maintaining process validation must use and report results from a laboratory that is certified as a Certified Process Validation Testing Laboratory.

(6) Required programs and standard operating procedures. Licensees must utilize a Quality Management System (QMS) based on consensus standards generated by entities such as ASTM International or the International Organization for Standardization (ISO) relevant to this process validation program. Licensees seeking to achieve process validation and licensees maintaining process validation shall implement, document, and adhere to the following programs as part of the licensee's standard operating procedures:

(A) Implement and maintain a Quality Management System (QMS) documented in a quality manual that outlines the medical marijuana licensee's commitment to quality and serves as a reference guide for all quality-related activities focused on ensuring consistency in medical marijuana and medical marijuana product quality.

(i) A formal quality policy statement expressing the organizational commitment to quality;

(ii) Specific, measurable quality objectives aligned with the quality policy, aiming

to ensure continuous improvement in product quality and operational efficiency;
(iii) A clear depiction of the organizational hierarchy, detailing roles and responsibilities related to quality management and process validation;
(iv) Procedures for an annual management review meeting to assess the effectiveness of the quality management system, discuss any non-conformities, and set directions for future improvements; and
(v) Mechanisms for identifying opportunities for improvements, implementing changes, and monitoring their effectiveness.

(B) Employee training program, including, but not limited to:
(i) A structured program that ensures all employees are adequately trained on their specific roles, quality principles, hygiene and sanitation practices, and any other relevant topics;
(ii) Initial and annual ongoing training requirements for all employees that at a minimum, include training on specific job responsibilities, emergency response and safety protocols, all the programs described in these Rules, and any other training required by these Rules;
(iii) Procedures for evaluating training to gauge the effectiveness of the training, including, but not limited to, training quizzes and shadowing by trained employees; and
(iv) Documentation of all training sessions, including attendees, trainers, topics covered, and date of training.

(C) Recordkeeping, record retention, and document control program including, but not limited to:
(i) A master list of documents related to process validation, including, but not limited to, document titles, version numbers, and dates of revision for all documents;
(ii) Procedures for accurately maintaining all records and documents related to product quality and compliance with these Rules, ensuring they are easily retrievable, and protected from unauthorized alterations;
(iii) Procedures for approving documents;
(iv) Defined retention periods for record retention for each type of record, indicating compliance with Oklahoma law and these Rules;
(v) Protocols and naming conventions for naming documents to ensure consistency and ease of identification; and
(vi) Procedures for document revisions and tracking document versions, ensuring that only the latest and approved version is in use.

(D) Disease and foreign material control program, including, but not limited to:
(i) Detailed policies on personal hygiene, including but not limited to, handwashing, grooming, and attire for employees and visitors;
(ii) Procedures for the use of personal protective equipment for employees and visitors;
(iii) Protocols for employees to report illnesses, ensuring they are relieved from duties that might risk contamination; and
(iv) Implemented measures to prevent contamination from foreign materials, including, but not limited to, regular inspections, use of sieves/filters, and metal detectors.

(E) Equipment program, including, but not limited to:
(i) A master list of equipment;
(ii) A defined system for equipment identification;
(iii) Equipment calibration protocols, including frequency of calibrations;

(iv) Equipment installation protocols, including documented procedures and appropriate records for verifying the equipment against the manufacturer's specifications including, but not limited to, model, capacity, checking for the presence and completeness of all equipment components and accessories, ensuring the equipment is installed in an appropriate environment including, but not limited to, clean and temperature-controlled, confirming that all necessary utility connections including, but not limited to, electrical and water are available and correctly set up, reviewing and storing equipment manuals, schematics, and installation instructions, and documenting any deviations or issues identified during installation and their resolutions;

(v) Operational check protocols, including procedures and appropriate records for verifying that all safety features and alarms are functional, testing the equipment under different settings to ensure it operates within the defined limits, confirming that the equipment can achieve and maintain required operational parameters including, but not limited to, temperature and pressure, documenting the equipment's response to potential failures or interruptions including, but not limited to, power outage, and recording any deviations or inconsistencies in operation and their resolutions;

(vi) Performance verification protocols, including procedures and appropriate records for running the equipment using actual or simulated materials to mimic real production scenarios, monitor and document key output parameters to ensure they meet the required specifications including, but not limited to, weight, conducting repeated runs to verify the consistency of the equipment's performance over time, and documenting any deviations in performance and their resolutions;

(vii) Equipment preventive maintenance and repair protocols with a preventive maintenance schedule; and

(viii) Documentation of all equipment-related activities.

(F) Sanitation program, including but not limited to:

(i)The cleaning and sanitation procedures for all equipment, tools, and facilities to ensure that all areas are free from potential contaminants and operate under hygienic conditions;

(ii) A defined frequency for cleaning and sanitation tasks;

(iii) A list of approved cleaning agents and sanitizers; and

(iv) Protocols for cleaning verification and validation.

(G) Environmental monitoring program that describes a system to regularly monitor and document environmental conditions to ensure conditions remain appropriate and consistent, including, but not limited to:

(i) Procedures for regular monitoring of environmental conditions such as temperature, humidity, and potential contaminants, including frequency of monitoring;

(ii) Use of calibrated instruments for monitoring, with defined frequency for calibration;

(iii) Defined environmental monitoring alert limits and environmental monitoring action limits to indicate there may be something going wrong within the environment that are based on trend analysis, risk assessment, standards, and/or regulatory requirements in these Rules. For the purposes of this section, "environmental monitoring action limit" means a predetermined threshold that signifies a process has deviated from its accepted operating range and corrective action(s) must be taken and documented to restore the process to its normal state. For the purposes of this section, "environmental monitoring alert limit" means a

predetermined threshold that serves as an early indication of a drift from normal environmental conditions, which, when exceeded, results in increased attention;
(iv) Procedures for corrective actions when alert or action limits are exceeded; and
(v) Documentation and trending of environmental monitoring data.

(H) Supplier qualification program, including, but not limited to:
(i) Procedures for initial assessment and approval of suppliers, including, but not limited to, audits, sample testing, and regular reviews of supplier performance, to meet the medical marijuana business's quality specifications and comply with these Rules;
(ii) Defined criteria and frequency for evaluating suppliers' quality systems and historical performance; and
(iii) Documentation of supplier performance and any corrective actions taken when supplier issues arise.

(I) Raw materials, ingredients, and final product qualification program, including, but not limited to:
(i) Protocols for inspecting and testing raw materials and ingredients upon receipt, as well as the final product before transfer;
(ii) Defined quality attributes and specifications for raw materials, ingredients, and final products;
(iii) Procedures for quarantine, approval, or rejection of raw materials, ingredients, and final products; and
(iv) Documentation of all inspections, tests, and decisions.

(J) Corrective and preventive action (CAPA) program that provides a systematic approach to investigate, address, and prevent issues related to product quality or safety, including, but not limited to:
(i) Procedures to identify, document, and address quality or safety issues;
(ii) Description of root cause analysis techniques that may be used to determine underlying causes of issues;
(iii) Defined procedures for implementing corrective actions and verifying their effectiveness to ensure that corrective actions prevent recurrence; and
(iv) Documentation and trending of all CAPA activities.

(K) Batch records program, including, but not limited to:
(i) Procedures for each stage of production or processing;
(ii)Traceability records for raw materials and ingredients used in each batch;
(iii) Procedures for reviewing and approving batch records; and
(iv) Procedures for archiving and retrieving batch records.

(L) Packaging and labeling program, including, but not limited to:
(i) Detailed step-by-step procedures for packaging and labeling and verifying packaging and labeling to ensure that final products are packaged under sanitary conditions and the labels provide accurate, compliant information that adheres to these Rules; and
(ii) Procedures for label control, including but not limited to storage, issuance, and reconciliation.

(M) Waste program, including, but not limited to:
(i) Defined categories of waste, including but not limited to waste disposal requirements of Oklahoma law and these Rules;
(ii) Protocols for segregating, storing, and disposing of waste, minimizing contamination risks, and ensuring compliance with these Rules;
(iii) Procedures for treating or decontaminating waste, if applicable; and
(iv) Documentation of all waste disposal including but not limited to documents

from licensed medical marijuana waste disposal facilities, disposal logs required under OAC 442:10-5-10, and authorized industrial waste disposal entities.

(N) Storage program, including, but not limited to:

(i) Protocols for ensuring compliance with these Rules and the proper storage of raw materials, chemicals, ingredients, in-process products, final products, and retained samples. This shall include temperature and humidity controls, where appropriate, approaches to protect stored materials and products from contaminants, and approaches to minimize safety hazards;

(ii) Protocols for stock rotation, such as First In, First Out (FIFO) and First Expired, First Out (FEFO); and

(iii) Measures to protect stored items from contamination, pests, and theft.

(O) Transport and shipping program, including, but not limited to:

(i) Procedures to ensure products are transported under conditions that maintain their quality, safety, and compliance with these Rules. This shall include considerations for temperature control, protection from contamination, and secure packaging;

(ii) Use of validated shipping containers or systems; and

(iii) Documentation of transport and shipping, including any deviations or issues.

(7) Process Validation Report. Licensees shall annually submit to the Authority a detailed Process Validation Report outlining the approach, intentions, and activities conducted during process validation and any results and findings. The Process Validation Report shall include, but is not limited to, the following:

(A) Introduction, including, but not limited to, the purpose of the process validation, a brief description of the processes being validated, and the scope of the process validation;

(B) Process validation team, including the list of employees involved in the process validation and their roles and responsibilities;

(C) Equipment, including, but not limited to, a list of equipment and instruments used and calibration and maintenance records for equipment;

(D) Process descriptions, including, but not limited to, detailed step-by-step description of each process that is required to produce final products. This includes, but is not limited to, all the processes within the programs described in this subchapter;

(E) Protocol, including, but not limited to, pre-defined criteria and methods for conducting process validation, sampling plans, including sample size, sampling points, and frequency, and acceptance criteria for each validation activity, prescribed by these Rules and the medical marijuana business's standard operating procedures;

(F) Results, including, but not limited to, detailed results from each validation activity, data, graphs, charts, and/or other relevant evidence, comparison of results against acceptance criteria;

(G) Deviations and corrective actions, including, but not limited to, a list of deviations, nonconformances, or anomalies observed during validation activities, root cause analysis for each deviation, corrective actions taken, and their outcomes;

(H) Risk assessment, including, but not limited to, a list of identified sources of potential risks from equipment, chemicals, work processes, human behaviors, or other sources, an evaluation of the likelihood each risk will lead to harm and the severity of the impact if the risk could lead to harm, a list of implemented measures to eliminate or reduce the risk, and procedures for how these measures will be monitored, recorded, and reviewed for continuous improvement;

(I) Quality attributes and specifications, including, but not limited to, references to where the medical marijuana business's quality attributes and specifications are listed in their

standard operating procedures and examples of actual results from approved raw materials, ingredients, and final products compared with specifications. Specifications serve as the criteria that describe the acceptable limits for the quality attributes. For the purposes of this section, "quality attributes" means the desired physical, chemical, biological, or microbiological properties or characteristics medical marijuana and medical marijuana products should have to ensure quality. For the purposes of this section, "specification" means any requirement with which a process, ingredient, medical marijuana, or medical marijuana product must conform, including but not limited to, the requirements set forth in these Rules and those written in a medical marijuana licensee's standard operating procedures;

(J) Process verification, including, but not limited to, procedures for how the medical marijuana business will conduct process verification activities along with their frequency, monitoring parameters, and acceptance criteria;

(K) Conclusion, including, but not limited to, a summary of the process validation results, a statement on whether the processes were successfully validated, and plans for any improvements or changes, if applicable;

(L) Attachments, including, but not limited to, raw data, calibration certificates, equipment manuals, testing results, and other relevant documents that supply information and evidence of process validation; and

(M) Approval and sign-off, including signatures of the validation team and management with dates confirming the accuracy and completeness of the report.

(8) Process validation self-assessment or third-party good manufacturing practices certification. Licensees must submit annually to the Authority at least one of the following:

(A) A process validation self-assessment, provided by the Authority, to determine the licensee's compliance with process validation requirements. For successful completion of the process validation self-assessment, licensees must achieve a score indicating eighty percent (80%) adherence or higher, in addition to adhering to the other requirements in this subchapter. The process validation self-assessment shall be submitted with any new or renewal process validation applications and must detail any corrective and preventive action taken or planned and any areas of non-compliance, if identified

(B) A Good Manufacturing Practices certification document from a certification body that is ISO 17021-1:2015 or ISO 17065:2012 accredited, recognized by the International Accreditation Forum (IAF), and approved by the Authority. The certification document shall be submitted with the audit report, the medical marijuana licensee's responses to deficiencies, and associated corrective and preventive action documentation, if applicable.

(d) Application.

(1) Application fee. The nonrefundable, annual registration fee of Five Thousand Dollars ($5,000.00) per licensee is in addition to any other fees due by the licensee.

(2) Submission. Applications for a licensee to achieve process validation shall be on the Authority prescribed form and shall include the following information about the licensee:

(A) Name of the establishment;

(B) Physical address of the establishment, including the county in which any licensed premises will be located;

(C) GPS coordinates of the establishment;

(D) Phone number and email of the establishment; and

(E) Hours of operation for any licensed premises.

(3) Supporting documentation. Each application for process validation shall be accompanied by the following documentation:

(A) Accreditation documentation, including documentation of enrollment in analyte specific proficiency testing results, showing applicants meet requirements stated in these Rules;
(B) Standard operating procedures, policies, protocol or procedures for receipt, handling, and disposition of samples of usable marijuana, as well as documented proof of required programs and standard operating procedures required by this subchapter;
(C) Documented compliance with required programs and standard operating procedures pursuant to OAC 10-11-1(c)(6);
(D) Process Validation report;
(E) Process validation self-assessment or third-party good manufacturing practices certification;
(F) If applicable, reference standards, sample analysis procedures, and documentation demonstrating that the analytical methods used by the laboratory are appropriate for their intended purpose;
(G) Policies for data recording, review, storage, and reporting and record retention requirements; and
(H) Any further documentation or information the Authority determines is necessary to ensure the applicant is qualified under Oklahoma law and these Rules.

(4) Incomplete application. Failure to submit a complete application with all required information and documentation shall result in a rejection of the application. The Authority shall notify the applicant via email through the electronic application account of the reasons for the rejection.

(e) Record retention requirements. Licensees must establish document retention policies and shall keep all records and documents related to their process validation ready and accessible at the address listed on their marijuana business license for inspection or audit by the Authority.

(1) Records shall be maintained by the licensee for as long as the licensee is continuing to operate under that validated process.

(2) Licensees shall retain all such documents and records for at least four (4) years after the licensee has stopped using the validated process or after the licensee has made a significant process change to a validated process. Any significant process change to the validated processes of a licensee is subject to the same document retention requirements and shall be retained for as long as the significant process change is part of an ongoing validated process, and for at least four (4) years after the licensee has stopped using the validated process or after the licensee has made a subsequent significant process change to the validated process.

(3) 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 in writing by the medical laboratory director.

(f) Biannual inspections.

(1) Submission of an application to operate under process validation constitutes permission for entry to and inspection of any licensed premises and any vehicles on the licensed premises used for the transportation of medical marijuana and medical marijuana products during hours of operation and other reasonable times. Refusal to permit or impeding such entry or inspection shall constitute grounds for administrative penalties, which may include but are not limited to fines as set forth in Appendix C and the nonrenewal, suspension, and/or revocation of a license.

(2) Licensees shall be subject to biannual inspections by the Authority that include random testing of products being produced under process validation. The Authority shall obtain the random sample during the biannual inspections and take samples to the quality assurance laboratory. The Authority shall have access to all products being produced or grown under process validation.

(3) The Authority may review any and all records of a licensee and may require and conduct interviews with such persons or entities and persons affiliated with such entities, for the purpose of determining compliance with Authority Rules and applicable laws. Failure to make documents or other requested information available to the Authority and/or refusal to appear or cooperate with an interview shall constitute grounds for administrative penalties, which may include, but are not limited to, fines as set forth in Appendix C and the denial, nonrenewal, suspension, and/or revocation of a license. All records shall be kept on-site and readily available.

(g) Certified Process Validation Testing Laboratory. A testing laboratory may apply to be certified as a Certified Process Validation Testing Laboratory to conduct testing for licensees pursuing or operating under process validation.

(1) **Accreditation.** Testing laboratories seeking to be a Certified Process Validation Testing Laboratory must be accredited by or 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. Accreditation or application for accreditation must be from one of these entities in both chemistry and biology or cannabis.

(2). Laboratories seeking to become a certified Process Validation Testing Laboratory must, in addition to all other requirements to achieve and maintain process validation required under this subchapter, Oklahoma law and these Rules:

(A) Conform to ASTM International Standard D8244-21a: Standard Guide for Analytical Laboratory Operations Supporting the Cannabis/Hemp Industry and demonstrate conformance by submitting at least one of the following:

(i) A Certified Process Validation Testing Laboratory self-assessment, provided by the Authority, to determine the licensee's percentage of compliance with ASTM International Standard D8244-21a. For successful completion of the self-assessment, a testing laboratory must achieve a score indicating eighty percent (80%) adherence or higher, in addition to adhering to the other requirements in Oklahoma law and these rules. The self-assessment shall be submitted with associated documentation detailing any corrective and preventive action taken or planned, if areas of non-compliance are identified.

(ii) A certification document demonstrating conformance to ASTM International Standard D8244-21a from a certification body that is ISO 17021-1:2015 accredited and approved by the Authority. The certification document shall be submitted with the audit report, the testing laboratory's responses to deficiencies, and associated corrective and preventive action documentation, if applicable.

(B) Follow ASTM International's D8282-19: Standard Practice for Laboratory Test Method Validation and Method Development to validate test methods that will be used to test samples of final products produced under process validation.

(C) At a minimum, pass five (5) consecutive blind proficiency tests administered by the quality assurance laboratory without a failure over the course of six (6) months.

(h) Revocation of process validation certification. The Authority may revoke the certification of licensees to operate under process validation or revoke the certification of a testing laboratory that is seeking to operate or operating as a Certified Process Validation Testing Laboratory.

(i) Surrender of process validation certification. A licensee operating under process validation may voluntarily surrender their authority to operate under process validation to the Authority at any time. If a licensee voluntarily surrenders their certification to operate under process validation, the licensee shall:

(A) Submit on a form prescribed by the Authority a report to the Authority including the reason for surrendering their certification to operate under process validation; the effective date of surrendering

their certification to operate under process validation; and where all records required under this subsection will be retained;

(B) Submit proof of the licensee's identity through submission of documentation identified in OAC 442:10-1-7 (relating to Proof of Identity); and

(C) Comply with all appliable requirements of Oklahoma law and these Rules as it relates to medical marijuana businesses not seeking or operating under process validation.

(j) Penalties. A licensee's failure to timely comply with the provisions of this subsection and/or provide required information and documentation to the Authority may result in revocation, suspension, and monetary penalties, in addition to any other penalties established by Oklahoma law and these Rules.

(1) Punishment for violations of process validation that, at a minimum, would prohibit a licensee from operating under process validation for five (5) years and the assessment of a fine not to exceed Fifty Thousand Dollars ($50,000.00). Any such fine levied against a licensee found to have violated the laws or rules of process validation shall be remitted to the Department of Mental Health and Substance Abuse Services,

(2) If an adulterated product that was produced under process validation fails testing and the batch or lot has been sold to a dispensary,

(A) A first violation shall be the assessment of a fine not to exceed Ten Thousand Dollars ($10,000.00) and a public recall of the product. The licensee shall further be required to revalidate the process.

(B) A second violation within two (2) years of a previous violation shall be the assessment of a fine not to exceed Seventy-five Thousand Dollars ($75,000.00) and a public recall of the product. The licensee shall further be prohibited from utilizing process validation for a minimum of five (5) years.

(C) A third violation within two (2) years of a previous violation shall be the assessment of a fine of Two Hundred Fifty Thousand Dollars ($250,000.00) and a public recall of the product. The licensee shall further be prohibited from utilizing process validation,

(3) Any willful violation of process validation shall result in:

(A) A first willful violation of process validation shall result in the assessment of a fine of Two Hundred Fifty Thousand Dollars ($250,000.00) and a license revocation hearing.

(B) A second willful violation of process validation shall result in the assessment of a fine of One Million Dollars ($1,000,000.00) and a hearing to permanently revoke the license.

(4) Punishment for violations by a Certified Process Validation Testing Laboratory that has been found to have been falsifying data, providing misinformation, or any unethical practices related to process validation at a minimum shall prohibit a licensee from operating under process validation for up to twenty- five (25) years and the assessment of a fine not to exceed One Million Dollars ($1,000,000.00). Any such fine levied against a licensee shall be remitted to the Authority for deposit into the Oklahoma Medical Marijuana Authority Revolving Fund. In addition to this fine, in response to a finding of a willful violation of process validation by the Authority, the Authority shall also be authorized to collect, levy, or impose any other fee, fine, penalty, or action as allowed by law.

APPENDIX A. TESTING THRESHOLDS [REVOKED]

APPENDIX B. LQC RESULTS [REVOKED]

APPENDIX C. SCHEDULE OF FINES [REVOKED]
APPENDIX C. SCHEDULE OF FINES [NEW]

OFFENSE	FINE AMOUNT	Citation
Failure to carry copy of both transporter license and transporter agent license while transporting medical marijuana or medical marijuana products	$50 per violation – transporter agent $500 per violation – commercial transporter, grower, processor, or dispensary	OAC 442:10-3-1(e)-(f); 63 O.S. § 427.16(E)
Unauthorized individual in vehicle transporting marijuana	$1,000 per violation	OAC 442:10-3-1(e)-(f)
Recordkeeping violations	$500 per violation	OAC 442:10-3-2(c); OAC 442:10-3-6; OAC 442:10-4-5; OAC 442:10-5-5(b); OAC 442:10-5-6; OAC 442:10-5-10(b); OAC 442:10-7-1(c); OAC 442:10-8-1(h); OAC 442:10-8-1(i)(7)(D); OAC 442:10-8-1(k)(4)(C); OAC 442:10-8-2(g); OAC 442:10-8-2(h); OAC 442:10-8-2(i); OAC 442:10-8-3(a); OAC 442:10-8-3(c)(5); OAC 442:10-9-6(c); OAC 442:10-9-6(d); OAC 442:10-9-6(e)

Failure to ensure information and records in OMMA online account are complete, accurate, and updated in timely manner	$500 per violation	OAC 442:10-4-1.1(7); OAC 442:10-4-2(e); OAC 442:10-5-1.1(7); OAC 442:10-5-2(e)
Refusal to permit Authority access to licensed premises	$5,000 per violation	OAC 442:10-4-4(a); OAC 442:10-5-4(a); OAC 442:10-9-5(a); 63 O.S. § 427.6(E)(7)
Failure to make documents or other requested information available to the Authority	$500 per violation	OAC 442:10-4-5(c)&(e); OAC 442:10-5-4(g); OAC 442:10-5-6(b)&(e); OAC 442:10-9-5(g); OAC 442:10-9-7(a); 63 O.S. § 427.6(E)(7)
Failure to appear for or cooperate with an interview	$500 per violation	OAC 442:10-4-4(f); OAC 442:10-4-5(e); OAC 442:10-5-4(g); OAC 442:10-5-6(e)(1); OAC 442:10-9-5(g)(1); OAC 442:10-9-7(a)(1)
Failure to maintain documents onsite and readily accessible	$500 per violation	OAC 442:10-4-4(f); OAC 442:10-4-5(c); OAC 442:10-4-5(e)(1); OAC 442:10-5-4(g); OAC 442:10-5-6(b); OAC 442:10-5-6(e)(1); OAC 442:10-9-5(g); OAC 442:10-9-7(a)(1); 63 O.S. § 427.6(B)(3)
Inventory tracking violations	$500 per violation	OAC 442:10-4-5; OAC 442:10-5-6; OAC 442:10-9-7(b); 63 O.S. § 427.13.

Unlawful purchase, sale, or transfer	$5,000 – First violation $15,000 – Each subsequent violation	OAC 442:10-4-6(c); OAC 442:10-5-6.1(c); 63 O.S. § 427.6(G).
Monthly report violations	$500 per violation	OAC 442:10-5-6.1(a); 63 O.S. §§ 421-423
Inaccurate reporting	$5,000 - first violation $10,000 – Each subsequent violation	OAC 442:10-5-6.1(b); 63 O.S. § 427.6(G)
Packaging & labeling violations	$500 per violation	OAC 442:10-5-8(d); OAC 442:10-7-1; OAC 442:10-7-2; 63 O.S. § 427.18
Failure to notify the Authority of actual loss, theft, and/or diversion	$1,000 per violation	OAC 442:10-5-13; 63 O.S. § 427.6(E)(5)
Prohibited onsite consumption of alcohol	$500 per violation	OAC 442:10-5-16(a)
Prohibited onsite smoking/vaping of medical marijuana	$500 per violation	OAC 442:10-5-16(a)
Employment of persons younger than 18	$500 per violation	OAC 442:10-5-16(b)

Delivery of medical marijuana or medical marijuana products to patients	$1,000 per violation	OAC 442:10-5-16(c)
Physician located in or providing medical services to patients at the same physical address of dispensary	$1,000 per violation	OAC 442:10-5-16(d)
Falsification or misrepresentations on any documents, forms, or other materials or information submitted to the Authority	$5,000 per violation	OAC 442:10-5-16(g)
Threatening or harming a patient, medical practitioner, or employee of the Authority	$5,000 per violation	OAC 442:10-5-16(h)
Failure to adhere to acknowledgment, verification, or other representation made to Authority	$1,000 per violation	OAC 442:10-5-16(i)
Possession, sale, or transfer of medical marijuana products by a grower	$1,000 – First violation $5,000 – Each subsequent violation	OAC 442:10-5-16(j)
Use of extraction equipment or processing utilizing butane, propane, carbon dioxide, or other potentially hazardous material in residential property	$5,000 per violation	OAC 442:10-5-16(k)

Acceptance, purchase, sale, or transfer of improperly packaged or labeled medical marijuana or medical marijuana product by a business licensee	$500 per violation	OAC 442:10-7-1 (b); 63 O.S. § 427.18(B)
Advertising violations	$500 per violation	OAC 442:10-7-3; 63 O.S. § 427.21
Use or sale or other transfer of medical marijuana or medical marijuana products exceeding allowable testing thresholds	$1,000 – First violation $5,000 – Each subsequent violation	OAC 442:10-8-1(d); 63 O.S. § 427.17(V)
Failure to assist Authority in a recall	$5,000 per violation	OAC 442:10-8-1(g)
Reporting test result for testing outside scope of accreditation	$1,000 per violation	OAC 442:10-8-2(b)
Improper influencing of testing process, improper manipulation of data, or improper benefit by a testing laboratory employee, owner, or agent	$5,000 per violation	OAC 442:10-8-2(d); 63 O.S. § 427.17(M)
Improper manipulation of test systems, including but not limited to, quality control, calibration data, and test validation.	$5,000 per violation	OAC 442:10-8-2(d); 63 O.S. § 427.17(M)

Testing performed by unqualified personnel	$1,000 per violation	OAC 442:10-8-2(f); 63 O.S. § 427.17(N)(10)
Operation of licensed testing laboratory without medical laboratory director onsite	$1,000 per violation	OAC 442:10-8-2(f)
Any inspection or audit violation not specifically listed above	$500 per violation	63 O.S. § 427.6(E)-(F)
Diversion to an unauthorized minor	$2,500 – First violation $5,000 and termination of license – Each subsequent violation	63 O.S. § 427.6(I)
Any other violation not listed above for which disciplinary action can be taken under 63 O.S. § 427.6(E)	$500 per violation	63 O.S. § 427.6(E)-(F)
Diversion for value by a patient or caregiver to an unauthorized person	$400 – First violation $1,000 and revocation of license – Each subsequent violation	OAC 442:10-2-9(a); OAC 442:10-2-9(b); 63 O.S. § 427.6(H)
Sharing less than three (3) grams of medical marijuana with an unauthorized person without transfer for value	$400	OAC 442:10-2-9(a); OAC 442:10-2-9(b); 63 O.S. § 427.6(H)(3)
Violations of process validation laws or rules	$50,000 per violation	OAC 442:10-11-1(j)(1); 63 O.S. § 427.17(N)(2)(h)

Adulterated product produced under process validation fails testing and the batch or lot has been sold to a dispensary	$10,000 – first violation $75,000 – second violation within two (2) years $250,000 – third violation within two (2) years	OAC 442:10-11-1(j)(2); 63 O.S. § 427.17(N)(2)(i)
Willful violation of process validation	$250,000 – first violation $1,000,000 – second violation	OAC 442:10-11-1(j)(3); 63 O.S. § 427.17(N)(2)(j)
Falsifying data, providing misinformation, or any unethical practices related to process validation by a Certified Process Validation Testing Laboratory	$1,000,000	OAC 442:10-11-1(j)(4); 63 O.S. § 427.17(N)(2)(m)

APPENDIX D. SAMPLE COLLECTION FOR FINAL MEDICAL MARIJUANA PRODUCTS [REVOKED]

APPENDIX E. SAMPLE COLLECTION FOR PRE-ROLLS [REVOKED]

APPENDIX F. REQUIRED TESTING BY BATCH TYPE [REVOKED]